Introduction to **Quality Management**

Leo Pittman

Introduction to Quality Management

Introduction to Quality Management

Leo Pittman

Introduction to Quality Management
Leo Pittman
ISBN: 978-1-9789-6515-7

Published by Library Press,
5 Penn Plaza,
19th Floor,
New York, NY 10001, USA

Cataloging-in-Publication Data

Introduction to quality management / Leo Pittman.
p. cm.
Includes bibliographical references and index.
ISBN 978-1-9789-6515-7
1. Quality control. 2. Total quality management. 3. Total quality control. 4. Industrial management.
I. Pittman, Leo.
HD62.15 .I58 2021
658.562--dc23

TABLE OF CONTENTS

PREFACE

The purpose of this book is to help students understand the fundamental concepts of this discipline. It is designed to motivate students to learn and prosper. I am grateful for the support of my colleagues. I would also like to acknowledge the encouragement of my family.

Quality is defined as how well the product is performing its intended function. Quality management focuses on ensuring that a product, service or organization is consistent. The four main components of quality management are quality assurance, quality control, quality improvement and quality planning. In order to get consistent quality, the techniques of quality assurance and control of products is used. The primary principles of quality management are evidence-based decision making, process approach, leadership, engagement of people and relationship management. This field uses many methods to improve the quality of product and services. These are process improvement, product improvement and people based improvement. This book is compiled in such a manner, that it will provide an in-depth knowledge about the theory and practice of this field. It presents the complex subject of quality management in the most comprehensible and easy to understand language. Those with an interest in this field would find this book on quality management helpful.

A foreword for all the chapters is provided below:

Chapter – What is Quality Management?

Product quality refers to the collection of characteristics and features of a product to meet the consumer wants and provide customer satisfaction. Quality management refers to the management of quality policy, creation and implementation of quality planning and assurance, and quality control and improvement. This is an introductory chapter which will briefly introduce about quality management.

Chapter – Quality Management Processes and System

Quality management process is defined as the set of processes which ensure the quality of a product. Six-sigma plan, external quality assessment, expediting, quality improvement, etc. are some of the procedures involved in it. This chapter has been carefully written to provide an easy understanding of these concepts under quality management processes.

Chapter – Quality Control

Quality control refers to a system that maintains standards of products by testing units within the specifications of the final product. Analytical and statistical quality control, quality inspection and maintenance, design inspection, quality audit, etc. are a few of its aspects. The topics elaborated in this chapter will help in gaining a better perspective of the related aspects of quality control.

Chapter – Quality Assessment and Improvement Tools

Quality assessment and improvement tools are used to audit, measure and improve the quality and standards of the product. Some of these tools are CUSUM, flowchart, quality storyboard, p-chart, Pareto chart, histogram, scatter plot, etc. This chapter closely examines the different quality assessment and improvement tools to provide an extensive understanding of the subject.

Chapter – Quality Assurance

Quality assurance deals with the prevention of defects and problems in products and provide safe delivery of products to consumers. Quality assurance can be grouped into three levels – strategic level, functional level and operational level. All the aspects related to quality assurance have been carefully analyzed in this chapter.

Chapter – Quality Standards

Quality management standards are the guidelines, requirements and specifications needed by a product to ensure its quality. It includes ISO 9000, ISO 9001, ISO 9002, ISO 14001, IATF 16949, etc. This chapter sheds light on these different quality standards for a thorough understanding of the subject.

Leo Pittman

What is Quality Management?

CHAPTER 1

Product quality refers to the collection of characteristics and features of a product to meet the consumer wants and provide customer satisfaction. Quality management refers to the management of quality policy, creation and implementation of quality planning and assurance, and quality control and improvement. This is an introductory chapter which will briefly introduce about quality management.

PRODUCT QUALITY

It can be said that product is of satisfactory quality, if it satisfiers the consumers/user. The consumer will buy a product or service only if it suits his requirements.

Therefore, consumers' requirements are first assessed by marketing department and then the quality decision is taken on the basis of the information collected. Although we have described the virtues of quality one basic question needs be answered: What is quality and who decided what quality?

Quality is "an asset which may be offered to the potential consumer of a product or service".

The following are other more explanatory definitions of quality:

- Quality is the performance of the product as per the commitment made by the producer to the consumer. Such commitment may be explicit or implicit i.e. in terms of written contract or in terms to the quality management expectation of the average consumer of the product. The performance of the product is concerned with the ultimate function and service which the product must provide to the final consumer.

  A product is known as a quality product only when it satisfies various criteria for its functioning for the consumer. In addition to the physical criteria, there is also a service and time factor to quality. The same quality of physical performance should be available over a reasonable length of time. Hence time is also unnecessary aspect of quality.

- Quality is either a written or non-written promise/commitment to a consumer, known or unknown in the market, because the market is decided by the plant/company, that to which type of consumer/customer to cater to quality is a strategic marketing decision taken by the company itself.

Thus it can be said that the quality decision is based on various marketing considerations production constraints, manpower constraints and equipment or technology constraints. In this way the decision concerning quality are not in the hands of one functional manager, since this involves overall strategic decision for the running business of a corporation.

- Once such a strategic policy regarding the quality is followed, it becomes the job of all functional managers such as the Production and Operations.

  Manager, to see that such strategic aims/objectives and goals are achieved. In this case all departments such as purchasing, production; warehousing and transport have made contribution so as to achieve the quality of products. So quality implementation is also a 'total organization effort'.

  The essential need of the products/services is that they must fulfil the requirements of those who will actually use them. Now because the use of the product differs from situation to situation, the requirement is viewed in different manners by various users.

  Simple definitions evolved for quality are: (i) Fitness for use (ii) Consistent, Conformance to consumer's needs, or poor/inferior quality of raw material entering into the plant/enterprise or improper techniques/method and processes being followed in the plant.

  A more comprehensive definition of quality as adopted by International Standards Organization is "the totality of features and characteristics of product or service that bear on its ability to satisfy stated or implied needs revolving around customer".

  It may be concluded that quality is a key attribute that consumers use to evaluate products or services. Thus it is everything to everyone involved in a business, to satisfy the total needs of every consumer/user whoever that customer may be, and is driven by the market conditions, i.e. by the competition and especially by the consumer.

  In the end, quality is the capability of a product or service to satisfy "knowingly" those preconceived composite needs of the consumers/user(s) that are intelligibly related to characteristics of performance, and do not lead to major overt or covert action or reactions by other people.

To manufacturer (in industry), it means 'best for certain customer conditions'.

The important customer conditions are:

- Selling price of the final product.
- Actual end use of the product.

These may be reflected in the following features of the product:

- The dimensional specification and operating characteristics of the product.
- Reliability and life of the product.
- The cost of production of the production.
- The production conditions required for the manufacture of product.
- Installation and maintenance objectives and related costs.

Quality Characteristics

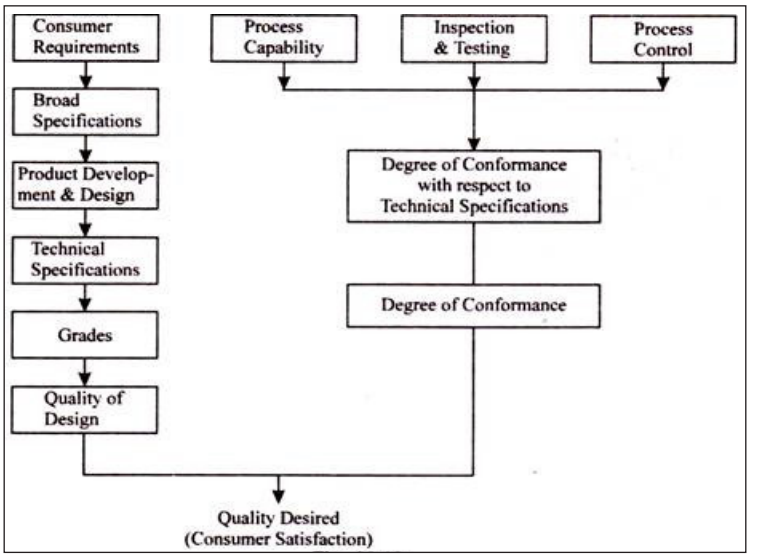
An element which makes a product/item fit for use is the quality characteristics. The quality characteristics also mean a process by which the fitness for use can be translated into the technologists' language for managing the quality. The quality characteristics are also classified into categories called 'parameters' of fitness for use.

Two such major parameters are known as:

- Quality of design.
- Quality of conformance.

The quality of design is concerned with consumers' satisfaction by variation in quality of products popularly called "grades". In contrast the quality of conformance is the extent to which the products/items and services conform to the intent of design.

The process capability, inspection and process control is involved in achieving this conformance so that product/goods produced meet the pre-decided specifications. The end of both these parameters is the quality as shown in figure.



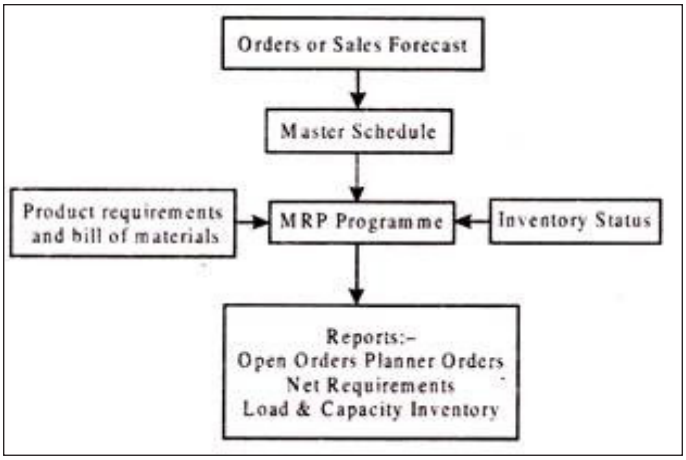
Costs of Quality

Quality management is not only concerned with maintaining the quality characteristics of a product but also with achieving the same at least cost.

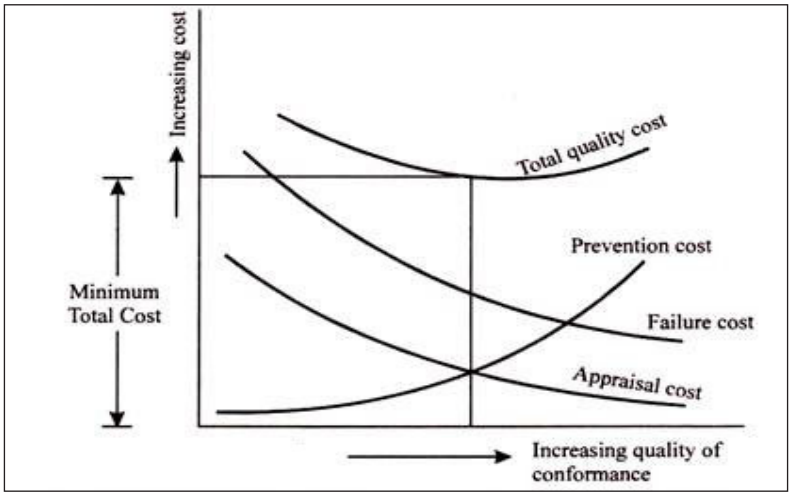
There are basically three categories of cost of quality:

- Costs of Appraisal.
- Costs of Prevention.
- Costs of Failure.

The relationship between these costs and total quality cost is shown in figure:



- Costs of Appraisal: These are the costs of inspection, testing and such checking operations which are essential to maintain the product quality the costs of the implementation of quality as well as the costs of monitoring and control are included in this cost.



- Costs of Prevention: These are the costs to prevent the manufacturing of poor quality products. These include costs of activity such as quality planning which tries to ensure that proper precautions have been taken to avoid wrong sampling plans being made or poor/inferior quality of raw material entering into the plant/enterprise or improper techniques/method and processes being followed in the plant.
- Costs of Failure: Inspire of prevention and appraisal, there will still be losses by virtue of rejections, rework and spoilage etc. to some extent. These costs as well as the costs of attending to consumer complaints and providing product service are included in the category of costs of failures.

The costs of quality can be analysed in two different ways:

- Category to Category Comparison: Comparing the relative costs involved on each of the above mentioned cost categories i.e., how much is spent on planning? How much on appraisal? and How much on failure?
- Time to Time Comparison: For instance, comparing one quarter's operation with the previous quarter's operation.

Impact of Poor Quality

Poor quality of products results in the extra cost of production. A manufacturer sometimes has to bear losses due to poor product quality.

This can be explained as follows:

- Reduction in sales is the result of poor quality of product which leads to lower production volume and hence reduced profitability. Such losses may prove detrimental to the existence of those manufacturing plants.
- Poor product quality also affects goodwill of manufacturer in the market. Goodwill is created as a result of good performance over a long period and goodwill once lost is very difficult to re-establish.
- A manufacturer or a supplier may be required to replace a product, if it proves to be of inferior quality during the guarantee period and replace the parts/components during warranty period.
- A manufacturer is liable to indemnify the customer for any loss sustained by him by virtue of poor product quality.
- A manufacturer may be compelled to sell the sub-stand products at reduced price.
- Defective products may lead to stoppages in production processes thus leading to higher cost of production.

- Sometimes, a manufacturer has to pay for rework on defective items/goods.
- Sometimes extra money is to be spent by producer for repair and servicing of defective products.
- A rejected/substandard product represents a loss to a manufacturer equivalent to material as well as labour cost plus other overhead costs.
- In case the proportion of defectives increases it makes essential for the industrial plant to invest extra amount for vigorous inspection and testing at various stages of production.
- The high proportion of production of defective/substandard products affects the morale of the work force badly.
- Sometimes it becomes necessary to identify the causes of failures or high rate of defective production. The manufacturer has to waste money on such investigations.

Importance of Quality

Quality is an important dimension of production and operations management. It is not sufficient to produce products/goods or services in the right quantity and at right time; it is important to ensure that the goods/items and services produced/provided are of the right quality.

The consumer of the final product of company/organization requires a certain quantity of products of requisite quantity as per his requirements. Without quality, the other dimensions of quality and time have little rather no relevance.

Quality management, which includes ensuring proper quality for a organization's/plant's output product, is important not only for its survival in the market, but also to expand its market if new product line is to be introduced and various other marketing ventures.

The lives of human beings are effected to a great extent by the quality of products and services. Quality failures may and would result in serious human inconveniences, wastage of money and sometimes loss of life.

In the early twentieth century, consumers/users were expected to pay extra for quality. However in the present day competitive business market quality is no longer an option. In other words, it is a positive need without which the survival of an organization is not possible.

Hence, a organisation/company which designs, produces and sells its products in today's market, must take into consideration the following trends related with quality:

- Consumers, 'industrial and defence personnel' have been increasing their quality requirement very sharply.

- The stringent consumers demand on quality compels for the review of in plant practices and techniques.

Taken together these trends to following two quality challenges i.e.

- Considerable improvement in the quality of many products/goods and quality practices.
- Substantial minimization in the overall cost of maintaining quality.

In order to fulfil the quality requirements of the consumers, a thorough, understanding is required regarding the interacting role of all major activities of an organization. These activities performed anywhere, put together substitute the "Quality function". So quality function may be defined as that set of activities, without mattering where performed, through which quality level can be achieved by the company.

Thus it can be concluded that the management of quality function requires the utilization of managerial, technical and analytical inferences, usually based on observations, including statistical concepts, concerning major functions of an organization.

When properly managed with factors/understanding mentioned above the following benefits can be achieved:

- Improved productivity of the system.
- Reduced costs of products/services.
- Improved image of the organization.
- Committed Consumers/Customers.
- Dedicated management of the unit/plant.
- Increased involvement of employees at various levels.

Quality management is related with quality assessment. Quality assessment is a probe of the level of quality being achieved. This assessment of quality leads to quality control and it includes action taken to do away with unacceptable quality products.

A typical quality control programme is based upon the periodic inspection at various stages of production, later followed by feedback on results and the adjustments made where found essential. The term quality assurance is quality control but with an emphasis on quality at the design stage of the products, processes and jobs and in the selection of manpower and their training.

Another term Total Quality Control (TQC) refers to a total commitment to quality in all its aspects, to commitment of quality in all functional areas of work and utilizes

behavioural techniques such as quality circles (QC,S) and zero defect programmes etc.

The biggest misconception among people regarding TQC is that it is restricted to product quality and it is not about the quality of all business processes. The concept of TQM is that, it takes quality from the shop floor to every conceivable activity in an organisation. Keeping the consumer at the centre of all thoughts, decisions and processes.

To Improve a industry's/company's operations effectiveness (TQM) is one of the techniques along with others such as supply chain management, reengineering, cellular manufacturing and bench marking etc.

Thus operational effectiveness techniques and TQM can elevate a company's operation to such a level which cannot be surpassed unless there is some alternative superior technology. This could be a short term competitive benefit. It is essential to appreciate that rival plants/industries can also adopt the same operational effectiveness techniques.

Quality management is also defined as "the system of establishing defect prevention actions and attitudes with a industrial unit/company or a organization on a permanent basis for the purpose of assuring conforming products or services directed at customer satisfaction."

The TQM provides a entirely different way of looking at the management style. It develops and provides a participative culture where each employee can directly participate in areas concerning his work as well as decisions relating to his work. So it is an approach to improve the effectiveness and flexibility of the organization as a whole.

The basic aim is to involve every person of every department of the organization to work together so as to eliminate errors and prevent waste. The cross functional goals such as quality cost, manpower development, quality of work life are satisfied by this improved performance. Thus all these activities ultimately provide customer and employee satisfaction.

QUALITY MANAGEMENT

Quality management is a discipline for ensuring that outputs, benefits, and the processes by which they are delivered, meet stakeholder requirements and are fit for purpose.

Quality management has four components: quality planning, quality assurance, quality control and continual improvement. These include procedures, tools and techniques that are used to ensure that the outputs and benefits meet customer requirements.

The first component, quality planning, involves the preparation of a quality management plan that describes the processes and metrics that will be used. The quality management plan needs to be agreed with relevant stakeholders to ensure that their expectations for quality are correctly identified. The processes described in the quality management plan should conform to the processes, culture and values of the host organisation.

Quality assurance provides confidence to the host organisation that its projects, programmes and portfolios are being well managed. It validates the consistent use of procedures and standards, and ensures that staff have the correct knowledge, skills and attitudes to fulfil their project roles and responsibilities in a competent manner. Quality assurance must be independent of the project, programme or portfolio to which it applies.

The next component, quality control, consists of inspection, testing and measurement. It verifies that the deliverables conform to specification, are fit for purpose and meet stakeholder expectations.

Quality control activities determine whether acceptance criteria have, or have not, been met. For this to be effective, specifications must be under strict configuration control. It is possible that, once agreed, the specification may need to be modified. Commonly this is to accommodate change requests or issues, while maintaining acceptable time and cost constraints. Any consequent changes to acceptance criteria should be approved and communicated.

The last component, continual improvement, is the generic term used by organisations to describe how information provided by quality assurance and quality control processes is used to drive improvements in efficiency and effectiveness. A P3 maturity model provides a framework against which continual improvement can be initiated and embedded in the organisation.

Project

Projects that are part of a programme may well have much of the quality management plan developed at programme level to ensure that standards are consistent with the rest of the programme. Stand-alone projects need to develop their own quality management plans, either from scratch or by adapting those from other similar projects. This may seem to be an administrative burden at the beginning of smaller projects, but is always worthwhile in the end.

Projects deliver tangible outputs that are subject to many forms of quality control, depending upon the technical nature of the work and codes affecting particular industries. Examples of inspecting deliverables include crushing samples of concrete used in the foundations of a building; x-raying welds in a ship's hull; and following the test script for a new piece of software.

Inspection produces data and tools such as scatter diagrams, control charts, flowcharts and cause and effect diagrams, all of which help to understand the quality of work and how it may be improved.

The main contribution to continual improvement that can be made within the timescale of a project is through lessons learned. Existing lessons learned should be consulted at the beginning of every project, and any relevant lessons used in the preparation of the project documentation. At the end of every project, the lessons learned should be documented as part of the post-project review and fed back into the knowledge database.

Programme

The responsibility of the programme management team is to develop a quality management plan that encompasses the varied contexts and technical requirements contained within the programme. This sets the standards for the project quality management plans and also acts as a plan for quality in the benefits realisation parts of the programme.

A comprehensive quality management plan at programme level can greatly reduce the effort involved in preparing project-level quality management plans.

Quality control of outputs is mainly handled at project level, but the programme may get involved where an output from one project is an input to another, or where additional inspection is needed when outputs from two or more projects are brought together.

The programme is responsible for quality control of benefits. This is a complex task since the acceptance criteria of a benefit may cover subjective as well as measurable factors but benefits should be defined in measurable terms so that quality control can be applied.

The typical scale of programmes means that they have a very useful role to play in continual improvement. Programme assurance will ensure that projects do take existing lessons learned into account and then capture their own lessons for addition to the knowledge database.

Portfolio

The very nature of a portfolio means that it is unlikely to need a portfolio quality management plan. Quality management for the portfolio should be indistinguishable from the quality management policies of the host organisation as a whole.

It may be necessary for the portfolio management team to provide guidance on the application of general policies or perhaps augment them where the portfolio creates special requirements.

The portfolio is responsible for delivering strategic objectives. These may be expressed in very broad terms resulting in difficulty in applying quality control. When establishing

the scope of a portfolio, attention should be given to defining acceptance criteria for strategic objectives so that they can be quality controlled.

Continual improvement is very much a concern at portfolio level. The portfolio management team needs to ensure that the management of projects and programmes becomes more effective and efficient with the passage of time.

QUALITY CIRCLE

The Quality Circle refers to the group of individuals who meet on a regular basis to discuss the work-related problems. Generally, the quality circles are small group gatherings, led by the supervisor or the manager who presents the solutions to the management.

The purpose behind the formation of a quality circle is to motivate employees to share the problems affecting their work area and help in improving the performance of the organization as a whole. Generally, the quality circles focus on issues such as occupational health and safety, improvement in the working environment and manufacturing processes, etc.

The quality circles are formed to fulfill any of the following objectives:

- To contribute towards the development of an organization.
- To create a healthy work environment such that employees find the place worthwhile to work.
- To explore the hidden potential of the individuals and drawing out the infinite possibilities.
- To improve the product quality and the productivity of the organization.
- To improve the team skills, capabilities, confidence and creativity through education, training, and participation of volunteers in the circles.

Often, six to twelve personnel from the same work area come together to form these circles. These members receive proper training in problem solving, group process and statistical processes.

TOTAL QUALITY MANAGEMENT

Total Quality Management is mainly concerned with continuous improvement in all work. It is a long term planning. It is the consistent improvement in the quality. It

is a never ending process. Total Quality Management consists of three words: Total, Quality and Management.

- Total: Make up of the whole.
- Quality: Degree of excellence a product or service provides.
- Management: It is a process of planning, organising, directing and controlling.

Therefore, TQM is the art of managing the whole to achieve excellence. TQM covers all the set rules, regulations, guidelines and principles that contribute in improving the organization continuously. It is a continuous process of improvement for individuals, groups of people and the whole organisation. It is the application of quantitative methods and human resources to improve all the processes within an organization to satisfy the needs of customers consistently. TQM integrates all the fundamental management techniques, existing improvement efforts, and technical tools under a disciplined approach. It covers the most quality principles and practices proposed by quality gurus.

Total Quality Management (TQM) is a management approach for an organization, centered on quality, based on the participation and commitment of all the internal and external customers and aiming at strategically long-term success through customer satisfaction, and benefits to all members of the organization and to society.

Total Quality Management (TQM) is a top-management strategy aimed at embedding awareness of quality in all organizational processes.

Total Quality Management is a total system approach and it is an integral part of the strategic decision making of the top management. It works horizontally across all the functions and departments. It involves all the employees of three levels, i.e., top level, middle level and bottom level. It extends backward and forward and covers supply chain management as well as logistics management also. So, we can say that it is a consistent effort by everyone in the organisation to meet the expectations of the customers leading 100 per cent satisfaction. TQM requires that the company maintain the quality standard in all aspects of its business. This requires ensuring that things are done right the first time and that defects and waste are eliminated from operations.

Characteristics of TQM

TQM Starts from Top Management

The quality concept is initiated by the top management. The whole credit of the initiation of total quality management goes to the top management. Only the top management can create an environment that develops team-oriented environment

and creates quality oriented culture that can prevent problems and continually improve.

It is a Consistent Process

To produce quality product and service is not an easy job. Sometimes it takes years to give the desired results. All the employees have to work consistently as a team in one direction to improve all the processes in the organisation.

It is a Part of Strategic Planning and Thinking

TQM policy is a long term planning. The quality policy must be the part of strategic planning to get the desired results.

It is Customer Focused

The end result of TQM is complete satisfaction of customers by giving them quality products and services. It is possible only when TQM programme is customer centric.

It is a Team Work

Success in terms of standard quality is possible only when the organizations has a culture of team formation and the employees work in teams and give their maximum. Teams can be formed vertically and horizontally. When top management is involving the lower level employees it is vertically and when the different departmental employees are involved then it is horizontally (employees of marketing, sales, production and finance departments are working for critical and complex projects). Teams are inter-organisational when the employees of other organisations are involved (like employees of banks, suppliers, audit companies, consultants etc.

It is Related with Consistent Improvement of Quality

To deliver quality products and services is not an easy job. All the processes have to be developed and standardised by consistent improvement.

Every Employee is Involved in Quality Improvement Aspect

All the employees internal as well as external are involved in the TQM programme. Internal employees include all the employees included from top to bottom and external employees are suppliers, banks and other institutions which are involved in the TQM process.

Every Employee is Responsible for the Success of TQM

If all the employees are determined and committed for the quality products and services, then only quality could be delivered.

The TQM Practices followed by Multinational Companies

The salient features of TQM approach followed by the best companies are as following:

- The companies create a sense of an environment of mutual trust, respect and dignity.
- The management act immediately on new ideas and suggestions.
- The companies are meeting and exceeding customers' requirements and expectations on consistent basis.
- The companies hear and learn from the dissatisfied/unhappy customers and responsible for complete customer satisfaction.
- The companies are committed to their both internal as well as external employees. They know the value of workers' involvement and intensive training.
- The companies develop the teams to have broad decision-making powers and responsibilities.
- They apologize for the complaints.
- The companies know that labour-management relations could do more for quality and productivity.
- The companies empower their employees to make them responsible.
- The companies implement statistical process control and monitor defect rates.

Important Factors in Total Quality Management

Total Quality Management (TQM) is a participative, systematic approach to planning and implementing a constant organizational improvement process. Its approach is focused on exceeding customers' expectations, identifying problems, building commitment, and promoting open decision-making among workers. There are five major steps to TQM, and each are essential to successful implementation.

Commitment and Understanding from Employees

It is key to ensure that all employees within your organization know about the Total Quality Management (TQM) policies and make them an fundamental part of their work. Your employees should know your corporate goals and recognize the importance of these goals to the overall success of your organization. Employees need to know what is expected from them and why. It may sound like a no-brainer but too often this is not driven home by management. When employees understand and share the same vision as management a world of potential is unleashed. If they are in the dark, commitment is lacking and policies will not be successfully deployed.

Quality Improvement Culture

The organizational culture needs to be modernized on a continuous basis to encourage employee feedback. Your employees are full of valuable knowledge. Listen to those executing the processes that keep your business moving daily. If employees have an idea on how to improve operations, they need to know management respects their ideas or they will not share.

Continuous Improvement in Process

There is no standing still. If you are not moving forward, you are moving backwards. Total Quality Management (TQM) is a continuous process and not a program. This requires constant improvement in all the related policies, procedures and controls established by management. Do your research. Keep your ear to the market and make an effort to routinely revise all aspects of your operation. There should be a constant effort to improve proficiency which will result in constant scopes for improvement (even if some improvements are small).

Focus on Customer Requirements

In today's market, customers require and expect perfect goods and services with zero defects. Focusing on customer requirements is significant to long term survival and essential in order to build relationships with customers. People do business based on emotion. Competitors will always be a risk. Keep your customers close and happy. Make sure precise requirements of all customers are documented and understood by everyone that touches the account.

Effective Control

It is essential to monitor and measure the performance of the business. It's easy to forget how many times in a year an employee does not conform to a controlled procedure or how many times a piece of equipment was down due to unplanned maintenance. If strict documentation is maintained, you will be able to objectively quantify areas for improvement and focus your efforts where they will provide the greatest return of both your time and financial resources.

IMPORTANCE OF QUALITY MANAGEMENT

Quality management plays a crucial role in the company's growth and performance. It is also a key resource in the competition for customer relationships, striving to deliver a superior experience. For the business to succeed, quality should be maintained at every level. Companies can implement a set of procedures to ensure their products meet the

highest quality standards and perform optimally. The end goal is to enhance customer satisfaction and drive business growth.

More Consistent Products and Increased Efficiency

Quality management value lies in its ability to help companies improve their products' reliability, durability and performance. These factors help differentiate a business from its competitors. Better products equal happier customers and higher revenue. Besides product quality, quality management systems, such as ISO 9001, ensure clear communication structures, responsibilities and tasks across all departments. This results in higher employee morale, improved performance and increased efficiency.

Greater Customer Satisfaction

The business cannot ignore the cost of bad customer relations. It takes 12 positive experiences to make up for one negative experience. If the products and services fail to meet customer expectations, the brand and revenue will suffer.

In today's competitive market, consumers are more demanding than ever. They can choose from thousands of brands and have access to millions of stores due to the advances in technology. If you want the business to stand out, it's critical to meet or exceed their expectations. It's no longer enough to make sure the products are "fine." They need to address customers' needs and comply with the highest quality standards.

Quality management can help you turn prospects into loyal customers. It does so by continuously improving the products, incorporating changes and eliminating defects. Furthermore, it provides companies with the information they need to develop goods and services that customers want. In the long run, this helps increase the market share and gives the business a competitive edge.

Lower Costs and Increased Profits

Organizations can implement total quality management (TQM) practices to identify areas of improvement in a variety of sectors, such as:

- Marketing and sales.
- Research.
- Manufacturing.
- Equipment maintenance.
- Administrative and legal departments.
- Finance and accounting.

When applied consistently over time, these processes can reduce the costs and increase the profit. For example, a quality product will require less rework down the road, leading to cost savings and fewer warranty claims.

Reduced Risks

Risk mitigation goes beyond choosing adequate business insurance coverage and investing in cutting-edge data security software. Once the products leave the building, there are plenty of risks to consider. Recalls, for instance, can result in significant long-term financial losses and affect the customer experience. They may also hurt the brand and reputation. As a business owner, you are responsible for bearing the costs of product recalls. You may have to deal with lawsuits and even file for bankruptcy. For this reason, companies cannot ignore or overlook the importance of quality management.

Fewer Human Errors

Quality management practices can reduce human error and improve a company's validation activities. The employees will have a set of guidelines to follow during their day-to-day operations, which helps eliminate guesswork and ensures compliance.

Keep up with the Competition

Small businesses must do everything they can to keep up with their larger competitors. Delivering superior products and services is paramount. Quality management systems provide the information and guidelines for doing things correctly. Furthermore, they help the business achieve optimum cost efficiency and utilization of available resources.

In the long run, these practices strengthen the company's brand, raising you to the level of the competitors. Since they improve the products and business operations, they lead to a stronger market position.

References

- Product-quality-definition-characteristics-and-importance, products-quality-90711: yourarticlelibrary.com, Retrieved 13 April, 2020
- Quality-management, body-of-knowledge-delivery: apm.org.uk, Retrieved 27 August, 2020
- Quality-circle: businessjargons.com, Retrieved 07 May, 2020
- Five-important-factors-in-total-quality-management: aboutthree.com, Retrieved 19 July, 2020
- Importance-quality-management-5377881: bizfluent.com, Retrieved 18 June, 2020

Quality Management Processes and System

CHAPTER 2

Quality management process is defined as the set of processes which ensure the quality of a product. Six-sigma plan, external quality assessment, expediting, quality improvement, etc. are some of the procedures involved in it. This chapter has been carefully written to provide an easy understanding of these concepts under quality management processes.

QUALITY MANAGEMENT PROCESS

A Quality Management Process aims to ensure the final deliverable does just that by focusing on quality throughout the project lifecycle; by incorporating it into the planning process and ensuring that what we think of as "good quality" is, in fact definable and measureable. If it cannot be defined then it cannot be measured and if it cannot be measured then how can anyone know that the project was of an acceptable quality?

Just as with any other part of a project a Quality Management Plan should be created as early as possible in the project lifecycle but will be modified throughout the lifecycle as it becomes clearer to all concerned what is required from the project.

Quality at all Times

Right from the earliest stages of the project we should be thinking about quality – it is not a final check or add-on to be done once the project is almost complete. A Quality Plan should cover all of the following as a minimum:

- Stakeholder expectations in terms of project quality.
- Defined Success criteria with acceptable tolerances.
- External and/or internal Standards to be adhered to.
- Who is responsible for ensuring quality on the project.
- How will quality be checked/tested and reviewed.
- How quality can be improved if it doesn't meet the expected standards.

Quality Assurance

This part of the process is intended to provide reassurance that the project is meeting

the expected definition of quality so, naturally, a quality review is an essential tool for doing this. It needs to measure the quality level against the definition of acceptable quality that was put in place at the start of the projects and, most likely, improved at stages during the lifecycle. As with so many parts of a project it is important to capture lessons learned so that future phases of a project do not make the same mistakes with respect to quality; and also so that opportunities can be identified where quality can be improved in a cost-effective way.

Quality Assurance is an ongoing process throughout the whole project lifecycle and is best managed via regular quality reviews and independent audits to ensure all tasks are being done in accordance with defined standards of quality.

Quality Control

Quality control is concerned with testing and measuring various aspects of a project to ensure project deliverables meet the pre-defined specification and the stakeholder's requirements. Because projects vary so widely in type and complexity the forms of testing and measuring quality also vary widely depending on the nature of the project and milestone deliverables. Some projects are creating physical products which may need to be checked against industry standards; other projects may be improving a business process, which needs to be testing using a pilot process.

Quality Improvement

On many projects there will be the chance to improve aspects of quality – or if there aren't there will be chances to improve the process so that future projects can benefit from the knowledge gleaned on the current project. By seeking to learn lessons from each project to benefit future projects a process of continuous quality improvement can be implemented within an organisation. Some of these may be part of existing industry standards such as ISO 9000, which is a set of international standards that can be applied to any industry and to projects of any size.

QUALITY MANAGEMENT SYSTEM

A quality management system (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction. It is expressed as the organizational goals and aspirations, policies, processes, documented information and resources needed to implement and maintain it. Early quality management systems emphasized predictable outcomes of an industrial product production line, using simple statistics and random sampling. By the 20th century, labor inputs were typically the most costly inputs in most industrialized societies, so focus shifted to team cooperation and dynamics, especially the early signaling of problems via a continual

improvement cycle. In the 21st century, QMS has tended to converge with sustainability and transparency initiatives, as both investor and customer satisfaction and perceived quality is increasingly tied to these factors. Of QMS regimes, the ISO 9000 family of standards is probably the most widely implemented worldwide – the ISO 19011 audit regime applies to both, and deals with quality and sustainability and their integration.

Other QMS, e.g. Natural Step, focus on sustainability issues and assume that other quality problems will be reduced as result of the systematic thinking, transparency, documentation and diagnostic discipline.

The term "Quality Management System" and the initialism "QMS" were invented in 1991 by Ken Croucher, a British management consultant working on designing and implementing a generic model of a QMS within the IT industry.

Elements

- Quality objectives.
- Quality manual.
- Organizational structure and responsibilities.
- Data management.
- Processes – including purchasing.
- Product quality leading to customer satisfaction.
- Continuous improvement including corrective and preventive action.
- Quality instrument.
- Document control.

Concept of Quality

The concept of a quality as we think of it now first emerged from the Industrial Revolution. Previously goods had been made from start to finish by the same person or team of people, with handcrafting and tweaking the product to meet 'quality criteria'. Mass production brought huge teams of people together to work on specific stages of production where one person would not necessarily complete a product from start to finish. In the late 19th century pioneers such as Frederick Winslow Taylor and Henry Ford recognized the limitations of the methods being used in mass production at the time and the subsequent varying quality of output. Birland established Quality Departments to oversee the quality of production and rectifying of errors, and Ford emphasized standardization of design and component standards to ensure a standard product was produced. Management of quality was the responsibility of the Quality department and was implemented by Inspection of product output to 'catch' defects.

Application of statistical control came later as a result of World War production methods, which were advanced by the work done of W. Edwards Deming, a statistician, after whom the Deming Prize for quality is named. Joseph M. Juran focused more on managing for quality. The first edition of Juran's Quality Control Handbook was published in 1951. He also developed the "Juran's trilogy", an approach to cross-functional management that is composed of three managerial processes: quality planning, quality control, and quality improvement. These functions all play a vital role when evaluating quality.

Quality, as a profession and the managerial process associated with the quality function, was introduced during the second half of the 20th century and has evolved since then. Over this period, few other disciplines have seen as many changes as the quality profession.

The quality profession grew from simple control to engineering, to systems engineering. Quality control activities were predominant in the 1940s, 1950s, and 1960s. The 1970s were an era of quality engineering and the 1990s saw quality systems as an emerging field. Like medicine, accounting, and engineering, quality has achieved status as a recognized profession.

As Lee and Dale state, there are many organizations that are striving to assess the methods and ways in which their overall productivity, the quality of their products and services and the required operations to achieve them are done.

Process

A QMS process is an element of an organizational QMS. The ISO 9001:2000 standard requires organizations seeking compliance or certification to define the processes which form the QMS and the sequence and interaction of these processes. Butterworth-Heinemann and other publishers have offered several books which provide step-by-step guides to those seeking the quality certifications of their products.

Examples of such processes include:

- Order processes.
- Production plans.
- Product/service/process measurements to comply with specific requirements e.g. statistical process control and measurement systems analysis.
- Calibrations.
- Internal audits.
- Corrective actions.
- Preventive actions.

- Identification, labeling and control of non-conforming products to prevent its inadvertent use, delivery or processing.
- Purchasing and related processes such as supplier selection and monitoring.

ISO9001 requires that the performance of these processes be measured, analyzed and continually improved, and the results of this form an input into the management review process.

Benefits of Quality Management System

The trend of implementing a quality management procedure is gaining popularity in all organizations, since there are tremendous benefits in using a quality management system. Some of the benefits are explained below:

Achievement of Project Scope

This system facilitates a business, to attain the objectives that have been defined in the organization strategy. It ensures the achievement of stability and reliability regarding the techniques, equipment, and resources being used in a project. All project activities are integrated and aligned towards the achievement of quality products. These efforts commence by identifying the customer needs and expectations, and culminate in their contentment.

Customer Satisfaction

A fully recognized and implemented quality management system, will ensure that the customer is satisfied by meeting their requirements, and will thus enhance the confidence of the customer. Attaining customer satisfaction is a great achievement for the organization, that will assist in capturing the market, or increase the market share.

Consistent Products

Implementing a quality management system can assist to attain more consistency in the project activities, and enhance the effectiveness by improvement in the resources and time usage.

Implementation of Best Practices and Process Improvement

The discipline of quality includes the efforts directed towards the improvement of processes, being used to maintain consistency, reduce expenditures, and ensure production within the schedule baseline. The systems, products, and processes are continually improved by the implementation of best practices, like modern manufacture techniques, use of primavera project management software including Primavera P6, and the use of proper quality control techniques.

Increase in Production

Improved production is achieved due to proper evaluation techniques being applied, and better training of the employees. A strict process control is directed towards performance consistency, and less scrap. Supervisors experience less late night problematic phone calls, since the employees are trained on troubleshooting.

Less Rework

Quality is measured continuously due to the appropriate procedures that ensure immediate corrective actions on occurrence of defects. Since efforts are directed towards quality products, rework due to warranty claims is minimized. This reduction increases customer confidence, and increase in business.

Increased Financial Performance

Investment in quality management systems are rewarded by improved financial performance. UCLA conducted a research on the companies being traded on the New York Stock Exchange, and observed that the financial performance of the companies that obtained ISO 9000 Quality Standard certification was improved significantly, compared to the other companies.

Increase in Market Share

Other quality management system benefits include proper management of project risks and costs, and identification of development prospects. This results in an increase in market share and reputation, and capability to react to industry opportunities.

Improvement in Internal Communications

The quality management system emphasizes the issues related to operations management. This encourages frequent interaction between project departments or groups, and promotes harmony. All these factors contribute to improved quality, and customer satisfaction.

SIX SIGMA

Six Sigma (6σ) is a set of techniques and tools for process improvement. It was introduced by American engineer Bill Smith while working at Motorola in 1980. Jack Welch made it central to his business strategy at General Electric in 1995. A six sigma process is one in which 99.99966% of all opportunities to produce some feature of a part are statistically expected to be free of defects.

Six Sigma strategies seek to improve the quality of the output of a process by identifying and removing the causes of defects and minimizing variability in manufacturing and business processes. It uses a set of quality management methods, mainly empirical, statistical methods, and creates a special infrastructure of people within the organization who are experts in these methods. Each Six Sigma project carried out within an organization follows a defined sequence of steps and has specific value targets, for example: reduce process cycle time, reduce pollution, reduce costs, increase customer satisfaction, and increase profits.

The term Six Sigma (capitalized because it was written that way when registered as a Motorola trademark) originated from terminology associated with statistical modeling of manufacturing processes. The maturity of a manufacturing process can be described by a sigma rating indicating its yield or the percentage of defect-free products it creates—specifically, within how many standard deviations of a normal distribution the fraction of defect-free outcomes corresponds to. Motorola set a goal of "six sigma" for all of its manufacturing.

Doctrine

The common Six Sigma symbol.

Six Sigma doctrine asserts:

- Continuous efforts to achieve stable and predictable process results (e.g. by reducing process variation) are of vital importance to business success.
- Manufacturing and business processes have characteristics that can be defined, measured, analyzed, improved, and controlled.
- Achieving sustained quality improvement requires commitment from the entire organization, particularly from top-level management.

Features that set Six Sigma apart from previous quality-improvement initiatives include:

- A clear focus on achieving measurable and quantifiable financial returns from any Six Sigma project.
- An increased emphasis on strong and passionate management leadership and support.
- A clear commitment to making decisions on the basis of verifiable data and statistical methods, rather than assumptions and guesswork.

The term "six sigma" comes from statistics and is used in statistical quality control, which evaluates process capability. Originally, it referred to the ability of manufacturing

processes to produce a very high proportion of output within specification. Processes that operate with "six sigma quality" over the short term are assumed to produce long-term defect levels below 3.4 defects per million opportunities (DPMO). The 3.4 dpmo is based on a "shift" of ± 1.5 sigma explained by Dr. Mikel J. Harry. This figure is based on the tolerance in the height of a stack of discs. Six Sigma's implicit goal is to improve all processes, but not to the 3.4 DPMO level necessarily. Organizations need to determine an appropriate sigma level for each of their most important processes and strive to achieve these. As a result of this goal, it is incumbent on management of the organization to prioritize areas of improvement.

Other early adopters of Six Sigma include Honeywell and General Electric, where Jack Welch introduced the method. By the late 1990s, about two-thirds of the Fortune 500 organizations had begun Six Sigma initiatives with the aim of reducing costs and improving quality.

In recent years, some practitioners have combined Six Sigma ideas with lean manufacturing to create a methodology named Lean Six Sigma. The Lean Six Sigma methodology views lean manufacturing, which addresses process flow and waste issues, and Six Sigma, with its focus on variation and design, as complementary disciplines aimed at promoting "business and operational excellence".

In 2011, the International Organization for Standardization (ISO) has published the first standard "ISO 13053:2011" defining a Six Sigma process. Other standards have been created mostly by universities or companies that have first-party certification programs for Six Sigma.

Difference from Lean Management

Lean management and Six Sigma are two concepts which share similar methodologies and tools. Both programs are Japanese-influenced, but they are two different programs. Lean management is focused on eliminating waste using a set of proven standardized tools and methodologies that target organizational efficiencies while integrating a performance improvement system utilized by everyone, while Six Sigma's focus is on eliminating defects and reducing variation. Both systems are driven by data, though Six Sigma is much more dependent on accurate data.

Methodologies

Six Sigma projects follow two project methodologies inspired by Deming's Plan–Do–Study–Act Cycle. These methodologies, composed of five phases each, bear the acronyms DMAIC and DMADV:

- DMAIC is used for projects aimed at improving an existing business process.
- DMADV is used for projects aimed at creating new product or process designs.

DMAIC

The five steps of DMAIC.

The DMAIC project methodology has five phases:

- Define the system, the voice of the customer and their requirements, and the project goals, specifically.
- Measure key aspects of the current process and collect relevant data; calculate the 'as-is' Process Capability.
- Analyze the data to investigate and verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered. Seek out root cause of the defect under investigation.
- Improve or optimize the current process based upon data analysis using techniques such as design of experiments, poka yoke or mistake proofing, and standard work to create a new, future state process. Set up pilot runs to establish process capability.
- Control the future state process to ensure that any deviations from the target are corrected before they result in defects. Implement control systems such as statistical process control, production boards, visual workplaces, and continuously monitor the process. This process is repeated until the desired quality level is obtained.

Some organizations add a Recognize step at the beginning, which is to recognize the right problem to work on, thus yielding an RDMAIC methodology.

DMADV or DFSS

The five steps of DMADV.

The DMADV project methodology, known as DFSS ("Design For Six Sigma"), features five phases:

- Define design goals that are consistent with customer demands and the enterprise strategy.
- Measure and identify CTQs (characteristics that are Critical To Quality), measure product capabilities, production process capability, and measure risks.
- Analyze to develop and design alternatives.
- Design an improved alternative, best suited per analysis in the previous step.
- Verify the design, set up pilot runs, implement the production process and hand it over to the process owners.

Quality Management Tools and Methods

Within the individual phases of a DMAIC or DMADV project, Six Sigma utilizes many established quality-management tools that are also used outside Six Sigma. The following table shows an overview of the main methods used:

- 5 Whys.
- Statistical and fitting tools:
  - Analysis of variance.
  - General linear model.
  - ANOVA Gauge R & R.
  - Regression analysis.
  - Correlation.
  - Scatter diagram.
  - Chi-squared test.
- Axiomatic design.
- Business Process Mapping/Check sheet.
- Cause & effects diagram (also known as fishbone or Ishikawa diagram).
- Control chart/Control plan (also known as a swimlane map)/Run charts.
- Cost–benefit analysis.
- CTQ tree.
- Design of experiments/Stratification.

- Histograms/Pareto analysis/Pareto chart.
- Pick chart/Process capability/Rolled throughput yield.
- Quality Function Deployment (QFD).
- Quantitative marketing research through use of Enterprise Feedback Management (EFM) systems.
- Root cause analysis.
- SIPOC analysis (Suppliers, Inputs, Process, Outputs, Customers).
- COPIS analysis (Customer centric version/perspective of SIPOC).
- Taguchi methods/Taguchi Loss Function.
- Value stream mapping.

Implementation Roles

One key innovation of Six Sigma involves the absolute "professionalizing" of quality management functions. Prior to Six Sigma, quality management in practice was largely relegated to the production floor and to statisticians in a separate quality department. Formal Six Sigma programs adopt a kind of elite ranking terminology (similar to some martial arts systems, like judo) to define a hierarchy (and special career path) that includes all business functions and levels.

Six Sigma identifies several key roles for its successful implementation:

- Executive Leadership includes the CEO and other members of top management. They are responsible for setting up a vision for Six Sigma implementation. They also empower the other role holders with the freedom and resources to explore new ideas for breakthrough improvements by transcending departmental barriers and overcoming inherent resistance to change.
- Champions take responsibility for Six Sigma implementation across the organization in an integrated manner. The Executive Leadership draws them from upper management. Champions also act as mentors to Black Belts.
- Master Black Belts, identified by Champions, act as in-house coaches on Six Sigma. They devote 100% of their time to Six Sigma. They assist Champions and guide Black Belts and Green Belts. Apart from statistical tasks, they spend their time on ensuring consistent application of Six Sigma across various functions and departments.
- Black Belts operate under Master Black Belts to apply Six Sigma methodology to specific projects. They devote 100% of their valued time to Six Sigma. They

primarily focus on Six Sigma project execution and special leadership with special tasks, whereas Champions and Master Black Belts focus on identifying projects/functions for Six Sigma.

- Green Belts are the employees who take up Six Sigma implementation along with their other job responsibilities, operating under the guidance of Black Belts.

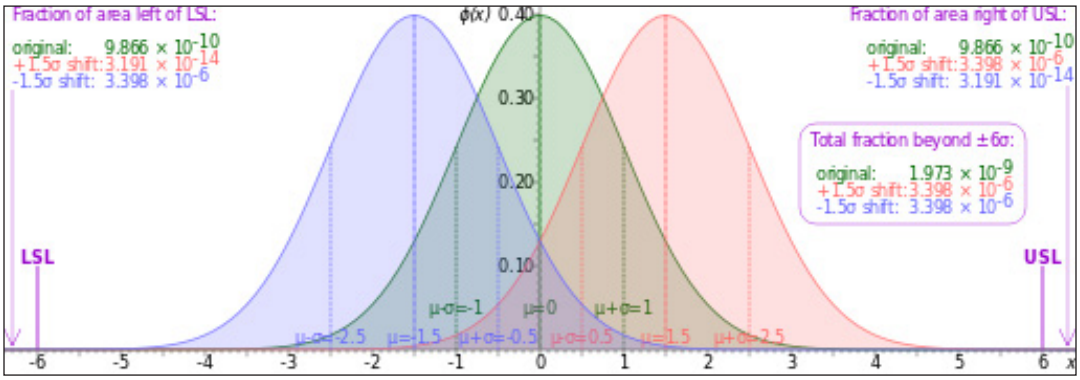
According to proponents of the system, special training is needed for all of these practitioners to ensure that they follow the methodology and use the data-driven approach correctly.

Some organizations use additional belt colours, such as Yellow Belts, for employees that have basic training in Six Sigma tools and generally participate in projects and "White belts" for those locally trained in the concepts but do not participate in the project team. "Orange belts" are also mentioned to be used for special cases.

Six Sigma Process

The term "six sigma process" comes from the notion that if one has six standard deviations between the process mean and the nearest specification limit, as shown in the graph, practically no items will fail to meet specifications. This is based on the calculation method employed in process capability studies.

Capability studies measure the number of standard deviations between the process mean and the nearest specification limit in sigma units, represented by the Greek letter σ (sigma). As process standard deviation goes up, or the mean of the process moves away from the center of the tolerance, fewer standard deviations will fit between the mean and the nearest specification limit, decreasing the sigma number and increasing the likelihood of items outside specification. One should also note that calculation of Sigma levels for a process data is independent of the data being normally distributed. In one of the criticisms to Six Sigma, practitioners using this approach spend a lot of time transforming data from non-normal to normal using transformation techniques. It must be said that Sigma levels can be determined for process data that has evidence of non-normality.



Graph of the normal distribution, which underlies the statistical assumptions of the Six Sigma model. In the centre at 0, the Greek letter μ (mu) marks the mean, with the horizontal axis showing distance from the mean, marked in standard deviations and given the letter σ (sigma). The greater the standard deviation, the greater is the spread of values encountered. For the green curve shown above, μ = 0 and σ = 1. The upper and lower specification limits (marked USL and LSL) are at a distance of 6σ from the mean. Because of the properties of the normal distribution, values lying that far away from the mean are extremely unlikely: approximately 1 in a billion too low, and the same too high. Even if the mean were to move right or left by 1.5σ at some point in the future (1.5 sigma shift, coloured red and blue), there is still a good safety cushion. This is why Six Sigma aims to have processes where the mean is at least 6σ away from the nearest specification limit.

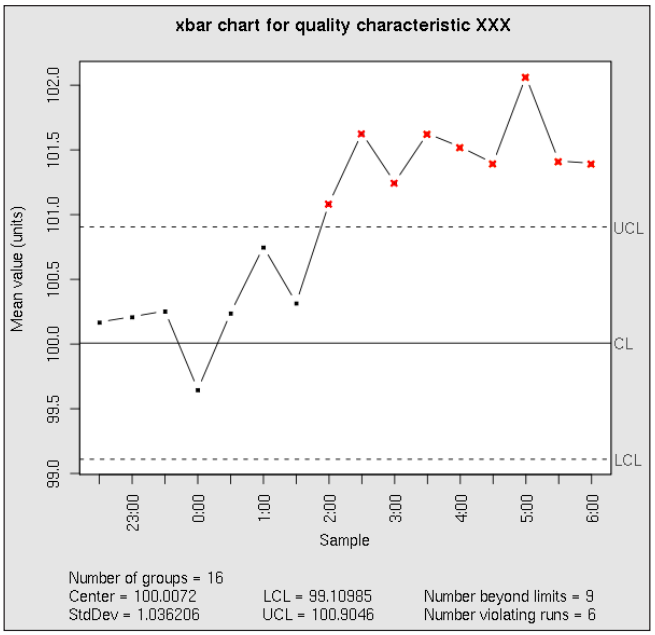
Role of the 1.5 Sigma Shift

Experience has shown that processes usually do not perform as well in the long term as they do in the short term. As a result, the number of sigmas that will fit between the process mean and the nearest specification limit may well drop over time, compared to an initial short-term study. To account for this real-life increase in process variation over time, an empirically based 1.5 sigma shift is introduced into the calculation. According to this idea, a process that fits 6 sigma between the process mean and the nearest specification limit in a short-term study will in the long term fit only 4.5 sigma – either because the process mean will move over time, or because the long-term standard deviation of the process will be greater than that observed in the short term, or both.

Hence the widely accepted definition of a six sigma process is a process that produces 3.4 defective parts per million opportunities (DPMO). This is based on the fact that a process that is normally distributed will have 3.4 parts per million outside the limits, when the limits are six sigma from the "original" mean of zero and the process mean is then shifted by 1.5 sigma (and therefore, the six sigma limits are no longer symmetrical about the mean). The former six sigma distribution, when under the effect of the 1.5 sigma shift, is commonly referred to as a 4.5 sigma process. The failure rate of a six sigma distribution with the mean shifted 1.5 sigma is not equivalent to the failure rate of a 4.5 sigma process with the mean centered on zero. This allows for the fact that special causes may result in a deterioration in process performance over time and is designed to prevent underestimation of the defect levels likely to be encountered in real-life operation.

The role of the sigma shift is mainly academic. The purpose of six sigma is to generate organizational performance improvement. It is up to the organization to determine, based on customer expectations, what the appropriate sigma level of a process is. The purpose of the sigma value is as a comparative figure to determine whether a process is improving, deteriorating, stagnant or non-competitive with others in the same business. Six sigma (3.4 DPMO) is not the goal of all processes.

Sigma Levels



A control chart depicting a process that experienced a 1.5 sigma drift in the process mean toward the upper specification limit starting at midnight. Control charts are used to maintain 6 sigma quality by signaling when quality professionals should investigate a process to find and eliminate special-cause variation.

These figures assume that the process mean will shift by 1.5 sigma toward the side with the critical specification limit. In other words, they assume that after the initial study determining the short-term sigma level, the long-term C_{pk} value will turn out to be 0.5 less than the short-term C_{pk} value. So, now for example, the DPMO figure given for 1 sigma assumes that the long-term process mean will be 0.5 sigma beyond the specification limit ($C_{pk} = -0.17$), rather than 1 sigma within it, as it was in the short-term study ($C_{pk} = 0.33$). Note that the defect percentages indicate only defects exceeding the specification limit to which the process mean is nearest. Defects beyond the far specification limit are not included in the percentages.

The formula used here to calculate the DPMO is thus,

$$DPMO = 1{,}000{,}000 \bullet (1 - \phi(level - 1.5))$$

Table: Long-term DPMO values corresponding to various short-term sigma levels.

Sigma level	Sigma (with 1.5σ shift)	DPMO	Percent defective	Percentage yield	Short-term C_{pk}	Long-term C_{pk}
1	−0.5	691,462	69%	31%	0.33	−0.17
2	0.5	308,538	31%	69%	0.67	0.17

3	1.5	66,807	6.7%	93.3%	1.00	0.5
4	2.5	6,210	0.62%	99.38%	1.33	0.83
5	3.5	233	0.023%	99.977%	1.67	1.17
6	4.5	3.4	0.00034%	99.99966%	2.00	1.5
7	5.5	0.019	0.0000019%	99.9999981%	2.33	1.83

QUALITY PLAN

A quality plan is a document, or several documents, that together specify quality standards, practices, resources, specifications, and the sequence of activities relevant to a particular product, service, project, or contract. Quality plans should define:

- Objectives to be attained (for example, characteristics or specifications, uniformity, effectiveness, aesthetics, cycle time, cost, natural resources, utilization, yield, dependability, and so on).
- Steps in the processes that constitute the operating practice or procedures of the organization.
- Allocation of responsibilities, authority, and resources during the different phases of the process or project.
- Specific documented standards, practices, procedures, and instructions to be applied.
- Suitable testing, inspection, examination, and audit programs at appropriate stages.
- A documented procedure for changes and modifications to a quality plan as a process is improved.
- A method for measuring the achievement of the quality objectives.
- Other actions necessary to meet the objectives.

At the highest level, quality goals and plans should be integrated with overall strategic plans of the organization. As organizational objectives and plans are deployed throughout the organization, each function fashions its own best way for contributing to the top-level goals and objectives.

At lower levels, the quality plan assumes the role of an actionable plan. Such plans may take many different forms depending on the outcome they are to produce. Quality plans may also be represented by more than one type of document to produce a given outcome.

Elements of a Strategic Quality Plan.

An example of a quality plan is a manufacturing company that machines metal parts. Its quality plan consists of applicable procedures (describing the production process and responsibilities), applicable workmanship standards, the measurement tolerances acceptable, the description of the material standards, and so forth. These may all be separate documents.

More variable information that pertains to a particular customer may be spelled out on individual work orders (sometimes called travelers). Work orders specify the machine setups and tolerances, operations to be performed, tests, inspections, handling, storing, packaging, and delivery steps to be followed.

An operating-level quality plan translates the customer requirements (the what) into actions required to produce the desired outcome (the how) and couples this with applicable procedures, standards, practices, and protocols to specify precisely what is needed, who will do it, and how it will be done. A quality control plan may specify product tolerances, testing parameters, and acceptance criteria. While the terminology may differ, the basic approach is similar for service and other types of organizations.

How to Write a Quality Plan

Quality assurance or quality control plans evaluate and/or modify an organization's procedures to help ensure they provide the desired results. Quality control plans are often viewed as a set of instructions that should be followed. They document the planning, implementation, and assessment procedures for a project, as well as any QA or QC activities.

Some areas may be more detailed than others, based on the project, process, or organization's needs. It is important to note that each plan is unique based on the organization's needs and their quality management system (QMS). However, quality control plans should always have a structure that permits improvements to the plan. This allows employees to offer input on how to improve efficiency and quality. In addition, the plan should be reviewed by others periodically, including stakeholders, to ensure the plan is comprehensive.

Three Elements of a Quality Plan.

Quality control plans generally include detailed information on:

- An overview or introduction of the project or process detailing the background, need, scope, activities, and important dates or deadlines.
- The organizational structure or org chart detailing necessary team members, including external vendors.
- Each team member's responsibilities and qualifications necessary to fulfill stated duties.
- Work verification (e.g., who is responsible for carrying out a task, as well as who is responsible for checking the work).
- Supplier standards (e.g., specify the standards the prospective suppliers must meet before they can bid on a contract, such as ISO 9001:2015).
- A list of qualified suppliers.
- Testing parameters.
- Performance standards and how performance will be documented.
- Acceptance criteria.
- Deliverables.
- A feedback mechanism for internal and/or external customer feedback.
- Quality control procedures.
- Audits.
- Training (e.g., overview, job-specific, or refresher training).

- Corrective action and preventive actions, including the persons responsible for CAPA.
- Suggested corrective action.
- Required notifications.
- Any references or related materials, including performance ratings or performance reports.

Quality Plan Documentation and Deployment

Quality plans result from both deployed strategic quality policies (which are linked to organizational strategic plans) and from the specific legal regulations, industry standards, organization policies and procedures, internal guidelines, and good practices needed to meet customers' requirements for products or services.

Strategic-level quality plans are developed and deployed through the strategic planning process. These broad-based quality plans become the guideline for each function's or department's supporting quality plan. Where appropriate, each function or department may develop and internally deploy operating-level quality plans.

Operating-level quality plans often are the resulting document(s) from a production scheduling function. As such, this documentation often includes blueprints, a copy of the customer's order, references to applicable standards, practices, procedures, and work instructions, and details on how to produce the specific product or service.

When the product or service is produced, the planning documents may be augmented by inspection documentation, statistical process control (SPC) charts, and copies of shipping documents and customer-required certifications. In the process, the plans are transformed from documents to records. In a fully computerized system, the documents mentioned may well be interactive computer screens accessed at operators' workplaces and control points. These screens, internally, become records when operators, inspectors, shippers, and others make computer entries to the screens.

A completed set of matrices, developed by a quality function deployment (QFD) process, may fulfill a component of an organization's quality plan. The purpose of QFD is to capture and deploy the customers' needs and requirements throughout the organization.

Documenting the quality plans has multiple uses, such as:

- Ensuring conformance to customer requirements.
- Ensuring conformance to external and internal standards and procedures.
- Facilitating traceability.

- Providing objective evidence.
- Furnishing a basis for training.
- Together with multiple plans for the organization's products, services, and projects, providing a basis for evaluating the effectiveness and efficiency of the quality management system (QMS).

Quality Planning Process

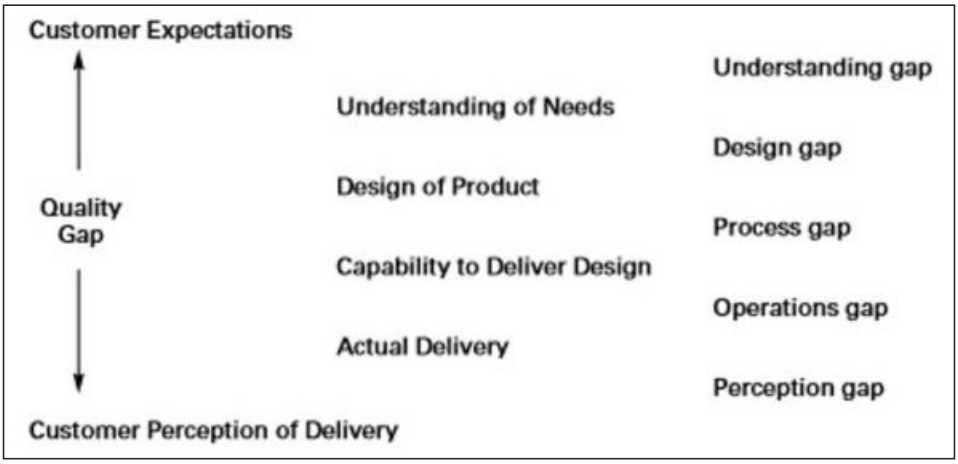
The Juran Trilogy

Conversion of goals into results (making quality happen) is done through managerial processes—sequences of activities that produce the intended results Managing for quality makes extensive use of three such managerial processes:

These processes are now known as the "Juran trilogy".

Quality Planning Problem

The quality planning process and its associated methods, tools, and techniques have been developed because in the history of modern society, organizations have rather universally demonstrated a consistent failure to produce the goods and services that unerringly delight their customers.



The Quality Planning Solution

Quality planning provides the process, methods, tools, and techniques for closing each of the component gaps and thereby ensuring that the final quality gap is at a minimum.

The Steps involved are:

Step 1: Establish the Project

- A quality planning project is the organized work needed to prepare by an organization to deliver a new or revised product. Activities associated with establishing a quality planning project:
  - Identify which projects are required to fulfill the organization's strategy.
  - Prepare a mission statement for each project.
  - Basis for establishing quality goals.
  - Establish a team to carry out the project.
  - Plan the project.

Identification of Projects

- Deciding which projects to undertake is usually the outgrowth of the strategic and business planning of an organization. Management needs to fulfill the following key roles:
  - Setting Quality Goals.
  - Nominating and Selecting Projects.
  - Selecting Teams.

- Supporting Project Team.
- Monitoring Project.

Prepare Mission Statement

- The mission statement is the written instruction for the team that describes the purpose of the project. The team mission describes:
  - Scope of the planning project.
  - The goals of the project.

Basis for Establishing Quality Goals

- The Technology as a basis.
- The Market as a basis.
- Bench marking as a basis.
- History as a basis.
- Quality goods are a moving target.
- Project goals.
- Measurement of goals.

An effective quality planning project goal must have five characteristics for it to provide a team with enough information to guide the planning process.

The Goal must be:

- Specific.
- Measurable.
- Agreed by those affected.
- Realistic.
- Time Specific.

Establish Team

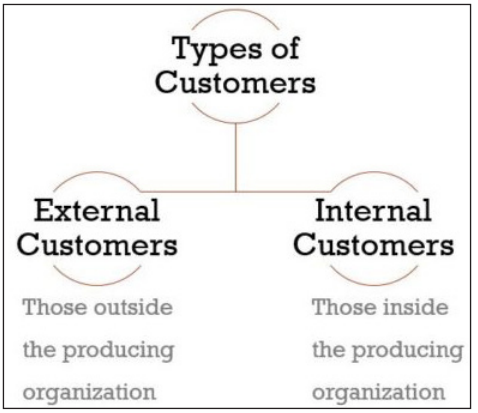
Team involvement promotes sharing of ideas, experiences, and a sense of commitment to being a part of and helping the organization achieve its goal. The diversity of team members brings a more complete working knowledge of the product and processes to be planned. The diversity of team members brings a more complete working knowledge of the product and processes to be planned.

Product Policies

Companies need to have very clear policy guidance with respect to quality and product development. Four of the most critical policies are:

- Deficiencies in new and carryover designs.
- Intended versus Unintended use.
- Requirement of formal Quality Planning Process.
- Custody of designs and change control.

Step 2: Identify the Customers



- External Customers:
  - The purchaser.
  - The end user/ultimate customer.
  - Merchants.
  - Processors.
  - Suppliers.
  - Original equipment manufacturers (OEMs).
  - Potential customers.
  - Hidden customers.
- Internal Customers.

Identifying the internal customers requires some analysis because many of these relationships tend to be informal, resulting in a hazy perception of who the customers

are and how they will be affected. Effectiveness in meeting the needs of these internal customers can have a major impact on serving the external customers.

Identifying the Customers

A high-level flow diagram of the processes related to the product help in identifying the customers that might have been missed and refining understanding of how the customers interact with the process.

Step 3: Discover Customer Needs

- The third step of quality planning is to discover the needs of both internal and external customers for the product. Discovering customer needs is a complex task. When designing a product, there are actually two related but distinct aspects of what is being developed:
    - The technology elements: What the product's features will actually do or how it will function.
    - The human elements: The benefits customers will receive from using the product.

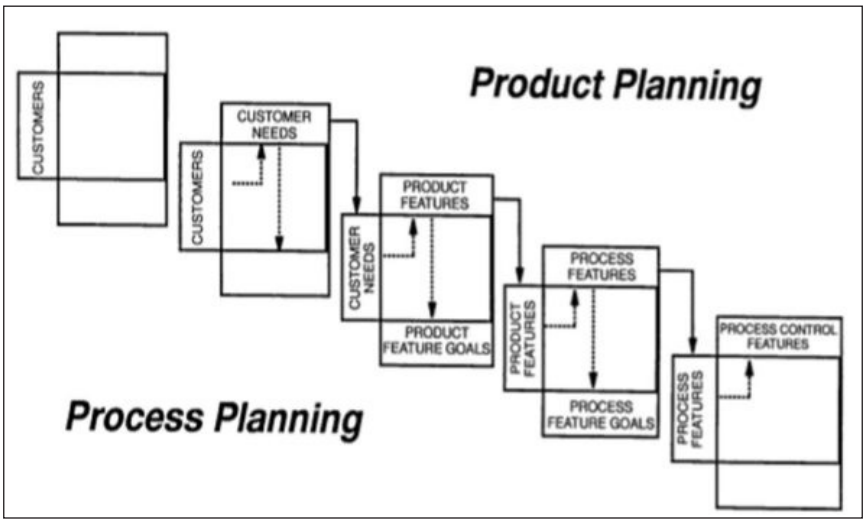
Key activities required for effective discovery of customer needs:

- Plan to Collect Customers' Needs:
    - Customer surveys, Routine communication.
    - Tracking customer complaints, Customer meetings.
- Collect List of Customers' Needs in their Language.
    - Must be stated in terms of benefits sought.
- Analyze and Prioritize Customer Needs:
    - Organizing, consolidating, and prioritizing the list of needs for both internal and external customers.
- Translate their needs into "our" language:
    - The customer's language, the supplier's ("our") language and a common language.
- Establish units of measurement and sensors.

Other Activities

- Stated Needs and Real Needs.
- Perceived Needs.

- Cultural Needs.
- Needs Traceable to Unintended Use.
- Human Safety.
- User Friendly.
- Promptness of Service.
- Customer Needs Related to Deficiencies.
- Warranties.
- Effect of Complaint Handling on Sales.
- Keeping Customers Informed.
- Quality Planning Spreadsheets:
    - Customer needs spreadsheet.
    - Needs analysis spreadsheet.
    - Product design spreadsheet.
    - Process design spreadsheet.
    - Process control spreadsheet.



Step 4: Develop the Product

Once the customers and their needs are fully understood, product that will meet those needs best is designed. Most companies have some process for designing and bringing new products to market. In this step, the focus is on the role of quality in product

development and how that role combines with the technical aspects of development and design appropriate for a particular industry.

- Overall, two quality objectives are there for this step:
  - Determine which product features and goals will provide the optimal benefit for the customer.
  - Identify what is needed so that the designs can be delivered without deficiencies.

Activities Involved

- There are six major activities in this step:
  - Group together related customer needs.
  - Determine methods for identifying product features.
  - Select high-level product features and goals.
  - Develop detailed product features and goals.
  - Optimize product features and goals.
  - Set and publish final product design.
- Group together related customer needs:
  - Based on the data developed in the preceding steps, the team can prioritize and group together those needs which relate to similar functionality.
  - This activity does not require much time, but it can save a lot of time later.
  - Grouping related needs together allows the planning team to "divide and conquer," with sub-teams working on different parts of the design.
- Determine methods for identifying product features:
  - Before starting to design, a team should develop a systematic plan for the methods it will use in its own design.
  - Some of the options are:
    - Benchmarking.
    - Basic Research.
    - Market Experiments.
    - Creativity.

- Select high level product features and goals:
  - As with all goals, product feature goals must meet certain criteria.
  - Product feature goals should be:
    - Measurable.
    - Optimal.
    - Legitimate.
    - Understandable.
    - Applicable.
    - Attainable.
- Develop detailed product features and goals.

For large and highly complex products, it is necessary to divide the product into a number of components and subcomponents for detailed design. In order to ensure that the overall design remains integrated, consistent, and effective in meeting customer needs, these large, decentralized project require:

- A steering or core team that provides overall direction and integration.
- Explicit charters with quantified goals for each component.
- Regular integrated design reviews for all components.
- Explicit integration of designs before completion of the product design phase.
- Optimize product features and goals:
  - Once the preliminary design is complete, it must be optimized.
  - Finding the optimum involves balancing the needs, whether they are multi-company needs or within-company needs.
  - There are several techniques that help achieve this optimality:
    - Design Review.
    - Joint Planning.
    - Structured Negotiation.
    - Create New Options.
    - Competitive Analysis.
    - Saleability Analysis.
    - Value Analysis.

- Set and publish final product design: After optimizing and testing design, the product features and goals to be included in the final design are selected. In this stage, the results of product development are officially transmitted to other functions through various forms of documentation. The team must determine the process for authorizing and publishing product features and product feature goals. Along with the features and goals, the team should include any procedures, specifications, flow diagrams, and other spreadsheets that relate to the final product design. If an organization has an existing process for authorizing product goals, it should be re-examined in light of recent experience.

Step 5: Develop the Process

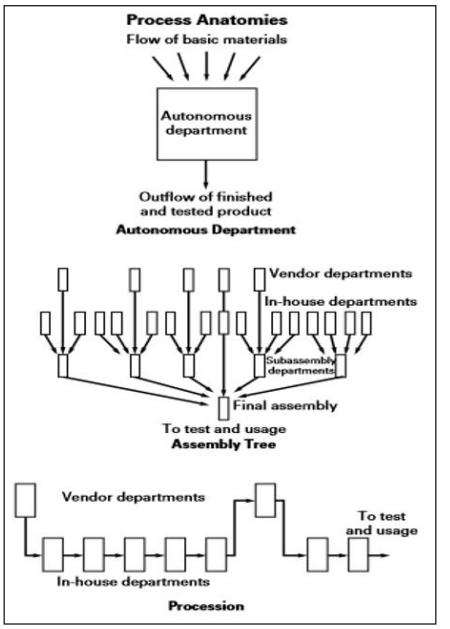
- "Process development" is the set of activities for defining the specific means to be used by operating personnel for meeting product quality goals.
- Some related concepts include:
  - Sub-processes: Large processes may be decomposed into these smaller units for both the development and operation of the process.
  - Activities: The steps in a process or sub-process.
  - Tasks: The detailed step-by-step description for execution of an activity.
- The eleven major activities involved in developing a process are:
  - Review product goals.
  - Identify operating conditions.
  - Collect known information on alternate processes.
  - Select general process design.
  - Identify process features and goals.
  - Identify detailed process features and goals.
  - Design for critical factors and human error.
  - Optimize process features and goals.
  - Establish process capability.
  - Set and publish final process features and goals.
  - Set and publish final process design.

Review Product Goals

Lack of participation between product and process development teams leads to reduction of the number of alternative designs. Cultural resistance shown by product design

team to proposals by the process design team to make changes to the product design. Review of product quality goals ensures that they are understood by those most affected by the process design.

- Identify operating conditions:
  - User's Understanding of the Process.
  - How the Process Will be Used.
  - The Environments of Use.
- Collect known information on alternate processes:
  - Process Anatomy:
    - The Autonomous Department.
    - The Assembly Tree.
    - The Procession.
- Process Quality Management:



- Measuring the Process:
  - Deficiency rates.
  - Cycle Time.
  - Unit Cost.
  - Output Rate.

- Select general process design: Most effective process redesigns are a combination of the tried and true existing processes with some significant quantum changes in some parts of the process. Testing Selected Processes:
  - Pilot test.
  - Modular test.
  - Simulation.
  - Dry run.
  - Acceptance test.
  - Comparisons and benchmarks.
- Identify process features and goals: A "process feature" is any property, attribute, and so on that is needed to create the goods or deliver the service and achieve the product feature goals that will satisfy a customer need. "What mechanisms do we need to create or deliver those characteristics (and meet quality goals) over and over again without deficiencies?"
- Identify detailed process features and goals.
- Design for critical factors and human error:
  - Technique Errors.
  - Lack of Instant Feedback.
  - Human Inattention Errors.
  - Principles of Errorproofing.
  - Elimination.
  - Replacement.
  - Facilitation.
  - Detection.
  - Mitigation.
- Optimize process features and goals.
- Establish process capability: Before a process begins operation, it must be demonstrated to be capable of meeting its quality goals. Any planning project must measure the capability of its process with respect to the key quality goals.

- Set and publish final process features and goals: This is the stage where the results of process development are officially transmitted to other functions through various forms of documentation. These include the specifications for the product features and product feature goals as well as the spreadsheets and other supporting documents. All this is supplemented by instructions, both oral and written.
- Set and publish final process design: After making the last revision to the process design spreadsheet, it should be checked once more to verify the following:
    - That each product feature has one or more process features with strong or very strong relation. This will ensure the effective delivery of the product feature without significant defects. Each product feature goal will be met if each process goal is met.
    - That each process feature is important to the delivery of one or more product features. Process features with no strong relationship to other product features are unnecessary and should be discarded.

Step 6: Develop the Control and Transfer to Operations

Planners develop controls for the processes, arrange to transfer the entire product plan to operational forces, and validate the implementation of the transfer. There are seven major activities in this step:

- Identify controls needed.
- Design feedback loop.
- Optimize self-control and self-inspection.
- Establish audit.
- Demonstrate process capability and controllability.
- Plan for transfer to operations.
- Implement plan and validate transfer.
- Identify controls needed:
    - Process control consists of three basic activities:
        - Evaluate the actual performance of the process.
        - Compare actual performance with the goals.
        - Take action on the difference.

- Design feedback loop:
  - Once the control subjects are selected, remainder of the feedback loop is designed by:
    - Setting the standards for control—i.e., the levels at which the process is out of control and the tools, such as control charts, that will be used to make the determination.
    - Deciding what action is needed when those standards are not met, e.g., troubleshooting.
    - Designating who will take those actions.

Optimize Self-control and Self-inspection

Operations, self-control takes place when workers know what they are supposed to do. Goals and targets are clearly spelled out and visible.Output of the workers is measured, and they receive immediate feedback on their performance. Workers have the ability and the means to regulate the outcomes of the process. They need a capable process along with the tools, training, and authority to regulate it.

- Establish Audit:
  - A separate audit plan should be developed for validating the transfer of the plan.
  - The audit plan for the transfer should include the following:
    - Goals to meet.
    - How meeting the goals will be measured.
    - The time phasing for goals, measurement, and analysis.
    - Who will audit.
    - What reports will be generated.
    - Who will have responsibility for corrective action for failure to meet specific goals.
- Demonstrate process capability and controllability:
    - Process capability must be addressed during the design of the process.
  - Process capability and controllability must be verified during implementation.
- Plan for transfer to operations: An information package is prepared consisting of certain standardized essentials: goals to be met, facilities to be used, procedures to be followed, instructions, cautions, etc. The package is accompanied by a formal document of transfer of responsibility.

- Implement plan and validate transfer: The final activity of the quality planning process is to implement the plan and validate that the transfer has occurred. A lot of time and effort is spent in making the product plan, and validating that it all works is well worth the effort.

EXTERNAL QUALITY ASSESSMENT

External Quality Assessment (EQA)/Proficiency Testing (PT) allows for a comparison of a laboratory's testing procedures to other laboratories across the world. Comparisons can be made to a peer group of laboratories or to a reference laboratory.

EQA involves running blind patient-like samples, comparing your results to peer results, in order to retrospectively monitor the accuracy of reporting. EQA samples should be treated as if they were a patient sample and therefore must be run by personnel who would normally use the device. This provides confidence in the reliability of patient test results.

Benefits of EQA

Participating in an EQA scheme allows a laboratory to gather valuable data, this data can be used in a variety of ways:

- Enables a comparison of performance between laboratories.
- Enables a comparison of performance between testing sites.
- Provides an early warning for systematic errors.
- Indicates areas for improvement.
- Provides evidence of quality.
- Identifies training areas.
- Detects equipment faults, identify reagent problems and review staff training.
- Compares performance to different analytical methods.

EQA provides assurance to both staff and customers that testing taking place at your laboratory provides accurate and reliable results. Problems can be identified early on and corrective action can be untaken. The reliability of methods, materials, and equipment can be evaluated and training can be developed and its impact monitored.

Large laboratory groups can compare their performance with sites across their group, ensuring accuracy and consistency no matter where testing takes place.

EQA participation is often a requirement for accreditation, gaining accreditation alone has a host of benefits, not least an increased confidence in results from customers, current and potential.

Benefits of EQA in Point of Care Testing

Point of care testing (POCT) refers to testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient. The popularity and demand for POCT has recently seen rapid growth, this comes from the advantages including the added convenience of being able to obtain a rapid result at the patient's bedside, thus allowing immediate action, saving time and improving the potential outcome for the patient.

Although there are many benefits of using POCT devices in terms of their convenience, these benefits are only true if the results produced are both accurate and reliable. Ensuring accuracy and reliability is the primary responsibility of Quality Control.

EQA is strongly recommended for all point of care devices and is recommended by ISO 22870, which providesspecific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189.

WHAT makes a Good EQA Scheme?

There are many External Quality Control schemes that come in different varieties. EQA schemes can be mandatory, required either by accreditation or law. Others are voluntary and carried out by laboratories who want to ensure that they are carrying out accurate testing and improve the quality of the lab's performance.

A good EQA scheme should offer:

- Enables a comparison of performance between laboratories.
- Frequent reporting and rapid report turnaround time to minimise the amount of time an error can go unnoticed.
- High quality material in a format that works for you.
- Well-designed reports that allow for quick and easy troubleshooting of erroneous results at a glance.
- A sample matrix similar to a real patient sample.
- Large participant numbers to provide a large peer group to compare results to.
- A realistic range of analyte concentrations.
- Your entire range of tests in consolidated programmes, saving you time and money.

Limitations of EQA

EQA is a great tool for comparing against a peer group and maintaining an effective QC strategy, however, it has its limitations.

EQA/PT alone cannot provide a complete evaluation alone; it is important to also run third party controls regularly. You can find out about the importance of third party controls here.

EQA results can also be affected by variables not relating to patient samples, including preparation, clerical functions, matrix effects, and selection of method. The errors can appear to be a downside to EQA but it can be used as a way to evaluate staff performance as well as assay performance.

QUALITY, COST AND DELIVERY

Quality, cost, delivery (QCD), sometimes expanded to QCDMS (Quality, Cost, Delivery, Morale, Safety), is a management approach originally developed to help companies within the British automobile sector. Make it work. QCD analysis is used to assess different components of the production process. It also provides feedback in the form of facts and figures that help managers make logical decisions. By using the gathered data it is easier for organizations to prioritize their future goals.

QCD helps to break down one big thing into many smaller ones, which helps organize and prioritize efforts and, psychologically, prevents the feeling of being overwhelmed.

QCD is a "three-dimensional" approach. If there is a problem with even one dimension, the others will inevitably suffer as well. One dimension cannot be sacrificed for the sake of the other two.

Benefits of QCD

QCD offers a method of measuring processes while being applicable to both simple and complicated business processes. It also represents a basis for comparing businesses. For example, a business measuring supplier delivery performance may easily compare its findings against other businesses' performance. But basically QDC altogether will be implemented as a single management in any corporate for man-power reduction.

QCDF

Flexibility is often included as a measure to QCD resulting in Quality, Cost, Delivery and Flexibility (QCDF). Flexibility relates to the capacity to adapt to changes/modifications .The modifications could be in a) input quality b) output quality c) product specifications d) delivery schedules.

Quality

Quality is the ability of a product or service to meet and exceed customer expectations. Customers' requirements determine the quality scope. It is almost always listed first, presumably because poor quality often results in bad business. Quality is the result of the efficiency of the entire production process formed of men, material, and machinery.

Even though quality is now seen as a competitive advantage, US business organizations in the 1970s tended to focus more on cost and productivity. That approach led to a major share of the US market being captured by Japanese business organizations, which onces again proves that in order to be successful an organization has to focus on all three QCD dimensions together.

It was not until the late 1970s and the beginning of the 1980s that the factor "quality" drastically shifted and became a strategic approach created by Harvard professor David Garvin. This approach focuses on preventing any mistakes and, also, puts a great emphasis on customer satisfaction.

Quality Basis

Gavin lists eight dimensions of quality:

- Performance: Performance is a product's primary operating characteristics. For example, for a stereo those characteristics would include sound quality, surround sound, and wifi connectivity.
- Conformance: Conformance refers to the degree to which a certain product meets the customer's expectations.
- Special features: Those are any additional features of a product or service. In other words, extras. An example of an extra could be free meals on an airplane, or free drinks at a museum visit. And for a TV, for example, it can be split screen, internet access, embedded apps etc.
- Aesthetics: Aesthetics refer to a product's looks, sound, feel, smell, or taste. When it comes to aesthetics, complete customer satisfaction is simply impossible as it is very subjective. For example, one group of customers may like the smell of a certain perfume while other may find it completely repelling.
- Durability: The durability of a product is how long the product lasts before it has to be replaced. Durability can be improved by the usage of long-life materials or improved technology processes in manufacturing. Some products are expected to be more durable than others. Those often include home appliances and automobiles for which durability is a primary characteristic of quality.
- Reliability: Reliability refers to the time until a product breaks down and has to be repaired, but not replaced. This feature is very important for products that have expensive maintenance.

- Serviceability: "Serviceability is defined by speed, courtesy, competence and ease of repair." Customers usually want products that are relatively quickly and easily serviceable.
- Perceived quality: The perceived quality may be affected by the high price or the good aesthetics of a product.

Product Components

The quality of a product depends almost entirely on the quality of the supplied materials. One cannot produce a high-quality end product from low-quality components. Suppliers and manufacturers must be willing to work together in order to reduce and eliminate errors and defects, and achieve higher quality end products. SMEs should discuss with their suppliers how quality improvements can affect the overall performance of the supply chain. A properly implemented quality procedure can reduce testing, scrap, rework, etc. This could result in a reduction of production costs.

Consequences of Poor Quality

- Business loss: Poor quality often results in unsatisfied customers which leads to business loss. In an environment where the customer can easily switch to a competitor, producing poor-quality products can be fatal to an organization.
- Productivity: Poor-quality products must often be reworked or scrapped entirely, which reduces the amount of usable output.
- Costs.

Costs

The biggest cost in most business organizations is the manufacturing cost. Production has a direct responsibility when it comes to controlling and reducing manufacturing cost.

There are four basic types of manufacturing costs:

- Raw materials.
- Direct labour.
- Variable overhead – production costs that increase or decrease depending on the quantity produced. For example, electricity is a variable overhead. If a company increases production, it will also increase the usage of equipment, which will result in a higher electricity bill.
- Fixed overhead.

Those are the production cost that stay the same even if the quantity produced increases or decreases. Those costs include:

- Salaries for employees that do not work directly on the production line (e.g. security guards, safety inspectors, etc.).
- Depreciation costs.
- Occupancy costs – property taxes, building insurance, etc.

Cost Reduction

Businesses have been under the pressure to drive down costs in order to be more competitive for many years. There are many books and articles nowadays that suggest different ways of reducing costs, some of which are as follows:

- Minimizing supplier costs.
- Adopting lean manufacturing.
- Eliminating waste.

Delivery

Logistics are an essential part in providing good customer service on time. Logistics customer service can be separated into three elements (before, during and after delivery of the product):

- Pre-transaction elements.
- Transaction elements.
- Post-transaction elements.

Increasing Profitability with QCD

There are seven measures used to increase profitability:

- Not right first time (NRFT): Not getting things right the first time means wasted resources, effort and time. This all leads to excessive costs for the company and poor-quality, high-priced products for the customer. NRFT measures the quality of a product and is expressed in "number of defective parts per million". The number of defective products is divided by the total quantity of finished products. This figure is then multiplied by 10^6 to get the number of defective parts per million.
- NRFT can be measured internally (defective parts identified within the production process) or externally (defective parts identified outside the production process (e.g. by the supplier or the customer).

- Delivery schedule achievement (DSA): DSA analyses how well a supplier delivers what the customer wants and when they want it. The goal is to achieve 100% on-time delivery without any special deliveries or overtime payments, which only increase the delivery cost. DSA measures the actual delivery performance against the planned delivery schedule. Failed deliveries include:
  - "Not on time" deliveries – both late and early.
  - "Incorrect quantity deliveries".
  - Both "not on time" and "incorrect quantity deliveries".
- People productivity (PP): PP is measured by the time it takes (in staff hours) to produce a good-quality product. Obtaining high PP is only possible when:
  - Most employees' work adds value to the process.
  - Non-value added work is reduced as much as possible.
  - Waste is completely eliminated.
- Stock turns (ST): The ST ratio shows how quickly a company turns raw materials into finished, ready-to-be-sold products. The quicker the better. A low ST means that the money is tied up in stock, and the company has fewer funds to invest in other parts of its business.
- Overall equipment effectiveness (OEE): The OEE shows how well a company uses its equipment and staff. OEE is calculated on the base of three elements:
  - Availability compares the planned and the actual time of the process run. For example, if a machine is planned to run 100 hours a week, but in reality runs only 50, then the availability is 50%.
  - Performance compares the ideal output and the actual output. For example, if a certain process is planned to take 10 minutes, but actually takes 20, then the productivity is 50%.
  - Quality to show the quality of a product, a company has to compare the number of good parts produced with the total parts produced. If it produces 100 parts per hour but only 50 of them are of saleable standard, then quality is running at 50%.
- Value added per person (VAPP): VAPP shows how well people are used to turn raw materials into finished goods. In order to calculate VAPP, three things need to be taken into account:
  - The sales value of a unit after production (output value).

- The raw material value of a unit before production (input value).
- The number of direct production process employees.

- Floor space utilisation (FSU): FSU measures the sales revenue generated by a square meter of factory floor space. Usually to achieve higher FSU the floor space has to be reduced. That means eliminating inventory and reducing the necessary space to a minimum.

PREVENTIVE ACTION

A preventive action is a change implemented to address a weakness in a management system that is not yet responsible for causing nonconforming product or service.

Candidates for preventive action generally result from suggestions from customers or participants in the process but preventive action is a proactive process to identify opportunities for improvement rather than a simple reaction to identified problems or complaints. Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

The focus for preventive actions is to avoid creating nonconformances, but also commonly includes improvements in efficiency. Preventive actions can address technical requirements related to the product or service supplied or to the internal management system.

Many organizations require that when opportunities to improve are identified or if preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of nonconformities and to take advantage of the opportunities for improvement. Additionally, a thorough preventive action process will include the application of controls to ensure that the preventive actions are effective. In some settings, corrective action is used as an encompassing term that includes remedial actions, corrective actions and preventive actions.

Risk and Decision Making

Preventive actions rely upon on the consequences of change. Once changed, inevitably, risks should be taken into consideration. In this case preventive actions aim to minimize or, where possible, eliminate the risks.

Risks arise when little is known and understood about a particular situation. The chances of risk are minimized whilst one has better knowledge of the opportunities and consequences that could follow a situation. In order to reduce risk, a full analysis of potential best and worst results is required. Before taking into consideration any plan, people should be aware of the consequences of both success and failure. Not only

the internal aspects - capability, expertise and willingness of staff- but also the external aspects of an organisation - stakeholders, customers, clients - should be assessed.

Strategic risk management works with defining an organisation's approach to risk in terms of condition, attitudes and expertise. It identifies the possible areas of risk and assures that the proper approach is used. Then operational risk management will insure that steps for minimizing or eliminating the risk are followed. A strategic approach of the risk management includes studying the environment and being aware of the issues that must be considered in any situation.

Risks can occur due to a range of unexpected possible and potential events outside of the organisation's control, such as: political instability, change in currency, changes of the weather which could lead to a change in customer behavior, etc.

Therefore, in an organisation it is important to know and understand what events could take place, where and why. So, managers should prioritize some steps of preventive actions in order to anticipate these kind of issues, especially focusing more on:

- Patterns of behaviour.
- Accidents.
- Single events and errors.

"Patterns of behavior" relates to the morale and motivation of people. The effects of human behavior (such as victimization, bullying, harassment and discrimination) could affect confidence, weakening the relationships meant to lead to performance.

Accidents could happen anytime and anywhere. Thus, an organisation has to assure that the accidents are kept to a minimal level. In this situation preventive actions should focus more on the nature and quality of the working environment, safety aspects and technology.

Single events and errors are very hard to be managed and impossible to be eliminated. The risk should be kept at a minimum through supervision systems, regular inspections and procedures.

In order to perform a change, an organisation has to do a forecast, deeply understanding where that event could lead and its consequences. Thus, the risk of a particular event and its probability of occurring should be clear. Using this information, one can understand and better make future decisions, proposal and initiatives.

Examples in Management

Preventive actions differ from one organisation to another. Their number is vast, among them counting:

- Assessing business trends.

- Monitoring processes.
- Notifications regarding any situation.
- Perform risk analysis.
- Assessing new technology.
- Regular training and checking.
- Recovery planning.
- Safety and security policies.
- Audit analysis.

Technology Safety and Security

Nowadays, due to fast changes in engineering, there is a large emphasis in the enhancement of safety and security regarding technology. However, in order to avoid some issues, more powerful safety analysis techniques are constantly being developed. As safety and security issues can occur anytime, intentionally or not, more preventive strategies against loss or hacking are enhanced. These actions aim to focus on the possible causes of the problem, rather than solving an already critical situation.

Computing

Computer security tries to defend computers by assuring that their networks are not accessed or disrupted. They approach different tactics in order to protect against attackers, creating barriers or lines of defense, through firewalls or encryption. However, losses result also from actions not executed properly (such as human errors) or from system errors among components.

Losses could be prevented through preventive strategies and tactics. Security analysts could find possible attackers, highlighting their reasons, potential and purpose. Owning proper knowledge, security experts could assess their own system and identify the most suitable defense strategy. Tracing is one of the methods used by people in order to find any issue or deficiency in their system.

Focusing first on strategy rather than tactics can be achieved by adopting a new system-theoretic causality model recently developed to provide a more powerful approach to engineering for safety. Causality models used in accidents are either traditional, caused by human errors, or more complex, caused by wrong interaction between components and systems errors.

STAMP (System-Theoretic Accident Model and Processes) is a model of accident causality used in investigating potential accidents that can occur. In this case, issues are seen as results of inadequate control of the safety components used.

Nowadays more powerful systems that analyse safety have been created. STPA (System-Theoretic Process Analysis) uses such techniques, being based on the STAMP model of causality. Once the cause is identified, STPA examines the system, creating a proper scenario that could solve the issue.

Information Systems

Regarding technology, not only the safety and security of computers and isolated devices can be threatened, but also of entire complex information systems. As not all decisions made in an organisation are based on known rules, the analytical manager will examine in details the situation and anticipates potential issues that can occur. However, many decisions could have a great impact on some aspect of the organisation and cannot be easily reversed.

Thus, modelling and simulating play the roles of preventive actions, being applied earlier for the design of the process, where real factual data is not available. It is an abstract representation, that includes all aspects of a process so its potential impact could be better analysed. Such a representation before implementing can be done through business process modeling (BPM).

On one hand, there are indeed the deterministic systems that rely on the input data and are capable of predicting accurate output. On the other hand, there is the probabilistic systemas well, which does not forecast with completely accuracy. However, both deterministic and probabilistic systems need some earlier actions that could prevent issues.

Analysis and design count are among the most important activities done before starting-up a business. During analysing, one gets a better understanding over the potential of the business; a diagrammatic model ensuring the agreement between IT professionals and system users. System design aims to design the way in which the system will work, this being eventually followed by system building.

EXPEDITING

Expediting is a concept in purchasing and project management for securing the quality and timely delivery of goods and components.

The procurement department or an external expeditor controls the progress of manufacturing at the supplier concerning quality, packing, conformity with standards and set timelines. Thus the expeditor makes sure that the required goods arrive at the appointed date in the agreed quality at the agreed location.

Expediting is especially needed in large scale projects, for example, in shipbuilding or when a refinery is being erected, because a delay caused by late delivery or inferior

quality will increase expense and could lead to unsatisfied clients, thus the loss of a project or reputational damage. To save these unnecessary costs and minimize potential risks, the supplier and customer may agree on the use of a third party expeditor. These are experts from companies specializing in this field who keep track of the deadlines, supervise progress on site and check whether the components are properly packed. After inspection they notify the involved parties and banks about their findings; if everything is as agreed the bank will initiate the transfer of the price of the goods to the supplier. In this way, the supplier secures his liquidity as he is paid immediately when the components leave his factory (letter of credit) and the customer/bank knows that the goods will be delivered correctly. Expediting is relevant for many industries, such as the oil and gas industry, the general energy industry and the infrastructure industry.

Expediting exists in several levels:

- Production control: The expeditor inspects the factory whether the production is up to the standards of the country the goods are destined for. This is especially necessary for food or engineering equipment like power plant components. He or she controls as well whether the regular audits for ISO 9001 etc. have been made.
- Quality control: The components are tested whether they function as required and whether they are made to the measurements and standards of the customer. A part of this quality control can be the testing for compliance with standards of the destination country, e.g. ASME.
- Packing/transport survey: This is the lowest and most used level of expediting, as the goods are only counted and the packing is controlled whether it will withstand the adversities of transport (pre-shipment inspection).
- Project management: At a large-scale project, not only goods are controlled. The expeditor also keeps an eye on the deadlines and milestones of the project and whether the supplier will be on time. This way he or she monitors the crucial procurement parts of the project.

As the different levels of expediting require different skills, specialists and laboratories, many third party expeditors specialize in only one or several of these levels, while few offer expediting services on all levels.

Larger companies normally have their own expeditors who can perform all four levels. Third parties then are only used when in-house capacity is overstretched or a neutral third party is needed.

Most of the time companies use third party inspector expeditors who are responsible for inspection of critical items as well as expediting. In strict quality control conditions, those quality inspector expeditors will give importance to quality work, rather than to expediting work, which may not be a useful technique to get expediting work completed.

Field Expediting

Field expediting provides clients with a comprehensive review of the precise standing of their order and any on site action to rectify any potential problem areas. Field expediting means the inspection and control of the expeditor on site. This gives clients a comprehensive review of the exact current status of their order and an educated projection of the future planning and status. Furthermore, while being on site, experts for expediting can identify possible problems and bottlenecks that could lead to potential delays.

Desk Expediting

Desk expediting is also known as telephone expediting. It is an important tool for producing companies to monitor order progress with manufacturers. Especially at milestone of a project, desk expediting can be helpful to check whether the project is still within the agreed schedule. Although desk expediting is a quick and easy way to be informed about the current status of a project, it should always be conducted in combination with field expediting to securely verify the actual status.

Telephone Expediting

Desk/Phone expediting provides a valuable tool for monitoring the progress of orders with a manufacturer. Contact is established at specific milestones within the order fabrication method and a brief outline of status standing obtained throughout the following conversation. Associate experienced expeditor will very quickly assess whether the order is progressing consistent with plan or whether alternative measures are needed to verify and presumably improve the order progress. Desk/phone expediting is best used as a tool to supplement field expediting. It's additionally a helpful approach of making the vendor aware that delays on the order won't be accepted by their shopper.

CONTINUED PROCESS VERIFICATION

Continued process verification (CPV) is the collection and analysis of end-to-end production components and processes data to ensure product outputs are within predetermined quality limits. In 2011 the Food and Drug Administration published a report outlining best practices regarding business process validation in the pharmaceutical industry. Continued process verification is outlined in this report as the third stage in process validation. Its central purpose is to ensure that processes are in a constant state of control, thus ensuring final product quality. Central to effective CPV is a method with which to identify unwanted process inconsistencies in order to execute corrective or

preventive measures. Once quality standards are set in place they must be monitored with regular frequency to confirm those parameters are being met. Continued process verification not only helps protect consumers from production faults, but business also see benefits in implementing a CPV program. Should product outputs not match target standards it can be very costly to investigate the problem source without existing CPV data.

Vital Components of Continued Process Verification

- An alert system to identify process malfunctions that lead to deviations from quality standards.
- A framework for gathering and analyzing data of final product quality and process consistency. Analysis should include source materials consistency and manufacturing equipment condition; and data should be collected in a format that allows for long term trend analysis as well as intra-production quality analysis.
- Continued review of quality qualification standards and process reliability. Departures from any predetermined standards should be flagged for review by trained personnel and appropriate measures undertaken to restore end-to-end quality standards.

Data Collection and Analysis

Crucial in effective CPV implementation is an appropriate data collection procedure. Data must allow for statistical analytics and trend analysis of process consistency and capability. A correctly implemented procedure will minimize overreactions to individual production outlier events and guarantee genuine process inconsistency are detected. While production variability can sometimes be obvious and even casually identified the FDA recommends using statistical tools to quantitatively detect problems and identify root causes. Initially, continued process verification should be based on quality standards established in the design phase. After a period of time variations can be detected by identifying deviation from historical data using statistical tools. Furthermore, these same tools can also be used to identify opportunities to optimize processes that may pre-emptively increase quality reliability.

SERVICE QUALITY

Service quality is a product of the effort that every member of the organization invests in satisfying customers. In its broadest sense service quality is defined as superiority or excellence as perceived by the customer.

More especially service quality has been defined as:

- The delivery of excellent or superior service relative to customer expectations.
- Quality is behavior – an attitude – that says you will never settle for anything less community, your stockholders or colleagues with whom you work every day.
- When we want to be effective – delivering good quality to the customer – we must produce services that meet "as much as possible" the needs of the consumer.
- Quality is providing a better service than the customer expects.

One that is commonly us defines services quality as the extent to which a service meets customer's needs or expectations. Today the most popular model of service quality in use is service quality gap model, perceived service quality as the difference between consumer expectations and their perceptions.

Customer Retention through Quality Improvement

The focus of the modern marketers has shifted away from a one-time sale to making repeated sales to the same customer. Increasing attention is being paid to medium and long term perspectives, rather than just the short-term perspective. This has been a major revolution in thinking in the field of marketing. Customer retention usually pays dividends by way of:

- Lifetime value of the customer: If the customer remains loyal to the company, naturally, the repeated purchases represent a cumulative value which is quite substantial compared to any single transaction.
- Reduced costs: It costs much more to acquire a new customer than to retain an old customer. Therefore, the focus of marketing has shifted away from the goal

of mere customer acquisition to customer retention in order to substantially reduce marketing costs.

Benefit from wider opportunities to market more products and services to customers who are already loyal to you. The key concept in customer retention is customer satisfaction. Satisfaction results when the customer feels that the value of a service received by him is substantially higher than the price he paid for acquiring the service. Customer satisfaction can be largely attributed to the quality of the service or product. Thus, delivery of high quality service is crucial to the high service value perception. When the major marketing goal of a company is customer retention, the quality of service delivery is, undeniably, the key differentiator.

Service Quality Assessment

Service quality a critical component of customer's perception will be the dominant element in customer evaluation. In cases where customer service or services are offered in combination with a physical product, service quality may also be very critical in determining customer satisfaction. Customers judge their quality of service on their perception of the technical outcome and how was the outcome delivered. For example, a legal service client will judge the quality of outcome, or how the court case was delivered, and also the quality of the process. Process quality also includes such things as lawyer's timeliness, the responsiveness in returning phone calls, his empathy for the client, his courtesy and interviewing skills. Similarly, a restaurant customer will judge the service on customer's perception of the meals (technical outcome quality) and on how the meal was served and on how the employees interacted with customers (process quality). Some researchers found that customers consider following five dimensions in their assessment of service quality:

- Reliability: This dimension is shown to have the highest influence on the customer perception of quality. It is the ability to perform the promised service dependably and accurately. When service delivery fails the first time, a service provider may get a second chance to provide the same service in the phase called 'Recovery'. The expectations of the customer are usually higher during the recovery phase than before because of the initial failure. Thus, the service provider is likely to come under greater scrutiny, thereby increasing the possibility of customer dissatisfaction. The reliability dimension, which ensures timely delivery time after time, helps the service provider to meet the customer expectations fully at the lowest level of service expectation.

- Responsiveness: It is the willingness of the service firm's staff to help customers and to provide them with prompt service. The customers may have queries, special requests, complaints, etc. In fact, each customer may have problems of his or her own. While the front-end employee may have been trained or equipped to deliver standardized services, the customers want them to go beyond this limit. It is the willingness to help the customer or willingness to go that extra

distance that is responsiveness. The second aspect of responsiveness is speedy response to a customer request. When response is delayed customers usually loses interest. Many sales representatives respond on the phone, 'We will call you back'. The call is never returned. The customer draws his or her own conclusion about the quality of service he is likely to receive in the future.

- Assurance: It is defined as the ability of the company to inspire trust and confidence in the service delivery. It refers to knowledge and courtesy of the service firm's employees and their ability to inspire trust and confidence in the customer toward the company. This dimension is considered vital for services that involve high risk as customers may not be able to evaluate all the uncertainties involved in the process by them. There are property developers/builders who provide a list of previous buyers of flats or apartments to potential buyers. The evaluation of construction services is beyond technical capabilities of most buyers. However, the prospective customers are free to call the previous customers. When prospective customers hear from them about the company and its satisfactory delivery, they feel assured and develop a more positive attitude towards the company.
- Empathy: It refers to the caring, individualized attention the service firm provides each customer. When service provider puts himself in the shoes of the customers, he may see the customer's viewpoint better. When customers feel that the provider is making his best effort to see their viewpoint, it may be good enough for most.
- Tangibles: It refers to physical facilities, equipment, and appearance of a service firm's employees. The job of the tangible and physical evidence of a service is multifunctional. When a patient in the waiting room of a clinic sees the doctor's certificate, he becomes aware of the quality of service he is about to receive. Tangibles provide the customer proof of the quality of service.

These dimensions represent how consumers organize information, about service quality in their minds. On the basis of exploratory and quantitative research, these five dimensions are found. These dimensions are relevant for banking, insurance, appliance repair and maintenance, securities brokerage, long distance telephone service, automobile repair service and others. The dimensions are also applicable to retail and business services. Sometimes customers will use all these dimensions to determine service quality perceptions at other times not. For example, in remote encounter such as an encounter with ATM, empathy is not likely to be relevant dimension and in an encounter such as scheduling a repair call, tangibles will not be relevant.

Using SERVQUAL to Measure Service Quality

The SERVQUAL instrument was based on the premise that service quality is the difference between customers' expectations and their evaluation of the service they received. The first part of the questionnaire asks customers to indicate the level of service they

would expect from a firm in a particular industry. The second part of the questionnaire asks customers to evaluate the service performed by a specific service firm. Gap Model is the method for calculating service quality that involves subtracting a customer's perceived level of service received from what was expected.

SERVQUAL uses 21 questions to measure the five dimensions of tangibles, reliability, responsiveness, assurance and empathy. Through SERVQUAL, firms can measure customers evaluations of their service performance. For example, if customers consistently give firm low scores for one dimension, such as reliability, then the firm's management can take steps to improve that particular dimension of their service offering.

QUALITY IMPROVEMENT

Quality improvement (QI) is a systematic, formal approach to the analysis of practice performance and efforts to improve performance.

A variety of approaches—or QI models—exist to help you collect and analyze data and test change. While it's important to choose a reputable QI model to guide your efforts, it's more important that you fully commit to using the QI process and good QI practices.

Benefits of QI

Understanding and properly implementing QI is essential to a well-functioning practice, and is necessary for any practice interested in improving efficiency, patient safety, or clinical outcomes.

In addition, good QI practices and improved patient outcomes position your practice for success by:

- Helping you prepare for the transition to value-based payment models.
- Allowing you to participate in the public reporting of physician-quality data.
- Giving you the opportunity to participate in the federal Quality Payment Program (QPP) following one of two tracks: the Merit-based Incentive Payment System (MIPS) or the Alternative Payment Model (APM).
- Equipping you with the skills necessary to apply for and complete national recognition programs.

Quality Improvement Basics

The QI process is grounded in the following basic concepts:

- Establish a culture of quality in your practice: Your practice's organization, processes, and procedures should support and be integrated with your QI efforts.

The culture of a practice—attitudes, behaviors, and actions—reflect how passionately the practice team embraces quality. The QI culture looks different for every practice, but may include establishing dedicated QI teams, holding regular QI meetings, or creating policies around your QI goals.

- Determine and prioritize potential areas for improvement: You will need to identify and understand the ways in which your practice could improve. Examine your patient population (e.g., to identify barriers to care, frequently diagnosed chronic conditions, or groups of high-risk patients) and your practice operations (e.g., to identify management issues such as low morale, long patient wait times, or poor communication). Use established quality measures.
- Collect and analyze data: Data collection and analysis lie at the heart of quality improvement. Your data will help you understand how well your systems work, identify potential areas for improvement, set measurable goals, and monitor the effectiveness of change. It's important to collect baseline data before you begin a QI project, commit to regular data collection, carefully analyze your results throughout the project, and make decisions based on your analysis.
- Communicate your results: Quality improvement efforts should be transparent to your staff, physicians, and patients. Include the entire practice team and patients when planning and implementating QI projects, and communicate your project needs, priorities, actions, and results to everyone (patients included). When a project is successful, celebrate and acknowledge that success.
- Commit to ongoing evaluation: Quality improvement is an ongoing process. A high-functioning practice will strive to continually improve performance, revisit the effectiveness of interventions, and regularly solicit patient and staff feedback.
- Spread your successes: Share lessons learned with others to support wide-scale, rapid improvement that benefits all patients and the health care industry as a whole.

Quality Improvement Models and Tools

Quality improvement models present a systematic, formal framework for establishing QI processes in your practice. Examples of common QI models include the following:

- Model for Improvement (Plan-Do-Study-Act [PDSA] cycles): The Institute for Healthcare Improvement's Model for Improvement combines two popular QI models: Total Quality Management (TQM) and Rapid-Cycle Improvement (RCI). The result is a framework that uses PDSA cycles to test interventions on a small scale.
- Six Sigma: Six Sigma is a method of improvement that strives to decrease variation and defects.

- Lean is an approach that drives out waste and improves efficiency in work processes so that all work adds value.

Quality improvement tools are standalone strategies or processes that can help you better understand, analyze, or communicate your QI efforts. Examples of QI tools include run charts, process maps, and fishbone diagrams.

CONTINUOUS QUALITY IMPROVEMENT

Continuous quality improvement, or CQI, is a management philosophy that organizations use to reduce waste, increase efficiency, and increase internal (meaning, employees) and external (meaning, customer) satisfaction. It is an ongoing process that evaluates how an organization works and ways to improve its processes.

The underlying philosophy of continuous quality improvement is that when problems arise it is generally a result of poor work design, unclear instructions, or the failure of leadership, not the people performing the processes. But for those organizations that utilize continuous quality improvement - as most do in some form or another nowadays - how they improve their products and processes permeates the culture of an organization; it's not just for the management team to worry about.

The philosophy behind CQI stresses the need for teamwork among all levels of employees and maintains that all employees are valuable members of the team. Assuming that employees are doing the day-to-day work that keeps the organization running, they are better equipped to suggest changes than perhaps the leaders are, who often are dealing with more bureaucratic matters. As such, employees are encouraged to analyze their work processes and make suggestions as to how to improve them for the good of the company.

Standard Work

Standard work is simply the documentation of the current best practice for any given task or process. That's it. It should be detailed and include any necessary supporting assets like diagrams or images. It needs to be accessible to everyone performing the work and is ideally designed by those involved. There's nothing tricky about it, but it is the key to continuous quality improvement. You just can't improve something that has no baseline from which to improve.

Catchball

The idea of Catchball comes from the Lean business management methodology. The idea is that no matter who starts a project, that person (often, but not always a manager) states the purpose, objectives and other ideas and concerns and then 'throws' them

to others for feedback, ideas, support, and action. This creates a bi-directional loop, which clear ownership and accountability. Everyone knows who has the "ball" so to speak.

The 5 Whys

The 5 Whys is a process for getting to the root cause of any problem. When something goes wrong, you ask "why." That answer leads to another "why" and so forth. It turns out that the underlying cause of most process breakdowns can be uncovered by asking why about 5 times.

Digital Huddle Boards

Huddle boards (also called Kaizen boards) are used to create a visual representation of improvement work. This helps people easily understand the health of continuous quality improvement within the organization and immediately detect when progress on any given project is stalled. In modern practice, they are electronic so they can be accessed from anywhere by any member of the team.

5S

5S is a workplace organization method that uses a list of five Japanese words: seiri (sort), seiton (set), seiso (shine), seiketsu(standardize), and shitsuke (sustain). An organized workplace is the key to efficiency and safety. It can also be enormously important when attempting to reduce waste, especially the wastes of motion and transportation.

Gemba Walks

During a Gemba Walk, a supervisor or other leader goes to the place where the work is done to observe and ask questions of the people doing the work. The goal is not to evaluate people's performance, but rather to seek opportunities for improvement and get a clear understanding of how the standard work is being executed in the real world. After the walk, the supervisor may use Catchball or another technique to begin the process of improvement.

Value Stream Mapping

Value Stream Mapping is a way of documenting and assessing everything that happens to bring value to the customer. It is an end-to-end analysis of how a service or product goes from the initial requires into the hands of the customer. Processes that add value are improved, while those that don't add value are eliminated. It is an excellent method for uncovering the current state and a jumping off point for quality improvement and waste reduction.

PDSA

PDSA stands for Plan, Do, Study, Act. It is a basic improvement cycle that helps teams act on opportunities for improvement. The planning phase involves understanding the current state of affairs and describing the desired state. During the "Do" step, potential improvements are introduced. This is followed by a period in which the results are studied. Finally, if the changes are positive, the standard work is updated, and the new process is enacted.

Mind Mapping

A mind map is a diagram used to visually organize information. It is a technique for visualizing connections between many related ideas or pieces of information. It can be extremely useful in brainstorming, problem-solving, project planning, and note-taking. Mind maps are like a tree, starting with a core thought (the trunk) and connecting it to related ideas, big (branches), and small (twigs). The visual structure makes gaps in knowledge readily apparent and relationships between ideas clear. It is useful anytime fresh thinking is needed and is effective for process development, product improvement, quality control, or any other opportunity for improvement.

These techniques are all very straightforward, but the key is in the execution. When they are applied thoughtfully they can be extremely powerful and produce the incremental daily improvement for which most organizations strive.

References

- Essential-elements-quality-management-process: parallelprojecttraining.com, Retrieved 13 August, 2020
- What-are-the-benefits-of-a-quality-management-system, methods-strategies-104270: brighthubpm.com, Retrieved 27 May, 2020
- Quality-plans, quality-resources: asq.org, Retrieved 14 July, 2020
- Eqa-importance: randox.com, Retrieved 12 April, 2020
- Service-quality, marketing-management: mbaknol.com, Retrieved 05 January, 2020
- What-is-continuous-quality-improvement-definition-process-methodologies: study.com, Retrieved 16 March, 2020
- 9-simple-continuous-quality-improvement-techniques, continuous-improvement-continuous-quality-improvement: blog.kainexus.com, Retrieved 10 July, 2020

Quality Control

CHAPTER 3

Quality control refers to a system that maintains standards of products by testing units within the specifications of the final product. Analytical and statistical quality control, quality inspection and maintenance, design inspection, quality audit, etc. are a few of its aspects. The topics elaborated in this chapter will help in gaining a better perspective of the related aspects of quality control.

Quality control is the process that allows you to ensure the conformity of your products or services. It's used to examine and test a product or service to make sure it meets the correct specifications and quality benchmarks. Through quality control testing, a quality inspector analyzes products, processes and other indicators using statistical analysis and sampling. Quality control monitors not only the product itself, but the way it is produced, stored and transported. When a product lacks conformity to quality standards, it is considered defective. Some quality control is voluntary, but sometimes quality control records must be kept for state and federal regulations.

Quality Control Tools

There are many approaches to quality control. The type you use depends on your specific product and should be determined before any quality control inspection begins. There are seven primary quality control tools which include:

- Checklists: At its most basic, quality control requires you to check off a list of items that are imperative to manufacture and sell your product.
- Fishbone diagram: This visual is helpful for determining what causes a specific problem, be it materials, machines, methods or manpower.
- Control chart: This helps you see how processes historically change using controls. The chart helps you find and correct problems as they happen, predict a range of outcomes and analyze variations.
- Stratification: Instead of looking at all factors together, stratification separates data so you can identify patterns and specific problem areas.
- Pareto chart: This type of bar chart provides a visual analysis of problems and causes so you can focus on the most significant issues.

- Histogram: A common graph that uses bars to identifies frequency distributions that indicate how often defects occur.
- Scatter Diagram: Plotting information along two axes on this graph can help visually identify relationships between variables.

A quality control inspector uses one or more of the available tools or methods to do a complete analysis of a product or service to determine where improvements can be made. An inspector typically gets training to know what method to use and how to properly use it.

Internal vs. External Quality Control

Depending on the product you manufacture and sell, you may opt for internal or external quality control inspections. If you establish an in-house protocol to check your system, this is called internal quality control. It can range from routine checking of equipment, having a coworker go over another employee's data analysis or running standards and controls on a regular basis. It is generally up to management to decide if internal quality control measures are reliable and performed as needed.

When products or data are sent to an outside business not affiliated with your company, this is external control. One example of external control is in food production. A food company may routinely analyze the nutritional value or shelf life of a food item it produces in its own lab, but to verify the results, the same food item will also be sent to an outside lab. This verification by a third party is important to obtain Food and Drug Administration labeling and to prove to the FDA that the food company's production methods are sound.

Benefits of Quality Control

Some of the importance or benefits of quality control are:

- Encourages Quality Consciousness: The most important advantage derived by introducing quality control is that it develops and encourages quality consciousness among the workers in the factory which is greatly helpful in achieving desired level of quality in the product.
- Satisfaction of Consumers: Consumers are greatly benefited as they get better quality products on account of quality control. It gives them satisfaction.
- Reduction in Production Cost: By undertaking effective inspection and control over production processes and operations, production costs are considerably reduced. Quality control further checks the production of inferior products and wastages thereby bringing down the cost of production considerably.

- Most Effective Utilisation of Resources: Quality control ensures maximum utilisation of available resources thereby minimising wastage and inefficiency of every kind.
- Reduction in Inspection Costs: Quality control brings about economies in inspection and considerably reduces cost of inspection.
- Increased Goodwill: By producing better quality products and satisfying customer's needs, quality control raises the goodwill of the concern in the minds of people. A reputed concern can easily raise finances from the market.
- Higher Morale of Employees: An effective system of quality control is greatly helpful in increasing the morale of employees, and they feel that they are working in the concern producing better and higher quality products.
- Improved Employer-employee Relations: Quality control develops to better industrial atmosphere by increasing morale of employees which ensures cordial employer-employee relations leading to better understanding and closeness between them.
- Improved Techniques and Methods of Production: By supplying technical and engineering data for the product and manufacturing processes, improved methods and designs of production are ensured by quality control.
- Effective Advertisement: Organisations producing quality products have effective advertisement. They win the public confidence by supplying those better quality products.
- Facilitates Price Fixation: By introducing quality control measures, uniform products of same quality are produced. This greatly facilitates the problem of price fixation. One price of standard products becomes prevalent in the market.
- Increased Sales: Quality control ensures production of quality products which is immensely helpful in attracting more customers for the product thereby increasing sales. It is greatly helpful in maintaining existing demand and creating new demand for the product. It has been rightly pointed out that quality control is a powerful instrument with the help of which markets both at home and abroad can be expanded.

ANALYTICAL QUALITY CONTROL

Analytical quality control, commonly shortened to AQC, refers to all those processes and procedures designed to ensure that the results of laboratory analysis are consistent, comparable, accurate and within specified limits of precision. Constituents

submitted to the analytical laboratory must be accurately described to avoid faulty interpretations, approximations, or incorrect results. The qualitative and quantitative data generated from the laboratory can then be used for decision making. In the chemical sense, quantitative analysis refers to the measurement of the amount or concentration of an element or chemical compound in a matrix that differs from the element or compound. Fields such as industry, medicine, and law enforcement can make use of AQC.

AQC processes are of particular importance in laboratories analysing environmental samples where the concentration of chemical species present may be extremely low and close to the detection limit of the analytical method. In well managed laboratories, AQC processes are built into the routine operations of the laboratory often by the random introduction of known standards into the sample stream or by the use of spiked samples.

Quality control begins with sample collection and ends with the reporting of data. AQC is achieved through laboratory control of analytical performance. Initial control of the complete system can be achieved through specification of laboratory services, instrumentation, glassware, reagents, solvents, and gases. However, evaluation of daily performance must be documented to ensure continual production of valid data. A check should first be done to ensure that the data should be seen is precise and accurate. Next, systematic daily checks such as analysing blanks, calibration standards, quality control check samples, and references must be performed to establish the reproducibility of the data. The checks help certify that the methodology is measuring what is in the sample.

The quality of individual AQC efforts can be variable depending on the training, professional pride, and importance of a particular project to a particular analyst. The burden of an individual analyst originating AQC efforts can be lessened through the implementation of quality assurance programs. Through the implementation of established and routine quality assurance programs, two primary functions are fulfilled: the determination of quality, and the control of quality. By monitoring the accuracy and precision of results, the quality assurance program should increase confidence in the reliability of the reported analytical results, thereby achieving adequate AQC.

Validation of analytical procedures is imperative in demonstrating that a drug substance is suitable for a particular purpose. Common validation characteristics include: accuracy, precision (repeatability and intermediate precision), specificity, detection limit, quantitation limit, linearity, range, and robustness. In cases such as changes in synthesis of the drug substance, changes in composition of the finished product, and changes in the analytical procedure, revalidation is necessary to ensure quality control.

All analytical procedures should be validated. Identification tests are conducted to ensure the identity of an analyte in a sample through comparison of the sample to a reference standard through methods such as spectrum, chromatographic behavior, and chemical reactivity. Impurity testing can either be a quantitative test or a limit test.

Both tests should accurately measure the purity of the sample. Quantitative tests of either the active moiety or other components of a sample can be conducted through assay procedures. Other analytical procedures such as dissolution testing or particle size determination may also need to be validated and are equally important.

Statistics

Because of the complex inter-relationship between analytical method, sample concentration, limits of detection and method precision, the management of Analytical Quality Control is undertaken using a statistical approach to determine whether the results obtained lie within an acceptable statistical envelope.

Inter-laboratory Calibration

In circumstances where more than one laboratory is analysing samples and feeding data into a large programme of work such as the Harmonised monitoring scheme in the UK, AQC can also be applied to validate one laboratory against another. In such cases the work may be referred to as inter-laboratory calibration.

Analytical Quality Control Criteria/Parameters and Check-list

Sampling

The sampling procedure is of vital importance for the interpretation of the result of the study/survey. It is important from a technical as well as statistical point of view. Often, however, the sampling process is separated from the analytical process, and the analyst has little or no information on the background of the samples.

Sample Representativity

The author must include information on what the samples represent and how they were selected. Depending on the nature of the publication, the quantity of information may differ considerably. Analytes are often more or less heterogeneously distributed in samples, e.g. cadmium in wheat grain. In cases where the sampling is a major issue, the following points may need to be described, but others may be equally important/applicable:

- Parts of sample analysed.
- Pooled samples.
- Weight of sub samples.
- Number of sub samples.
- Statistical considerations.

Sampling Procedure, Transport and Storage

Sampling procedures often involve a risk of either contaminating the sample, or of losing parts of the analyte. Transports involve risks of, e.g. overheating or freezing of the samples and cross contamination. Storage of samples involves risks of, e.g. loss of liquid (time/temperature, freezing out), contamination and chemical changes of matrix and/or analyte.

A description of these procedures is therefore necessary. Analytes that are susceptible to negative effects require more detailed descriptions than others.

Inexplicably high results may have been caused by contamination in a pre-analytical stage, which is often difficult to identify. A clear description of the sampling procedure may make it possible to conclude where or how the contamination occurred. Since contamination seldom is uniform it may be detected by large variations in replicated analysis (provided that it is larger than the normal heterogeneity). The risk of contamination varies with the type of sample, analyte and concentration level; e.g. in the case of certain trace elements the contamination risk is great all through the sampling and analytical process, whereas in sampling and analysis of pesticides or natural toxins the risk is very small. If different samples arrive to the lab in the same container cross contamination can be a problem.

It should be clearly described what has been analysed, e.g., homogenate of a whole fish, or a specific organ/tissue, and if the result is based on fresh or dry weight.

Loss of Analyte

Just as for contamination, loss of analyte during sampling and shipping may be outside of the analyst's control. Loss of analyte can occur for several reasons and at different stages in the analytical process. Volatile analytes may be lost if the sample is exposed to high temperatures, e.g., during transport or storage. Other analytes, e.g., metals, may be lost if the sample "leaks" liquid. Loss of liquid will increase the dry matter and the concentration of the analyte (if not lost with the liquid), just as hygroscopic samples will decrease the dry matter and the analyte concentration.

Measurement Method and Procedure

Appropriate Choice of Method

The method must be fit for the analytical purpose. The choice of method is usually not decided only by the analytical need. Often factors such as tradition, availability of instruments and analytical cost influence the choice of method. It can therefore be of importance to briefly describe the rationale behind the choice of method.

Clarity of Method Description

The description of the method should be clear and unambiguous. The method principle and a reference should be given. A statement on the degree of method validation should

be given, e.g., in-house or collaboratively validated. It should be clearly described if the result is based on fresh or dry weight.

Unit of measurement: Check with the journal which unit is preferred and do not mix units. The units ng/g, µg/g, µg/kg, mg/kg, ng/ml µg/ml, µg/l and mg/l are by far the most used in international journals. Do not use, e.g. nmol/l or ppm, unless there is a specific reason for doing so. When comparing with legal requirements, e.g., maximum limits, use the same unit as in the legal text.

Awareness of Interferences

The author must show awareness of the interferences present in the method/technique used. Common examples of interferences are background absorbance and mass overlap in AAS and ICP-MS, respectively, and ion suppression in LC/GC-MS. In other analytical techniques other types of interferences may be predominant.

Determination of Recovery

This primarily concerns methods involving an extraction step or pre-concentration of the analyte. In other types of methods, e.g., the determination of total levels of elements, recovery can even result in confusing/erroneous information. Recovery must not be confused with bias and cannot replace the use of CRMs or results from PT. It must be clearly stated if reported results are adjusted for recovery or not.

Handling of Sample Blanks

In analysis where contamination during sample preparation and analysis is a potential problem the determination of analytical blanks is crucial. The blank may also provide the basis for the limit of detection. Chemical blanks should reflect the analytical process and will show if contamination has occurred during sample pre-treatment or analyte detection. If the blank level is significant it must be clearly stated whether it has been deducted from the sample reading prior to calculation of the result, or not. Contamination that has occurred prior to sample pre-treatment will go unnoticed through this procedure.

Reporting Limit

The reporting limit is usually given as the limit of detection (LOD) or the limit of quantification (LOQ). The reporting limit is particularly important when low concentrations are determined. In method validation the limit of detection (LOD) is one of the parameters that need to be established. If the measured levels are lower than 10 times the established LOD it is prudent to report the LOD. As the concentration increase the importance of stating the LOD decreases. Give the result as "< (numerical figure/unit)", e.g. <0.01µg/L. Do not report results as, e.g., "Not detected" or "Below LOD or LOQ".

Where appropriate, the Lowest Calibrated Level can be reported as the lowest level under AQC. The lowest point of the calibration curve, measured in each batch shows that response at that level is in accordance with QC.

Definition of the Reporting Limit

There are several ways to calculate/define the reporting limit (LOD or LOQ) and this must therefore be clearly described. A common method is based on the standard deviation (SD) for a signal at, or close to, the LOD. The LOD is then calculated as 3 x SD and the LOQ as 6 (or 10) x SD.

Number of Replicates

State if the sample is replicated and how (e.g., all duplicates, or every 10^{th} in duplicate/triplicate). Replication is a way to check for inhomogeneity or contamination. If the results are affected by (random) contamination or inhomogeneity, it may be seen as large variations in replicate analysis. Systematic contamination, however (e.g., by contaminated chemicals, or calibration errors), will not be detected. Replicates are used to calculate repeatability SD.

Certified Reference Materials

The use of Certified Reference Materials (CRMs, the US/NIST uses the trademark "Standard Reference Material", i.e., SRM) is vital in the AQC system, and is primarily used to estimate bias (trueness or systematic errors). The CRM must be relevant in terms of matrix and analyte concentration. If a relevant CRM is available it shall be used and the result reported. If an available and relevant CRM is not used it should be stated why. Spike recovery may in some cases provide a (limited) complement.

Relevant Matrix

The matrix of the CRM must be as similar as possible to the samples. There is no guide available to assist the analyst in the choice, so the analyst must make the best possible choice based on the information available. If a broad survey of many different types of foodstuffs is carried out it may be necessary to chose several CRMs, in order to have a representative selection.

Reference to CRMs

When CRMs have been used in a study its identity should be clearly stated, e.g., NIST SRM 1570a Spinach, or BCR CRM 185R Bovine liver.

Proficiency Testing

The analyte level in a Proficiency Test (PT) sample is unknown to the analyst at the

time of measurement, and is the only independent way of demonstrating analytical proficiency. The individual results from PT are usually expressed as z-scores. Satisfactory results from repeated participation in relevant PTs makes strong evidence for analytical competence.

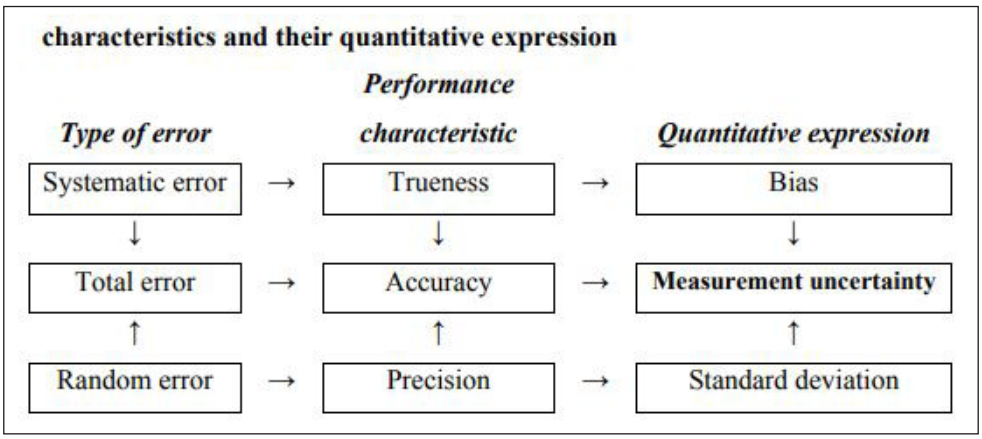
If a relevant (with respect to the matrix and analyte concentration) PT programme is available it should be used, and the result reported in the publication. If a suitable PT programme is not used, it should, if possible, be stated why. Reported PT results should be relevant in terms of time and instruments (i.e. having been analysed approximately at the time of the samples and using same method and instrumentation as for the samples). If results from several PTs are available, it is up to the analyst/author to decide if all the results should be reported. There must, however, not be a biased selection of results. State the name of the PT-provider.

Relevant Matrix

The same requirements as for CRMs apply. However, the number of available PTs is limited so the analyst/laboratory may need to widen the search to find suitable programme.

Measurement Uncertainty

An analytical value comprises two parts; the result and its uncertainty. Measurement uncertainty (MU) is important from many aspects: Interpretation of results near legal limits require information about the MU. It is also a requirement for accreditation. Many users of published data need the MU in order to validate the analytical data. Figure shows the components of MU and their relation. Even if the author has not calculated the MU, information should nevertheless be provided on method bias and standard deviation.



The relationship between type of error, performance.

Random Error (Standard Deviation)

The random error can be estimated from the repeated measurements under laboratory

internal reproducibility conditions, e.g. by repeated analysis of the same sample at different days.

Systematic Error (Bias)

Bias, which is derived from the systematic error, is primarily determined by way of:

- CRMs (SRMs).
- Participation in PT.

Bias is determined for two purposes:

- For bias determination in the method validation process. These results are normally not presented in publications.
- For verification of results in a survey or study. Such results should always accompany the analytical results.

Bias is mainly applicable to methods not including an extraction or preconcentration step. The result of a CRM-analysis should be tested for bias using a valid statistical procedure. There are several ways to test for bias. If the result from a CRM is unbiased it may be assumed that the results of the samples, together with which the CRM was analysed, also are unbiased. If significant bias is detected it should, in principle, not be corrected for, but the cause of the bias should be identified and eliminated, and the samples reanalysed. There may be isolated cases where correction for bias is justified, but these are exceptions. In certain applications (e.g., pesticide analysis) bias may be determined by spiked samples.

PT is usually not carried out in connection with specific samples or surveys, but shows the general competence of the analyst/laboratory, at a specific time or over a period of time. This state of the art information about the lab is important and PT-results should be described in the report/manuscript.

Unexpected/Extreme Results

An unexpected or extreme result deviates considerably from the expected or known level or range. For example: If the Pb-level in a “normal” milk sample is found to be 0.03 mg/kg it is higher than what is generally expected. Thus it is a level that would benefit from verification in order to maintain credibility. Even higher levels must definitely be verified. It is not possible to state a specific level at which a result goes from “normal” to “unexpected/unlikely”. It is up to the expertise and experience of the analyst, and the reviewer, to make that judgement.

Verification by another Method

Ideally an unexpected/unlikely result should be verified using a different method, with

an alternative detection technique. Such options are, however, not always available, in which case it is the responsibility of the analyst to find a way to ensure that the results are valid, or highlight that the result is unconfirmed.

Verification by another Laboratory

Having the sample analysed by another competent laboratory is usually a reliable way of verifying a result. It must be kept in mind, however, that if the other lab uses an identical analytical procedure there is a possibility that an analytical problem is duplicated. A different method is therefore preferable.

Organisation of the AQC in the Manuscript

The information on AQC should be written in a consistent way that is easy to follow by the reader. Preferably, the journal shall give advice in the instructions to authors.

Analytical papers should be written in a consistent way for clarity. The structure is usually as described below, and the AQC activities should be mentioned or detailed where relevant:

- Abstract: Mention that a systematic AQC-procedure has been used, or that these guidelines has been used.
- Introduction: Strengthen the AQC-statement in the abstract, and with a reference. Do not present any analytical data here.
- Analytical procedure and/or Materials and methods: Follow the recommendations in these guidelines. Do not present analytical data from QC-analysis here.
- Results (and discussion): Present the AQC-results in a logical and consistent way. If discussion is included, make a statement on how the AQC -results have strengthened the analytical results.
- Discussion: If the discussion is separated from the results, make a statement on how the QC-results have strengthened the analytical results.
- Conclusion(s): If relevant for the text.
- References: Include a reference to these guidelines for clarity.

Presentation of AQC Results

The QC results should be the first part under Results (and discussion). Whether data should be described in the text or in separate tables largely depends on the style of the journal and the quantity of data. Sometimes the number of results from e.g. CRMs (and PT) can be considerable. It must then be decided if the results should be presented individually or in a more generalised form. The results should be described together

with their standard deviation and bias which, ideally, should be combined to show the total MU.

Presentation of Analytical (CRM) Results in Tables

- The unit of measurement should be clearly stated in all tables, and the text, and be of the same unit as the results of the study/survey.
- The number of significant figures in the found results should not exceed the number supported by the MU.

STATISTICAL PROCESS CONTROL

Statistical process control (SPC) is a method of quality control which employs statistical methods to monitor and control a process. This helps to ensure that the process operates efficiently, producing more specification-conforming products with less waste (rework or scrap). SPC can be applied to any process where the "conforming product" (product meeting specifications) output can be measured. Key tools used in SPC include run charts, control charts, a focus on continuous improvement, and the design of experiments. An example of a process where SPC is applied is manufacturing lines.

SPC must be practiced in 2 phases: The first phase is the initial establishment of the process, and the second phase is the regular production use of the process. In the second phase, a decision of the period to be examined must be made, depending upon the change in 5M&E conditions (man, machine, material, method, movement, environment) and wear rate of parts used in the manufacturing process (machine parts, jigs, and fixtures).

An advantage of SPC over other methods of quality control, such as "inspection", is that it emphasizes early detection and prevention of problems, rather than the correction of problems after they have occurred.

In addition to reducing waste, SPC can lead to a reduction in the time required to produce the product. SPC makes it less likely the finished product will need to be reworked or scrapped.

SPC was pioneered by Walter A. Shewhart at Bell Laboratories in the early 1920s. Shewhart developed the control chart in 1924 and the concept of a state of statistical control. Statistical control is equivalent to the concept of exchangeability developed by logician William Ernest Johnson. Along with a team at AT&T that included Harold Dodge and Harry Romig he worked to put sampling inspection on a rational statistical basis as well. Shewhart consulted with Colonel Leslie E. Simon in the application of control charts to munitions manufacture at the Army's Picatinny Arsenal in 1934.

That successful application helped convince Army Ordnance to engage AT&T's George Edwards to consult on the use of statistical quality control among its divisions and contractors at the outbreak of World War II.

W. Edwards Deming was an important architect of the quality control short courses that trained American industry in the new techniques during WWII. The graduates of these wartime courses formed a new professional society in 1945, the American Society for Quality Control, which elected Edwards as its first president. Deming traveled to Japan during the Allied Occupation and met with the Union of Japanese Scientists and Engineers (JUSE) in an effort to introduce SPC methods to Japanese industry.

Common and Special Sources of Variation

Shewhart read the new statistical theories coming out of Britain, especially the work of William Sealy Gosset, Karl Pearson, and Ronald Fisher. However, he understood that data from physical processes seldom produced a normal distribution curve (that is, a Gaussian distribution or 'bell curve'). He discovered that data from measurements of variation in manufacturing did not always behave the way as data from measurements of natural phenomena (for example, Brownian motion of particles). Shewhart concluded that while every process displays variation, some processes display variation that is natural to the process ("common" sources of variation. Other processes additionally display variation that is not present in the causal system of the process at all times ("special" sources of variation), which Shewhart described.

Application to Non-manufacturing Processes

In 1988, the Software Engineering Institute suggested that SPC could be applied to non-manufacturing processes, such as software engineering processes, in the Capability Maturity Model (CMM). The Level 4 and Level 5 practices of the Capability Maturity Model Integration (CMMI) use this concept.

The notion that SPC is a useful tool when applied to non-repetitive, knowledge-intensive processes such as research and development or systems engineering has encountered skepticism and remains controversial.

Fred Brooks points out that the complexity, conformance requirements, changeability, and invisibility of software results in inherent and essential variation that cannot be removed. This implies that SPC is less effective in the domain of software development than in, e.g., manufacturing.

Variation in Manufacturing

In manufacturing, quality is defined as conformance to specification. However, no two products or characteristics are ever exactly the same, because any process contains many sources of variability. In mass-manufacturing, traditionally, the quality

of a finished article is ensured by post-manufacturing inspection of the product. Each article (or a sample of articles from a production lot) may be accepted or rejected according to how well it meets its design specifications. In contrast, SPC uses statistical tools to observe the performance of the production process in order to detect significant variations before they result in the production of a sub-standard article. Any source of variation at any point of time in a process will fall into one of two classes:

- Common causes: 'Common' causes are sometimes referred to as 'non-assignable', or 'normal' sources of variation. It refers to any source of variation that consistently acts on process, of which there are typically many. This type of causes collectively produce a statistically stable and repeatable distribution over time.
- Special causes: 'Special' causes are sometimes referred to as 'assignable' sources of variation. The term refers to any factor causing variation that affects only some of the process output. They are often intermittent and unpredictable.

Most processes have many sources of variation; most of them are minor and may be ignored. If the dominant assignable sources of variation are detected, potentially they can be identified and removed. When they are removed, the process is said to be 'stable'. When a process is stable, its variation should remain within a known set of limits. That is, at least, until another assignable source of variation occurs.

For example, a breakfast cereal packaging line may be designed to fill each cereal box with 500 grams of cereal. Some boxes will have slightly more than 500 grams, and some will have slightly less. When the package weights are measured, the data will demonstrate a distribution of net weights.

If the production process, its inputs, or its environment (for example, the machine on the line) change, the distribution of the data will change. For example, as the cams and pulleys of the machinery wear, the cereal filling machine may put more than the specified amount of cereal into each box. Although this might benefit the customer, from the manufacturer's point of view it is wasteful, and increases the cost of production. If the manufacturer finds the change and its source in a timely manner, the change can be corrected (for example, the cams and pulleys replaced).

Application of SPC

The application of SPC involves three main phases of activity:

- Understanding the process and the specification limits.
- Eliminating assignable (special) sources of variation, so that the process is stable.
- Monitoring the ongoing production process, assisted by the use of control charts, to detect significant changes of mean or variation.

Control Charts

The data from measurements of variations at points on the process map is monitored using control charts. Control charts attempt to differentiate "assignable" ("special") sources of variation from "common" sources. "Common" sources, because they are an expected part of the process, are of much less concern to the manufacturer than "assignable" sources. Using control charts is a continuous activity, ongoing over time.

Stable Process

When the process does not trigger any of the control chart "detection rules" for the control chart, it is said to be "stable". A process capability analysis may be performed on a stable process to predict the ability of the process to produce "conforming product" in the future.

A stable process can be demonstrated by a process signature that is free of variances outside of the capability index. A process signature is the plotted points compared with the capability index.

Excessive Variations

When the process triggers any of the control chart "detection rules", (or alternatively, the process capability is low), other activities may be performed to identify the source of the excessive variation. The tools used in these extra activities include: Ishikawa diagram, designed experiments, and Pareto charts. Designed experiments are a means of objectively quantifying the relative importance (strength) of sources of variation. Once the sources of (special cause) variation are identified, they can be minimized or eliminated. Steps to eliminating a source of variation might include: development of standards, staff training, error-proofing, and changes to the process itself or its inputs.

Process Stability Metrics

When monitoring many processes with control charts, it is sometimes useful to calculate quantitative measures of the stability of the processes. These metrics can then be used to identify/prioritize the processes that are most in need of corrective actions. These metrics can also be viewed as supplementing the traditional process capability metrics. Several metrics have been proposed, as described in Ramirez and Runger. They are: (1) a Stability Ratio which compares the long-term variability to the short-term variability, (2) an ANOVA Test which compares the within-subgroup variation to the between-subgroup variation, and (3) an Instability Ratio which compares the number of subgroups that have one or more violations of the Western Electric rules to the total number of subgroups.

Mathematics of Control Charts

Digital control charts use logic-based rules that determine "derived values" which

signal the need for correction. For example, derived value = last value + average absolute difference between the last N numbers.

Techniques of Applying Statistical Quality Control

Quality Control Charts

A quality control chart is a graphic presentation of the expected variations in quality. Certain presumptions are taken into consideration before drawing these charts e.g., inherent nature of certain variables in a product, tolerance limits and probability of chance in variations etc.

Tolerance limits are clearly shown by these charts with regard to a particular product. Variations in quality beyond these limits clearly disclose that the production process is out of control and the quality of the product has not been achieved in accordance with the predetermined standards. On the other hand, a process is said to be in control if the finished product remains within the tolerance limits.

Quality control charts are very helpful in spotting the causes responsible for variations from the set standards on the basis of information disclosed by these charts. Different types of quality control charts may be used for recording different types of analysis.

Some of the important quality control charts are chart of averages and that of range etc. Information disclosed by these charts is very accurate and an authentic one.

Acceptance Sampling

This is another technique of statistical quality control. This is also referred as 'Sampling Inspection plan.' This method is usually followed after goods have been produced or are in the final stage of production. Thus, it can be said that it is a post mortem of the quality of the product that has already been produced.

Under this method, a sample of the product produced is selected at random to study in detail whether the product conforms to the pre-determined standards or not. A limited percentage of defective products are allowed.

But it has been observed that sometimes the sample selected turns out to be good, but the lot represented by the sample may be defective or sub-standard. In order to have more accurate and exact results, more than one sample of the product should be selected for carrying out the Sampling Inspection Plan.

The technique Acceptance Sampling undertakes two limiting levels of quality viz., (i) The Acceptable Quality Level (AQL) i.e. the least number or percentage of defective products that the buyer expects to purchase and the seller expects to sell and (ii) The Lot Percentage Tolerance Defective (LPTD) refers to that limit where the buyer wants to be certain about the rejection of the lot.

This technique can be greatly helpful for improving relations between vendor and the customer which may be adverse on account of disputes relating to quality. Both the parties may sit together and mutually decide the limits within which quality should be accepted.

Advantages of Statistical Quality Control

Following are the important benefits derived from the technique of statistical qualify control:

- Lesser cost of Inspection: Statistical quality control is based on sampling technique which involves lesser cost of inspection thereby cost of production is considerably reduced.
- Increase in Profits: By minimising rejections, statistical quality control ensures the production of standard products which bring higher profits for the producer.
- Setting Tolerance Limits: Quality control charts clearly lay down the tolerances limits beyond which the product is to be rejected. The results shown by these charts are more authentic and correct.
- Develops Quality Consciousness: Statistical quality control is greatly helpful in developing the feeling of quality consciousness among the workers working in an organisation. This improves their functioning and reduces the number of defective operations undertaken by them.
- Enhances Reputation of the Concern: By adopting the techniques of statistical quality control, pre-determined quality of the product is achieved and consumers get desired quality products. This brings good name to the firm and increases its goodwill among the people.

Improved Relations between Vendor and Customers

It is greatly helpful in improving relations between supplier and the purchaser of material, by clearly fixing the tolerance limits with regard to quality of the goods supplied. This minimises the possibility of any dispute between both the parties.

Besides the above mentioned benefits, statistical quality control ensures smooth and unrestricted production by removing breakdown of machinery and work stoppages as it greatly helps in detection of the troubles soon, which are immediately corrected without delay.

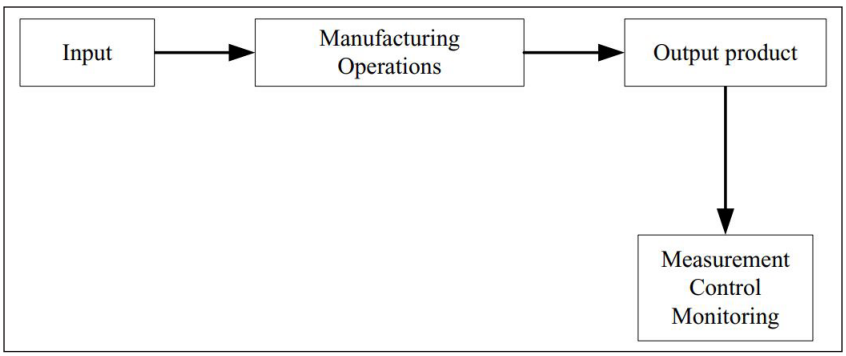
QUALITY INSPECTION AND MAINTENANCE

As markets grow more diversified with increased sophistication of quality requirements, customers demand a higher level of product quality. Quality, as a competitive

advantage and business strategy, becomes an essential element of many organizations to triumph in the competition. A company that delights consumers with improved and well-controlled quality may surpass its competitors.

A finished product may exhibit several quality characteristics. Quality control (QC) techniques apply by inspecting and measuring the product quality characteristics using inspection equipment and some procedures. For single production system, the QC is applied into the output of the system as illustrated in figure. By comparing to the standard, the product can be identified whether conforms to requirements or fails, consider as accepted or rejected as well. Inspection provides useful information about the current demonstrated product quality. Then, any managerial decision made based on this information, which is concentrate more on the effort of product and process improvement program. Many procedures, especially for acceptance inspection, has been developed to conduct the inspection which technically effective and/or economically efficient. Consistent monitoring on quality will ensure that products meet the requirements defined by either the manufacturer's product design department or by customers.

As the output of manufacturing process, failed product may be caused by the preceding process. Since the increasing trend on mechanization and automation, the role of equipment in production operations is more important than before. The performance of equipment must be kept in an ideal condition and run effectively. The equipment or machine may experience an aging and deteriorate with time and production, which has an impact on the product's quality. The diminished product quality is often characterized by increasing the rejection rate and declining the machine's performance. The rejected product may demonstrate the deterioration of the downstream process; therefore, maintenance of production equipment cannot be segregated from the overall production management task. Beside, maintenance is crucial to restore the equipment or machine to an acceptable condition.



Systematically presentation of production system.

Both, inspection and maintenance have an important role in production system. Understanding and highlighting their advantage independently suggest realizing the connection between quality inspection and equipment maintenance. Proceeding observations on various publications inspire us the meaningful of their relationship as such a

way to achieve better quality assurance and establishing the performance of production system. Thus, the importance of quality assurance through equipment maintenance becomes increasingly indispensable.

Quality and Inspection

There are two reasons for the necessity of quality control system. First, QC is an effective daily management process; and second, QC is a requirement for developing quality improvement program, it is imperative that the process is initially controlled. QC accomplishes its missions by doing an inspection. As a basic operational technique and one of the earliest aspects of QC, inspection plays an important role in a production system to gain the information about the demonstrated product quality.

Inspections Techniques

Inspections are performed at various times during the manufacturing process. Include inspection on raw materials and components from outside sources (incoming inspection), and final inspection on finished product to ensure the functional quality and the appearance of the product (outgoing inspection).

The modern view of QC encompasses a broader scope of activities throughout the company. For instance, Total Quality Management (TQM) philosophy suggested the process control inspection along production line rather than final inspection only. This diversion keeps the inspection as an essential technique in quality assurance and doesn't reduce the necessity for inspection instead. Industrial experience shows that the manufacturer may monitor its process at every stage, the acceptance inspection for the final product and incoming raw materials inspection are still necessary. The acceptance inspection is kind of middle bridge between 100% inspection and zero inspection, which has a primary advantage of fewer resources needed including money, labor, and time.

Acceptance inspection provides decision rules for product acceptance determination based on sample taken from the lot product, well-known as acceptance sampling or sampling plan. Acceptance sampling is not a substitute for adequate process monitoring and control to reduce variability. Acceptance sampling does not estimate the lot quality, but sentence it, does not provides any direct form of quality control of a lot; nor use to control and systematically improve quality as process control yet do. Nevertheless, acceptance sampling still constitutes quality science. Moreover, acceptance sampling is a necessary defensive measure, instituted as a protective tool against the threat of quality deterioration and provides valuable feedback for process control. Acceptance sampling is an instrument for producer to quicken the process control. The most effective use of acceptance sampling is as an audit tool to ensure that the output matches the requirement. When the statistical process control (SPC) optimizes the capability of the process, the acceptance sampling prevents the nonconforming product to be pass

and then delivered to the next process or the customer, a usefull effort to maintain the product quality.

Acceptance Inspection

A major classification of acceptance sampling is based on data type, include variables sampling plans and attributes sampling plans. Variables sampling plans (VSP) are preferred over attributes sampling plans, need smaller sample size than would be required for attributes sampling plans, in order to achieve the same operating characteristic curve. The significant savings even better when the destructive testing is applied or expensive items are involved. This phenomena reported by many publications.

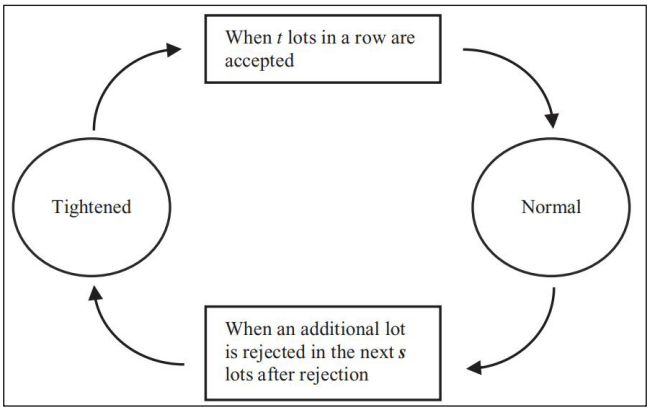
Classification based on the sampling procedures differentiates single sampling plan and conditional sampling plans. A single sample acceptance plan is the most common and easiest plan to use due to its administration simplicity. However, this is not the most efficient sampling plan, in terms of the average number of samples. Beside, the inspection plans need to alter as the demonstrated product quality history may change. Acceptance sampling must consider the possibility of shifting in product quality. Accordingly, employing two or more sampling plans for different levels of product quality, called sampling system is preferred than applying an individual single-sampling plan. The criteria for choosing the appropriate single-plan and switching between one single-plan to another offers the flexibility of the sampling scheme. Hence, it will be more beneficial to accommodate and keep track of the quality history, in order to gain the advantages of each single-plan. All publications were shown to be more efficient compared to single sampling plan and the comparable attribute TNT sampling system.

Under the TNTVSS sampling scheme, inspection conducts in two plans, normal inspection and tightened inspection. Normal inspection is implemented at initial of the inspection activity, while tightened inspection is institute when recent product quality history has deteriorated. Nevertheless, if the recent quality has been improved and is found to be good, it is quite reasonable for inspector to ease or lighten the sampling plans back to the normal inspection. The differentiation between normal and tightened inspection is their sample size. Inspect the product quality with sample size n_T under tightened inspection. While, use sample size n_N for normal inspection, where $n_T > n_N$.

The operating procedure of the variables TNTVSS scheme is given as follows:

- Step 1: Conduct inspection under tightened single sampling plan with sample size n_T and acceptance value k. Accept the lot if the estimated capability index $C_I \geq k$. When subsequent t lots in a row are accepted, then switch to normal inspection.
- Step 2: Conduct inspection under normal single sampling plan with sample size n_N and acceptance value k. Reject the lot if the estimated capability index $C_I < k$. When an additional lot is rejected in the next s lots after rejection, switch to tightened inspection.

Where, the switching provisions (s,t) are intended to accommodate the changing in product quality performance. The acceptance criteria is evaluated based on the comparison between the estimated capability index and the critical acceptance value. When the estimated capability index larger than the critical acceptance value, then the lot is accepted, otherwise, then the lot is rejected. The operating procedure are depicted in figure.



The operating procedure of TNTVSS.

Equipment Maintenance

Whenever items or equipment failed to operate or perform its intended function, the option of maintenance may be carried out, including repairs or replaces. The purpose of maintenance is to keep the item's good condition, to rectify failures, and to restore the item to its operational state following failure or deterioration condition. The following item's performance depends on the maintenance action after failure.

A maintenance policy states how and when the maintenance action will be carried out. Corrective maintenance (CM) and preventive maintenance (PM) are the main option of maintenance actions related with the time of operation whether unscheduled or scheduled. PM performed at prescribed point in an item's life, not based on functional failure or product deficiencies. PM retains the items in the specified condition, by providing systematic inspections and prevention of incipient failure. PM is carried out to reduce the likelihood of failure or to prolong the item's life.

Comparison between two maintenance philosophies attach different perspective between them. Traditional maintenance philosophies have mainly focused on the availability of production equipment. Meanwhile, the modern maintenance philosophies realized that maintenance has a significant impact on improved quality.

Maintenance and Quality

The role of maintenance in completing the production purpose has already been addressed in the literature. In most models, the problem statement is how to meet the

production schedule under the limiting constraints on maintenance. Meanwhile, the role of quality in production discussed in many literatures, including that proposed quality control modeling for single state production systems.

They mentioned that the link between maintenance and quality, although not completely missing, is not adequately addressed in the literature. There are no adequate models relating to quality and maintenance. They proposed a broad framework for modeling the maintenance and quality relationship.

Then, the idea of incorporating maintenance in quality philosophies discussed in many literatures. In the total quality control approach, introduced by, maintenance is one of the characteristics of the total composite product, which will meet the expectations of the customer. In TQM, maintenance plays a role in quality. Moreover, they pointed out that the best equipment will not work satisfactorily unless it is cared for. The ISO 9000 series states that process and equipment maintenance should be performed in a planned manner guaranteeing continuous performance.

On the other hand, some research on maintenance attempted to incorporate the quality concept in their design. In equipment management, one of the six big losses of any equipment is directly related to quality, i.e. process defect, as identified by, who introducing total productive maintenance (TPM) principle. Moreover, the quality rate is becoming one of the three components affecting overall equipment effectiveness (OEE). Quality management orientation proposed by, found that the company foundation of quality management is an effective way to improve maintenance performance. Many papers discussed integration between process monitoring (control chart) and process maintenance to increase their joint efficiency provides in. However, among many references described, no literatures highlighted the interaction between maintenance and quality inspection. Albeit, inspection issue discuss in research of maintenance, they mainly discussed on the inspection policies for equipment or manufacturing facilities. Therefore, we focus more on the inspection of product quality, that may influenced by the machine condition.

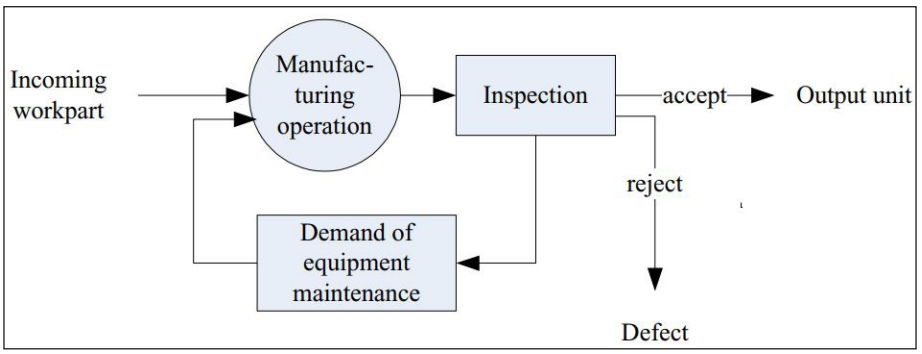
Interaction between Quality Inspection and Maintenance

There are significant-vast literatures on inspection (i.e. acceptance sampling) and maintenance, however, their focus tends to be on each topic separately. Presently, there have been no research attempts to study the connection between quality inspection and maintenance. In fact, acceptance sampling is a way to inspect the product and sentence the lot as rejected due to the low capability or producing of non-conforming products. On the other hand, one of the symptoms of the deteriorating process may produce nonconforming items. The restoration action may not always be conducted due to machine breakdowns. The non-conforming items act as a signal of the deterioration of the process. Therefore, lot rejection may provide adequate feedback for corrective or rectification action. Maintenance that prevents an abnormal condition or restoration from producing a quality failure is necessary. A system that incorporate both quality and

equipment maintenance is crucial. The idea to integrate and combine these two topics provides an excellent opportunity on managing the production system.

The typical TNT sampling scheme can be applied to the inspection of final product. The quality of the final product measured in the value of capability indices, also represents the quality of an ongoing process. As the flexibility of TNT sampling system offers, we may change the provision according to the condition of an ongoing process. This changing of provisions will always keep the same protection for both sides, no matter if supplier producer or predecessor-successor machine. The response to any process deterioration is restoring the process back to an acceptable condition, as a maintenance task and function. This situation may illustrate such a connection between inspection and maintenance. Modern production is run by utilizing the production machinery. If the machinery is not in a good and acceptable condition, the product quality may shift, therefore, selected maintenance activities are important, since they affect the equipment performance and the quality of the final product accordingly.

Discussion about maintenance and quality cannot be segregated from the production process. Although, it is clear that maintenance and quality interact, models that relate them both has not been adequately developed in the literatures. Therefore, we propose a broad interaction framework between inspection and maintenance as illustrated in figure. In particular single production system, machine or device conduct the manufacturing process to serve the final product. Inspection on quality of the product under particular TNT sampling plan may result rejection or acceptance of the lot product. The rejected lot may trigger for examination on manufacturing process or machine, moreover, become a demand of equipment maintenance. Whenever proper maintenance policy apply, machine can be restored to its operational state following deterioration condition, then the product quality and process capability may improve.



The framework of inspection and maintenance interaction in production system.

There are two approaches can be considered to elaborate the framework. First, from the maintenance side, concerns more on how the maintenance aspects may affects the product quality inspection. For instance, selection of maintenance policy (corrective maintenance, preventive maintenance, etc), maintenance strategy (repair, replace, etc), in-house or outsourcing maintenance, schedule or unscheduled maintenance,

may influence the forthcoming product quality. The improved quality may result different on inspection plans, say normal inspection under TNTVSS. The impact of poor maintenance on quality is not offset by the vast research yet. Second, from the quality side, concerns on how the current demonstrated quality may interfere the selection of maintenance aspects. For instance, determination of the acceptance critical value may drive to different decision on the lot, but different level of it may guide to the appropriate maintenance policy. Moreover, determination of maintenance policy based on the demonstrated quality history, rather than the condition of the machine, as the common approach in maintenance fields and research.

In addition, the conditions of the manufacturing process may let us consider many factors that probably affect to the complexity of the proposed interaction. Most of research consider the downstream manufacturing process prior to the final process, where the final product inspection is conducted, as a black box. Many factors can be revealed such as, numbers of the production routing, the structure of manufacturing system (serial or non-serial system), or the machine state at each production process, and so on. Moreover, the information and data collection from the inspection activities do not intensively provide insight feedback to the downstream process and its maintenance. Considering many types of acceptance inspections plans and maintenance policies, then the variations of research left to be conducted are abundant.

Performance of equipment is substantial to preserve the performance of production process, as the increasing trend on mechanization and automation. Since the current market improved, customer demand high-quality product. The well-maintained equipment ensures the product quality will conform to requirements. Many literatures discussed the roles and advantages of quality inspection and equipment maintenance individually and separately. The investigations on these two aspects reveal their possible interactions. The proposed interaction framework between inspection and maintenance provides logical thinking that may interrelate these aspects to provide better quality assurance.

The two approaches provide elaboration accompanying the proposed framework. The inspection becomes a trigger for the demand of maintenance. The rejected lot result from low process capability or producing of nonconforming products, could be the symptoms of the deteriorating process. The appropriate maintenance policy needed to restore the process deterioration back to the acceptable conditions. Thus, determination of maintenance policy based on the demonstrated quality history, rather than the condition of the machine, would provide more reliable maintenance decision. On the other hand, determination of maintenance policy and strategy may affect to the forthcoming product quality. Improper maintenance policy selection may result on not improved product quality.

The meaningful of the relationship serves a way to achieve better quality assurance and establishing the performance of production system. Yet it provides a comprehensive

managerial thinking in equipment maintenance. It is worth to note, the importance of quality assurance through equipment maintenance becomes increasingly indispensable.

DESIGN FOR INSPECTION

Design for Inspection (DFI) is an engineering principle that proposes that inspection methods and measurement instruments used to certify manufacturing conformity, should be considered early in the design of products. Production processes should be designed in such a way that features of the product are easy to inspect with readily available measurement instruments, and so that measurement uncertainty is considered in the tolerance that are applied. The concept can be applied in almost all engineering disciplines. DFI describes the process of designing or engineering a product in order to facilitate the measurement in order to reduce the overall costs of manufacturing and delivering products that satisfy customers.

The role of inspection in the manufacturing process is to ensure that the manufacturing process is producing components that meet the specification requirements. Inspection does not assure the quality of the product, only a robust and repeatable manufacturing process can achieve this. Therefore, inspection is often considered as an overhead although an extremely important one. Similar to Design for Manufacture (DFM) and Design for Assembly (DFA) (which seek to avoid designs which are difficult to make), the concept of DFI considers measurement capabilities at an early stage in the product development life cycle and uses knowledge of the fundamental principles of metrology to achieve cost reduction. If the inspection method and instruments are considered and selected at the design stage, the likelihood that a tolerance feature cannot be inspected or requires a specialised instrument is substantially reduced. High precision features require specialised manufacturing and metrology, these can have limited availability in the supply chain and therefore often have increased cost. The concept of DFI should complement and work in collaboration with DFM and DFA. There are three key areas when considering DFI, datum selection, tolerances and accessibility, plus general metrology considerations. Getting the most from inspection techniques will help improve quality. It is still difficult for systems designers to build machines that allow finished products to be inspected easily. To do so requires an understanding of the product being manufactured and how inspection tasks can improve the quality control process.

Inspection can represent a significant percentage of an existing product's manufacturing cost. DFI may naturally be called for in redesign of a product to reduce that cost component when it is high. However, DFI will not always reduce inspection costs: it can also lead to increased rate of inspection, because more convenient or higher quality measurement may justify increasing measurements, say from a sampling rate satisfactory to support a basic level of tolerance to a higher rate (e.g. to 100%). Or DFI may

make it economical for 100% inspections to measure more features or to make repeated measures of the same feature at different points within the manufacturing process. This would be justified if it would reduce internal failure costs (such as costs of rework or scrap) or external failure costs (such as customer returns) within the cost of quality framework.

FIRST ARTICLE INSPECTION

A first article inspection (FAI) is a design verification and design history file and a formal method of providing a reported measurement for a given manufacturing process. Both the supplier and purchaser perform the First Article on the ordered product. The evaluation method consists of comparing supplier and purchasers results from measuring the properties and geometry of an initial sample item against given specifications, for example a drawing. Items to be checked by the supplier and purchaser FAI are wide and varied and may include distances between edges, positions of holes, diameters and shapes of holes, weight, density, stiffness, color or surface finish. Despite the name, the inspected article may not necessarily be the 'first' produced, but a random sample of 3 parts from the first lot provided to the purchaser. First article inspection is typically called for in a purchase order contract between the producer and buyer of some manufactured article, both perform the First Article inspection to ensure that the production process reliably produces what is intended, design verification of the print, and is part of the purchasing, and design control requirements.

Depending on the inspection capability, the type of product and the governing specification, a first article inspection may be conducted by an approved 2nd party supplier that is a dimensional metrology laboratory using a variety of calibrated tools such as coordinate-measuring machines (CMM), cmm/vision systems and programmable 3-axis measurement systems.

First article inspections are commonplace for military subcontractors. The protocol is, however, required for design verification, purchasing controls, from the supplier and the purchasers receiving inspection in many non-military industries, particularly aerospace, automotive and medical manufacturing.

Manufacturers delivering products to government bodies or in regulated industries such as medical device must typically meet more stringent requirements than international requirements. If there are special test requirements outside of the suppliers capability then test maybe subcontracted to a 3rd party accredited testing lab. Medical Device 21 CFR 820.

Some general standards which apply to first article inspection are produced by the ISO (International Organization for Standardization), the IEC (International

Electrotechnical Commission), the IAF (International Accreditation Forum) the ILAC (International Laboratory Accreditation Cooperation) however more stringent regulations may apply in the U.S. in regulated industries.

First article inspection forms part of a more comprehensive quality management system which is able to assure continuing conformance with applicable specifications. It is required to be performed by the supplier prior to delivery and the purchaser at receiving as part of the supplier approval process, design verification, and purchasing controls in 21 CFR 820.

Types

To verify the accuracy of drawings and ensure that they reflect any changes made to parts design during the prototype design.

- To verify the production process in every parameter, rather than just concentrating on "critical" dimensions.
- To verify all tooling used to produce a part, to ensure that it is capable of producing parts to specifications.
- To verify the ability of the manufacturer to meet the needs of production.

Enhanced First Article Inspections

With the use of modern computers in the manufacturing environment, first article inspections are no longer being used with the traditional three form layout on paper but instead recorded digitally and stored on servers for easy access and organization. Recording the first article digitally eliminates errors with the help of software that keeps track of the FAIs and generates reports immediately after successful completion of an FAI.

PROCESS CAPABILITY

A process is a unique combination of tools, materials, methods, and people engaged in producing a measurable output; for example a manufacturing line for machine parts. All processes have inherent statistical variability which can be evaluated by statistical methods.

The process capability is a measurable property of a process to the specification, expressed as a process capability index (e.g., C_{pk} or C_{pm}) or as a process performance index (e.g., P_{pk} or P_{pm}). The output of this measurement is usually illustrated by a histogram and calculations that predict how many parts will be produced out of specification (OOS).

Two parts of process capability are: 1) measure the variability of the output of a process, and 2) compare that variability with a proposed specification or product tolerance.

Measure the Process

The input of a process usually has at least one or more measurable characteristics that are used to specify outputs. These can be analyzed statistically; where the output data shows a normal distribution the process can be described by the process mean (average) and the standard deviation.

A process needs to be established with appropriate process controls in place. A control chart analysis is used to determine whether the process is "in statistical control" If the process is not in statistical control then capability has no meaning. Therefore, the process capability involves only common cause variation and not special cause variation.

A batch of data needs to be obtained from the measured output of the process. The more data that is included the more precise the result, however an estimate can be achieved with as few as 17 data points. This should include the normal variety of production conditions, materials, and people in the process. With a manufactured product, it is common to include at least three different production runs, including start-ups.

The process mean (average) and standard deviation are calculated. With a normal distribution, the "tails" can extend well beyond plus and minus three standard deviations, but this interval should contain about 99.73% of production output. Therefore, for a normal distribution of data the process capability is often described as the relationship between six standard deviations and the required specification.

Capability Study

The output of a process is expected to meet customer requirements, specifications, or engineering tolerances. Engineers can conduct a process capability study to determine the extent to which the process can meet these expectations.

The ability of a process to meet specifications can be expressed as a single number using a process capability index or it can be assessed using control charts. Either case requires running the process to obtain enough measurable output so that engineering is confident that the process is stable and so that the process mean and variability can be reliably estimated. Statistical process control defines techniques to properly differentiate between stable processes, processes that are drifting (experiencing a long-term change in the mean of the output), and processes that are growing more variable. Process capability indices are only meaningful for processes that are stable (in a state of statistical control).

QUALITY AUDIT

Running a small business is sometimes complicated and overwhelming when you consider the many duties, yet it's still a rewarding experience. Part of managing a successful business involves setting standards for the way the company operates. One way to take your business to the "next level" is to perform regular quality audits.

A quality audit is a process by which you review and evaluate an element of your business to ensure that you're meeting certain standards. The standards vary—you can set them or you can follow standards set by your industry.

Types

A quality audit can apply to various aspects of a business, but a few types stand out. You can perform a quality audit of your inventory or service to assure that it's acceptable for consumption by the public. This is particularly important in the case of a product or service that could pose a threat to public safety. Some business owners perform quality audits on employees, or rather the way employees perform. This is particularly important in an atmosphere where workers must interact directly with customers. The business may also perform quality audits on management, which would require a third-party evaluator in the case of a small company managed by the owner. Finally, if the company has to maintain information in databases, you can also perform data quality audits.

Significance

Performing quality audits are important for a few key reasons. For one, it ensures that the business is offering a value to the public. For instance, selling a high-quality product or employing high-quality customer service personnel can fuel future sales. It's also useful for advertising the business—informing the public that the company is committed to quality standards and performs these regular audits may help increase consumer confidence in the business. Finally, regular quality audits help protect the business from issues that could arise from selling a poor quality product.

ISO

Some companies seek ISO 9001 certification, which requires a set of strict standards of quality established by the International Organization for Standardization. Others seek Six Sigma training and certification to help improve the business and ensure quality. The business must study and meet the standards set by the organization to become certified. The specific requirements vary by industry and the certification can help keep the business competitive.

Key Steps in Quality Audits

Planning

The actions taken prior to the audit are decisive for the success of the activities. Planning begins with the preparation of a plan, which will guide the execution of the audit. This plan should present all the activities in a timeline, as well as the scope, detailing the processes, departments or products to be audited. At this stage, it is also important that the auditor identifies all related documentation, such as quality policies or procedures. Also at this stage, a preliminary list of the people to be interviewed can be drawn up.

Preparation

This is the moment when the auditors can learn more about the company's QMS, taking a closer look at the system documentation. It is important that each member of the audit team be prepared for the activity, with access to the verification checklist. The checklist is essential to guide the auditor so that no details to be assessed are overlooked, as well as for recording the findings and observations.

Execution

The execution of audits takes place with the collection of information, which determines if the department in question is following established standards and quality control procedures. At this stage, the auditor interviews people, asking questions and taking note of the findings. Depending on the findings, audit plans and checklists may have their scope widened, and may be subject to further evaluation. It is at this time that non-conformities will be registered, that is, situations that have occurred which are in conflict with standardized processes and procedures.

Follow-up

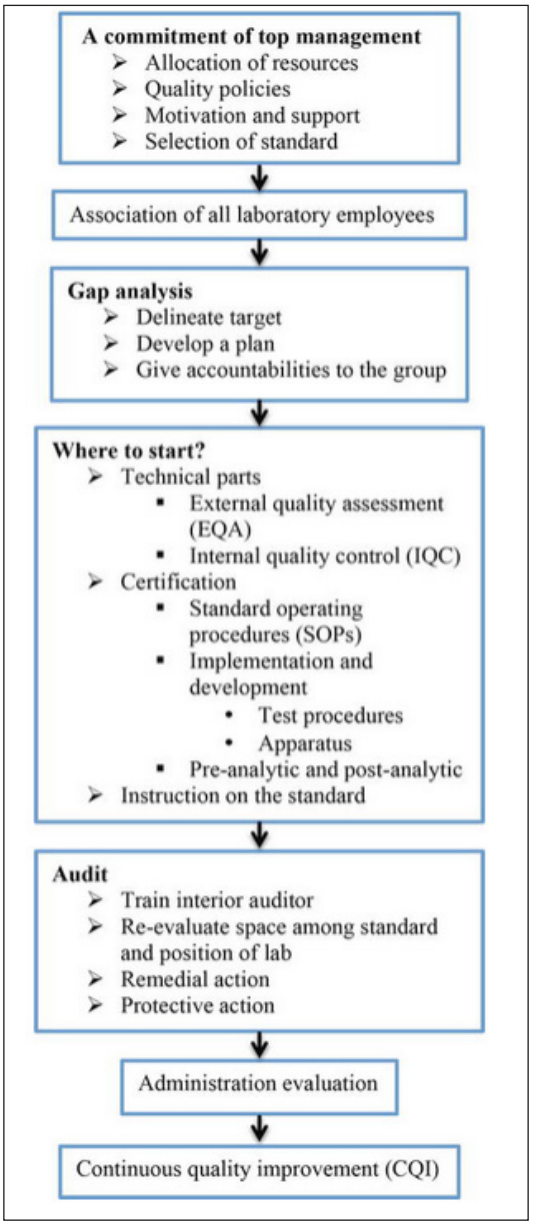
Once the audit is completed, the "real" work begins. The audit team meets to review problem areas and to determine recommendations for correcting quality problems. This information will be included in the Audit Results report.

This report is an important input for strategic meetings held by leaders. It helps to evaluate the results and define how to implement the improvement actions suggested by the audit team.

IMPLEMENTATION OF QUALITY CONTROL

Quality standards are an integral part of the quality system. They are designed to help laboratories meet regulatory requirements, including local health regulations, and

monitor laboratory functions, thereby ensuring laboratory safety and consistency of performance. A quality system can be developed in a step-wise manner and implementation .



Key steps in implementing a quality system.

The methodologies for the implementation of quality control can be differ in diverse organizations. Irrespective the methodologies of the continuous improvement program, each organization desire to use the proper tools and techniques in the process of implementation. The selection of tools and techniques is depend on the demands and applied appropriately to the approach and process.

The PDCA is an essential concept for quality improvement processes, easy to understand and followed by most of the organizations. The most significant characteristic of PDCA lies in the "act" phase after the completion. The six-sigma procedure is consistent and delivers a rigorous outline of results concerned with management. It must be distinguished that the greatest results from six-sigma are accomplished and eradicating unproductive procedures, especially when the members of the team are new to the concerned tools and techniques.

Implementation of Laboratory Quality Standards

The implementation process for laboratory quality standards must follow a stepwise attitude conferring to an implementation strategy drawn up by the national laboratory, in discussion with the National Laboratory Coordinating Committee. Certain countries can desire to progress national laboratory quality standards for all level of health care system.Implementing laboratory quality standards guidelines are as follows.

National Level

- Achieve nationwide agreement for established standards through peer review.
- Achieve consent to established standards via the suitable nationwide experts.
- Make a short-term, medium-term and long-term implementation plan for objectives, timelines and activities, and revealing yearly budgets.
- Recognize suitable implementing agencies such as non-government, governmental agencies, and the private sectors.
- Explain partaking health facilities and institutions.
- Use existing SOPs, checklists, record forms, guidelines and appraisal forms, audit checklists, recording formats etc. or develop the documents for the country specific.
- Establish the national procedures for the referral of samples and laboratory networking.
- Establish the annual plans with budgets.

Laboratory Level

A similar procedure will be mandatory by different laboratories. The head of the laboratory will require taking a leadership role and involving all the staff. Several changes are informal to implement and some are extra expensive or tougher to implement.

The changes that make the implementation of quality control simple and easy:

- Introduction of SOPs for specific activities or procedures. This can be the collection

of the sample, comprising phlebotomy for the investigation of a specific analysis.

- Arrange meetings with the users consistently. This will inform the users of the service to upgrade the quality of laboratory.

Challenges and Future Trends in QC Implementation

Quality control by manual approach could be established in several companies, such as, to observe cuprum pipe pressing procedure, specific control chart is employed to identify the existence of precise distinctions in the process. Furthermore, the chart is made by hand hence it needs a large amount of time period for chart preparation. However, the workers appear found to be more comfy with hard copy records as well as the manual process in making a record for the created items. The absence of confident in soft copy file supposed to be dread that someone may interfere and alter the data that can depreciate the company reputation.

Earlier studies have been showed comparable difficulties in applying quality control between native manufacturing institutes. Among the serious difficulties are concerning insignificant process observing, incapability to accomplish data analysis, the accomplishment of control chart just on the completed products and not in a real-time approach. Additionally, real-time quality control additionally affords countless competence to the management since it takes time to make manual control charts as well as the time permitted to accomplish significant data analysis, is reduced. Study by Mohd Nizam et al. and Rosmaizura et al. show obstacles in developing an online Statistical Process Control (SPC) system and the outcome of the study illustrate that aspects associated with highest management support, inter-departmental correlation, budgets to improve the system and education on SPC are hindering manufacturing institutes via showing real-time process censoring. It is well documented that strong obligation by top management is very important for the fruitful accomplishment of SPC.

In forthcoming days, it is supposed that manufacturers will face a progressively undefined exterior atmosphere through an increasing consequence of alterations in worldwide competition, technological improvement and customer necessities. Flexibility, cost, time and quality are considered as amongst the very significant competitive weaponry for the success of manufacturing companies. Manufacturers face the task of refining the efficacy and lowering prices. Hence, QC techniques would be constantly used to support the organizations to develop, revolutionize their goods and progression in order to be acknowledged by customers. Because of the rising concern on maintainable place and source for the upcoming generation, manufacturers are expected to give more consideration to the environmental effect from their operations. So, application of environment preservation, atmosphere friendly industrial practices and green technology seem to be dominant.

MATHEMATICALLY FUZZY APPROACH TO QUALITY CONTROL

Quality control, which initially emerged and developed in the sphere of material production and consumption, now is rapidly spreading also in nonmaterial spheres, such as development and implementation of various projects, economic programs and managerial solutions, which in essence are the processes which quality is considered from the point of view of operations research theory.

The fact that quality is functional is known since the last quarter of the twentieth century. At that time Russian researchers V. Solodovnikov and N. Filimonov have formulated the concept of quality functional. Curiously enough, they came to the conclusion about necessity of mathematically fuzzy (hereinafter MF) approach to evaluation of acceptability of performance of complicated control systems. This fully complies with the methodology of mathematical fuzziness which foundations were laid by the American scientist Lotfi Zadeh, who discovered that the more complicated is a system, so much the less we are capable to provide precise and at the same time practically valuable judgment about its behavior. Therefore, for the systems which complexity exceeds certain threshold level, "precision" and "significance" become almost mutually exclusive characteristics. Besides, the functionality of quality is known since the times, when Japanese scientist G. Taguchi proposed "quality loss function" for radio-electronic components and products, for which the operating performance was evaluated using binary scale (e.g., "bad" or "good"). At the same time, QFD ("Quality function deployment") method has been developed in the USA; it is the procedure for transforming user demands into quality parameters of the processes of product planning, manufacturing, installation and enhancement (quality improvement).

MF approach to quality control is possible only in case if it is considered, figuratively speaking, from mathematically "rigorous" point of view. Therefore, it is necessary to clarify, to which class of mathematical representations the concept "quality" may be ascribed. For this purpose we must briefly deepen into terminological aspects of quality as a mathematical phenomenon. With this objective in mind, process approach on the basis of standard is already used.

All this has laid the groundwork of modern quality control, both for material and nonmaterial objects, which in the context of above said we will name simply "objects". As prominent Austrian-British philosopher of the 20-th century L. Wittgenstein notes in his treatise, "objects contain the possibility of all states of affairs". Quality is judged by presence with the object of one (one-dimensional) or several parallel (multidimensional or vectorial) properties, hereinafter denoted as P where necessary. They represent different aspects of the object and are determined by values which in qualitative sense are common for many objects, but in quantitative sense are individual for each object .

Therefore, the value is a denominated property and serves as the quality index (hereinafter – QI) of the object.

The properties may be either point-wise, i.e. occurring singly in full scope which is denoted by 1 (while their absence is denoted by 0), or permanent, i.e. persisting continuously during prescribed time interval. Occurrence of point-wise property or loss of permanent property must be confirmed by the result of appropriate QI check. In contrast to single occurrence of point-wise property, loss of permanency (incurring loss of quality of the object) may take place either at a point or within a finite interval. In case of a point-wise property in nonmaterial sphere of activities, specifically, a quality management process or quality management system (hereinafter – QMS), the fact of its certification at an industrial enterprise, suppose, in year 2011, is subject to confirmation by certificate granted by a certification body.

An example of a point-wise property in the sphere of material production may be the JIT (Just-in-time) logistics concept, created in late 1950-ies in the Japanese company Toyota Motors, later accepted by other Japanese automobile manufacturers and now having worldwide recognition. It suggests supply of a resource exactly at the time when it is needed, allowing reduction of stock reserves and related expenses. Examples in nonmaterial sphere of activity may be the just-in-time fulfillment of contractual obligations and payments; an analog of this in social-behavioral aspect is just-in-time coming of a subordinate functionary to his chief, as well as paying visits. In case of permanent property, the interval of loss of permanence represents the period (or time) of property recovery, e.g., recovery of system performance or device operability, respectively.

An example of interval loss of permanence, e.g., in the sphere of management activity, may be a short-term stoppage of work of an institution or enterprise administration for a few hours during working day for reasons which might be foreseen and timely eliminated. Exception here might be only force majeure circumstances. An example of such loss in material sphere is a temporary exceedance of allowable limits of mains voltage. An example of point-wise loss of permanent property may be occurrence of defective products at an industrial enterprise in conditions of prescribed zero defects of production, e.g., violation of requirements to the appearance of the items (in particular, items made of plastics).

QI may be either quantitative, if it has metric scale, or qualitative, if its values are established according to ranking scale or to classificatory scale of quality gradations. Point-wise property may have any of the above mentioned scales. Permanent property may have only metric scale, and only in anticipation of eventual interval loss of quality. However, if possibility of point-wise loss of property is envisioned, then only non-graded (free) axis is conceivable. The above said allows making some conclusions and generalizations:

- Quality is inherent to any object; in contrast to property, quality cannot appear and disappear.

- Quality is functional; it may be either compliant or incompliant with the requirements raised to it by reason of presence or absence of the property with the object.
- Verbal evaluations "1" and "0" correspond to presence or absence of the property.
- If the object has several properties, quality becomes multidimensional and exists only when its presence is supported concurrently by all qi.
- Property may be either point-wise (occurring one-time) or permanent, i.e. Persisting continuously.
- Existence or absence of a property is evidenced by the values of qi, either measured or evaluated by other methods.
- These values must either lie within required (prescribed) limits of appropriate scales or be point-wise.

Now it is permissible to ask: If quality is functional, to which kind of mathematical functions it should be categorized, and what should be the appearance of mathematical function of quality? To get the answer, let us turn to the theory of functions, which allows, in case of single QI, taking it as independent variable x, to search for quality function (hereinafter – QF) in the generalized form as,

$$Q =]Q(x) \quad x \in E,$$

where: Q is the symbolic value "1" in case of compliance, or "0" in case of incompliance of quality with the requirements raised to it, Q(x) is the quality function (QF),] is the symbol of a mathematical operation, decision rule or method for determining compliance or incompliance of quality with the requirements raised to it, E means the definition domain of QF.

As is known, the concept of "function" is characterized by the following attributes:

- Representation method.
- Range of values.
- Range of definition.

If these concepts will provide substance to the formal expression $Q =]Q(x) \quad x \in E$, then QF will be actually found. Let us start from representation method. Four such methods are known:

- Analytic.
- Graphical.

- Tabular.
- Verbal (in the form of verbal expression).

As Russian scientist N. Nazarov has rigorously proved, quality is not a quantitative value; hence, two methods remain applicable – graphical and verbal. Graphical representation method for function assignment is not enough; its mathematical formulation is required. Only verbal representation of a function remains available for this purpose. Addressing to, we find precedents of verbal representation of functions. These include:

- Dirichlet function: Equaling to 1, when x is rational number, and 0, when x is irrational number.
- Boolean function: Which has the same range of values as the previous function, though the range of its definition is different.

This gives ground to assume that QF may also be set verbally, i.e., following, to assign value 1 to quality presence, and value 0 – to quality absence, what, apropos, represents the range of values of QF sought for. It should be noted here that by no means these values are the measure or, horrible ictum1) , the quantity of quality. 1 and 0 here lose their numerical value and quantitative essence in favor of verbal essence, accepting the sense of propositions "is present" and "is absent", respectively, i.e. become nothing more than the symbols of verbal evaluations. Further on we will denote the verbal evaluations of quality range of values as ⌋Q (quality is compliant with the requirements raised to it) and ⌉Q (quality is incompliant with the requirements raised to it). The symbols ⌋ and ⌉ represent the right parts of notations "floor" – ⌊ ⌋ and "ceiling" – ⌈ ⌉, located to the left of Q. The symbols ⌋ and ⌉ are generalized into symbolic operator ⌉ appearing in the formula $Q = ⌉Q(x) \quad x \in E$. This mnemonics corresponds to the widely known manual gestures, and the symbols are ⌋ and ⌉contained in character sets of standard computer software.

Taking the above said into consideration, QF may be set on the basis of decision rule:

$$Q \; ⌉Q(x) = \begin{cases} \{1, \text{ if } ⌋Q; \\ 0, \text{ if } ⌉Q. \end{cases}$$

The meaning of the equality sign "=" in formulas $Q = ⌉Q(x) \; x \in E$, and above, as well as the essence of values 1 and 0 in above equation, is solely symbolic, linguistic and, therefore, is not numerical, because the question is only about presence or absence of the quality P with the object being checked. As can be seen from above, the range of values as well as representation method of QF searched for is the same as for Boolean function. It remains to clarify the range of definition E of the function searched for. This range, which we will denote as EQ, represents the set of values taken by QIs. The appearance of this set of values depends on the applied method of QI gradation according to the principle of preference of various ranking scales. It may be single as well, i.e. may

consist of one element, e.g., for already mentioned single (one-time) measurements or evaluations. From the point of view of mathematical inequalities, functional requirements to QI may be presented either by semi-open intervals,

$$x \geq x_l \ [xl, \infty), \qquad x \leq x_r \ (0, xr]$$

or by segment,

$$x_l \leq x \leq x_r \quad [x_l, x_r]$$

where x_l and x_r are the so-called functional thresholds, left and right, respectively. The range of definition EQ of quality function is represented by the set,

$$E_Q = \{x_l, ..., x_r\}$$

while the range of definition E_B of Boolean function is represented by the set,

$$E_B = \{1, 0\}.$$

If cardinalities of E_Q and E_B sets are compared, it is evident that, except for point-wise properties, when $E_Q = \{1\}$,

$$\text{card } E_Q \geq \text{card } E_B,$$

where card means cardinality of a set.

Naturally, for point-wise properties,

$$\text{card } E_Q < \text{card } E_B,$$

From the point of view of theory of functions, relationships $\text{card } E_Q \geq \text{card } E_B$, and $\text{card } E_Q < \text{card } E_B$, allow to make conclusion that QF is an extension of Boolean function in regard of range of definition. The results of fulfillment of functional requirements $x \geq x_l \ [xl, \infty) - x \leq x_r \ (0, xr]$ are presented in table below.

Quality index, QI	Relationships of QI and Functional thresholds functional thresholds	Functional thresholds	
		Left x_l	Right x_r
x	≥	⌋Q	⌉Q
	≤	⌉Q	⌋Q

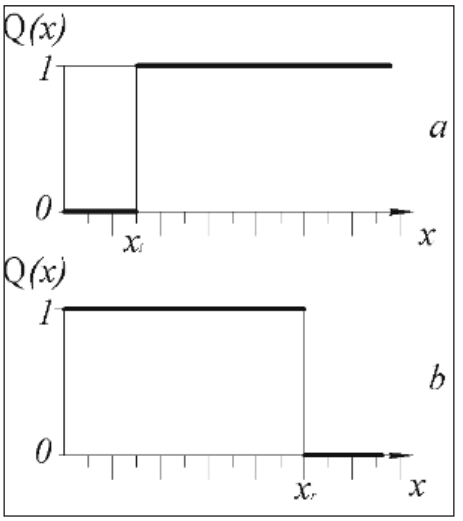
Dependence of quality Q (⌋Q or ⌉Q) on fulfillment of functional requirements If the object possesses not one but several properties, then a certain quality function Q_j will correspond to each j-th property. In this case, assertion about the quality Q_o of the object in whole may be made only on the basis of logical proposition:

$$Q_0 = Q_l \,\&\, Q_2 \,\&\, ... \,\&\, Q_j \,\&\, ... \,\&\, Q_n \quad j = \overline{(l, n)},$$

where Q_j means quality of j–th property of the object, & means logical conjunction sign. Expression $Q_0 = Q_1 \& Q_2 \& \ldots \& Q_j \& \ldots \& Q_n \quad j = \overline{(1,n)}$, testifies that JQ_o is achievable only on condition of JQ_j for each QI. Figuratively speaking, it may be collated (both in form and fact) with a chain which breaks if only one of its links is broken. Thus, by means of QF, mathematical-logical formulation $Q_0 = Q_1 \& Q_2 \& \ldots \& Q_j \& \ldots \& Q_n \quad j = \overline{(1,n)}$, was obtained, corresponding to the known assertion that quality is represented by the set of object properties.

Mathematically Fuzzy Characteristic Functions of Quality

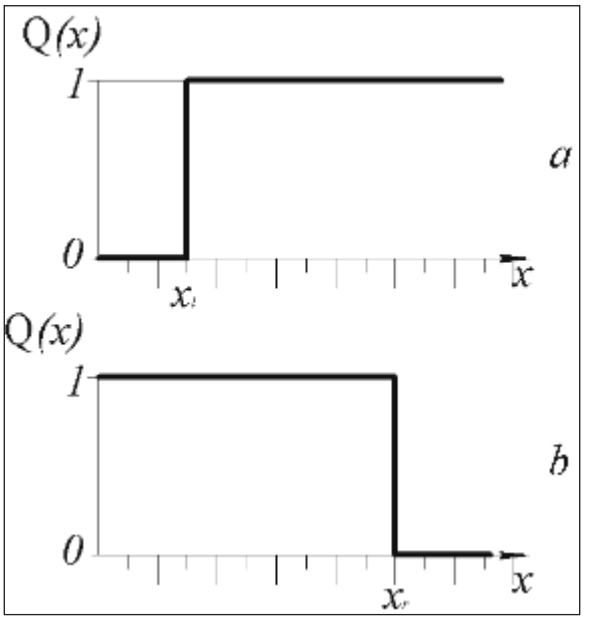
The graphical method of setting QF $Q\ JQ(x) = \begin{cases} 1, \text{ if } \lrcorner Q; \\ 0, \text{ if } \urcorner Q. \end{cases}$ may give visual presentation of the mutual relationship of the only two possible values Q(x) of quality, 0 and 1, with QI values lying, along x axis; for this purpose figure show graphical presentation of QF for the half-intervals $x \geq x_l \ [xl, \infty)$, and $x \leq x_r \ (0, xr]$, respectively, of its domain of definition.



Analytic quality function Qa = Qa (x) for functional thresholds:
a) left, $x \geq x_l$, b) right, $x \leq x_r$, x – quality index.

Reviewing of figurefrom the point of view of mathematical analysis leads to a conclusion that these are the plots of discontinuous piecewise-linear functions with discontinuities at points x_l and x_r. Numerical 0 of QI x at each plot coincides at the origin of coordinates with nonnumerical zero relating to absence of the property with the object. Discontinuity of the function is explained by the fact that 0 and 1 along vertical axis are non-numerical. There is no mathematical fuzziness here, and cannot be in principle. However, if one looks at these plots from, so to say, the point of view of mathematical fuzziness, then, pursuant to, it is obvious that the plot at figure resembles the rectangular mathematically fuzzy (MF) Snumber (sigmoid), while the plot at figure resembles

the rectangular MF Z-number (zetoid). In order to pass from purely outward resemblance to exact matching with these MF numbers, “eine grosse Kleinichkeit”2 is needed – vertical segments, the so-called terms 3, connecting 0 and 1 of functional thresholds – x_l and x_r.



Mathematically fuzzy (MF) quality function Q = Q (x) for functional thresholds: a) left (sigmoid S) $x \geq x_l$, b) right (zetoid Z) $x \leq x_r$, x – quality index.

This fact is taken into consideration at figure, which, as may be ascertained, is the MF analog of figure and presents the graphical method of setting QF as MF number for these thresholds. We will denote such MF function as characteristic function (hereinafter - CF), it structurally repeats the decision rule $Q\ ]Q(x) = \begin{Bmatrix} \{1, \text{ if } \lrcorner Q; \\ 0, \text{ if } \urcorner Q. \end{Bmatrix}$ for QF and the MF characteristic of functional thresholds $x \geq x_l\ [xl, \infty), x \leq x_r\ (0, xr]$, or of the combination thereof $x_l \leq x \leq x_r\ [xl, xr]$:

$$Q =]Q(x) = \alpha_Q(x) = \begin{Bmatrix} 1, \text{ if } \lrcorner Q; \\ 0, \text{ if } \urcorner Q. \end{Bmatrix}$$

where $\alpha_Q(x)$ is the membership function, in this case - of QI x to the property Q(x). Now let us find out, which MF number corresponds to segment $x_l \leq x \leq x_r\ [xl, xr]$ of QF domain of definition. As shown at figure, it will correspond to intersection of sigmoid 1 and zetoid 2 mentioned above. Using the terminology of the theory of sets, this intersection represents the set:

$$\Pi = (S \cap Z) = \{x \mid x \in S \text{ и } x \in Z\},$$

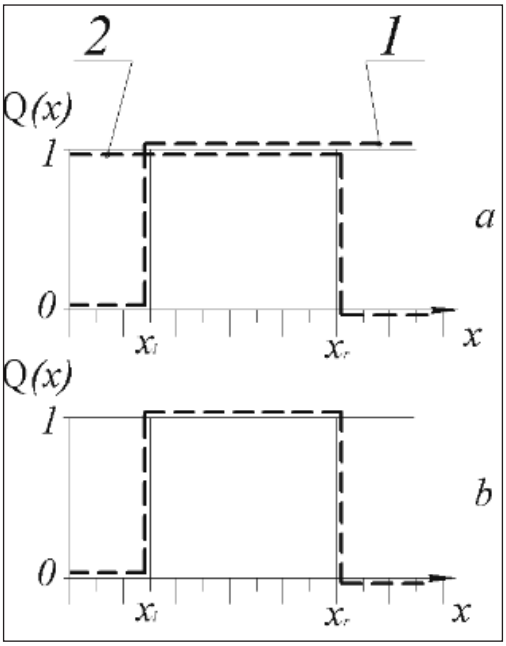
where: S, Z – the sets corresponding to S- and Z- numbers.

∩ – operator of intersection of sets.

| – Sheffer stroke.

∈ – logical inclusion sign.

x – QI.



Formation of MF rectangular tolerant Π-number from sigmoid S and zetoid Z.
a) intersection of sigmoid (1) and zetoid (Z), b) characteristic Π-number
of quality, or Π-oid, x – quality index,Q (x) – MF quality function.

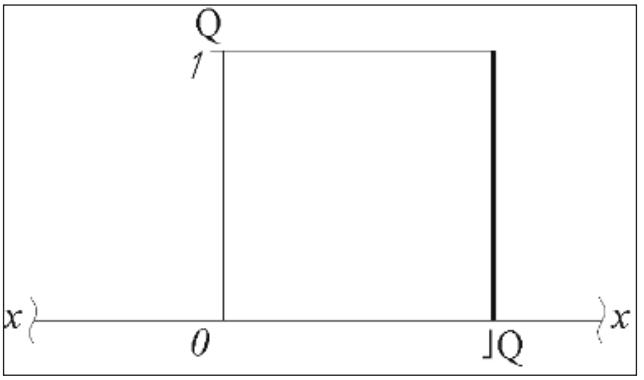
Figure shows the result of this intersection – the rectangular tolerant (closed) MF number, let us name it Π-number or Π-oid by analogy with S- and Z-numbers. The characteristic property of Π-number is fulfillment of conditions,

$$\lfloor Q \in \Pi \quad \text{and} \quad \lceil Q \notin \Pi,$$

where ∉ means logical exclusion sign. Relations $\lfloor Q \in \Pi$ and $\lceil Q \notin \Pi$, mean that quality is compliant with the raised requirements (⌊Q) only within Π number, and is incompliant with the raised requirements outside it, i.e. (⌈Q).

As these three MF numbers correspond to three possible domains of definition $x \geq x_l [xl, \infty), x \leq x_r (0, xr] - x_l \leq x \leq x_r \quad [xl, xr]$ of QF, they may be considered as the main (basic) MF characteristic numbers of quality. As far as the domains $x \geq x_l [xl, \infty), x \leq x_r (0, xr] - \quad x_l \leq x \leq x_r \quad [xl, xr]$ are concerned, they may be named the domains of S-, Z- and Πquality, or briefly S-, Z- and Π- quality, designated as Q_S,

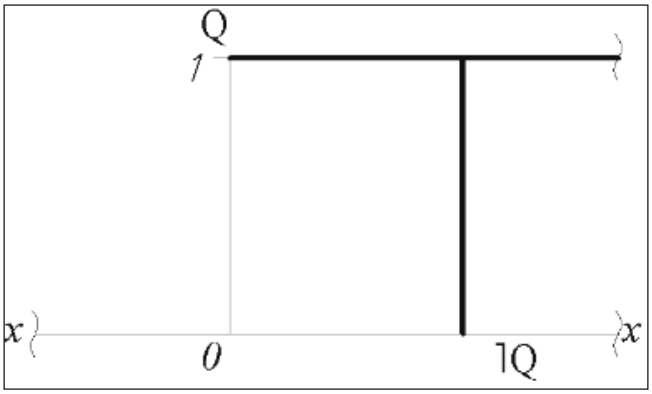
Q_Z and Q_Π, respectively. Thus, not only traditional mathematical methods, but also the methodology of mathematical fuzziness, may be applied to quality as the subject of applied mathematical research. Basing on the main MF characteristic numbers of quality, auxiliary (or second-rank) MF numbers may be derived, which are met in course of quality control of point-wise values or permanent values.



Degenerate Π-number or singleton I corresponding to point-wise MF quality function x – x – free axis of singleton location, Q – axis of verbal values of quality (0 and 1).

In case of point-wise property of the object, when $x_l = x_r$, Π-number degenerates into the so called singleton. We will denote it as MF I-number, due to its appearance, and will regard it as additional characteristic number of quality.

In case of permanent property of the object, its point-wise absence may be characterized by anti-singleton, let us denote it as Ī. Geometric appearance of this singleton is shown at figure as drooping vertical straight segment symbolizing point-wise absence of property (]P). As may be seen at figure, its x – x axis has neither arrow orientation nor scale, and incompliance of quality (]Q) with the raised requirements occurs here once and at single point.



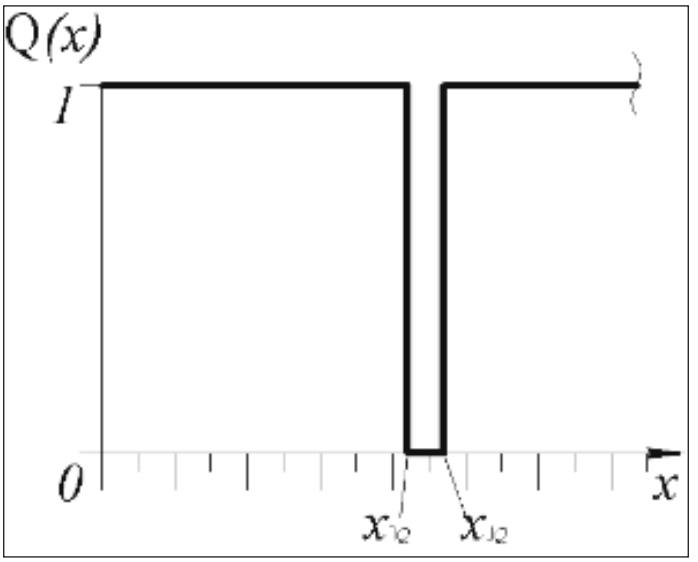
Anti-singleton Ī of permanent quality function Q (x) x – x – free axis of anti-singleton location, Q – axis of verbal values of quality (0 and 1).

Examples from material and non-material spheres characterized by singleton I and by antisingleton Ī were presented above, where point-wise properties and their absence

were discussed. A propos, another characteristic number related to loss (⌉P) and recovery (⌋P) of property P may be seen there.

According to the stated above, loss of property (⌉P) leads to incompliance of quality with the requirements raised to it (⌉Q), while recovery of property (⌋P) restores such compliance to (⌋Q). It is shown at figure and characterizes ⌉ and Q at the interval (x⌉Q, x⌋Q), where x⌉Q and x⌋Q denote the points of incompliance (⌉) and compliance (⌋Q) of quality of permanence by the property P(x) at QI axis x. Its width,

$$b = x_{\rfloor Q} - x_{\lceil Q}$$



MF U-number of interval absence of permanency of MF quality function Q (x) x – quality index, x⌉Q , x⌋Q - points of loss and recovery of permanency of the property characterized by MF quality function at the interval (x⌉Q , x⌋Q).

in terms of MF language is the base or carrier of time (or period) of quality recovery. Appearance of this number at figure resembles the letter U, therefore we will name it MF auxiliary characteristic number U of quality absence. For reasons of simplicity, later we will denote MF characteristic numbers S, Z, П, I in general case by common symbol Ǫ (the so-called “candle apple”).

Similarly, MF characteristic numbers Ī and U in general will be represented by common symbol Ǭ, but they are not discussed here in detail because they are subjects for separate study as they refer to cases difficult for prediction and to unforeseen situations. Therefore, further we will basically discuss the generalized MF quality characteristic numbers Ǫ or, what is the same, quality Ǫ-numbers. By the way, all the symbolic notations used above were taken from the corresponding Unicode tables of Microsoft Office Word; in particular, hexagonal numbers of symbols Ǫ и Ǭ are 01EA and 01EC, respectively. Classification of MF characteristic numbers of quality and of quality absence is presented in table.

Table: Mathematically fuzzy characteristic numbers of quality.

Rank	Quality presence	Name	Designation	Position at x axis of quality index
Main Auxiliary	Ϙ	Sigmoid	S	Local
		Zetoid	Z	
		Π-oid	Π	
		Singleton	I	
	$\bar{Ϙ}$	Anti-singleton	$\bar{I}$	Free
		U-oid	U	

Examples from the field of production quality control characterized by MF characteristic numbers of quality are given in table.

Table: Examples of production quality control characterized by MF characteristic numbers of quality.

MF characteristic numbers of quality	Objects and/or facilities of quality control
1	2
S	Check of dimensions of male parts by go gauges “GO”. Check of dimensions of female parts by no-go gauges “NO GO”. Internal diameter of male thread. Functional characteristics of a micro switch: forward travel (until direct actuation) of the driving element; overtravel (after direct actuation); force of reverse actuation at the driving element; operational life (limit number of changeovers).
Z	Check of dimensions of female parts by go gauges “GO”. Check of dimensions of male parts by no-go gauges “NO GO”. Check of defects of geometric shape using universal measuring instruments or by amplitude sensor. Internal diameter of male thread. Functional imperfections of elastic members (e.g., nonlinearity and hysteresis of their elastic response). Functional characteristics of a micro switch: force of direct actuation; voltage drop at normally closed contacts.
Π	Check of limiting dimensions of machine parts confined by tolerance range, using universal measuring instruments and/or by double-limit contact sensor.
I	Just-in-time delivery of component parts, subassemblies, units etc. to the assembly line.
$\bar{I}$	Hang-up of contacts of micro switches in the zone of expected direct and/or reverse actuation
U	Single or intermittent failures of measuring or automatic checking facilities

Vectorial nature of properties of objects and of corresponding QIs, especially in regard of complicated systems , allows speaking about composite MF characteristic numbers of quality which we will denote as Q^n-numbers, where n means the number of dimensions of object properties vector. The corresponding $\bar{Q}^n$-numbers will be considered here only fragmentary, because they are more suitable for analysis of catastrophic situations (so to say, "post-flight analysis"), rather than to quality control. In this connection, QF also becomes vectorial, i.e. multi-component.

For simplicity reasons, let us consider the elementary case of a two-dimensional vector of properties which we will denote as vectorial MF characteristic two-component number Q^2 of quality. Indices 1 and 2 in the latter notation correspond to the set of two numbers, the main and auxiliary, from Q- and/or $\bar{Q}$-range. If such two-component number is composed only from Q-numbers, then, naturally, it will represent a Q^2-number. If even one of the numbers of the two-component set happens to be $\bar{Q}$-number, then, by virtue of relation $Q =]Q(x) = \alpha_Q(x) = \begin{Bmatrix} 1, \text{ if } \lrcorner Q; \\ 0, \text{ if } \urcorner Q. \end{Bmatrix}$, the resulting Q^2-number also will be $\bar{Q}$-number. This rule applies to similar composite numbers of any vectorial dimensionality. As the saying is, a scabbed sheep will mar the flock. From the point of view of theory of sets, two-component MF numbers of quality represent a union of two heterogeneous sets, what is presented in general form as,

$$Q_2 = Q_{12} = (Q_1 \cup Q_2) = \{x \mid x_1 \in Q_1 \text{ and } x_2 \in Q_2\},$$

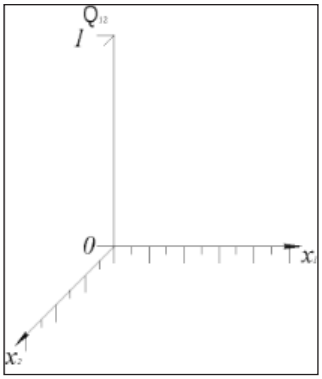
where Q_1 and Q_2 mean the main and auxiliary MF numbers, respectively, $\cup$ means the sign of logical uniting of sets.

As $x_1 \neq x_2$ in the area under consideration (where $\neq$ is the symbol of absence of equivalence), then numbers Q_1 and Q_2 cannot lie in the same plane. Therefore, following, let us create from the two planes corresponding to them the dimensionless nonnumerical (verbal) axis containing the verbal segment [0,1] corresponding to its nonnumerical property.

Such a coordinate system for the two-component MF characteristic number of quality Q_2 (Q_1 – main number, Q_2 – auxiliary number conjugated with Q_1) is shown at figure. The main plane x_1-0-1, corresponding to Q_1 number, lies in the plane of drawing, and the auxiliary plane x_2 -0-1 forms a spatial right angle with it. Classification of the main two-component characteristic numbers of quality is given in table.

Table : Classification of two-component characteristic numbers of quality.

Type	Logical set structure	Geometric image
1	SvZvП ∪ SvZvП	Piecewise-planar surface
2	SvZvП ∪ I	Planar piecewise linear form
3	I ∪ SvZvП	-*-
4	I ∪ I	Vertical linear segment



Coordinate system of the composite MF characteristic quality number Q_2 . a - main coordinate plane x_1 - 0 - 1, corresponding to the main number Q1 ; b - auxiliary coordinate plane x_2 - 0 - 1, corresponding to the auxiliary number Q_2 ; c – plane of quality absence; Q1,2 - axis of verbal quality values (0 and 1) common for numbers Q_1 and Q_2.

Their coordinate axes correspond to the axes at figure. In a similar way, one can systemize and represent graphically other kinds of MF numbers of this table, as well as various combinations of Q- and $\bar{Q}$-numbers, because it is easy to show that formula $Q_2 = Q_{12} = (Q_1 \cup Q_2) = \{x \mid x_1 \in Q_1 \text{ and } x_2 \in Q_2\}$, also covers the case when $Q_2 = \bar{Q}$.

Investigation of geometric images of Q_2-numbers in table 5 shows that all of them, except ΠΠ-number, consist of only two geometric forms resembling street shelters: a shed, e.g., ZSnumber, or a booth, e.g., ΠS-number. It is not too difficult to note that the entire variety of images of Q_2-numbers obtained using the coordinate method considered above may be reproduced by sequential rotations around the vertical axis at the angles being multiple of π/2, namely:

for the “shed”:

SZ↳ZZ↳ZS↳SS↳SZ.

for the “booth”:

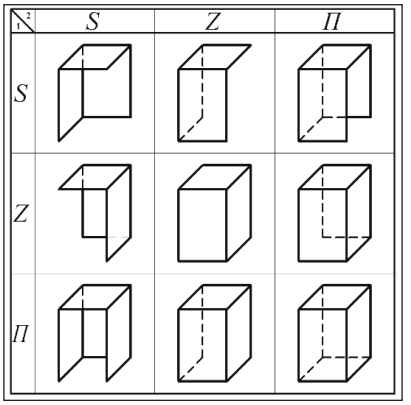
ΠS↳SΠ↳ΠZ↳ZΠ↳ΠS.

where ↳ means the mathematical symbol of rotation at the angle π/2, in this case – counterclockwise.

Presence of rotations SZ↳ZZ↳ZS↳SS↳SZ and ΠS↳SΠ↳ΠZ↳ZΠ↳ΠS indicates eventual group-theoretical properties of the structure formed by Q_2-numbers.

MF characteristic numbers of quality allow identifying and classifying multi-component (vectorial) double goals and goals of larger dimensionality stipulated by a joint action, e.g., by implementation of QMS into manufacturing activity of an enterprise. The table of kinds of QMS measurable goals is convenient for this purpose, where only the due dates of achieving the goals are changed for later dates.

Table: Geometric image of mathematically fuzzy two-component Q-numbers of quality.



As one may see, the goals of this table are characterized by single-component Q-, two component Q_2, while the latter of the goals in the list – by ternary (three-component) MF Q_3 –number IZS. In this connection, it seems that we deal with the structure of notations of MF numbers which may be regarded as MF symbolic language of quality control. A word in this language is a sequence of Q-numbers, ordered by the priority of actions corresponding to them, namely, to organizing and implementing the measures related to quality assurance and quality control, as shown, in particular, in table 6. From the semantic point of view, this corresponds to the known statement: "the meaning of a certain word is its usage in the language".

For practical application of the stated above MF approach to quality control it is necessary to know, at least in first approximation, the influence of measurement errors on the Q-numbers which characterize this quality. Basing on the investigations, it may be shown, that if one turns a priori to the probability function of MF appurtenance of this error, then for the case of most commonly encountered Gaussian normal probability law, this MF function is a symmetrical MF R-L-number. Upon completion of additive MF operations with the main (S-, Z- and П-) characteristic numbers of quality, it leads to changing of location of the latter on the scale of QI x which is measured. For the simplest three-term R-L-number which is appropriate here, S-number shifts by two inter-term intervals to the right, Z-number shifts by same distance to the left, while П-number symmetrically narrows from left and from right by one inter-term interval without shifting.

References

- Types-quality-control-7867675: bizfluent.com, Retrieved 28 April, 2020
- 12-importance-or-benefits-of-quality-control-production-management, production-managemen t-26173: yourarticlelibrary.com, Retrieved 14 June, 2020
- Quality-audit-3812: smallbusiness.chron.com, Retrieved 09 August, 2020
- The-4-key-steps-in-quality-audits: blog.softexpert.com, Retrieved 14 January, 2020

- Bothe, D. R., “Measuring Process Capability”, 2001, ISBN 0-07-006652-3
- Techniques-of-applying-statistical-quality-control-production-management, production-management-26171: yourarticlelibrary.com, Retrieved 06 March, 2020
- Ramirez, B.; Runger, G. (2006). “Quantitative Techniques to Evaluate Process Stability”. Quality Engineering. 18 (1). pp. 53–68. doi:10.1080/08982110500403581

Quality Assessment and Improvement Tools

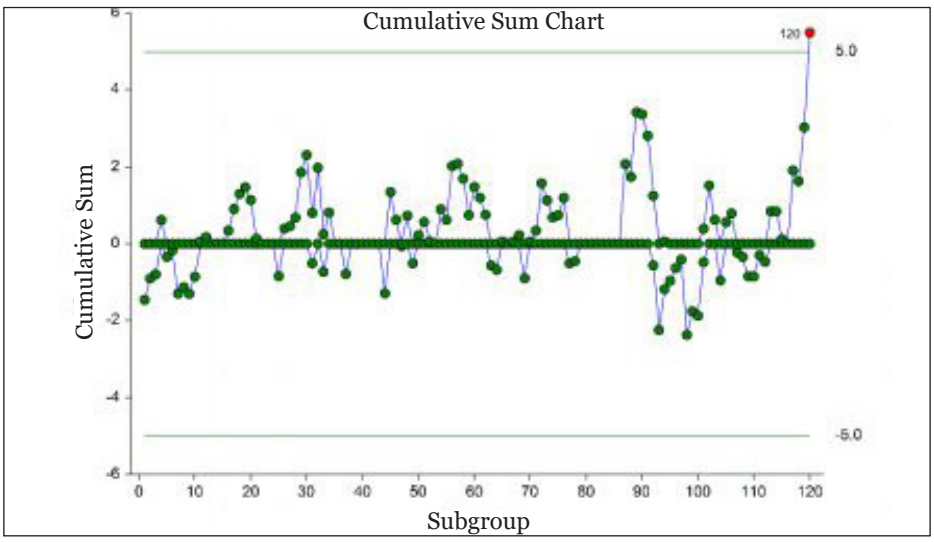
CHAPTER 4

Quality assessment and improvement tools are used to audit, measure and improve the quality and standards of the product. Some of these tools are CUSUM, flowchart, quality storyboard, p-chart, Pareto chart, histogram, scatter plot, etc. This chapter closely examines the different quality assessment and improvement tools to provide an extensive understanding of the subject.

CUSUM

The CUSUM chart is used to monitor the mean of a process based on samples taken from the process at given times (hours, shifts, days, weeks, months, etc.). The measurements of the samples at a given time constitute a subgroup. Rather than examining the mean of each subgroup independently, the CUSUM chart shows the accumulation of information of current and previous samples. For this reason the CUSUM chart is generally better than the X-bar chart for detecting small shifts in the mean of a process.

The CUSUM chart relies on the specification of a target value and a known or reliable estimate of the standard deviation. For this reason, the CUSUM chart is better used after process control has been established.



Other Control Charts for the Mean of a Process.

The CUSUM chart typically signals an out-of-control process by an upward or downward drift of the cumulative sum until it crosses the boundary. An assignable cause is suspected whenever the CUSUM chart indicates an outof-control process.

The X-bar chart is the most common control chart for monitoring the process mean. The X-bar chart is usually used in Phase I monitoring, when process control is being established. The X-bar chart is useful for detecting large changes in the process mean. The CUSUM chart is based on an established target mean and a reliable value for sigma. The CUSUM chart is useful for quickly detecting small shifts in the process mean.

An alternative to the CUSUM chart is the exponentially weighted moving average (EWMA) chart. The EWMA chart has similar properties to the CUSUM chart, and is also useful for detecting smaller shifts in the process mean.

When only a single response is available at each time point, then the individuals and moving range (I-MR) control charts can be used for early phase monitoring of the mean and variation. CUSUM and EWMA charts may also be used for single responses, and are useful when small changes in the mean need to be detected.

Control Chart Formulas

Suppose we have k subgroups, each of size n. Let x_{ij} represent the measurement in the j^{th} sample of the i^{th} subgroup.

The i^{th} subgroup mean is calculated using:

$$\overline{x}_i = \frac{\sum_{j=1}^{n} x_{ij}}{n}$$

Estimating the Target Value

In the CUSUM procedure, the target value may be input directly, or it may be estimated from a series of subgroups. If it is estimated from the subgroups the formula for the grand average is:

$$\overline{\overline{x}}_i = \frac{\sum_{i=1}^{k}\sum_{j=1}^{n_i} x_{ij}}{\sum_{i=1}^{k} n}$$

If the subgroups are of equal size, the above equation for the grand mean reduces to:

$$\overline{\overline{x}} = \frac{\sum_{i=1}^{k} \overline{x}_i}{k} = \frac{\overline{x}_1 + \overline{x}_2 + \ldots + \overline{x}_k}{k}$$

Either the range or the standard deviation of the subgroups may be used to estimate sigma, or a known (standard) sigma value may be entered directly. If the standard deviation (sigma) is to be estimated from the ranges, it is estimated as:

$$\hat{\sigma} = \frac{\bar{R}}{d_2}$$

where,

$$\bar{R} = \frac{\sum_{i=1}^{k} R_i}{k}$$

$$d_2 = \frac{E(R)}{\sigma} = \frac{\mu_R}{\sigma}.$$

The calculation of E(R) requires the knowledge of the underlying distribution of the x_{ij}'s. Making the assumption that the x_{ij}'s follow the normal distribution with constant mean and variance, the values for d_2 are derived through the use of numerical integration. It is important to note that the normality assumption is used and that the accuracy of this estimate requires that this assumption be valid.

When n is one, we cannot calculate R_i since it requires at least two measurements. The procedure in this case is to use the ranges of successive pairs of observations. Hence, the range of the first and second observation is computed, the range of the second and third is computed, and so on. The average of these approximate ranges is used to estimate σ.

Estimating Sigma – Mean of Standard Deviations

The true standard deviation (sigma) may be input directly, or it may be estimated from the standard deviations by,

$$\hat{\sigma} = \frac{\bar{S}}{c_4}$$

Where,

$$\bar{S} = \frac{\sum_{i=1}^{k} S_i}{k}$$

$$c_4 = \frac{E(S)}{\sigma} = \frac{\mu_S}{\sigma}$$

The calculation of E(s) requires the knowledge of the underlying distribution of the x_{ij}'s.

Making the assumption that the x_{ij}'s follow the normal distribution with constant mean and variance, the values for c_4 are obtained from,

$$c_4 = \sqrt{\frac{2}{n-1}} \frac{\Gamma\left(\frac{n}{2}\right)}{\Gamma\left(\frac{n-1}{2}\right)}.$$

Estimating Sigma – Weighted Approach

When the sample size is variable across subgroups, a weighted approach is recommended for estimating sigma,

$$\hat{\sigma} = \overline{S} = \left[\frac{\sum_{i=1}^{k} (n_i - 1) S_i^2}{\sum_{i=1}^{k} n_i - k} \right]^{1/2}$$

CUSUM Charts

Following the CUSUM procedure presented by Ryan, the steps for creating a CUSUM chart may be summarized as follows:

- Calculate the zi using the formula:

$$z_i = \frac{\overline{x}_i - \overline{\overline{x}}}{\hat{\sigma}_{\overline{x}}}$$

- Calculate the lower and upper cumulative sums as follows:

$$S_{Li} = -\max\left[0, \left(-z_i - k\right) + S_{Li-1}\right]$$
$$S_{Hi} = \max\left[0, \left(z_i - k\right) + S_{Hi-1}\right]$$

- Plot S_{Hi} and S_{Li} on a control chart. The control limits are chosen as plus or minus h. The usual choice for k is 0.5 (for detecting one-sigma shifts in the mean) and h is typically set to 5.

- When an out-of-control situation is detected, the corresponding sum may be left as it is, or reset to an appropriate starting value. In NCSS, the re-starting value may be set to zero or the fast initial restart (FIR) value of h/2.

Data Structure

In this procedure, the data may be in either of two formats. The first data structure option is to have the data in several columns, with one subgroup per row.

Example Dataset

S1	S2	S3	S4	S5
2	6	3	8	5
8	8	7	7	9
6	2	2	4	3
5	6	7	6	10
48	2	6	5	0

The second data structure option uses one column for the response data, and either a subgroup size or a second column defining the subgroups.

Alternative Example Dataset

Response	Subgroup
2	1
6	1
3	1
8	1
5	1
8	2
8	2
7	2
7	2
9	2
6	3
2	3

In the alternative example dataset, the Subgroup column is not needed if every subgroup is of size 5 and the user specifies 5 as the subgroup size. If there are missing values, the Subgroup column should be used, or the structure of the first example dataset.

Input Type

Specify whether the data is in a single response column or in multiple columns with one subgroup per row.

- Response Column and Subgroup Column or Subgroup Size:

Response	Subgroup
5	1
6	1
4	1
3	2
7	2
6	2

4	3
5	3
8	3

- Multiple Columns with One Subgroup Per Row:

X1	X2	X3
5	6	4
3	7	6
4	5	8

Variables – Response Column

Response Variable

Specify the column with the data values. The data values are separated into subgroups below using the Subgroup Specification options.

Subgroup Specification

Specify whether subgroups are defined by a Subgroup ID variable, or by a subgroup size. If the subgroup size is 3, then subgroups are formed by going down the response column in groups of 3. The first subgroup would be 5, 6, 4; the second would be 3, 7, 6; and so on.

Subgroup ID Variable

Specify the column containing the subgroup identifiers:

Response	ID Variable
5	1
6	1
4	1
3	2
7	2
6	2
4	3
5	3
8	3

A new subgroup is created for each change in the Subgroup ID Variable, going down.

Subgroup Size

Specify the number of individuals in each subgroup:

Response
5
6

4
3
7
6
4
5
8

If the subgroup size is 3, then subgroups are formed by going down the response column in groups of 3. The first subgroup would be 5, 6, 4; the second would be 3, 7, 6; and so on.

X1	X2	X3
5	6	4
3	7	6
4	5	8

If only one variable is specified, NCSS automatically generates an individuals chart with a moving-range of size 2.

Stages

Number of Stages

Specify whether the analyses and charts are to be produced based on a single set of subgroups, or a series of sets of subgroups. Typically a single stage is used unless you wish to have separate estimation for various segments of the subgroups. When using multiple stages, the software requires that there be at least one subgroup in every stage specified.

Stage Specification

Specify whether the various stages will be defined using a variable (column) with a unique value for each stage, or by entering a range of rows for each stage.

Stage Variable

X1	X2	X3	Stage
5	6	4	1
3	7	6	1
4	5	7	1
6	5	4	1
3	7	6	1
5	8	3	2
2	6	4	2
3	6	5	2
4	5	8	2

Enter a Range for Each Stage

Example: 1-50, 51-100, 101-150

This would produce three stages. The first stage would be made up of rows 1 to 50, the second stage would be rows 51 to 100, and the third stage would be rows 101 to 150.

Stage Variable

Specify the variable (column) that contains the identifiers for each stage:

X1	X2	X3	Stage Variable
5	6	4	1
3	7	6	1
4	5	7	1
6	5	4	1
3	7	6	1
5	8	3	2
2	6	4	2
3	6	5	2
4	5	8	2

A new stage is created for each change in the Stage Variable, going down.

Stage Ranges

Enter a range for each stage using a dash. Separate each stage with a comma.

Example: 1-50, 51-100, 101-150

This would produce three stages. The first stage would be made up of rows 1 to 50, the second stage would be rows 51 to 100, and the third stage would be rows 101 to 150.

Specify Rows in Target Value and Sigma Calculations

Specification Method

Select which method will be used to specify the rows of the data to be used to form subgroups:

- All Rows: All rows in the response columns will be used.
- Enter First Row and Last Row: Specify the first row and the last row of the data for use in calculations.
- First N Rows (Enter N): The data beginning at Row 1 and ending at Row N will be used in calculations.
- Last N Rows (Enter N): Subgroups will be formed from the last N rows of the dataset.

- Keep Rows Variable: Specify a variable and a value in that variable column that will be used to determine which rows are used to form the subgroups.
- Remove Rows Variable: Specify a variable and a value in that variable column that will be used to determine which rows will not be used to form the subgroups.
- First Row: Specify the beginning row to be used for the first subgroup.
- Last Row: Specify the last row to be used for the last subgroup.
- N: Enter the number of rows to be used in forming subgroups.
- Keep Rows Variable: This variable (column) is used to specify which rows of the data will be used to form the subgroups for the calculations.
- Keep Rows Value: This value determines which rows of the Keep Rows Variable will be used in the calculation portion of the analysis.
- Remove Rows Variable: This variable (column) is used to specify which rows of the data will not be used to form the subgroups for the calculations.
- Remove Rows Value: This value determines which rows of the Remove Rows Variable will not be used in the calculation portion of the analysis.

Specify Rows in Chart

Specification Method

Select which method will be used to specify the rows of the data to be used to form subgroups for the charts.

- All Rows: All rows in the response columns will be used.
- Enter First Row and Last Row: Specify the first row and the last row of the data for use in the plots.
- First N Rows (Enter N): The data beginning at Row 1 and ending at Row N will be used in the plots.
- Last N Rows (Enter N): Subgroups will be formed from the last N rows of the dataset.
- Keep Rows Variable: Specify a variable and a value in that variable column that will be used to determine which rows are used to form the subgroups.
- Remove Rows Variable: Specify a variable and a value in that variable column that will be used to determine which rows will not be used to form the subgroups.

- First Row: Specify the beginning row to be used for the first subgroup.
- Last Row: Specify the last row to be used for the last subgroup.
- N: Enter the number of rows to be used in forming subgroups.
- Keep Rows Variable: This variable (column) is used to specify which rows of the data will be used to form the subgroups for the plots.
- Keep Rows Value: This value determines which rows of the Keep Rows Variable will be used in the plots.
- Remove Rows Variable: This variable (column) is used to specify which rows of the data will not be used to form the subgroups for the plots.
- Remove Rows Value: This value determines which rows of the Remove Rows Variable will not be used in the plots.

Labels (Optional)

- Subgroup Label Variable: Specify a variable (column) that contains the desired x axis (subgroup) labels for plots. If left blank, the plot will use the subgroup number. The format of the labels is controlled on the x axis tab of the plot format window.
- Point Label Variable: Specify a variable (column) that contains the desired individual point labels for plots. If left blank, no point labels are shown. The format of the labels is controlled on the main chart tab of the plot format window.
- Target and Sigma Tab: The options on the Target and Sigma tab are used to specify the target value and sigma.

Target Value Options

Target Value Specification

Specify whether the target value is estimated from the data, or whether it will be specified directly.

- From Rows in Calculations Data: Estimate the target value from the subgroups specified for calculations.
- Enter Target Values: Specify the target value directly. If multiple stages are used, separate the target value for each stage by spaces.
- Use a Variable with Target Values: Specify a column containing the target value in row 1. If multiple stages are used, a target value should be entered in a separate cell for each stage, beginning with row 1 for the first stage.

- Target Values: Enter the target value to be used. If multiple stages are used, separate the target values for each stage by spaces.
- Target Values Variable: Specify a column containing the target value in row 1. If multiple stages are used, a target value should be entered in a separate cell for each stage, beginning with row 1 for the first stage.

Sigma Estimation Options

Sigma Specification

Specify the method by which Sigma will be estimated for use in the charts:

- From Rows in Calculations Data: R-bar or s-bar Estimate. Estimate sigma based on the average of the ranges or standard deviations (whichever is specified under R-bar or s-bar Estimation). Only the subgroups specified for use in calculations will be used.
- From Rows in Calculations Data: Weighted Approach Estimate. This method estimates s-bar using a special formula that is recommended when the subgroup size varies across subgroups. Only the subgroups specified for use in calculations will be used.
- Enter Sigma Values: In this case the sigma value is entered directly. If multiple stages are used, separate the sigma values for each stage by spaces.
- Use a Variable with Sigma Values: Specify a column containing the sigma value in row 1. If multiple stages are used, a sigma value should be entered in a separate cell for each stage, beginning with row 1 for the first stage.
- Sigma Values: Enter the value to be used for the sigma. If multiple stages are used, separate the sigma values for each stage by spaces.
- Sigma Variable: Specify a column containing the sigma value in row 1. If multiple stages are used, a sigma value should be entered in a separate cell for each stage, beginning with row 1 for the first stage.

Reports Tab

The following options control the format of the reports:

Specify Reports

- Target Value and Sigma: This report gives the numeric values of the target value and sigma, as well as the sigma estimation.

Report Options

- Precision: Specify the precision of numbers in the report. A single-precision

number will show seven-place accuracy, while a double-precision number will show thirteen-place accuracy. Note that the reports are formatted for single precision. If you select double precision, some numbers may run into others. Also note that all calculations are performed in double precision regardless of which option you select here. This is for reporting purposes only.

- Variable Names: This option lets you select whether to display variable names, variable labels, or both.
- Page Title: This option specifies a title to appear at the top of each page.
- Plot Subtitle: This option specifies a subtitle to appear at the top of each plot.
- CUSUM Chart Tab: This panel sets the options used to define the appearance of the CUSUM chart.

Select Plots

CUSUM Chart

This chart is controlled by three form objects:

- A checkbox to indicate whether the chart is displayed.
- A format button used to call up the plot format window.
- A second checkbox used to indicate whether the chart can be edited during the run.

Threshold Limit (h)

This value and the corresponding negative value constitute the out-of-control limit for the CUSUM chart. The threshold value is sometimes called the decision interval. It is typically set to five.

Reference Value (k)

The reference value (k) is the mean-shift detection constant for the CUSUM chart. It is sometimes called the allowance, or slack value. It is typically set to 0.5.

Start Method

The start method specifies whether the cumulative sum starting value is zero, or whether a fast initial response value (FIR) is used.

- Zero: Prior to the first cumulative sum of the chart, the cumulative sum is set to zero.
- Fast Initial Response (FIR): Prior to the first cumulative sum of the chart, the cumulative sum is set to h/2.

Restart Method

After an out-of-control signal is encountered, the restart method specifies whether the cumulative sum is set to zero, a restarting fast initial response (FIR) value, or is left as is.

- Zero: After an out-of-control signal, and before the next cumulative sum, the cumulative sum is set to zero.
- Fast Initial Response (FIR): After an out-of-control signal, and before the next cumulative sum, the cumulative sum is set to h/2.
- None: After an out-of-control signal, no adjustment is made to the cumulative sum value.

Storage Tab

The options on this panel control the automatic storage of the means on the current dataset.

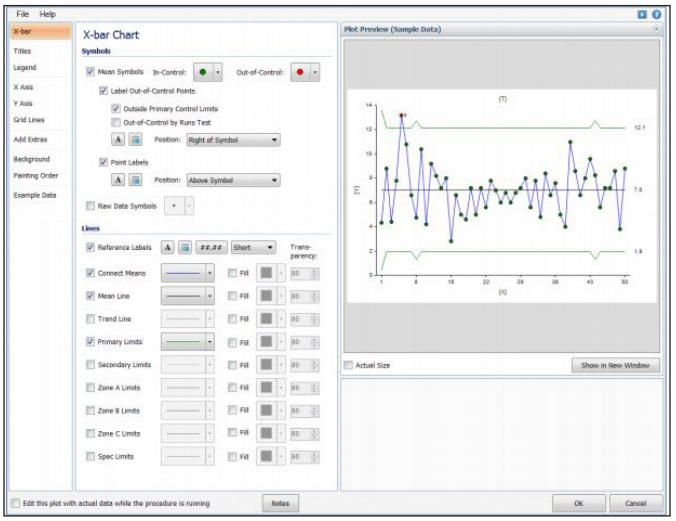
Storage Columns

Store Means in Column

You can automatically store the mean of each subgroup into the column specified here. Warning: Any data already in this column is replaced. Be careful not to specify columns that contain important data.

Quality Control Chart Format Window Options

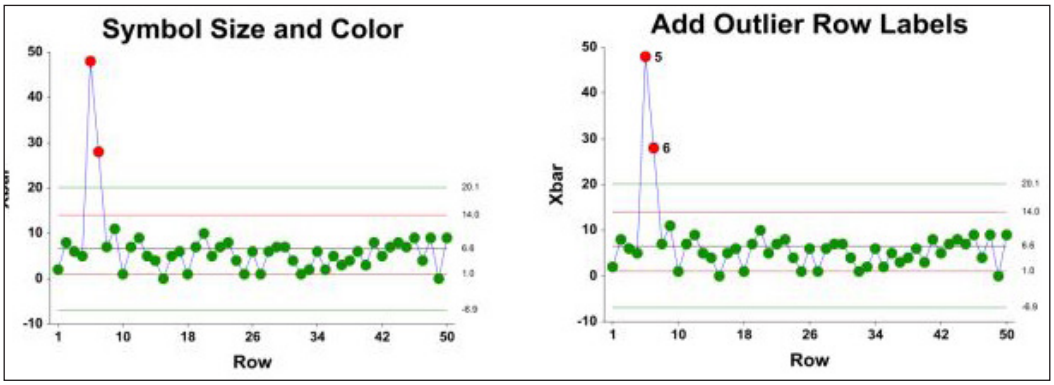
This topic describes a few of the specific options available on the first tab of the control chart format window, which is displayed when a quality control chart format button is pressed. Common options, such as axes, labels, legends, and titles are documented in the Graphics Components.



[Xbar]/[Range] Chart Tab

Symbols Section

You can modify the attributes of the symbols using the options.

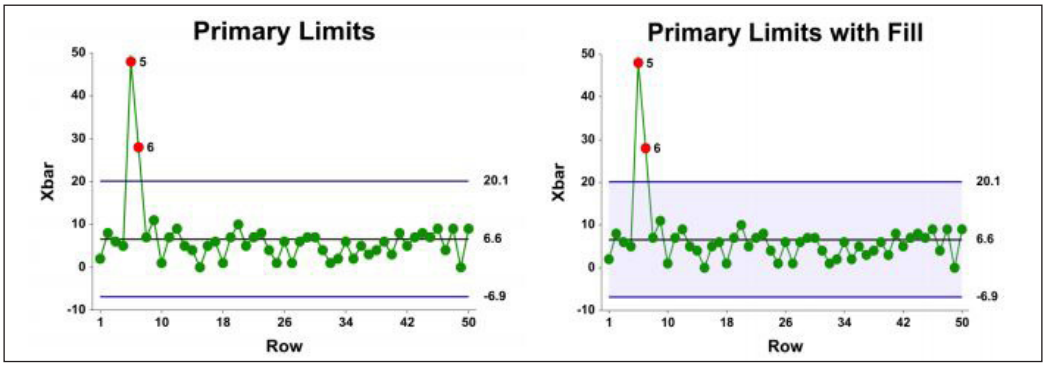


A wide variety of sizes, shapes, and colors are available for the symbols. The symbols for in-control and out-ofcontrol points are specified independently. There are additional options to label out-of-control points. The label for points outside the primary control limits is the subgroup number. The label for points that are out-of-control based on the runs test is the number of the first runs test that is signaled by this point.

The user may also specify a column of point labels on the procedure variables tab, to be used to label all or some of the points of the chart. The raw data may also be shown, based on customizable raw data symbols.

Lines Section

You can specify the format of the various lines using the options. Note that when shading is desired, the fill will be to the bottom for single lines (such as the mean line), and between the lines for pairs of lines (such as primary limits).



Lines for the zones, secondary limits, and specification limits are also specified here.

EVOLUTIONARY OPERATION

Evolutionary Operation (EVOP) is a manufacturing process-optimization technique developed in the 1950s by George E. P. Box.

In EVOP experimental designs and improvements are introduced, while an ongoing full-scale manufacturing process continues to produce satisfactory results. The idea is that process improvement should not interrupt production.

EVOP is a process or technique of systematic experimentation. Evolutionary Operation (EVOP) is based on the understanding that every production lot has the ability to contribute valuable information on the effect of process variables on a particular product characteristic or feature. Typical methods used involve structured designs of experiments (DOE) which may result in interrupting production flow to conduct the trials or experiments. EVOP, on the other hand, is intended to introduce small changes in the process variables during normal production flow. These changes are not large enough to result in non-conforming product, but are significant enough to determine the optimum process ranges.

Application

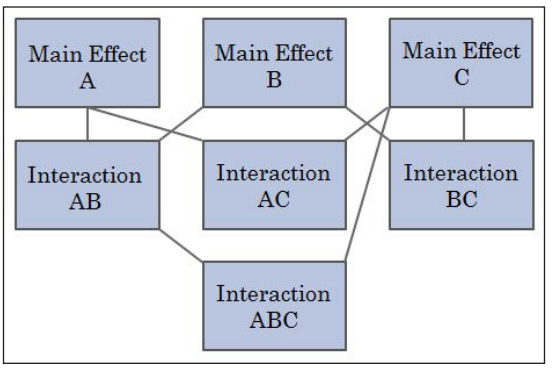
Applicable virtually to any applied discipline. Optimization is addressed in all spheres of human enterprise from natural sciences and engineering of whatever discipline, through economics, econometrics, statistics and operations research to management science. Practitioners of mathematical programming who require global optimization methods in diverse technological application. EVOP has been implemented in the following quantitative sectors:

- Nuclear reactor technology.
- Mechanical engineering.
- Civil engineering.
- Structural engineering.
- Electrical engineering.
- Electronic engineering.
- Chemical engineering.
- High performance control systems.
- Fuzzy logic.
- Metallurgy.

- Space technology.
- Integrated circuit design.
- Transport network.
- Database.
- Image processing.
- Molecular biology.
- Environmental engineering.
- Finance and stock.

ROBUST PARAMETER DESIGN

A robust parameter design, introduced by Genichi Taguchi, is an experimental design used to exploit the interaction between control and uncontrollable noise variables by robustification—finding the settings of the control factors that minimize response variation from uncontrollable factors. Control variables are variables of which the experimenter has full control. Noise variables lie on the other side of the spectrum, and while these variables may be easily controlled in an experimental setting, outside of the experimental world they are very hard, if not impossible, to control. Robust parameter designs use a naming convention similar to that of FFDs. A $\mathbf{2}^{(m1+m2)-(p1-p2)}$ is a 2-level design where m1 is the number of control factors, m2 is the number of noise factors, p1 is the level of fractionation for control factors, and p2 is the level of fractionation for noise factors.



Effect sparsity: Interactions can only significantly effect the response if at least one of the parent factors has an effect on the response.

Consider an RPD cake-baking example from Montgomery, where an experimenter wants to improve the quality of cake. While the cake manufacturer can control the

amount of flour, amount of sugar, amount of baking powder, and coloring content of the cake, other factors are uncontrollable, such as oven temperature and bake time. The manufacturer can print instructions for a bake time of 20 minutes but in the real world has no control over consumer baking habits. Variations in the quality of the cake can arise from baking at 325° instead of 350° or from leaving the cake in the oven for a slightly too short or too long period of time. Robust parameter designs seek to minimize the effects of noise factors on quality. For this example, the manufacturer hopes to minimize the effects in fluctuation of bake time on cake quality, and in doing this the optimal settings for the control factors are required.

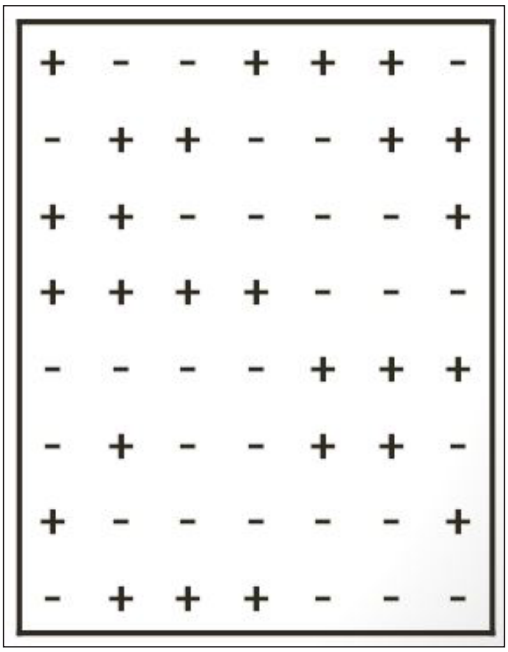
RPDs are primarily used in a simulation setting where uncontrollable noise variables are easily controlled. Whereas in the real world noise factors are hard to control, in an experimental setting control over these factors is easily maintained. For the cake-baking example, the experimenter can fluctuate bake time and oven temperature to understand the effects of such fluctuation that may occur when control is no longer in his hands.

Robust parameter designs are very similar to fractional factorial designs (FFDs) in that the optimal design can be found using Hadamard matrices, principles of effect hierarchy and factor sparsity are maintained, and aliasing is present when full RPDs are fractionated. Much like FFDs, RPDs are screening designs and can provide a linear model of the system at hand. What is meant by effect hierarchy for FFDs is that higher-order interactions tend to have a negligible effect on the response. As stated in Carraway, main effects are most likely to have an effect on the response, then two-factor interactions, then three-factor interactions, and so on. The concept of effect sparsity is that not all factors will have an effect on the response. These principles are the foundation for fractionating Hadamard matrices. By fractionating, experimenters can form conclusions in fewer runs and with fewer resources. Oftentimes, RPDs are used at the early stages of an experiment. Because two-level RPDs assume linearity among factor effects, other methods may be used to model curvature after the number of factors has been reduced.

Construction

Hadamard matrices are square matrices consisting of only + and −. If a Hadamard matrix is normalized and fractionated, a design pattern is obtained. However, not all designs are equal, which means that some designs are better than others, and specific design criteria are used to determine which design is best. After obtaining a design pattern, experimenters know to which setting each factor should be set. Each row in the pattern indicates a run, and each column indicates a factor. For the partial design pattern shown left, the experimenter has identified seven factors that may have an effect on the response and hopes to gain insight as to which factors have an effect in eight runs. In the first run, factors 1, 4, 5, and 6 are set to high levels while factors 2, 3, and 7 are set to low levels. Low levels and high levels are settings typically defined by the subject matter expert. These values are extremes but not so extreme that the response is pushed into non-smooth regions. After each run, results are obtained; and by

fluctuating multiple factors in single runs instead of using the OFAT method, interactions between variables may be estimated as well as the individual factor effects. If two factors interact, then the effect one factor has on the response is different depending on the settings of another factor.



Partial design pattern: Hadamard matrices can be normalized and fractionated to produce an experimental design.

Fractionating Hadamard matrices appropriately is very time-consuming. Consider a 24-run design accommodating six factors. The number of Hadamard designs from each Hadamard matrix is 23 choose 6; that is 100,947 designs from each 24×24 Hadamard matrix. Since there are 60 Hadamard matrices of that size, the total number of designs to compare is 6,056,820. Leoppky, Bingham, and Sitter used complete search methodology and have listed the best RPDs for 12, 16, and 20 runs. Because complete search work is so exhaustive, the best designs for larger run sizes are often not readily available. In that case, other statistical methods may be used to fractionate a Hadamard matrix in such a way that allows only a tolerable amount of aliasing. Efficient algorithms such as forward selection and backward elimination have been produced for FFDs, but due to the complexity of aliasing introduced by distinguishing control and noise variables, these methods have not yet been proven effective for RPDs.

Design Criteria

To fully understand the design criteria, an understanding of history and fractional factorial designs is necessary. FFDs seek to understand which factors have an effect on a response and seek to optimize the response by finding the appropriate factor settings. Unlike RPDs, FFDs do not distinguish between control and noise variables.

Resolution and Minimum Aberration

In 2003, Bingham and Sitter defined maximum resolution and minimum aberration for two-level fractional factorial designs. Resolution determines the worst amount of aliasing present, and aberration determines how much of that worst-case aliasing is present in the design. Resolution III designs alias main effects with two-factor interactions. Resolution IV designs alias main effects with three-factor interactions. Resolution V designs alias main effects with four-factor interactions. As the resolution increases, the level of aliasing becomes less serious because higher order interactions tend to have negligible effects on the response. Resolution measures regular designs; that is, effects are either fully aliased or not aliased at all. Consider the following statement, "Factor A is aliased with the two-factor interaction of factors BC." This means that if the two-factor interaction BC has an effect on the response, then the estimation of factor A's effect on the response is contaminated because factor A's effect cannot be distinguished from BC's effect. Clearly a resolution V design is preferred over a resolution IV design.

Designs of the same resolution are not always equal, and the knowledge of which type of aliasing is the worst involved is not enough to know which design is better. Instead further investigation of how much of the worst-case aliasing is needed. This idea is known as minimum aberration. Better designs contain the least amount of the worst-case aliasing. If designs D1 and D2 are both resolution V designs, but D1 has more instances of main effects aliased with 4-factor interactions, then D2 is the better design. D2 is the better design because there is a larger quantity of well-estimated effects.

Generalized Resolution and Generalized Minimum Aberration

Fontana, Pistone, and Rogantin had created an indicator function for two-level fractional factorial designs, and in 2003 Ye expanded the indicator function for regular and nonregular designs. In doing this, Ye established generalized resolution and generalized minimum aberration. Whereas regular designs are designs with run size equaling a power of two; nonregular designs can be any multiple of four. In nonregular designs, effects can be fully aliased, partially aliased, or not aliased at all. Generalized minimum aberration and generalized resolution take this partial aliasing into account.

Formally, Ye distinguishes between regular and nonregular designs and states that any polynomial function can be written as,

$\mathbf{F(x)= \sum_J \in_P b_J X_J (x)= \sum_J \in_{PC} \sum_K \in_{PN} b_{J \cup K} X_{J \cup K} (x),}$ where $\mathbf{b_L = 1/2^m \sum_x \in_F X_L (x)}$ and $\mathbf{b_o = n/2^m.}$

If $\mathbf{|b_{J \cup K}/b_o| = 1}$ then the design is regular; otherwise partial aliasing exists.

Table: Priority of effects.

Priority	Effects
1.0	C,N
1.5	CN
2.0	CC,NN
2.5	CCN,CNN
3	CCC,CCNN
3.5	CCCN,CNNN
4	CCCC,NNN,CCCNN,CCNNN
4.5	CCCCN,CNNNN

RPDs must protect the estimation of top priority effects.While Ye developed this indicator function, Bingham and Sitter were working on clarification of resolution and aberration for robust parameter designs. In 2006, Leoppky, Bingham, and Sitter published the extended word-length pattern and indicator function for robust parameter designs. Because RPDs are concerned about minimizing process variation due to noise factors, the priority of effects changes from the hierarchy of effects of FFDs. Main effects are still the first priority, and two-factor interactions are still the second priority; but if any interactions have a control-by-noise (CN) interaction, then that interaction is increased by 0.5 on the priority scale. For example, a CCN three-factor interaction would be a priority 3 in a FFD because three-factor interactions are the third priority, two-factor interactions are the second priority, and main effects are the first priority. However, since RPDs are concerned about noise variables, the CCN interaction is a priority 2.5 effect. The CN interaction bumps the priority up by 0.5; so the traditional priority 3 minus the 0.5 for the CN interaction results in a 2.5 priority.

Design Comparison

Further investigation of the principles introduced will provide a deeper understanding of design comparison.

For regular fractional factorial designs, the word length will determine what types of aliasing are present. For example, the word “2367” can be broken into aliasing structures as follows:

Aliasing structure	Meaning of aliasing structure
2=367	The estimation of the effect of factor 2 on the response is aliased with the three-factor interaction of factors 3, 6, and 7.
3=267	The estimation of the effect of factor 3 on the response is aliased with the three-factor interaction of factors 2, 6, and 7.
6=237	If the three-factor interaction of factors 2, 3, and 7 have an effect on the response, the estimation of factor 6 on the response is contaminated.

7=236	No distinction can be made from the effect of factor 7 and the effect of the three-factor interaction 236.
23=67	Two factor interactions cannot be estimated accurately because they are aliased with other two-factor interactions.

The word 2367 is of length 4, and the worst-case aliasing is that main effects are aliased with three-factor interactions, and two-factor interactions are aliased with other two-factor interactions.

Word lengths become less simplistic when talking about RPDs because the priority of effects has changed. Consider the word 23578 where factors 2, 3, and 5 are control variables and factors 7 and 8 are noise variables. The following aliasing strings can be derived from this word:

2=3578, 3=2578 5=2378 or C=CCNN

7=2358, 8=2357 or N=CCCN

23=578, 25=378, 35=278 or CC=CNN

27=358 and 28=357 or CN=CCN

235=78 or CCC=NN

Now that one can see what types of aliasing occur, one must use Leoppky, Bingham, and Sitter's priority of effects to determine the worst amount of aliasing present. This means that any CN interaction bumps that priority up by 0.5; and the word length is obtained by summing each side of the aliasing string. The table below finds the sums for each aliasing type found in the word 23578.

Priority(C) = 1	Priority(CCNN) = 3	Sum = 4
Priority(N) = 1	Priority(CCCN) = 3.5	Sum = 4.5
Priority(CC) = 2	Priority(CNN) = 2.5	Sum = 4.5
Priority(CN) = 1.5	Priority(CCN) = 2.5	Sum = 4
Priority(CCC) = 3	Priority(NN) = 2	Sum = 5

Since lower sums indicate worse aliasing, this word has the worst-case aliasing of length 4. It is important to understand that in an FFD the differentiation between control and noise would not be taken into account, and this word would be of length 5; but RPDs are concerned with this distinction and even though the word appears to be length 5, design criteria determines priority 4. Now, assume design D1 contains only the word just analyzed (23578). If D1 was compared to D2, and the worst-case aliasing found in D2 was priority 3.5, then D1 would be the better design. If, however, the worst-case aliasing of D2 was priority 4, then minimum aberration must be taken into consideration. For each design, we would calculate the frequencies of each type of worst-case aliasing. The better design would be chosen as the design that minimizes the occurrence

of worst-case aliasing. These frequencies can be organized using the extended word length pattern (EWLP).

Notation

The notion of minimum aberration can be understood from the definition provided in Leoppky, Bingham, and Sitter:

> For any two $2^{(m1+m2)-(p1+p2)}$ fractional factorial robust parameter designs, D1 and D2, we say that D1 has less aberration than D2 if there exists an r such that, $\mathbf{B_i (D1) = B_i (D2)}$ for all $\mathbf{i < r - 1}$ and $\mathbf{B_r (D1) < B_r (D2)}$. If no other design has less aberration than D1, then D1 is the minimum aberration fractional factorial robust parameter design.

Leoppky, Bingham, and Sitter also provide the RPD indicator function as:

> For a given design, D, and a run, $\mathbf{x \in D}$, define a contrast $\mathbf{X_{L(x)} = \prod_l \in_L x_l}$ on D, where $\mathbf{L \in P}$ and **P** is the set of all subsets of **{1, 2, ..., m}**. Further, define $\mathbf{P_C}$ to be the set of all subsets of **{1, 2,..., m}** and $\mathbf{P_N}$ to be the set of all subset of **{1, 2, ..., m}**, where an element of P is of the form $\mathbf{L \equiv J \cup K}$ where $\mathbf{J \in P_C}$ and $\mathbf{K \in P_N}$.

Extended Word-length Pattern

Bingham and Sitter generate the EWLP by providing the following concept:

> Let F be a robust parameter design with indicator function $\mathbf{F(x)= \sum_J \in_{P-C} \sum_K \in_{PN} b_{J \cup K} X_{J \cup K} (x)}$, if $\mathbf{b_{J \cup K} \neq 0}$, then $\mathbf{X_{J \cup K}}$ is a word of the design F with word length $\mathbf{r + (1-|b_{J \cup K}/b_o|)/2}$, where $\mathbf{|b_{J \cup K}/b_o|}$ is a measure of the degree of confounding for the word $\mathbf{X^{J \cup K}}$. Further let $\mathbf{g^{r+l/2t}}$ be the number of words of length **(r+l/2t)**, where r = 2.0, 2.5, 3.0, ... according to table. Thus, the robust parameter design extended word length pattern is $(g_{2.0,...,}\mathbf{g_{2.0+((t-1))/2t}}_{,...,}\mathbf{g_{m-1,...,}g_{m+(t-1)/2t}})$.

Consider designs D1 and D2 with the following EWLPs:

D1: [(0 0 3)(2 3 1)(2 5 5)]

D2: [(0 0 3)(2 4 0)(2 4 6)]

One can read an EWLP from left to right since the left side indicates the most serious level of aliasing, and the aliasing becomes less serious as we move to the right. D2 is the better design because there is one more occurrence of more serious aliasing than in D1.

Uses and Examples

Design of experiments (DOE) is a fundamental part of experimentation, modeling, and

simulation. Banks states, "Experimental design is concerned with reducing the time and effort associated with simulating by identifying the information needed to be gathered from each simulation replication, how many replications need to be made, and what model parameter changes need to be compared." After a conceptual model has been implemented as a programmed model, DOE is necessary to perform experimentation and obtain simulation results in the most timely and cost-efficient manner. The following examples demonstrate situations where RPDs can be used to draw significant conclusions.

Example:

Consider the permanent marker manufacturing example adapted from Brewer, Carraway, and Ingram. The subject matter experts (SMEs) have recognized seven factors that may affect the quality of the marker: amount of ink, propanol content, butanol content, diacetone content, quality of container, humidity, and temperature. Amount of ink, propanol content, butanol content, diacetone content, and quality of container are determined by the manufacturer; humidity and temperature, while easily controlled in an experimental setting, cannot be controlled once the product has left the manufacturer's hands. Even if the manufacturer states to keep the marker temperature between 35 and 80 degrees Fahrenheit, consumers may be in 90 degree weather or take little note of the advice. This variation is uncontrollable and affects the consumers opinion of the product; therefore, the manufacturer wants the product to be robust to variations due to temperature.

To run every possible combination of factors would be 128 runs. However, by fractionating this matrix, the effects of factors can be seen in much fewer runs. Therefore, fractionating is less costly and less time consuming.

After the RPD has been created, the quality of permanent marker is tested at the end of each run. This is an example of live simulation because in order to test the quality of the marker, simulating the humidity and temperature of the real-world is necessary. The permanent marker manufacturing company opts to simulate high or low temperatures and humidity instead of traveling to specific locations where the marker may be used. The manufacturer saves time and money and gets close to the same effect as someone using the marker in extreme weather conditions or elsewhere.

Example:

Imagine being hired as a store manager and wanting to increase efficiency of labor. You have noticed that the same number of people are staffed at all hours of the day, but the store is busier from noon until 3:30 pm and empty after 7:00 pm. You do not want to risk being understaffed, so you choose to simulate different scenarios to determine the best scheduling solution. Control factors that effect scheduling optimality may include number of people on a shift whereas uncontrollable factors may include weather and traffic flow.

A constructive model is implemented to understand the dilemma at hand, and an RPD

is the method used to determine the settings of the control factors we need in order to minimize the effects of the noise factors. In other words, one can use an RPD to determine how many people are needed on each shift so that the store is not understaffed or overstaffed regardless of the weather conditions or flow of traffic.

Analyzing

Because RPDs relate so closely to FFDs, the same analysis methods can be applied. ANOVA can be used to determine which factors are significant. Center points can be run to determine if curvature is present. Many statistics software packages have split-plot designs stored and ready for analysis. RPDs are screening designs and are often used to reduce the number of factors that are thought to have an effect on the response.

ROBUSTNESS VALIDATION

Robustness validation is a skills strategy with which the Robustness of a product to the loading conditions of a real application is proven and targeted statements about risks and reliability can be made. This strategy is particularly for use in the automotive industry however could be applied to any industry where high levels of reliability are required.

Initiators and Participants

The Handbook for Robustness Validation of Semiconductor Devices in Automotive Applications with international cooperation from SAE, ZVEI, AEC and JSAE (Japanese Society of Automotive Engineers) was published, in which the guidelines for the contemporary validation of semiconductor components in the automotive applications were compiled. Companies were involved in this from the entire supply chain in the field of automotive electronics. In addition to vehicle manufacturers and suppliers, a large group of semiconductor manufacturers, this concept of skill is complemented with a current database. This so-called Knowledge Matrix is a list of currently known failures includes mechanisms with causes.

Robustness Validation is used to assess the reliability of electronic components by comparing the specific requirements of the product with the actual “real life values”. With the introduction of this methodology, a specific list of requirements (usually based on the OEM) is required. The requirements for the product can be defined in the environmental requirements (mission profiles) and the functional requirements (use cases).

Mission Profiles

The mission profiles describes the loads and stresses acting on the product in actual use. These are, for example, changes in temperature, temperature profile, vibration

and working of electrical and mechanical fields, or other environmental factors. It is important to specify the relevant stressors in their nature, intensity and duration of exposure, as well as the mix as closely as possible. With these details it is possible, within specified accuracy, projections regarding reliability of application and its components in field applications.

Use Cases

The use cases describe the nature and frequency of the operating conditions for which the product is designed. One should make sure that this addition to the normal operation of the possible cases of special operation and emergency operation. Intentional abuse is not included.

Robustness Margin

The lifetimes can be hedged by specific, tailored to the application and the failure mechanisms, determined tests. An essential process are End of life tests. From the distance of the requirements to the test results, the reliability and robustness of the device can be determined.

Product Development

Today's standard qualification procedures for electronic components, assemblies and components for the automotive industry is based on the use of standardized tests at the end of the product development of parts and components. In contrast, Robustness Validation is a process that includes the entire product development process, as well as mass production. The qualification of the components based on the robustness analysis is thus implicit. With the introduction of robustness validation, priorities are focused on the development process again. The aim is to reduce the construction error's during the later phases of the project, which means front loading measures in the product development time line process.

It is necessary that the requirements from the product to the next level of the value chain be broken down in order to meet specific statements about possible vulnerabilities. Back in the early phases of the project is the knowledge (e.g., from knowledge bases Lessons Learned) gained from previous projects in order to avoid known vulnerabilities. Using the analysis of the changes of the new product and the use of different methods, such as REM, RBFM or design reviews, new potential vulnerabilities are identified early in order to make potential risks.

Other Applications of Robustness Validation

In addition to the publication of the Handbook for Robustness Validation for semiconductor devices in 2007 the ZVEI in 2008, published the manual in which this procedure is described for the development and qualification of electronic control units

in automobiles. There are also other activities in the field of sensors and electronic systems in the vehicle.

ACCEPTANCE SAMPLING

Acceptance sampling uses statistical sampling to determine whether to accept or reject a production lot of material. It has been a common quality control technique used in industry. It is usually done as products leaves the factory, or in some cases even within the factory. Most often a producer supplies a consumer a number of items and a decision to accept or reject the items is made by determining the number of defective items in a sample from the lot. The lot is accepted if the number of defects falls below where the acceptance number or otherwise the lot is rejected.

In general, acceptance sampling is employed when one or several of the following hold:

- Testing is destructive.
- The cost of 100% inspection is very high.
- 100% inspection takes too long.

A wide variety of acceptance sampling plans are available. For example, multiple sampling plans use more than two samples to reach a conclusion. A shorter examination period and smaller sample sizes are features of this type of plan. Although the samples are taken at random, the sampling procedure is still reliable.

Rationale

Sampling provides one rational means of verification that a production lot conforms with the requirements of technical specifications. 100% inspection does not guarantee 100% compliance and is too time consuming and costly. Rather than evaluating all items, a specified sample is taken, inspected or tested, and a decision is made about accepting or rejecting the entire production lot.

Plans have known risks: an acceptable quality limit (AQL) and a rejectable quality level, such as lot tolerance percent defective (LTDP), are part of the operating characteristic curve of the sampling plan. These are primarily statistical risks and do not necessarily imply that defective product is intentionally being made or accepted. Plans can have a known average outgoing quality limit (AOQL).

Acceptance Sampling for Attributes

A single sampling plan for attributes is a statistical method by which the lot is accepted or rejected on the basis of one sample. Suppose that we have a lot of size M; a random sample

of size $N < M$ is selected from the lot; and an acceptance number B is determined. If it is found the number of nonconforming is less than or equal to B, the lot is accepted; and if the number of nonconforming is greater than B, the lot is not accepted. The design of a single sampling plan requires the selection of the sample size N and the acceptance number B.

MIL-STD-105 was a United States defense standard that provided procedures and tables for sampling by attributes (pass or fail characteristic). MIL-STD-105E was cancelled in 1995 but is available in related documents such as ANSI/ASQ Z1.4, "Sampling Procedures and Tables for Inspection by Attributes". Several levels of inspection are provided and can be indexed to several AQLs. The sample size is specified and the basis for acceptance or rejection (number of defects) is provided. MIL-STD-1916 is currently the preferred method of sampling for all Department of Defense (DoD) contracts.

Variables Sampling Plan

When a measured characteristic produces a number, other sampling plans, such as those based on MIL-STD-414, are often used. Compared with attribute sampling plans, these often use a smaller sample size for the same indexed AQL.

DESIGN REVIEW BASED ON FAILURE MODE

Design Review Based on Failure Mode (DRBFM) was created by Tatsuhiko Yoshimura, (Toyota). It is based off the approach that accidents are, considered to be, avoidable if found during the development of a design. Improper designs contribute to reduction in brand image, poor reliability and negative financial impacts. Many companies battle with the improvement process to mitigate design risk and often brainstorm updates to processes rather than determine actions to change the designs.

DRBFM is a visual process that may link to Failure Mode and Effects Analysis (FMEA) and Fault Tree Analysis (FTA), based on experience. Each member compares "good design" to the intentional changes and predicts possible failures. With the use of GD3 and brainstorming techniques, it evaluates design and manufacturing with respect to the technical causes. The method creates a robust format for problem solving.

DRBFM is a cross functional disciplined process used to evaluate proposed changes to designs. The model is comprised of three core parts:

- Problem solving: A disciplined method used to solve complex issues.
- Recurrence prevention: The use of a collection of processes within a system designed to prevent recurrence related to the problem-solving methodology.
- Proactive prevention: A process to search for hidden issues in new or changed designs.

DRBFM also focuses on proactive prevention using the GD3 approach:

- Good Design: Reliable designs contributing to customer satisfaction.
- Good Discussion: Review of current design with respect to "Good Design".
- Good Design Review: Problem discovery and mitigation.

Why Perform Design Review based on Failure Mode?

In addition to reducing design related issues, companies benefit from improved brand imaging, lower product cost and improved product development timing. Soft benefits include higher employee morale and increased job satisfaction.

How to Perform Design Review based on Failure Mode?

The systematic approached is used to create a comprehensive procedure that is proactive, ensuring a global view of the product hierarchy. This provides a map to ensure all levels of communication are addressed. These interactions contribute to including not only the designer, but the full system communication.

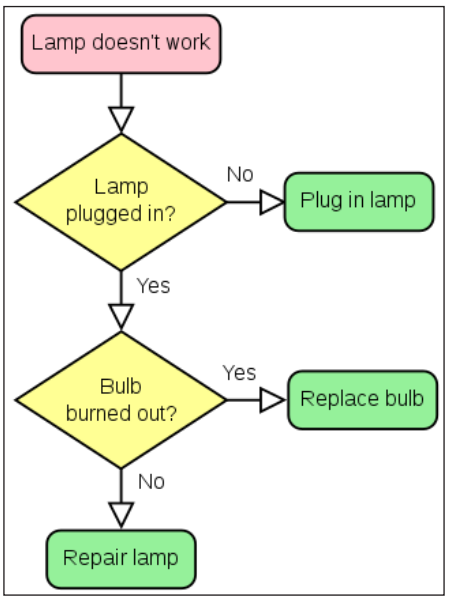
The following steps outline the process that applies mainly to intentional changes to designs, however can be applied to new designs while incorporating tools such as FMEA and FTA. When starting with an FMEA, focus on the components that are associated with the 'deliberate change'. The DRBFM should be started on prototype drawings to increase the effectiveness of the process.

- Select the team based on the system and interactions (based on design change).
  - Include representation from system, sub systems and components.
    - If this fails, the entire process will suffer.
- Visualize the differences between the changes with respect to the "Good Design".
  - Scope must be identified to the change.
    - Since most companies spend their time identifying issues without properly resolving them or ignoring the solution altogether, the team needs to stay within the defined scope. Facilitation can help manage the team's focus and ensure the team understands what may adversely affect an already proven feature or features within the "Good Design".
  - If the 'contents of the change' are not shared by the designer, process suffers.
    - The FMEA process is used to determine details based on the functions affected by the 'intentional change'.

        - Information is then transferred from the FMEA to the left hand columns on the DRBFM worksheet.
        - This is the responsibility of the designer.
    - All participants must participate from item 1.
        - Discussion begins on the right hand side of the DRBFM worksheet.
        - Interactions between components will correlate to interactions between sub systems and system. Therefore, anything that is not understood at the feature or component change will be seen at higher level functions.
- "Good Discussion" begins on the possible problems related to the intended change.
    - Assemble all drawings, component examples, similar designs, etc.
    - Designers should prepare for a constructive debate regarding the change 'function of the target part'.
    - The facilitator is responsible for the success of the review.
        - They are responsible for keeping the tension at an acceptable level to spark ideas without turning offensive.
    - The rest of the participants should be prepared to offer their ideas and experience.
        - Try to keep total number of participants between 10 and 15 (at most).
    - 'Predicting the concerns of the change' by carefully considering the interactions based on the change (review by looking, disassembling, comparing, measuring, include surrounding areas – interactions, customer viewpoint, etc).
    - 'Cause of concerns': The majority of failures occur due to interactions.
        - Consider stresses, forces, corrosion, oils, surfactants, temperature, handling, fasteners, correlation to the manufacturing process (Process FMEA), etc.
        - Review one component/concern at a time. FTA may be a useful tool for this part of the process.
        - If concerns are identified, they must be mitigated.
            - Review conventional methods of design mitigation (lower risk).
            - Items left will stand out requiring more focus to resolve using the DRBFM process 'unnoticed point inspection' (includes past failures).

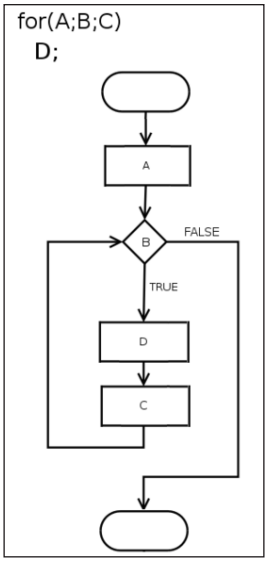
        - Enter actions as design, evaluation or process.
        - Include responsible department, person and due date.
    - All are documented in the DRBFM Worksheet as identified in the meetings.
        - If this is delayed, items will accrue and render the team stuck.
- 'Measures for all concerns': "Good Design Review".
    - Passively verify all actions are implemented into the drawings, evaluations and process design.
    - Actively verify on completed test parts and review (wear, disassembled, cut, etc).
    - All causes identified are now reviewed by the designer to determine if they are associated with specific measures. (Note: it is very difficult to change or validate if there is no baseline to measure against).

FLOWCHART



A simple flowchart representing a process for dealing with a non-functioning lamp.

A flowchart is a type of diagram that represents a workflow or process. A flowchart can also be defined as a diagrammatic representation of an algorithm, a step-by-step approach to solving a task.



Flowchart of a C-style for loop.

The flowchart shows the steps as boxes of various kinds, and their order by connecting the boxes with arrows. This diagrammatic representation illustrates a solution model to a given problem. Flowcharts are used in analyzing, designing, documenting or managing a process or program in various fields.

Flowcharts are used in designing and documenting simple processes or programs. Like other types of diagrams, they help visualize what is going on and thereby help understand a process, and perhaps also find less-obvious features within the process, like flaws and bottlenecks. There are different types of flowcharts: each type has its own set of boxes and notations. The two most common types of boxes in a flowchart are:

- A processing step, usually called activity, and denoted as a rectangular box.
- A decision, usually denoted as a diamond.

A flowchart is described as "cross-functional" when the chart is divided into different vertical or horizontal parts, to describe the control of different organizational units. A symbol appearing in a particular part is within the control of that organizational unit. A cross-functional flowchart allows the author to correctly locate the responsibility for performing an action or making a decision, and to show the responsibility of each organizational unit for different parts of a single process.

Flowcharts depict certain aspects of processes and are usually complemented by other types of diagram. For instance, Kaoru Ishikawa defined the flowchart as one of the seven basic tools of quality control, next to the histogram, Pareto chart, check sheet, control chart, cause-and-effect diagram, and the scatter diagram. Similarly, in UML, a standard concept-modeling notation used in software development, the activity diagram, which is a type of flowchart, is just one of many different diagram types.

Nassi-Shneiderman diagrams and Drakon-charts are an alternative notation for process flow.

Common alternative names include: flow chart, process flowchart, functional flowchart, process map, process chart, functional process chart, business process model, process model, process flow diagram, work flow diagram, business flow diagram. The terms “flowchart” and “flow chart” are used interchangeably.

The underlying graph structure of a flowchart is a flow graph, which abstracts away node types, their contents and other ancillary information.

Types

Sterneckert suggested that flowcharts can be modeled from the perspective of different user groups (such as managers, system analysts and clerks), and that there are four general types:

- Document flowcharts, showing controls over a document-flow through a system.
- Data flowcharts, showing controls over a data-flow in a system.
- System flowcharts, showing controls at a physical or resource level.
- Program flowchart, showing the controls in a program within a system.

Notice that every type of flowchart focuses on some kind of control, rather than on the particular flow itself.

However, there are some different classifications. For example, Andrew Veronis named three basic types of flowcharts: the system flowchart, the general flowchart, and the detailed flowchart. That same year Marilyn Bohl stated “in practice, two kinds of flowcharts are used in solution planning: system flowcharts and program flowcharts...”. More recently, Mark A. Fryman identified more differences: “Decision flowcharts, logic flowcharts, systems flowcharts, product flowcharts, and process flowcharts are just a few of the different types of flowcharts that are used in business and government”.

In addition, many diagram techniques are similar to flowcharts but carry a different name, such as UML activity diagrams.

Building Blocks

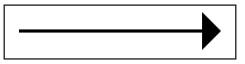
Common Symbols

The American National Standards Institute (ANSI) set standards for flowcharts and their symbols in the 1960s. The International Organization for Standardization (ISO)

adopted the ANSI symbols in 1970. The current standard, ISO 5807, was revised in 1985. Generally, flowcharts flow from top to bottom and left to right.

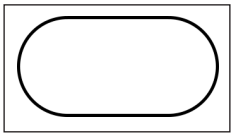
ANSI/ISO Shape

Flowline (Arrowhead)



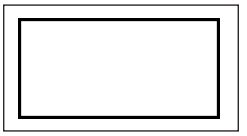
Shows the process's order of operation. A line coming from one symbol and pointing at another. Arrowheads are added if the flow is not the standard top-to-bottom, left-to right.

Terminal



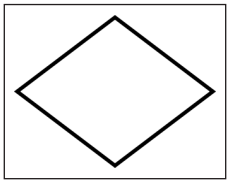
Indicates the beginning and ending of a program or sub-process. Represented as a stadium, oval or rounded (fillet) rectangle. They usually contain the word "Start" or "End", or another phrase signaling the start or end of a process, such as "submit inquiry" or "receive product".

Process



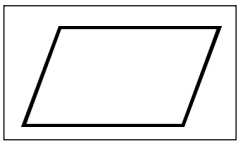
Represents a set of operations that changes value, form, or location of data. Represented as a rectangle.

Decision



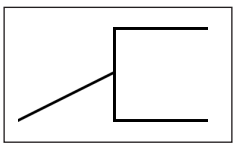
Shows a conditional operation that determines which one of the two paths the program will take.The operation is commonly a yes/no question or true/false test. Represented as a diamond (rhombus).

Input/Output



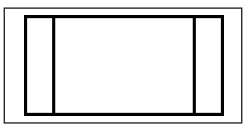
Indicates the process of inputting and outputting data,as in entering data or displaying results. Represented as a parallelogram.

Annotation



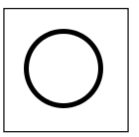
Indicating additional information about a step in the program. Represented as an open rectangle with a dashed or solid line connecting it to the corresponding symbol in the flowchart.

Predefined Process



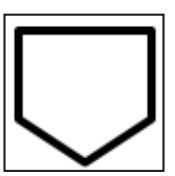
Shows named process which is defined elsewhere. Represented as a rectangle with double-struck vertical edges.

On-page Connector



Pairs of labeled connectors replace long or confusing lines on a flowchart page. Represented by a small circle with a letter inside.

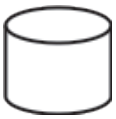
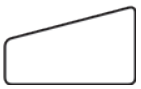
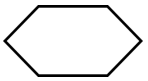
Off-page Connector



A labeled connector for use when the target is on another page. Represented as a home plate-shaped pentagon.

Other Symbols

The ANSI/ISO standards include symbols beyond the basic shapes. Some are:

Shape	Name	Description
	Data File or Database	Data represented by a cylinder (disk drive).
	Document	Single documents represented a rectangle with a wavy base.
		Multiple documents represented stacked rectangle with a wavy base.
	Manual operation	Represented by a trapezoid with the longest parallel side at the top, to represent an operation or adjustment to process that can only be made manually.
	Manual input	Represented by quadrilateral, with the top irregularly sloping up from left to right, like the side view of a keyboard.
	Preparation or Initialization	Represented by an elongated hexagon, originally used for steps like setting a switch or initializing a routine.

Parallel Processing

Parallel Mode represented by two horizontal lines at the beginning or ending of simultaneous operations.

For parallel and concurrent processing the Parallel Mode horizontal lines or a horizontal bar indicate the start or end of a section of processes that can be done independently:

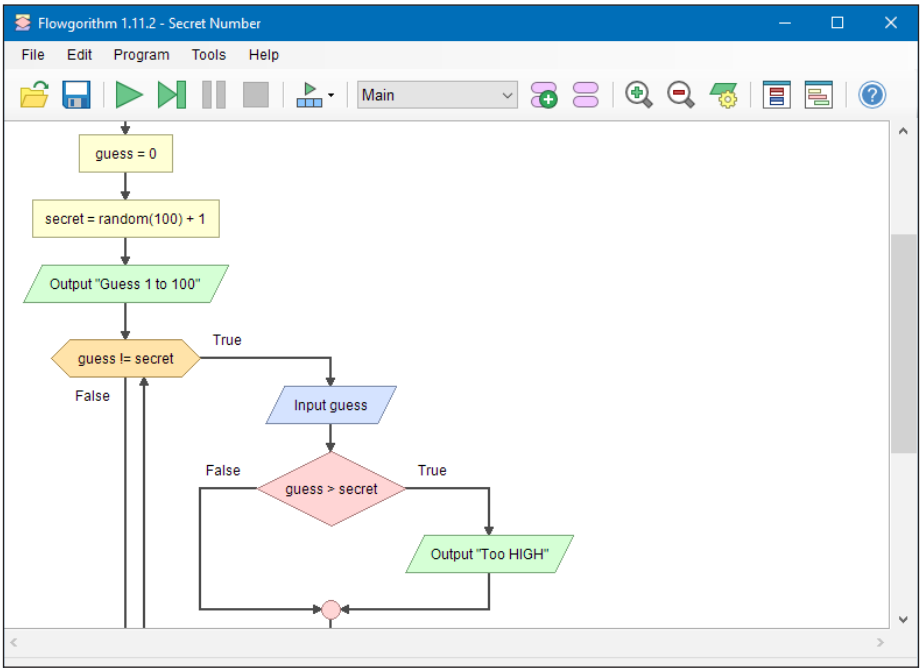
- At a fork, the process creates one or more additional processes, indicated by a bar with one incoming path and two or more outgoing paths.
- At a join, two or more processes continue as a single process, indicated by a bar with several incoming paths and one outgoing path. All processes must complete before the single process continues.

Software

Diagramming

Any drawing program can be used to create flowchart diagrams, but these will have no

underlying data model to share data with databases or other programs such as project management systems or spreadsheet. Some tools such as yEd, Inkscape and Microsoft Visio offer special support for flowchart drawing. Many software packages exist that can create flowcharts automatically, either directly from a programming language source code, or from a flowchart description language.



Flowgorithm.

There are several applications and visual programming languages that use flowcharts to represent and execute programs. Generally these are used as teaching tools for beginner students. Examples include Flowgorithm, Raptor. LARP, Visual Logic, Fischertechnik ROBO Pro, and VisiRule.

QUALITY STORYBOARD

A quality storyboard is a method for illustrating the quality control process (QC story). Some enterprises have developed a storyboard format for telling the QC story, for example at Yokogawa-Hewlett-Packard in Japan, the story is told using a flip chart which is 6 feet by 6 feet (2 x 2 meters). The project team uses colored markers to show the PDSA cycle (Shewhart cycle) plus the SDSA cycle (SDSA = Standardize, Do, Study, Act). A QC story is an element of policy deployment. After each manager writes an interpretation of the policy statement, the interpretation is discussed with the next manager above to reconcile differences in understanding and direction. In this way they play “catchball” with the policy and develop a consensus.

Worker Participation in Managerial Diagnosis

When the management attempts to make a managerial diagnosis, it is important that the people whose work is being diagnosed be properly prepared to enter the discussion. For this purpose, it is very helpful if everyone knows how to tell the QC story. Telling the story properly requires seven steps:

- Problem definition: This step includes an explanation of why the problem is important (which will tie it to the priority statements of the top management or to a problem that is essential as seen at the lower levels). Normally this step includes a discussion of the losses that occur because of the problem, the team that will work on it, and an estimate of what might be done. A target is often specified though it is understood that reaching such a target cannot be guaranteed. A schedule is proposed.
- Data collection: This step involves observing the time, place, type and symptoms of the problem. It involves data gathering and display in an attempt to understand the important aspects of the problem.
- Analysis: In this step the various tools of quality analysis are used, such as Control charts, Pareto charts, cause-and-effect diagrams, scatter diagrams, histograms, etc.
- Action: Based on the analysis, an action is taken.
- Study: The results are studied to see if they conform to what was expected and to learn from what was not expected. Data are taken to confirm the action.
- Act/Standardization: Appropriate steps are taken to see that the gains are secured. New standard procedures are introduced.
- Plans for the future/Continuity: As a result of solving this problem, other problems will have been identified and other opportunities recognized.

These seven steps DO NOT describe how a problem is solved. Problem solving requires a great deal of iteration and it is often necessary to go back to a previous step as new data are found and better analyses are made. However, when it comes time to report on what was done, the above format provides the basis for telling the story in a way that makes it comprehensible to the upper levels of management.

Guide to Construct a Quality Storyboard

Definition of the problem:

- Does the Problem definition contain three parts: Direction, Measure, Reference?
- Did you avoid words like “improve” and “lack of”?

- Have you avoided using "and" to address more than one issue in the Problem definition?

Why Selected:

- Have you explained how you know this is the most important issue to work on?
- Have you shown how the issue relates to the customer or customer satisfaction, or how it will benefit the customer?
- Have you explained the method used to select the issue?

Initial state:

- Have you described, in numerical terms, the status of the measure in the Problem definition?
- Have you collected time series data?
- Have you provided some historical information about the status of the measure?
- Are data displayed in a visual, graphical format?
- Is there a flowchart or other explanation of the status of the process at the beginning of the project?
- Have you included other facts that would help the reader understand the initial situation?

Analysis of Causes:

- Is there a clear statement of the major causes of the issue?
- Have you explained how the possible causes were theorized?
- Are data included showing how the main causes were identified?
- Are data displayed in such a way that the connection between the issue and the causes is clear?
- Have you explained how the data were collected and over what time period they were collected?

Plans:

- Is there a complete Purpose Statement and objectives designed to move toward the purpose: Direction, measure, reference, target, time frame, and owner?
- Is it clear how the target was derived from the analysis?
- Is it clear that the actions in the plan are aimed at correcting root causes?
- Have you indicated what alternative solutions were considered, and how they were evaluated to select the best improvement theory?

- Have you included a copy of the planning documents?
- Have you indicated whether the plan was implemented on schedule?

Study:

- Is there a comparison of the target in the improvement theory and the actual results?
- Are the results displayed in the same graphical format as the information in "Initial state" or "Analysis"?
- Have you indicated whether the results were achieved in the expected time frame?
- If the results did not match the objectives or were achieved outside the expected time, have you provided an analysis of the differences?
- Have you included any other related results, good or bad?

Act/Standardization:

- Have you explained the actions taken to hold the gain and updated all related documentation, training in the new process, skills training, physical reorganization, sharing, or process monitoring?

Future Plans:

- Have you included a list of possible next projects?
- Have you indicated which of the possible projects will be the next issue for improvement?

Quality storyboards were also used by Florida Power & Light as part of their quality drive during the 1980s to win the Deming Prize.

MULTI-VARI CHART

In quality control, multi-vari charts are a visual way of presenting variability through a series of charts. The content and format of the charts has evolved over time.

Multi-vari charts were first described by Leonard Seder in 1950, though they were developed independently by multiple sources. They were inspired by the stock market candlestick charts or open-high-low-close charts.

As originally conceived, the multi-vari chart resembles a Shewhart individuals control chart with the following differences:

- The quality characteristic of interest is measured at two extremes (around its

diameter, along its length, or across its surface) and these measurements are plotted as vertical lines connecting the minimum and maximum values over time.

- The quality characteristic of interest is plotted across three horizontal panels that represent:
  - Variability on a single piece.
  - Piece-to-piece variability.
  - Time-to-time variability.
- The quality characteristic of interest is plotted against upper and lower specifications rather than control limits.

Table: The three panels are interpreted.

Panel	Condition	Corrective action
Variability on a single piece	Lengths of the vertical lines (i.e., the range) exceed one-half the specifications (or more)	Repair or realignment of tool
Piece-to-piece variability	Excessive scatter	Examine process inputs for excessive variability—lengths of the vertical lines are estimates of process capability
Time-to-time variability	Appearance of a non-stationary process	Examine process inputs or steps for evidence of shifts or drifts

Recent Usage

More recently, the term "multi-vari chart" has been used to describe a visual way to display analysis of variance data (typically be expressed in tabular format). It consists of a series of panels which portray minimum, mean, and maximum responses for each treatment combination of interest rather than for periods of time.

Because it is a two-dimensional representation of multiple dimensions (one for each factor in the ANOVA), the multi-vari chart is only useful for comparing the variability among at most four factors.

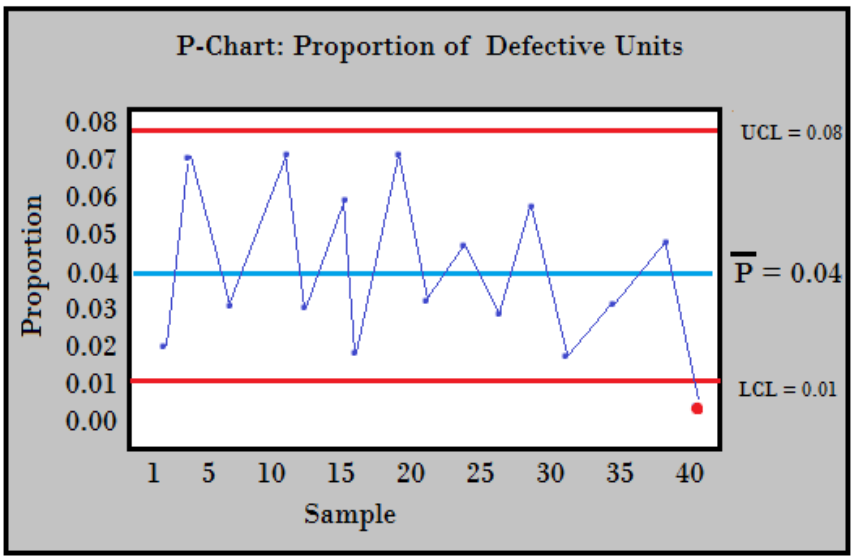
The chart consists of the following:

- One horizontal panel for each level of the outermost factor.
- One cluster of points representing the minimum, mean, and maximum responses for the particular treatment combination, connected by lines for each level of the innermost factor.
- In the case of four factors, vertical panels for each level of the next-innermost factor.
- As with control charts, the vertical axis depicts the quality characteristic of interest (or experimental response).

P-CHART

A p-chart (sometimes called a p-control chart) is used in statistical quality control to graph proportions of defective items. The chart is based on the binomial distribution; each item on the chart has only two possibilities: pass or fail. An "item" could be anything you're interested in charting, including: gadgets from a production line, wait times, or delivery times.

Groups of different sizes are charted together. Proportions make more sense than individual counts, which would give too much weight to larger samples. The proportions are shown on the y-axis. The x-axis shows the size of the sample, which is usually around 20-40 groups. Fewer than 20 groups will not show an accurate picture of the process.



The NP chart is very similar to the p-chart. However, an NP chart plots the number of items while the p-chart plots proportions of items.

Uses

P-charts are used to:

- Detect sudden changes in systems, which can be attributed to a cause.
- Assess the need for stratification into subgroups, like location, employee, or time of day.
- Show whether the system is stable (i.e. in control).
- Compare systems before and after a major change. For example, call center times before and after employee training.

P-charts are not very useful for tracking trends over time, or small shifts in the process.

What Kind of Data is Shown?

Although you can pretty much chart anything, the items should meet these two conditions in order for you to use a p-chart:

- N items are in the set. In other words, you must have a known number of items being counted. You can't use unknown or unlimited quantities.
- The probability of a failure must be consistent across all items in the sample. For example, call wait times exceed 5 minutes ("fail") 5% of the time. If you have inconsistent probabilities (e.g. high-dollar customers are prioritized).

Before you chart your data, you should establish norms for your system. Use data from a system that is in control. Find the average probability (P) and upper/lower control limits for acceptable defects.

SHEWHART INDIVIDUALS CONTROL CHART

In statistical quality control, the individual/moving-range chart is a type of control chart used to monitor variables data from a business or industrial process for which it is impractical to use rational subgroups.

The chart is necessary in the following situations:

- Where automation allows inspection of each unit, so rational subgrouping has less benefit.
- Where production is slow so that waiting for enough samples to make a rational subgroup unacceptably delays monitoring.
- For processes that produce homogeneous batches (e.g., chemical) where repeat measurements vary primarily because of measurement error.

The "chart" actually consists of a pair of charts: one, the individuals chart, displays the individual measured values; the other, the moving range chart, displays the difference from one point to the next. As with other control charts, these two charts enable the user to monitor a process for shifts in the process that alter the mean or variance of the measured statistic.

Interpretation

As with other control charts, the individuals and moving range charts consist of points

plotted with the control limits, or natural process limits. These limits reflect what the process will deliver without fundamental changes. Points outside of these control limits are signals indicating that the process is not operating as consistently as possible; that some assignable cause has resulted in a change in the process. Similarly, runs of points on one side of the average line should also be interpreted as a signal of some change in the process. When such signals exist, action should be taken to identify and eliminate them. When no such signals are present, no changes to the process control variables (i.e. "tampering") are necessary or desirable.

Assumptions

The normal distribution is NOT assumed nor required in the calculation of control limits. Thus making the IndX/mR chart a very robust tool. This is demonstrated by Wheeler using real-world data and for a number of highly non-normal probability distributions.

Calculation and Plotting

Calculation of Moving Range

The difference between data point, x_i, and its predecessor, x_{i-1}, is calculated as $MR_i = \left| x_i - x_{i-1} \right|$. For m individual values, there are $m-1$ ranges.

Next, the arithmetic mean of these values is calculated as,

$$\overline{MR} = \frac{\sum_{i=2}^{m} MR_i}{m-1}$$

If the data are normally distributed with standard deviation σ then the expected value of $\overline{MR}$ is $d_2\sigma = 2\sigma / \sqrt{\pi}$.

Calculation of Moving Range Control Limit

The upper control limit for the range (or upper range limit) is calculated by multiplying the average of the moving range by 3.267:

$$UCL_r = 3.267\overline{MR}.$$

The value 3.267 is taken from the sample size-specific $\mathbf{D}_4$ anti-biasing constant for **n=2**, as given in most textbooks on statistical process control.

Calculation of Individuals Control Limits

First, the average of the individual values is calculated:

$$\overline{x} = \frac{\sum_{i=1}^{m} x_i}{m}.$$

Next, the upper control limit (UCL) and lower control limit (LCL) for the individual values (or upper and lower natural process limits) are calculated by adding or subtracting 2.66 times the average moving range to the process average:

Next, the upper control limit (UCL) and lower control limit (LCL) for the individual values (or upper and lower natural process limits) are calculated by adding or subtracting 2.66 times the average moving range to the process average:

$$UCL = \bar{x} + 2.66\overline{MR}$$

$$LCL = \bar{x} - 2.66\overline{MR}$$

The value 2.66 is obtained by dividing 3 by the sample size-specific $\mathbf{d}_2$ anti-biasing constant for n=2, as given in most textbooks on statistical process control.

Creation of Graphs

Once the averages and limits are calculated, all of the individuals data are plotted serially, in the order in which they were recorded. To this plot is added a line at the average value, **x** and lines at the **UCL** and **LCL** values.

On a separate graph, the calculated ranges $\mathbf{MR}_i$ are plotted. A line is added for the average value, **MR** and second line is plotted for the range upper control limit ($\mathbf{UCL}_r$).

Analysis

The resulting plots are analyzed as for other control charts, using the rules that are deemed appropriate for the process and the desired level of control. At the least, any points above either upper control limits or below the lower control limit are marked and considered a signal of changes in the underlying process that are worth further investigation.

Potential Pitfalls

The moving ranges involved are serially correlated so runs or cycles can show up on the moving average chart that do not indicate real problems in the underlying process.

In some cases, it may be advisable to use the median of the moving range rather than its average, as when the calculated range data contains a few large values that may inflate the estimate of the population's dispersion.

Some have alleged that departures in normality in the process output significantly reduce the effectiveness of the charts to the point where it may require control limits to be set based on percentiles of the empirically-determined distribution of the process output although this assertion has been consistently refuted.

Many software packages will, given the individuals data, perform all of the needed calculations and plot the results. Care should be taken to ensure that the control limits are correctly calculated, per the above and standard texts on SPC. In some cases, the software's default settings may produce incorrect results; in others, user modifications to the settings could result in incorrect results. Sample data and results are presented by Wheeler for the explicit purpose of testing SPC software. Performing such software validation is generally a good idea with any SPC software.

CONTROL CHART

Control charts, also known as Shewhart charts (after Walter A. Shewhart) or process-behavior charts, are a statistical process control tool used to determine if a manufacturing or business process is in a state of control. It is more appropriate to say that the control charts are the graphical device for Statistical Process Monitoring (SPM). Traditional control charts are mostly designed to monitor process parameters when underlying form of the process distributions are known. However, more advanced techniques are available in the 21st century where incoming data streaming can-be monitored even without any knowledge of the underlying process distributions. Distribution-free control charts are becoming increasingly popular.

If analysis of the control chart indicates that the process is currently under control (i.e., is stable, with variation only coming from sources common to the process), then no corrections or changes to process control parameters are needed or desired. In addition, data from the process can be used to predict the future performance of the process. If the chart indicates that the monitored process is not in control, analysis of the chart can help determine the sources of variation, as this will result in degraded process performance. A process that is stable but operating outside desired (specification) limits (e.g., scrap rates may be in statistical control but above desired limits) needs to be improved through a deliberate effort to understand the causes of current performance and fundamentally improve the process.

The control chart is one of the seven basic tools of quality control. Typically control charts are used for time-series data, though they can be used for data that have logical comparability (i.e. you want to compare samples that were taken all at the same time, or the performance of different individuals); however the type of chart used to do this requires consideration.

Chart Details

A control chart consists of:

- Points representing a statistic (e.g., a mean, range, proportion) of measurements

of a quality characteristic in samples taken from the process at different times (i.e., the data).

- The mean of this statistic using all the samples is calculated (e.g., the mean of the means, mean of the ranges, mean of the proportions).
- A center line is drawn at the value of the mean of the statistic.
- The standard deviation (e.g., sqrt(variance) of the mean) of the statistic is also calculated using all the samples.
- Upper and lower control limits (sometimes called "natural process limits") that indicate the threshold at which the process output is considered statistically 'unlikely' and are drawn typically at 3 standard deviations from the center line.

The chart may have other optional features, including:

- Upper and lower warning or control limits, drawn as separate lines, typically two standard deviations above and below the center line.
- Division into zones, with the addition of rules governing frequencies of observations in each zone.
- Annotation with events of interest, as determined by the Quality Engineer in charge of the process' quality.
- Action on special causes.

(n.b., there are several rule sets for detection of signal; this is just one set. The rule set should be clearly stated).

- Any point outside the control limits.
- A Run of 7 Points all above or all below the central line - Stop the production.
    - Quarantine and 100% check.
    - Adjust Process.
    - Check 5 Consecutive samples.
    - Continue The Process.
    - A Run of 7 Point Up or Down.

Chart Usage

If the process is in control (and the process statistic is normal), 99.7300% of all the points will fall between the control limits. Any observations outside the limits, or systematic patterns within, suggest the introduction of a new (and likely unanticipated) source of variation, known as a special-cause variation. Since increased variation means

increased quality costs, a control chart "signaling" the presence of a special-cause requires immediate investigation.

This makes the control limits very important decision aids. The control limits provide information about the process behavior and have no intrinsic relationship to any specification targets or engineering tolerance. In practice, the process mean (and hence the centre line) may not coincide with the specified value (or target) of the quality characteristic because the process design simply cannot deliver the process characteristic at the desired level.

Control charts limit specification limits or targets because of the tendency of those involved with the process (e.g., machine operators) to focus on performing to specification when in fact the least-cost course of action is to keep process variation as low as possible. Attempting to make a process whose natural centre is not the same as the target perform to target specification increases process variability and increases costs significantly and is the cause of much inefficiency in operations. Process capability studies do examine the relationship between the natural process limits (the control limits) and specifications, however.

The purpose of control charts is to allow simple detection of events that are indicative of actual process change. This simple decision can be difficult where the process characteristic is continuously varying; the control chart provides statistically objective criteria of change. When change is detected and considered good its cause should be identified and possibly become the new way of working, where the change is bad then its cause should be identified and eliminated.

The purpose in adding warning limits or subdividing the control chart into zones is to provide early notification if something is amiss. Instead of immediately launching a process improvement effort to determine whether special causes are present, the Quality Engineer may temporarily increase the rate at which samples are taken from the process output until it is clear that the process is truly in control. Note that with three-sigma limits, common-cause variations result in signals less than once out of every twenty-two points for skewed processes and about once out of every three hundred seventy (1/370.4) points for normally distributed processes. The two-sigma warning levels will be reached about once for every twenty-two (1/21.98) plotted points in normally distributed data. (For example, the means of sufficiently large samples drawn from practically any underlying distribution whose variance exists are normally distributed, according to the Central Limit Theorem).

Choice of Limits

Shewhart set 3-sigma (3-standard deviation) limits on the following basis:

- The coarse result of Chebyshev's inequality that, for any probability distribution, the probability of an outcome greater than k standard deviations from the mean is at most $1/k^2$.

- The finer result of the Vysochanskii–Petunin inequality, that for any unimodal probability distribution, the probability of an outcome greater than k standard deviations from the mean is at most $4/(9k^2)$.
- In the Normal distribution, a very common probability distribution, 99.7% of the observations occur within three standard deviations of the mean.

Shewhart summarized the conclusions by saying:

> "The fact that the criterion which we happen to use has a fine ancestry in highbrow statistical theorems does not justify its use. Such justification must come from empirical evidence that it works. As the practical engineer might say, the proof of the pudding is in the eating."

Although he initially experimented with limits based on probability distributions, Shewhart ultimately wrote:

> "Some of the earliest attempts to characterize a state of statistical control were inspired by the belief that there existed a special form of frequency function f and it was early argued that the normal law characterized such a state. When the normal law was found to be inadequate, then generalized functional forms were tried. Today, however, all hopes of finding a unique functional form f are blasted."

The control chart is intended as a heuristic. Deming insisted that it is not a hypothesis test and is not motivated by the Neyman–Pearson lemma. He contended that the disjoint nature of population and sampling frame in most industrial situations compromised the use of conventional statistical techniques. Deming's intention was to seek insights into the cause system of a process under a wide range of unknowable circumstances, future and past. He claimed that, under such conditions, 3-sigma limits provided a rational and economic guide to minimum economic loss from the two errors:

- Ascribe a variation or a mistake to a special cause (assignable cause) when in fact the cause belongs to the system (common cause). (Also known as a Type I error or False Positive).
- Ascribe a variation or a mistake to the system (common causes) when in fact the cause was a special cause (assignable cause). (Also known as a Type II error or False Negative).

Calculation of Standard Deviation

As for the calculation of control limits, the standard deviation (error) required is that of the common-cause variation in the process. Hence, the usual estimator, in terms of sample variance, is not used as this estimates the total squared-error loss from both common- and special-causes of variation.

An alternative method is to use the relationship between the range of a sample and its standard deviation derived by Leonard H. C. Tippett, as an estimator which tends to be less influenced by the extreme observations which typify special-causes.

Rules for Detecting Signals

The most common sets are:

- The Western Electric rules.
- The Wheeler rules (equivalent to the Western Electric zone tests).
- The Nelson rules.

There has been particular controversy as to how long a run of observations, all on the same side of the centre line, should count as a signal, with 6, 7, 8 and 9 all being advocated by various writers.

The most important principle for choosing a set of rules is that the choice be made before the data is inspected. Choosing rules once the data have been seen tends to increase the Type I error rate owing to testing effects suggested by the data.

Alternative Bases

In 1935, the British Standards Institution, under the influence of Egon Pearson and against Shewhart's spirit, adopted control charts, replacing 3-sigma limits with limits based on percentiles of the normal distribution. This move continues to be represented by John Oakland and others but has been widely deprecated by writers in the Shewhart–Deming tradition.

Performance of Control Charts

When a point falls outside the limits established for a given control chart, those responsible for the underlying process are expected to determine whether a special cause has occurred. If one has, it is appropriate to determine if the results with the special cause are better than or worse than results from common causes alone. If worse, then that cause should be eliminated if possible. If better, it may be appropriate to intentionally retain the special cause within the system producing the results.

Even when a process is in control (that is, no special causes are present in the system), there is approximately a 0.27% probability of a point exceeding 3-sigma control limits. So, even an in control process plotted on a properly constructed control chart will eventually signal the possible presence of a special cause, even though one may not have actually occurred. For a Shewhart control chart using 3-sigma limits, this false alarm occurs on average once every 1/0.0027 or 370.4 observations. Therefore, the in-control average run length (or in-control ARL) of a Shewhart chart is 370.4.

Meanwhile, if a special cause does occur, it may not be of sufficient magnitude for the chart to produce an immediate alarm condition. If a special cause occurs, one can describe that cause by measuring the change in the mean and/or variance of the process in question. When those changes are quantified, it is possible to determine the out-of-control ARL for the chart.

It turns out that Shewhart charts are quite good at detecting large changes in the process mean or variance, as their out-of-control ARLs are fairly short in these cases. However, for smaller changes (such as a 1- or 2-sigma change in the mean), the Shewhart chart does not detect these changes efficiently. Other types of control charts have been developed, such as the EWMA chart, the CUSUM chart and the real-time contrasts chart, which detect smaller changes more efficiently by making use of information from observations collected prior to the most recent data point.

Many control charts work best for numeric data with Gaussian assumptions. The real-time contrasts chart was proposed to monitor process with complex characteristics, e.g. high-dimensional, mix numerical and categorical, missing-valued, non-Gaussian, non-linear relationship.

Criticisms

Several authors have criticised the control chart on the grounds that it violates the likelihood principle. However, the principle is itself controversial and supporters of control charts further argue that, in general, it is impossible to specify a likelihood function for a process not in statistical control, especially where knowledge about the cause system of the process is weak.

Some authors have criticised the use of average run lengths (ARLs) for comparing control chart performance, because that average usually follows a geometric distribution, which has high variability and difficulties.

Some authors have criticized that most control charts focus on numeric data. Nowadays, process data can be much more complex, e.g. non-Gaussian, mix numerical and categorical, or be missing-valued.

STRATIFICATION

Stratification is defined as the act of sorting data, people, and objects into distinct groups or layers. It is a technique used in combination with other data analysis tools. When data from a variety of sources or categories have been lumped together, the meaning of the data can be difficult to see. This data collection and analysis technique separates the data so that patterns can be seen and is considered one of the seven basic quality tools.

When to use Stratification

- Before collecting data.
- When data come from several sources or conditions, such as shifts, days of the week, suppliers, or population groups.
- When data analysis may require separating different sources or conditions.

Here are examples of different sources that might require data to be stratified:

- Equipment.
- Shifts.
- Departments.
- Materials.
- Suppliers.
- Day of the week.
- Time of day.
- Products.

Stratification Procedure

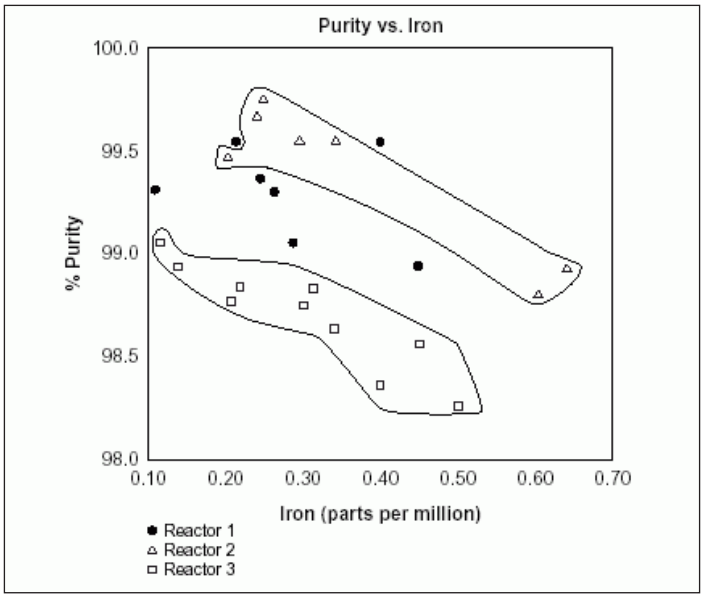
- Before collecting data, consider which information about the sources of the data might have an effect on the results. Set up the data collection so that you collect that information as well.
- When plotting or graphing the collected data on a scatter diagram, control chart, histogram, or other analysis tool, use different marks or colors to distinguish data from various sources. Data that are distinguished in this way are said to be "stratified."
- Analyze the subsets of stratified data separately.

Stratification Example

The ZZ-400 manufacturing team drew a scatter diagram to test whether product purity and iron contamination were related, but the plot did not demonstrate a relationship. Then a team member realized that the data came from three different reactors. The team member redrew the diagram, using a different symbol for each reactor's data.

Now patterns can be seen. The data from reactor 2 and reactor 3 are circled. Even

without doing any calculations, it is clear that for those two reactors, purity decreases as iron increases. However, the data from reactor 1, the solid dots that are not circled, do not show that relationship. Something is different about reactor 1.



Stratification Diagram.

Stratification Analysis Considerations

- Survey data usually benefit from stratification.
- Always consider before collecting data whether stratification might be needed during analysis. Plan to collect stratification information.
- On your graph or chart, include a legend that identifies the marks or colors used.

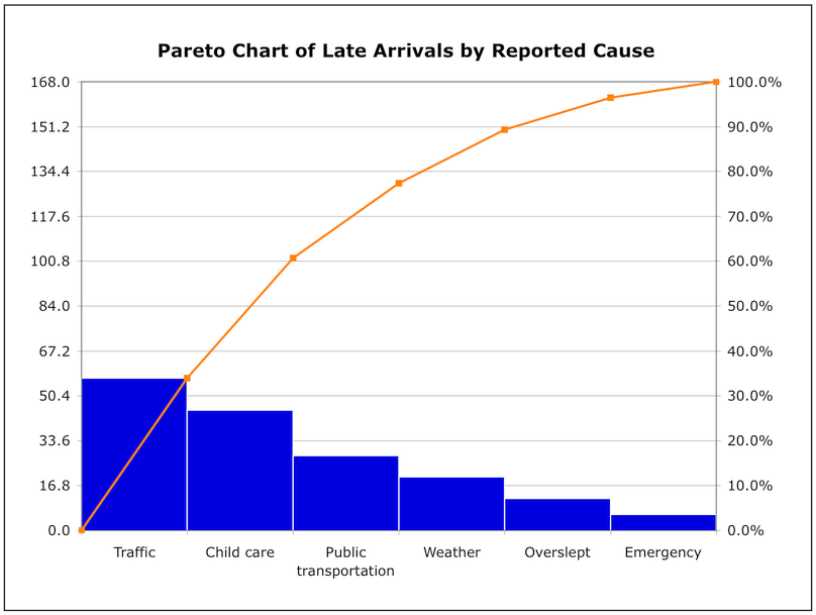
Create a Stratification Diagram

Stratification template (Excel) Analyze data collected from various sources to reveal patterns or relationships often missed by other data analysis techniques. By using unique symbols for each source, you can view data sets independently or in correlation to other data sets.

PARETO CHART

A Pareto chart is a type of chart that contains both bars and a line graph, where individual values are represented in descending order by bars, and the cumulative total is

represented by the line. The chart is named for the Pareto principle, which, in turn, derives its name from Vilfredo Pareto, a noted Italian economist.



Simple example of a Pareto chart using hypothetical data showing the relative frequency of reasons for arriving late at work.

The left vertical axis is the frequency of occurrence, but it can alternatively represent cost or another important unit of measure. The right vertical axis is the cumulative percentage of the total number of occurrences, total cost, or total of the particular unit of measure. Because the values are in decreasing order, the cumulative function is a concave function. To take the example below, in order to lower the amount of late arrivals by 78%, it is sufficient to solve the first three issues.

The purpose of the Pareto chart is to highlight the most important among a (typically large) set of factors. In quality control, it often represents the most common sources of defects, the highest occurring type of defect, or the most frequent reasons for customer complaints, and so on. Wilkinson devised an algorithm for producing statistically based acceptance limits (similar to confidence intervals) for each bar in the Pareto chart.

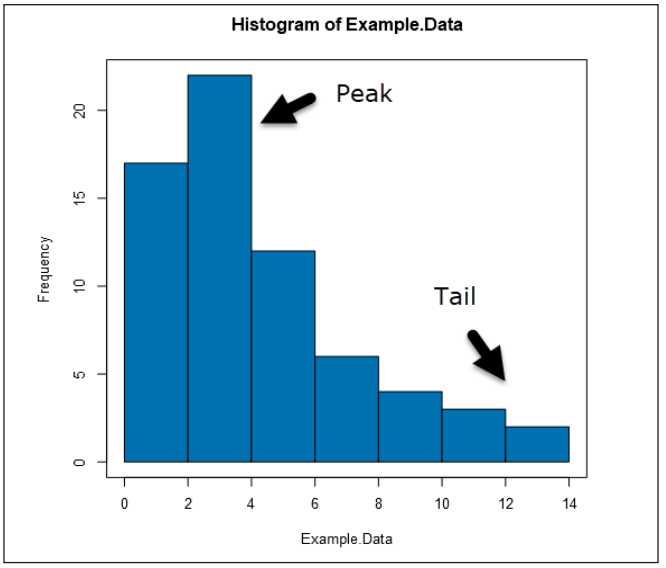
These charts can be generated by simple spreadsheet programs, such as Apache OpenOffice/LibreOffice Calc and Microsoft Excel, visualization tools such as ThoughtSpot or Tableau Software, specialized statistical software tools, and online quality charts generators.

The Pareto chart is one of the seven basic tools of quality control.

Guide to Quality Control by Japanese organizational theorist Kaoru Ishikawa contains the first published example of a Pareto chart.

HISTOGRAM

Histograms or bar charts are quality improvement tools that are instantly recognizable but are often neglected. They can offer a powerful analysis of your problems. Continuous process improvement requires that we collect data through simple quality tools such as tally charts, but then we need to be able to analyze this data. One of the simplest tools to do this with is a histogram or bar chart, a quality tool that many of us will be familiar with.



Histogram.

A histogram is a graphical representation of data. The data is represented by columns on a graph which vary in height depending on the frequency (how many times) the specific range of data occur.

Why use a Histogram as a Quality Tool?

- Displays data in an easy-to-interpret graphical manner.
- Shows frequency of occurrence of data values.
- Reveals the centering, variation and shape of the data.
- Illustrates the underlying distribution of the data.
- Enables future prediction of process performance.
- Enables identification in changes in processes parameters.
- Allows you to answer the question: “Is the process capable of meeting the customer requirements?”

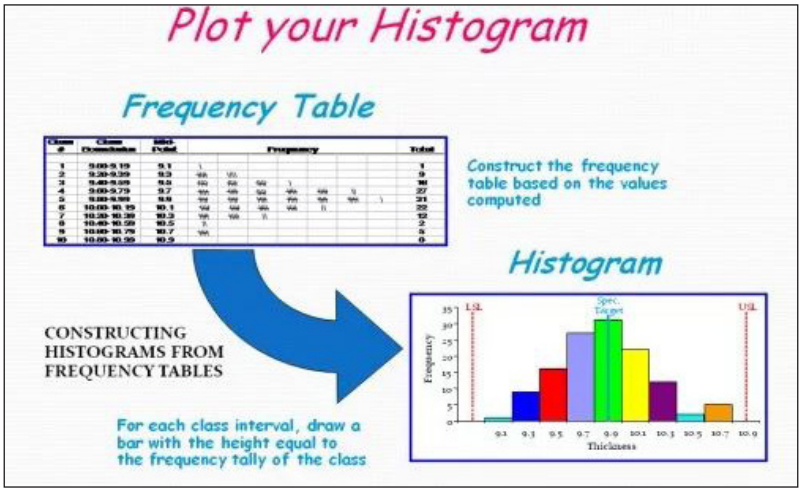
Continuous process improvement is core to the survival of any business. Histograms and other quality tools are key to achieving continual process improvement of your business.

How to make a Histogram

The first thing to do is to collect your data. We can collect data using a tally chart, recording occurrences of specific ranges of measurement or we can just create a table of results when we take the measurements.

To use this quality tool we must draw the histogram, for this we need to know the number of "class intervals" (number of columns) and the "interval width" (the width of each column on our bar chart).

Plotting your Histogram



Histogram Plot.

Class Intervals on your Bar Chart

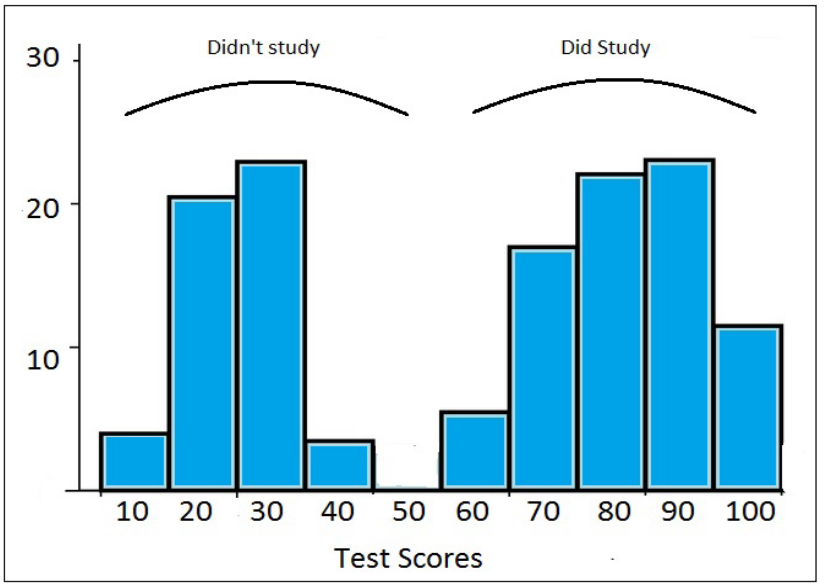
To define the number of class intervals, the "official" method is to take the square root of the total number of measurements, for example if you have 400 measurements then the class interval will be 20. However if you are not too comfortable with square roots the following table can be used as a simple guide.

Number of Samples Class Intervals

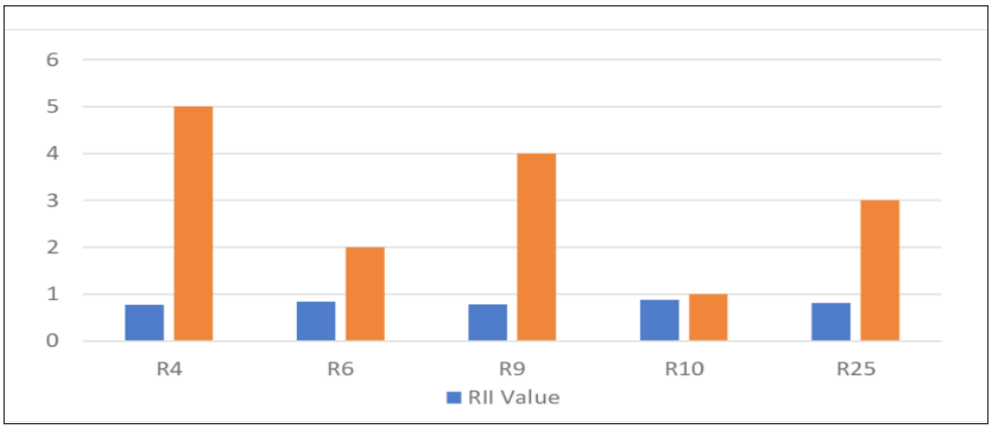
- Under 50 5 - 7.
- 50 – 100 6 - 10.
- 100 – 250 7 - 12.
- Over 250 10 – 20.

This will tell you how many individual columns will form your histogram or bar chart when you use this simple quality tool.

Histogram Analysis



Bi-Modal Distribution Bar Chart.



Bar Chart Analysis.

The position of the histogram relevant to the specification limits and the shape of the histogram can tell us a huge amount about the process being analyzed. Data that follows the "normal distribution" forms what is called a bell shaped curve, this is the typical shape that is seen when we plot a histogram of variable data.

However we do occasionally see different shapes, a multi-modal distribution is one that has more than one peak. A bi modal distribution is one in which there are two peaks on the graph, this would indicate that there is something that has changed during the

data gathering, for instance a change in settings between two shifts or a change in raw materials being processed.

We can also see skewed distributions, those where the data is bunched up to one side with a long tail. This can occur in situations where for instance you cut material to length, the method will not allow longer cuts but it will allow shorter ones.

Comparison of the shape of the distribution of the histogram to the specification limits can tell us whether the process is capable of meeting the required specification. If the tails are within the upper and lower specification limits then we are within the limits. The peak of the bar chart can also tell us if we are close to the nominal specification and allow us to make any necessary corrections.

For such a simple to use quality tool the histogram or bar chart is a very powerful way to find out a lot of information regarding the capability of our processes and to help us to make continuous improvement.

CP and CPK

Within business statistics or discussions on statistical process control you may here people talking about the process CP or CPK. This is a comparrison of the actual process spread and position against the specification.

The simplest way to think about it is to compare the base of your histogram to the specification, if your histogram has a spread of 5 points and your tolerance is 10 points then you would have a CP of 2. This however can be adjusted according to your process setting and the process nominal giving the CPK. The CPK is more often than not lower than the CP due to the actual process being closer to the specification limits.

This is a simplified view of CP and CPK which would otherwise be calculated using the process standard deviation. Six standard deviations (+/- 3) being divided into the total tolerance to give your CP.

Histograms in Six Sigma

If you are implementing a six sigma project you will almost certainly start your data analysis by plotting your data as a histogram. This often results in a multi-nodal dis-tribution due to multiple influences on your data. Most six sigma projects started by inexperienced black belts fail to ensure that the process that they wish to study is first standardized.

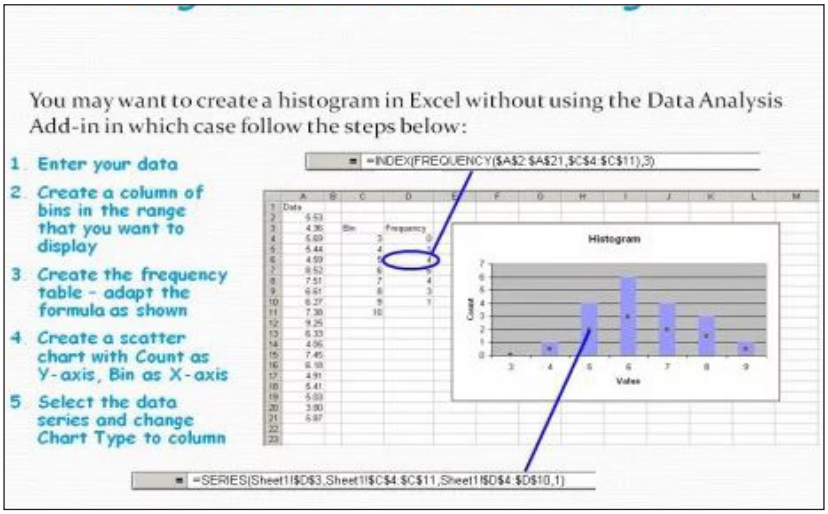
By this we mean things as simple as making sure that the best method is defined, documented and then followed the same way by everyone. These differences are often the cause of most of the variation that the six sigma project is seeking to reduce and as such tackling them initially can actually remove the need for a full blown six sigma project.

This is why many now implement lean six sigma and implement tools such as 5S which

helps you to standardize your project before you begin intensive and sometimes wasteful data collection and analysis.

Histogram Software

Software that is readily available in most businesses, such as Excel, can be easily used to make bar charts of all sorts of descriptions. Excel will allow you to create histograms not just as bar charts but in other formats such as pie charts.



Bar Chart and Histogram Using Excel software.

Continuous Process Improvement

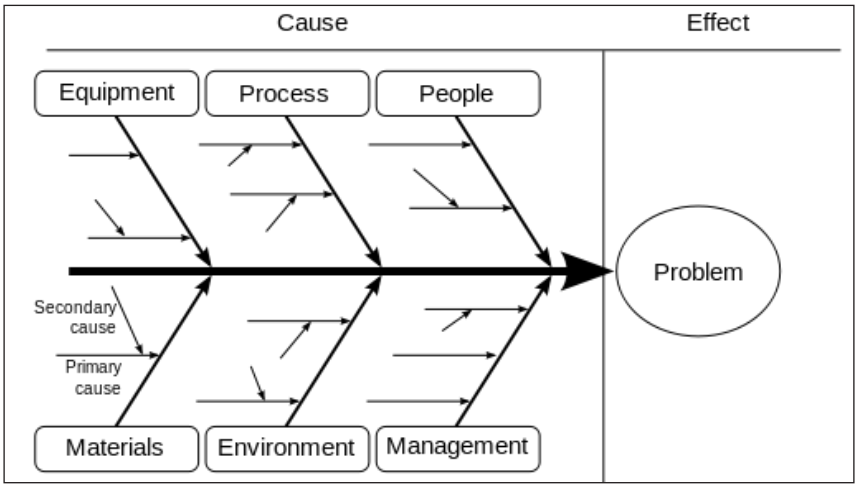
Histograms and Bar Charts are a simple and important quality tool to help you to continually improve your processes. Continuous Process Improvement however does not just happen, it must be planned and managed carefully. Tools such as histograms are used as part of larger improvement programs and are used in conjunction with other tools such as tally charts or SPC.

ISHIKAWA DIAGRAM

Ishikawa diagrams (also called fishbone diagrams, herringbone diagrams, cause-and-effect diagrams, or Fishikawa) are causal diagrams created by Kaoru Ishikawa that show the causes of a specific event.

Common uses of the Ishikawa diagram are product design and quality defect prevention to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation. Causes are usually grouped into major categories to identify and classify these sources of variation.

The defect is shown as the fish's head, facing to the right, with the causes extending to the left as fishbones; the ribs branch off the backbone for major causes, with sub-branches for root-causes, to as many levels as required.



Sample Ishikawa diagram shows the causes contributing to problem.

Ishikawa diagrams were popularized in the 1960s by Kaoru Ishikawa, who pioneered quality management processes in the Kawasaki shipyards, and in the process became one of the founding fathers of modern management.

The basic concept was first used in the 1920s, and is considered one of the seven basic tools of quality control. It is known as a fishbone diagram because of its shape, similar to the side view of a fish skeleton.

Mazda Motors famously used an Ishikawa diagram in the development of the Miata (MX5) sports car.

Advantages

- Highly visual brainstorming tool which can spark further examples of root causes.
- Quickly identify if the root cause is found multiple times in the same or different causal tree.
- Allows one to see all causes simultaneously.
- Good visualization for presenting issues to stakeholders.

Disadvantages

- Complex defects might yield a lot of causes which might become visually cluttering.
- Interrelationships between causes are not easily identifiable.

Root Causes

Root-cause analysis is intended to reveal key relationships among various variables, and the possible causes provide additional insight into process behavior.

The causes emerge by analysis, often through brainstorming sessions, and are grouped into categories on the main branches off the fishbone. To help structure the approach, the categories are often selected from one of the common models shown below, but may emerge as something unique to the application in a specific case.

Each potential cause is traced back to find the root cause, often using the 5 Whys technique.

Typical categories include:

The 5 Ms (used in Manufacturing)

Originating with lean manufacturing and the Toyota Production System, the 5 Ms is one of the most common frameworks for root-cause analysis:

- Man/mind power (physical or knowledge work, includes: kaizens, suggestions).
- Machine (equipment, technology).
- Material (includes raw material, consumables, and information).
- Method (process).
- Measurement/medium (inspection, environment).

These have been expanded by some to include an additional three, and are referred to as the 8 Ms:

- Mission/mother nature (purpose, environment).
- Management/money power (leadership).
- Maintenance.

The 8 Ps (used in Product Marketing)

This common model for identifying crucial attributes for planning in product marketing is often also used in root-cause analysis as categories for the Ishikawa diagram:

- Product (or service).
- Price.
- Place.
- Promotion.
- People (personnel).

- Process.
- Physical evidence.
- Performance.

The 8 Ps are primarily used in product marketing.

The 4 Ss (used in Service Industries)

An alternative used for service industries, uses four categories of possible cause:

- Surroundings.
- Suppliers.
- Systems.
- Skill.

Fishbone Diagram in Lean

A recurring theme in a lean or Six Sigma transformation is removing the clutter to reveal waste or opportunities for improvement. A fishbone diagram aims to break down and organise the Causes of an issue to reveal what elements have the greatest impact. Grouping the "causes" means you can think about the different elements of the problem as separate from the overall process. One or two of these "causes" will have a greater effect than the others and will guide you to the root of the problem. This structure also allows you to tackle smaller chunks which have a large impact on the problem. Looking at elements of the problem and not the whole process will likely make finding your solution less daunting and problem solving more manageable.

After you have determined your root cause, prioritise or screen the causes to determine which are having the largest effect. Once identified focus on these. An easy Cause screening method involves looking at each one and asking two questions:

How likely is this cause to be the major source of the issue or variation?

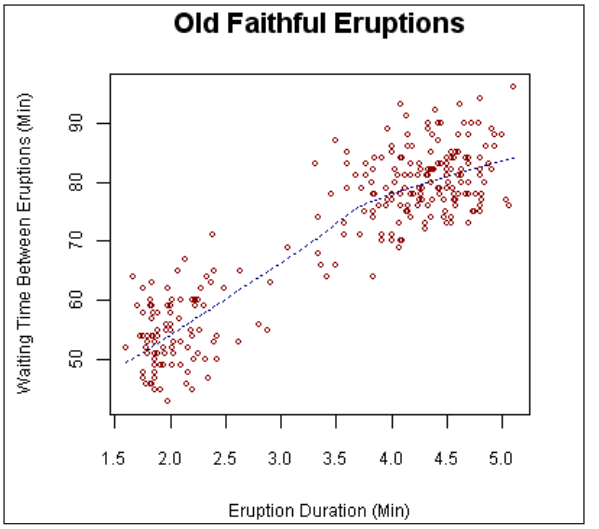
- V - Very Likely.
- S - Somewhat Likely.
- N - Not Likely.

How easy would it be to fix or control?

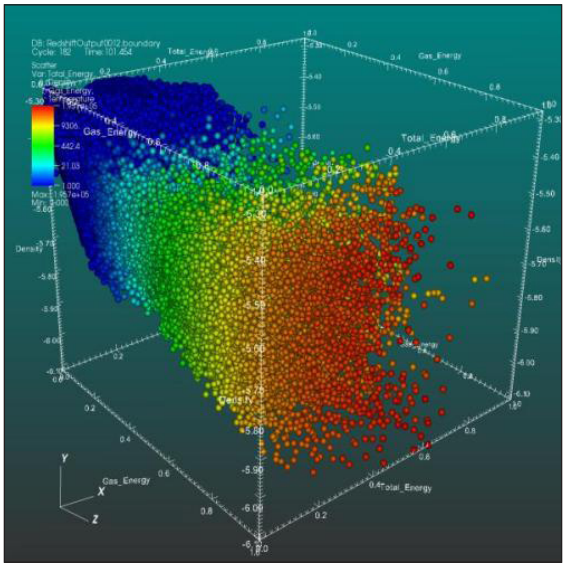
- V - Very Easy.
- S - Somewhat Easy.
- N - Not Easy.

Put the answers of the two questions together. Work on the Causes that have a result of VV, VS, and SV.

SCATTER PLOT



Waiting time between eruptions and the duration of the eruption for the Old Faithful Geyser in Yellowstone National Park, Wyoming, USA. This chart suggests there are generally two types of eruptions: short-wait-short-duration, and long-wait-long-duration.



A 3D scatter plot allows the visualization of multivariate data. This scatter plot takes multiple scalar variables and uses them for different axes in phase space. The different

variables are combined to form coordinates in the phase space and they are displayed using glyphs and colored using another scalar variable.

A scatter plot (also called a scatterplot, scatter graph, scatter chart, scattergram, or scatter diagram) is a type of plot or mathematical diagram using Cartesian coordinates to display values for typically two variables for a set of data. If the points are coded (color/shape/size), one additional variable can be displayed. The data are displayed as a collection of points, each having the value of one variable determining the position on the horizontal axis and the value of the other variable determining the position on the vertical axis.

A scatter plot can be used either when one continuous variable that is under the control of the experimenter and the other depends on it or when both continuous variables are independent. If a parameter exists that is systematically incremented and/or decremented by the other, it is called the control parameter or independent variable and is customarily plotted along the horizontal axis. The measured or dependent variable is customarily plotted along the vertical axis. If no dependent variable exists, either type of variable can be plotted on either axis and a scatter plot will illustrate only the degree of correlation (not causation) between two variables.

A scatter plot can suggest various kinds of correlations between variables with a certain confidence interval. For example, weight and height, weight would be on y axis and height would be on the x axis. Correlations may be positive (rising), negative (falling), or null (uncorrelated). If the pattern of dots slopes from lower left to upper right, it indicates a positive correlation between the variables being studied. If the pattern of dots slopes from upper left to lower right, it indicates a negative correlation. A line of best fit (alternatively called 'trendline') can be drawn in order to study the relationship between the variables. An equation for the correlation between the variables can be determined by established best-fit procedures. For a linear correlation, the best-fit procedure is known as linear regression and is guaranteed to generate a correct solution in a finite time. No universal best-fit procedure is guaranteed to generate a correct solution for arbitrary relationships. A scatter plot is also very useful when we wish to see how two comparable data sets agree to show nonlinear relationships between variables. The ability to do this can be enhanced by adding a smooth line such as LOESS. Furthermore, if the data are represented by a mixture model of simple relationships, these relationships will be visually evident as superimposed patterns.

The scatter diagram is one of the seven basic tools of quality control.

Scatter charts can be built in the form of bubble, marker, or/and line charts.

Example:

For example, to display a link between a person's lung capacity, and how long that

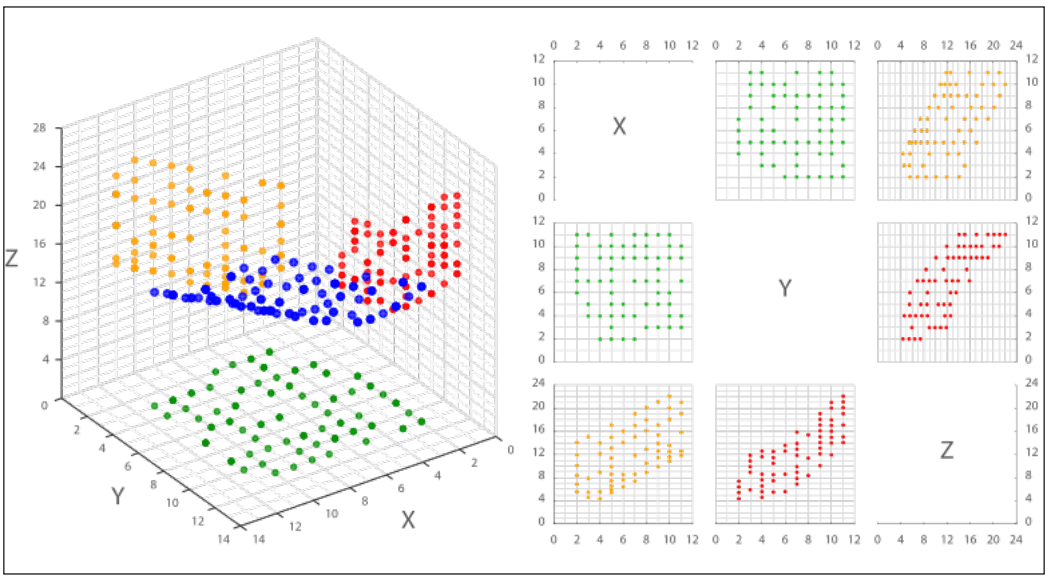
person could hold their breath, a researcher would choose a group of people to study, then measure each one's lung capacity (first variable) and how long that person could hold their breath (second variable). The researcher would then plot the data in a scatter plot, assigning "lung capacity" to the horizontal axis, and "time holding breath" to the vertical axis.

A person with a lung capacity of 400 cl who held their breath for 21.7 seconds would be represented by a single dot on the scatter plot at the point (400, 21.7) in the Cartesian coordinates. The scatter plot of all the people in the study would enable the researcher to obtain a visual comparison of the two variables in the data set, and will help to determine what kind of relationship there might be between the two variables.

Scatter Plot Matrices

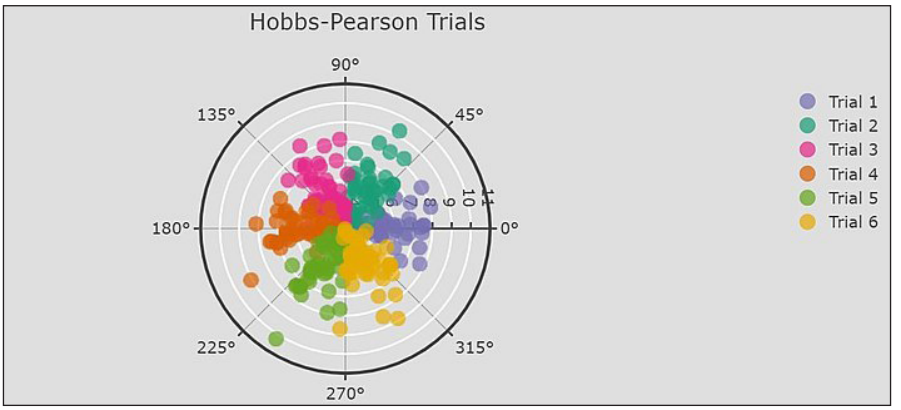
For a set of data variables (dimensions) X_1, X_2, ... , X_k, the scatter plot matrix shows all the pairwise scatter plots of the variables on a single view with multiple scatterplots in a matrix format. For k variables, the scatterplot matrix will contain k rows and k columns. A plot located on the intersection of i-th row and j-th column is a plot of variables X_i versus X_j. This means that each row and column is one dimension, and each cell plots a scatter plot of two dimensions.

A generalized scatter plot matrix offers a range of displays of paired combinations of categorical and quantitative variables. A mosaic plot, fluctuation diagram, or faceted bar chart may be used to display two categorical variables. Other plots are used for one categorical and one quantitative variables.



Visualization of 3D data along with the correspondent scatterplot matrix.

Example of Scatter Plot



Hobbs Pearson Trials.

CHECK SHEET

A check sheet is a structured, prepared form for collecting and analyzing data. This is a generic data collection and analysis tool that can be adapted for a wide variety of purposes and is considered one of the seven basic quality tools.

When to use a Check Sheet?

- When data can be observed and collected repeatedly by the same person or at the same location.
- When collecting data on the frequency or patterns of events, problems, defects, defect location, defect causes, or similar issues.
- When collecting data from a production process.

Looking for more Quality Tools?

Try Plan-Do-Study-Act (PDSA) Plus QTools™ Training:

- Check Sheet.
- QTools™ Bundle.
- Plan-Do-Study-Act plus QTools™

Check Sheet Procedure

- Decide what event or problem will be observed. Develop operational definitions.
- Decide when data will be collected and for how long.

- Design the form. Set it up so that data can be recorded simply by making check marks or X's or similar symbols and so that data do not have to be recopied for analysis.
- Label all spaces on the form.
- Test the check sheet for a short trial period to be sure it collects the appropriate data and is easy to use.
- Each time the targeted event or problem occurs, record data on the check sheet.

Check Sheet Example

The figure below shows a check sheet used to collect data on telephone interruptions. The tick marks were added as data was collected over several weeks.

Table: Telephone Interuptions.

Reason	Day					
	Mon	Tues	Wed	Thurs	Fri	Total
Wrong Number	IIII	II	I	IIII	IIII II	20
Info request	II	II	II	II	II	10
Boss	IIII	II	IIII II	I	IIII	19
Total	12	6	10	8	13	49

References

- Montgomery, D. C. (2009). Statistical Quality Control: A Modern Introduction, Wiley, ISBN 978-0-470-23397-9
- Robbie T. Nakatsu (2009). Reasoning with Diagrams: Decision-Making and Problem-Solving with Diagrams. John Wiley & Sons. pp. 68–69. ISBN 978-0-470-40072-2
- Montgomery, Douglas (2005). Introduction to Statistical Quality Control. Hoboken, New Jersey: John Wiley & Sons, Inc. ISBN 978-0-471-65631-9. OCLC 56729567. Archived from the original on 2008-06-20
- A Poots, T Woodcock (2012). "Statistical process control for data without inherent order". BMC Medical Informatics and Decision Making. 12. doi:10.1186/1472-6947-12-86. PMC 3464151. PMID 22867269
- Stratification, quality-resources: asq.org, Retrieved 14 February, 2020
- Histograms-Bar-Charts-Quality-Tools, business: toughnickel.com, Retrieved 14 April, 2020
- Dale, Barrie G. et al. (2007); Managing Quality 5th ed; ISBN 978-1-4051-4279-3 OCLC 288977828
- Friendly, Michael; Denis, Dan (2005). "The early origins and development of the scatterplot". Journal of the History of the Behavioral Sciences. 41 (2): 103–130. doi:10.1002/jhbs.20078. PMID 15812820
- Check-sheet, quality-resources: asq.org, Retrieved 13 August, 2020

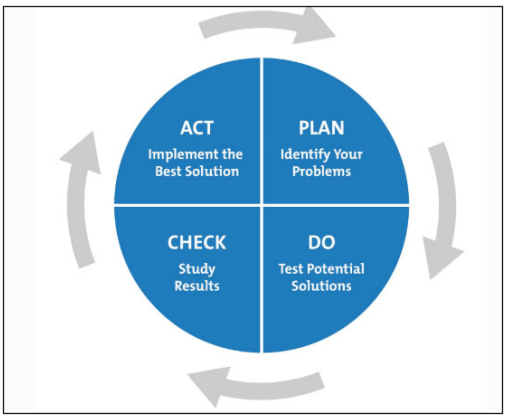
Quality Assurance

CHAPTER 5

Quality assurance deals with the prevention of defects and problems in products and provide safe delivery of products to consumers. Quality assurance can be grouped into three levels – strategic level, functional level and operational level. All the aspects related to quality assurance have been carefully analyzed in this chapter.

Quality Assurance (QA) is defined as an activity to ensure that an organization is providing the best possible product or service to customers. QA focuses on improving the processes to deliver Quality Products to the customer. An organization has to ensure, that processes are efficient and effective as per the quality standards defined for software products. Quality Assurance is popularly known as QA Testing.

Quality assurance has a defined cycle called PDCA cycle or Deming cycle. The phases of this cycle are shown in the figure below.



These above steps are repeated to ensure that processes followed in the organization are evaluated and improved on a periodic basis. Let's look into the above steps in detail:

- Plan: Organization should plan and establish the process related objectives and determine the processes that are required to deliver a high-Quality end product.
- Do: Development and testing of Processes and also "do" changes in the processes.

- Check: Monitoring of processes, modify the processes, and check whether it meets the predetermined objectives.
- Act: Implement actions that are necessary to achieve improvements in the processes.

An organization must use Quality Assurance to ensure that the product is designed and implemented with correct procedures. This helps reduce problems and errors, in the final product.

COMPONENTS OF QUALITY ASSURANCE

The components of a QA programme are often grouped into three levels, variously labelled: the strategic or organisational level (dealing with the quality policy, objectives and management and usually produced as the Quality Manual); the tactical or functional level (dealing with general practices such as training, facilities, operation of QA); and the operational level (dealing with the Standard Operating Procedures (SOPs) worksheets and other aspects of day to day operations).

Setting up the System

There is no single method for establishing a QA system. Each organisation has its own problems that will require special consideration and planning. However, once the decision to implement a QA system has been taken and the necessary funds and facilities have been made available, then a plan must be drawn up. For a new project the QA system can be drawn up before the start but if the project is already established then a QA system can be retrofitted. In the latter situation, existing practices must be evaluated with respect to QA needs and any QA checks and procedures that are already in place. It is better to build on procedures already in place and only to remove them if they are clearly unsatisfactory. If too many changes are imposed too quickly, especially where they are seen to increase work load, they are unlikely to be met with a favourable response and implementation will be poor. The QA programme must be seen to be practical and realistic and not to include trivial or unnecessarily time-consuming or difficult tasks.

The Quality Manual

The Quality Manual is composed of the management documents needed to implement the QA programme and includes:

- A quality policy statement, including objectives and commitments.
- The organisation and management structure of the project, its place in any parent organisation and relevant organisational charts.

- The relationship between management, technical operations, support services and the quality system.
- Procedures for control and maintenance of documentation.
- Job descriptions for key staff and reference to the job descriptions of other staff.
- Identification of approved signatories.
- Procedures for ensuring traceability of all paperwork, data and reports.
- The laboratory's scope for calibrations and tests.
- Arrangements for ensuring that all new projects are reviewed to ensure that there are adequate resources to manage them properly.
- Reference to the calibration, verification and testing procedures used.
- Procedures for handling calibration and test items.
- Reference to the major equipment and reference measurement standards used.
- Reference to procedures for calibration, verification and maintenance of equipment.
- Reference to verification practices including inter-laboratory comparisons, proficiency testing programmes, use of reference materials and internal quality control schemes.
- Procedures to be followed for feedback and corrective actions whenever testing discrepancies or departure from documented procedures are detected.
- Procedures to be followed for feedback and corrective actions whenever testing discrepancies or departure from documented procedures are detected.
- Complaints procedure.
- Procedures for protecting confidentiality and property rights.
- Procedures for audit and review.

Standard Operating Procedures

Standard Operating Procedures (SOPs) are the documents detailing all specific operations and methods, including sampling, transportation, analysis, use of and calibration of equipment, production of reports and interpretation of data. They are the internal reference manual for the particular procedure and should detail every relevant step. Anybody of the appropriate training level should be able to follow the SOP. They should, where necessary, cross-reference other SOPs and refer to them by number. Method SOPs may originate from organisations such as the International Organization

for Standardization (ISO), British Standards Institute (BSI), American Standard Technical Method (ASTM) or from the instructions that come with the test kit where a commercially produced method is used. Such SOPs have the advantage of not requiring verification and save time in writing "in-house" SOPs. However, if they are used they must be used without modification. If any modification at all takes place, the alterations must be documented. Sometimes "in house" methods are preferred, and it is vital that such methods are properly verified. This may be done by reference to scientific literature and by "in house" validation.

The procedure should be written in short, clear sentences. Equipment SOPs should include methods and frequency of maintenance, cleaning, calibration and servicing. Method SOPs should include all the information necessary to carry out the procedure without reference to other documents with the exception of fully documented SOPs. Any statements regarding ranges for measurement variables such as temperature, weights, etc. should be within the scope of the facility, i.e. not so wide that they affect the result but not so narrow that they are not practically achievable or necessary. Calculations should include any equations and demonstration of statistical control. Where applicable, criteria for the acceptance of data should be stated and acceptable ranges quoted. Disposal methods for reagents, test materials and other consumables should also be stated.

Some SOPs, such as those for office procedures, will be customised. The person most technically competent to carry out the procedure described should write the SOP. An SOP should have a descriptive title and also have a unique reference and version number. The purpose of the SOP should be stated alongside the variables measured, the expected range of values, the limitations of the method and the expected precision and accuracy. Any documents regarding the source of the method should be stated. Safety notes should include any foreseeable risks involved in the procedure, alongside procedures to minimise risk and procedures in case of an accident. Any special training required for the operator, and special apparatus required for the procedure (including all reagents and materials required) should be stated along with such information as the grade, reference number, size and company of origin. The storage, handling, recording and subsequent disposal of the sample should also be covered in the SOP, including storage temperatures, sample splitting, traceability, and any other issues. The style and format of the final data report should be given where applicable and reporting procedures and archiving requirements should also be included.

Auditing and Checking Compliance

When all the documentation for the QA system is in place, it should be piloted. During this time, the QA manager should conduct a series of audits covering all aspects of the system. Traceability of data is a key component which can be checked by picking data at random and tracing them back through all relevant paperwork to the sampling procedure. A review of the system with positive and negative areas clearly defined should be written at the end of the pilot phase.

One method of implementation is to apply for accreditation from a recognised QA system. The ISO standard, ISO 9000, is suitable for the monitoring programme as a whole and is available in many countries. These systems are expensive but do allow the QA programme to be assessed independently against an agreed standard. Sometimes formal accreditation is required by regulatory and commercial bodies.

Maintaining Quality Assurance

In order to maintain the QA system, it is necessary to check periodically each area of the system for compliance. This involves auditing the component parts to assess whether they continue to meet the original criteria. This procedure should be formerly documented. Reports on all audits should be made available to management and to the persons responsible for the work concerned. Deviations from required standards must be corrected as soon as possible. The audit must be independent, and should be thorough and unannounced.

Equipment Maintenance and Calibration

All equipment, whether site, office or laboratory, must be maintained on a regular basis as documented in the relevant SOPs, codes of practice and manufacturer's guidelines. Laboratories must apply standards within the limits established for the care of a particular piece of equipment. This applies to general equipment, such as glassware, as well as to sophisticated analytical instruments and vehicles. It especially applies to field equipment.

The care and cleaning of equipment is very important to ensure analytical quality. Regular internal and external calibration checks must be performed on equipment such as balances, pipettes and pH meters. The frequency of these checks depends on the stability of the equipment in question but should be based on established practice. The form and frequency of these checks should be documented in the relevant SOPs. Calibration and maintenance records should be kept for all equipment, thus allowing the repair status to be monitored.

Sampling

Any analysis can only be as good as the sample taken. Variations in sampling procedures can have a marked effect on the results of analysis. It is very difficult to quantify these effects and therefore procedures for sampling operations should be documented carefully so that all relevant information is recorded at the time of sampling by the field worker.

The Sampling Plan

For any sampling programme, a sampling plan must be prepared to allow full control of the sampling process so that any change seen between two sampling rounds can be attributed to changes in environmental conditions and not to changes in procedure.

Items to be considered in preparing a sampling plan include planning issues, fieldwork procedures and field safety issues.

Planning Issues

Planning issues include identification of the objective of sampling (e.g. to test compliance with a bathing water regulation), choice of site (location, type of water body), the type and number of samples to be collected (sample types, e.g. water, sediment, the number of samples, appropriate equipment) and timing of sampling (considering the state of tides).

Fieldwork Procedures

Consideration must be given to sampling SOPs (for equipment, sampling method, storage, etc.), as well as size of sample and sample containers. Preservation must be decided in consultation with staff from the analysing laboratory, who will advise clients on the volume and type of sample and who will usually provide sampling containers and preservatives where necessary. Ensuring field quality control includes the use of blanks, duplicate samples, replicate samples and spiked samples. Storage and holding time (conditions for storage, such as in an ice box, maximum time before analysis for unstable parameters, etc.) must also be considered.

The laboratory staff must be made aware when samples are due to arrive so that they can make the appropriate arrangements. When choosing an analytical laboratory it is important to be aware of the location of the laboratory in relation to the sampling site, as well as the latest time of day that they are prepared to accept samples.

Other factors include deciding where to carry out analysis, i.e. in the laboratory or on site. Some analyses may be better performed on site, such as dissolved oxygen measurements, calibration of field measuring equipment, flow pumps and thermometers, etc. and sample treatments such as filtration. Some samples need to be split or subsampled. Where this is done, great care needs to be taken because samples are frequently very variable. Contingency plans need to be prepared for situations such as bad weather and vehicle breakdown. Field sampling sheets also need to be prepared. These can be filled in manually on paper forms or on a portable computer providing that the software has been properly validated. When designing field report forms it is important that the place, time and date of sampling, sampling conditions, any field measured variables, equipment used (with an inventory number), any necessary sample preparation and the name of the operator are included in the form. Practical difficulties, such as how many samples the field worker will need to carry, parking and access to the site also need to be considered.

Field Safety Issues

Field safety can have a bearing on the quality of data generated where field operators may be inclined to use a less than optimum procedure in order to protect themselves.

This must be taken into account when writing the sampling procedure. For example, insisting on sampling water at chest height may deter some operators if the conditions in the water to be sampled are rough. Sampling from boats can be especially hazardous in rough weather. Even the 30 cm depth stipulation of the European Union's Bathing Water Directive can be difficult to comply with. When devising a plan, areas of risk may have to be borne in mind, including water depth and sampling conditions, currents, wildlife, traffic and weather. Staff must always be provided with the appropriate protective equipment and SOPs should be developed with the safety of operators of paramount concern.

Field Quality Assurance

In spite of the difficulties involved in site work, QA is critical at this point. If a good, practical, field QA programme is put into operation, confidence in the data collected should be ensured. All equipment must be kept clean and in good order, and records should be kept of all maintenance and of any irregularities that may affect the results. Conditions in the working area should not expose the operator to undue risk of any type.

Standardised and approved methodologies must be used at all times. If a method proves unworkable on site, then an alternative must be found quickly and agreed by all those involved. Operators must not change procedures without referral to the management procedure. Where unavoidable changes are made, for example, in bad weather, they must be fully documented. Nevertheless, a good sampling plan should make provisions for bad weather.

Prevention of Sample Contamination and Losses

It is important that samples are protected from contamination and deterioration before their arrival in the laboratory. This can be ensured by using only recommended sample containers. Where reusable containers are used, it is essential that they have been cleaned properly and, if necessary, sterilised before use. Containers that have been sterilised must remain sterile until the sample is collected. The inner portion of the sample container should not be touched by the operator. If the seal on the bottle is broken (in the case of a commercially purchased microbiological sample bottle), or if the protective paper or foil has been lost from the top (home-made sampling containers), the bottle should be discarded.

Recommended preservation methods must be used. Where this involves chemical preservatives, the chemicals must be of analytical grade, and provided and tested for efficacy by the analytical laboratory.

Field measurements, such as pH and temperature, must be made on a separate subsample which is then discarded in order not to contaminate samples for interlaboratory

analysis. Conductivity measurements should not be made with a sample that has been used previously for measuring pH, because potassium chloride from the pH probe may affect the conductivity reading.

All sample containers should be kept in a clean environment, away from dust, dirt and fumes. Petroleum products and fumes may contaminate samples with heavy metals and hydrocarbons. This can be a major problem on boats, where leaks and seepage of petroleum products are common. Samples must be stored in a cool box or portable refrigerator and transported to the laboratory as soon as possible. Cool boxes are more efficient if they contain some water.

Field Quality Control

Quality Control (QC) is an essential part of the field QA programme. It requires the collection of replicate samples to check the repeatability of sampling, and the submission of field blanks and duplicates to check for contamination, handling and storage problems and other errors that may affect the results from the time of sampling to the time of analysis. The timing and frequency of these samples should be documented in the sampling plan.

Laboratory Facilities

Except for any on-site analysis, analysis is usually performed in a laboratory. It is essential that any facilities are adequately equipped to deal with the analyses required and are convenient for the delivery of samples. This should have been ascertained before the start of the monitoring programme.

Small-scale organisations responsible for monitoring may find it more convenient to use outside facilities for analysis and sometimes for sampling. In these cases, the use of a laboratory belonging to an accreditation scheme is advisable and, moreover the laboratory should be inspected for compliance by an experienced member of the monitoring programme. An inspection should take into account the following features:

- Lines of communication between staff and management.
- Staff training and qualifications.
- Resources.
- Equipment maintenance and calibration.
- Standard Operating Procedures.
- Traceability of results.
- Sample handling and storage.

Where in-house facilities are used, it is essential that the monitoring work does not overload the laboratory. Resources (staff, space, equipment and supplies) must be sufficient for the planned workload. The laboratory must be well managed and must conform to all relevant health and safety guidelines. All analyses performed must be within the remit and expertise of the facility and SOPs must be in operation for all analyses.

Sample Receipt and Storage

Procedures for sample handling, transport and storage prior to analysis should ensure that the quality of the sample is not compromised. The condition of each sample and its storage location should be recorded along with its proposed analyses. If the sample is split, this must also be recorded. All samples must be identified uniquely with a number or code. It is important to ensure that the passage of a sample, and any associated paperwork, through the laboratory is fully documented and, therefore, traceable.

Reporting

The efforts of QA are directed ultimately towards ensuring that any data produced are suitable for their intended use; this applies to the results and any interpretations. The first stage in the reporting process is the examination of the results to see if they are fit to report (although raw data should have been checked prior to this stage). Results must be reported accurately and in a way that aids interpretation. To facilitate this, information may need to be included that has a bearing on interpretation, such as sampling conditions or the method of analysis. All data included must be checked by an experienced analyst with reference to site reports, calibration and QC data. Many laboratories have a system which requires the checking and countersigning of analytical reports (usually by the laboratory manager) to act as a safeguard against erroneous or misleading data leaving the laboratory. This type of system is only effective when conscientiously applied.

MAINTENANCE PHILOSOPHY

Maintenance Philosophy is the mix of strategies that ensure an item works as expected when needed. Maintenance is a form of risk management that is required if and only if an item fails to satisfy the minimum level of specification performance when the items or system is required.

Maintenance is optional and may not be required if the partially failed item still satisfies the minimum level of specification performance or if the item is not required for a span of time.

Maintenance takes place in four phases:

- Failure Detection.
- Fault isolation.
- Corrective action.
- Operational verification.

An item is said to be degraded when faults exist but normal operation can continue. Automatic recovery is used to avoid the need for maintenance.

Automatic recovery from failure is required for systems and resources that cannot be accessed during deployment, such as rockets, missiles, satellites, submersibles, and items that are buried or encapsulated. There are multiple approaches:

- Custom items designed specifically for ultra high reliability.
- Redundant items with reconfiguration features that automatically bypass failure.
- Lot testing to reduce manufacturing defects.

Redundant items increase failure rate and reduce reliability if recovery is not automatic.

Failure Detection

Failure Detection involves two different maintenance strategies that interact with life-cycle cost and availability:

- Conditional.
- Periodic.

Conditional

Conditional maintenance relies on indicators that tell users when an item is failed.

- System is totally failed and cannot operate as expected.
- System will function as expected but is degraded.

This requires automatic fault detection and reporting.

Condition Based Maintenance (CBM) requires clearly observable or audible notification that is suitable for unsophisticated and untrained users, which includes the following:

- Colored indicator (red or yellow light).
- Display showing the phrase failed or degraded next to the item name.

- Gage with clearly defined green, yellow, and red bands for normal versus faulted.
- Audible indications, such as a buzzer, bell, or synthesized voice.

Recovery maintenance actions begin after notification occurs.

Items are said to be instrumented when notification takes place automatically upon failure. There are two approaches:

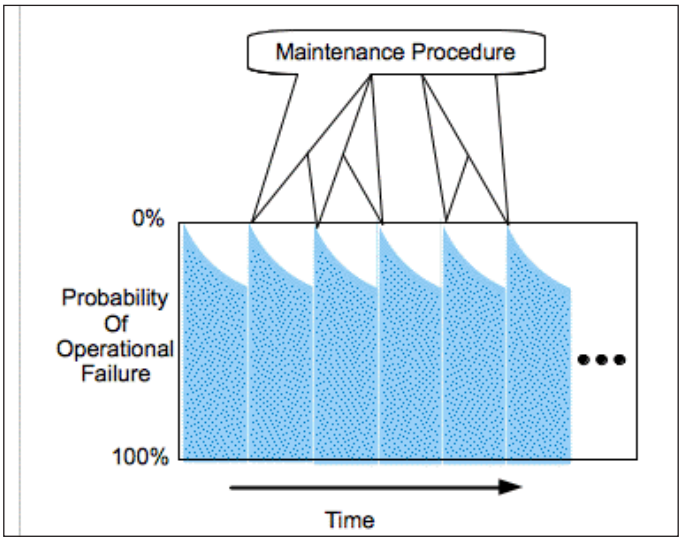
- End-To-End (ETE).
- Self-reporting devices.

ETE testing involves an automated process that periodically injects something into the item, then the outputs are examined to determine if they satisfy the level of performance required by the specification. This may be intrusive, and could interfere with normal operation briefly.

Self-reporting devices include automatic built-in-test (BIT) features that are less intrusive.

Items without the kinds of notifications suitable for CBM have silent failure modes that require periodic preventative maintenance actions.

Periodic



Probability of operational failure accumulates as time passes until diagnostic or preventative maintenance actions eliminate any actual failures.

Operational failure will eventually occur when an item is used in its normal mode of operation if there is no intervention. The procedures associated with periodic maintenance are generally called a Periodic Maintenance System (PMS).

There is risk that the system will not work as expected, and this risk grows as time passes due to increasing possibility of silent faults that cause operational failure.

Periodic maintenance actions control risk of operational failure. This relies on invasive procedures that renders a system inoperable for a brief period while users run manual diagnostic or preventative procedures. The following are a few examples:

- Calibration.
- Built In Test (BIT).
- External Diagnostics (instrumentation).
- System Operational Test (SOT).

The item is down and is unavailable for normal operation during the time while a periodic maintenance procedure is being performed.

Failure is statistical. There is a random chance that the system or item will not function when required. Reliability declines as the time passes, and probability of failure increases until action is taken.

The item will eventually fail if there is no intervention.

Periodic maintenance increasingly reduces operational failure risks as procedure are used more often. Average reliability improves as the time between maintenance actions is reduced.

$$\text{Reliability} = 0.5 \times \left(1 + e^{(-\lambda \times \text{Time Between Maintenance Actions})}\right)$$

As an example, an item with no CBM features will work as expected about 90% of the time if periodic maintenance is performed about 5 times more frequently than the MTBF.

$$0.9 \approx 0.5 \times \left(1 + e^{-0.2}\right)$$

Fault Isolation

Fault Isolation is the strategy used to identify the root cause for a failure. There are two methods:

- Automatic Fault Isolation.
- Manual Fault Isolation.

Automatic Fault Isolation

Automatic Fault Isolation identifies the root cause for failure with no manual intervention. This is generally used to control redundant items when it is necessary to automatically bypass failures.

Manual Fault Isolation

Manual Fault Isolation is when maintenance personnel must identify root cause for a failure. This usually requires the following:

- Manual diagnostic tests.
- Test equipment.
- Spare parts.
- Documentation.
- Training.

Device instrumentation used with CBM is generally used to reduce the time and effort required to isolate root cause.

Corrective Action

Corrective Action is the activity that restores performance for the item or system after a failure.

There are two kinds of corrective action:

- Automatic.
- Manual.

Automatic Corrective Action

Automatic correction is possible for redundant systems when fault-detection, fault-isolation, and fault-bypass are all automatic. Automatic corrective action is also called Active Recovery and Self Healing. This technique can be used to increase the MTBF to the length of time an item will be required to be used without maintenance.

As an example, failure is expected for space vehicles that can be required to operate correctly for as much as 10 years in a hostile environment.

Redundancy can be achieved by launching a large number of satellites, which is a practical solution for things like the Global Positioning System (GPS) because each vehicle occupies a slightly different orbit.

This is not possible for geosynchronous orbit, where all functions must be accomplished by one vehicle that performs all functions must maintain stable position over one specific spot over the earth surface. Satellites intended to operate in geosynchronous orbit must incorporate active recovery that prevents total failure when one or more parts fail.

Automatic Corrective Action incorporates all of the spare parts into the design to accommodate all of the failures that can be anticipated during a specific period of time.

Manual Corrective Action

Manual corrective action is when trained maintenance personnel perform a calibration or replacement action to restore operation.

Corrective actions for redundant items includes manual reconfiguration when automatic fault bypass is not available, which depends upon maintenance coverage.

Failed part replacement depends upon the Lowest Replaceable Unit (LRU). This could be a part inside an item, or it could be the whole item. This decision is made based on which is less expensive to replace. As an example, a new disk drive costs about $200 to purchase, the technical assistance to replace the disk drive is $500, and a refurbished computer costs about $600. If you replace your own disk drive and install your own operating system, then it is less expensive to purchase the disk drive. If you need technical help then it is less expensive to replace the whole computer.

Operational Verification

Operational Verification is any action that is performed to verify that the item or system is operational. This generally involves using the system in its normal mode of operation, which could involve actual operation or simulated operation.

Reliability

Maintenance is closely associated with reliability because maintenance is required to restore capability that has been lost due to failure.

Electronic devices decay in a way that is mathematically equivalent to radioactive decay processes for unstable atoms. Electronic failure is governed by random processes, where Mean Time Between Failure identifies the average number of hours until failure occurs. Lambda λ identifies the number of failures expected per hour.

$$\lambda = \frac{1}{\text{Mean Time Between Failure}}$$

Reliability is the probability that a failure will not occur during a specific span of time.

$$\text{Reliability} = e^{(-\lambda \times \text{Time})}$$

$$\text{Probability of Failure} = 1 - \text{Reliability}$$

Failure rate relies on logarithmic math to simplify calculations using λ that is very similar to the type of analysis used for electronic circuits.

Overall failure rate for a complex item is the sum of all the failure rates for all of the individual components in the item. This applies to situations where failure of one component causes the entire item to fail. The type of calculation is similar to a series electronic circuit.

$$\lambda_1 + \lambda_2 + \ldots + \lambda_n = \sum_{k=1}^{N} \lambda_k$$

Overall failure rate for items with full redundant overlap is the inverse of the sum of MTBF for all of the individual redundant items. This applies to situations where all of the components in the item must all fail before the item fails. The type of calculation is similar to a parallel electronic circuit.

$$\lambda = \left(\frac{1}{\frac{1}{\lambda_1} + \frac{1}{\lambda_2} + \ldots + \frac{1}{\lambda_n}} \right) = \left(\frac{1}{\sum_{k=1}^{N} \frac{1}{\lambda_k}} \right)$$

A reliability block diagram is used to construct a model for large items. This provides traceability when funding and manpower requirements are identified using reliability calculations.

Failure rate for silicon and carbon devices doubles for each 5 °C temperature rise. Electronic devices operating at 60 °C will fail 64 times more frequently than the same kind of items operating at 30 °C. This relationship holds true above 25 °C.

Transportation reliability is similar, but values are expressed in terms of distance, such as fault per mile or faults per kilometer.

Failure rate can be expressed in terms of the number of cycles. Thermal shock caused by heating and cooling can induce failure when power is cycled on and off. Most mechanical switches are built to operate 10,000 cycles before failure, which is about 30 years for a cycle rate of 1 action per day.

Distance, cycle, and decay reliability all have separate contributions that effect the overall failure rate.

Availability

Availability is generally used with systems that incorporate periodic maintenance. Availability is the probability that an item will operate correctly during a period of time when used at random times during that period.

$$Availability = \frac{Available\ Time}{Total\ Time}$$

$$Total\ Time = Available\ Time + Down\ Time$$

$$Down\ Time = Maintenance\ Time + Faulted\ Time$$

Available time is the time while the system is fully operational. Down time is the time while the system is unavailable for normal use, and this consist of the time while periodic maintenance is being performed and the amount of time while the system is faulted.

Availability calculations are meaningful for items with replaceable parts only when failure modes have adequate coverage.

$$Coverage > Availability$$

Readiness

Readiness is meaningful when the item does not require down time for periodic maintenance. This is a useful measurement for items that incorporate automatic recovery or condition based maintenance.

Readiness is the probability that an item will operate as expected when used at any random time while the item is in the correct mode of operation.

$$Readiness = 1\ \lambda - \times Mean\ Time\ To\ Recover$$

Mean Time To Recover form manual actions is generally measured or estimated. The following is an example of the kind of values that could be used for estimating the mechanical portion of the recovery time associated with replacing a failed circuit card.

- Static wrist strap: 120 seconds.
- Bolts and screws with captive nut: Remove 15 seconds; replace 30 seconds.
- Bolts and screws with loose nut: Remove 30 seconds; replace 60 seconds.
- Small cables: Disconnect 15 seconds; reconnect 60 seconds.
- Circuit card: Remove 30 seconds; insert 120 seconds.

Readiness calculations are meaningful for items with replaceable parts only when failure modes have adequate coverage.

$$Coverage > Readiness$$

Coverage

Maintenance coverage evaluates the proportion of faults detected by CBM and PMS.

$$Coverage = \frac{Faults\ Detected\ By\ CBM + Faults\ Detected\ By\ PMS}{Total\ Possible\ Faults}$$

A rough estimate of coverage can be made by observing the ratio between operational failures and maintenance actions.

$$Coverage \approx \frac{Total\ Faults\ Excluding\ Operational\ Failure}{Total\ Faults\ Including\ Operational\ Failure}$$

Availability calculations, readiness calculations, and related claims are only valid if coverage exceeds availability.

AUTOCODING

OAL Autocoding with Cognex.

Autocoding refers to software solutions that help manufacturers, particularly those in the food industry, ensure that products have the correct packaging and correct 'sell by' date codes, thereby reducing the number of Emergency Product Withdrawals (EPW). The term was first used during an initiative between Geest PLC and Tesco PLC in 2001.

The key objective of the software was to reduce the number of EPW's associated with date and price coding errors, and pot and lid marriage errors. This still remains the main objective of autocoding software, but functionality has been expanded to encompass quality assurance and OEE performance data.

System Elements

All autocoding systems comprise a products database which contains standard reference information for each product including packaging type, labels and sell by date criteria. In most cases a touch screen industrial PC is positioned on the shop-floor to allow the operator to select the next product from a product schedule.

1D and 2D Barcode Scanning

The shop-floor touch screen device is linked to barcode scanners deployed to scan the code on each piece of packaging, including promotional labels and sleeves. Originally the bar codes scanned were based on standard 1D codes but to avoid mistakes 2D bar codes were introduced in 2004 so that each packaging type could hold a unique identity. To checks that the scanners are operational Autocoding solutions include two way communications with all hardware devices, or prevent the lines starting if links are not available.

Date Code Printing

To ensure that 'sell by dates' are accurate, most autocoding systems directly control the line printers through the software application. Once the operator has selected the product to run, the product reference table identifies the date range to use and the printer output is sent directly to the printer. Again, like the bar code scanners, autocoding systems include two-way communications with date code printers, and prevent the production lines from starting if links are not available.

Line Stops

OAL Autocoding system line stops.

If any error is detected, such as wrong film/pack, wrong lid, wrong case, or printer fault, the line is stopped. This is a standard requirement and is achieved through the use of PLCs.

PROGRAM ASSURANCE

Program assurance is a systematic approach to measure the likelihood of success of a program and proposing improvements that will ensure success.

It is used for:

- Performing internal and independent reviews and assessments for program performance.
- Ensuring implementation of robust risk management to address potential problems before they occur.

Program assurance also:

- Performs independent technical assessments of the systems engineering, quality assurance, lessons learned, technologies, production, and programmatic practices (cost, schedule, performance, quality, risk).
- Systematically performs independent assessments for overall mission-assured success.
- Monitors and measures a system safety program/process to determine its effectivemenss.
- Monitors and measures QA to assure implementation and determine effectiveness.
- Assures a supplier quality assurance system, practice, or process is defined and implemented.

For large programs assurance is generally independent. It may be undertaken by an external body or an internal department that reports independently from the program manager. In both cases it generally provides an independent view of the program status to the program board or executive. For smaller programs program assurance may be undertaken from within the program or report into a portfolio office.

The key difference between program assurance and program quality management or audit, is that program assurance tends to look at the potential impact of the program's approach.

Assurance may either focus on program delivery, program solutions or both may have equal weight. Within major IT programs external assurance often focuses on program delivery and would concentrate on program plans and capability. Where assurance also covers the solution this would include the business processes, systems, infrastructure, service and hosting. Solution may also cover the approach to design, delivery and implementation.

Program assurance tends to cover three separate styles of assurance: Continuous assurance throughout the life of the program; Point reviews or periodic reviews; focused reviews that concentrate on a particular aspect of a program. For very large programs all three would be undertaken with continuous assurance reporting to the program board on a regular basis, and point or focused reviews being undertaken at strategic points.

QUALITY TEST METHOD

For every manufacturer, quality assurance is an important part of building a reputable brand and gaining the trust of customers. While quality standards vary from one industry to another, the means for testing product quality are fairly standard. There are

many different types of quality control and by taking multiple steps to check quality, companies can increase their chances of becoming known for offering consistently reliable products. This can, in turn, result in an increase in return customers as well as word-of-mouth marketing.

Company Quality Check Policy

One of the best overall quality control methods is to institute a company-wide quality control policy. This policy should make it clear that product quality is a high priority, and should assign employees tasks for checking product quality at all stages, from design to manufacture and finishing. Giving employees a convenient means of reporting quality problems or defects can lead to early detection and can save money in the long term. After all, it is far more inexpensive to fix a problem with a design at the design stage than repairing or fully discarding completed products with a built-in design.

Prototype Quality Testing

Testing prototypes is a quality checking method that relies on real-world testing by employees and their families, or by potential customers selected from the general public. Prototype products should be as close as possible to production versions, and users should be asked to fill out surveys or report problems with the product.

For example, if you own a shoe company and want to ensure that your shoes will hold up to real world conditions, you can send employees home with pairs for themselves and their families. After a set period, for example, a month or three months, ask them to bring the shoes back in and answer some survey questions about how often they wore them, what activities they performed in them and how comfortable and supportive they found the shoes.

Failure or Stress Testing

Failure testing, or stress testing, is one of the most common quality check methods for industrial products. Factories often contain a special area for failure testing, where products are subjected to repeated use and misuse until they fail in some way.

This testing can include subjecting the products to extreme temperatures, submerging electronic devices in water, and crushing or dropping products. Mattress testing, for example, involves repeatedly pressing weights on the mattress to see how it will hold up to wear after a long period.

Failure testing not only gives manufacturers an idea of how much a product can endure, but also gives them knowledge about what the form the failure will take and whether or not the broken product will represent a safety risk.

Manufacturing Quality Inspections

Continuous quality checking should also occur at the point of manufacturing. Employees who perform quality checks in a factory may look for defects at several stages of production, or check random samplings of products at the end of the process. Measuring tools can serve to check whether products meet certain quality standards in terms of size or shape, and a simple visual inspection can ensure that no severely flawed products leave the factory.

EXTERNAL QUALITY ASSURANCE

External quality assurance seeks to ensure that assessment and internal quality assurance activities have been conducted in a consistent, safe and fair manner. The process must take place on behalf of an awarding organisation (AO) for each accredited centre which offers their qualifications. This is to ensure the learners who have been registered with them have received a quality service, and that the assessment and IQA decisions are valid and reliable.

Possible Risks

As an external quality assurer only samples activities, there is the possibility some aspects might be missed, however, EQAs are very thorough and often get a 'sense' of what is not right.

There are risks involved and these should be considered when planning an EQA sampling strategy. For example, a high turnover of staff or certificates claimed in short periods of time.

An external quality assurer (EQA) should look out for:

- Appeals and complaints.
- Achievement (or not) of previous action and improvement points.
- Assessment methods used and types of evidence provided by learners.
- Assessor expertise, knowledge and competence, whether new, experienced, qualified or working towards an assessor/IQA qualification (staff should have appropriate job descriptions and partake in CPD).
- Assessors (or teachers/trainers) who assess the same subject but with different groups of learners.
- Authenticity of learners' work.

- Case-loads and pressures of work placed upon staff, for example, expected targets to be met, funding based on achievements, staff having unclear roles.
- Changes to qualifications, standards, documents, policies and procedures, and records.
- Language barriers.
- Locations and distance of learners, assessors and internal quality assurers.
- Numbers of learners and how quick (or how long) they take to achieve.
- Possible plagiarism by learners.
- Previous risk rating of the centre.
- Reliability of witnesses, if used, and how they are supported.
- Turnover of staff.
- Type of qualification or programme being assessed, problem areas or units.
- Use of appropriate holistic assessments and recognition of prior learning.
- Use of technology and its reliability in assessment and IQA.
- Whether evidence and records are manual or electronic.
- Whether the learners have been registered with the awarding organisation and when (an external quality assurer should not sample from a learner who is not registered).

Areas where Malpractice could Occur in Centres

- An internal quality assurer overruling an assessor (perhaps due to pressures to meet targets) when the assessor did not pass the learner.
- Assessment records being completed and signed when assessments did not take place.
- Certificates being claimed for learners who do not exist, or who have not yet completed.
- Dates of commencement and achievement not agreeing with those that the learners state, or as noted in records.
- Dates on centre records not matching those when the activities took place.
- Learners' work and supporting records which are not available, belong to someone else, or have missing items.

- Minutes of meetings being produced when they didn't actually take place.
- Signatures on documents not matching those of the people concerned.
- Standardization records being completed for activities that did not take place.

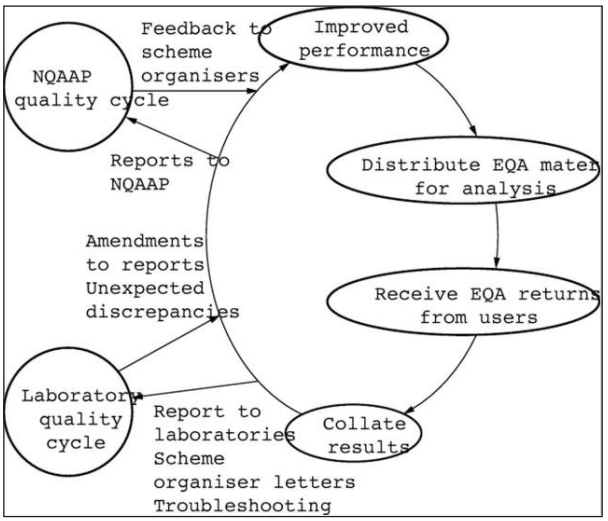
Management of External Quality Assurance

The term "External Quality Assurance (EQA)" has a variety of possible definitions.1 Perhaps the most all embracing definition of quality in healthcare is one of the earliest from Donabedian2: "The managed process whereby the comparison of care (in the present context, laboratory results) against predetermined standards is guaranteed to lead to action to implement changes, and ensuring that these have produced the desired improvement".

Donabedian's definition by implication outlines the cyclical nature of quality improvement.

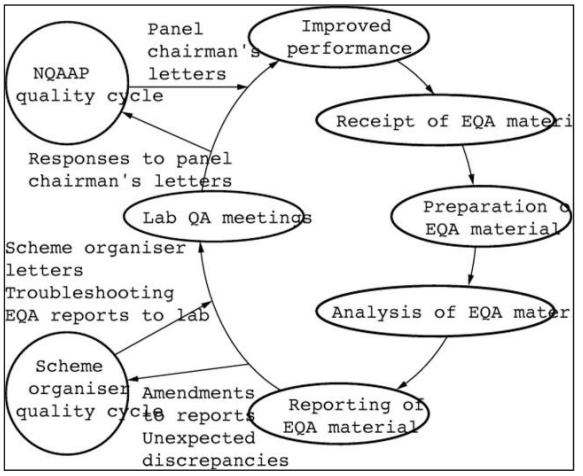
> "Management can have measurable effects on performance—an aspect that is usually only appreciated when things go wrong."

We need to apply the broadest use of this definition to laboratory practice to ensure that its benefits are passed on to patient care in the form of more reliable results. The traditional subdivision of laboratory practice into its service elements of preanalytical, analytical, and postanalytical phases is insufficient to describe laboratory practice as influenced by EQA. The substance and style of laboratory management will have influence beyond these phases on the ability of the laboratory to deliver a reliable service to patients. Management can have measurable effects on performance—an aspect that is usually only appreciated when things go wrong.

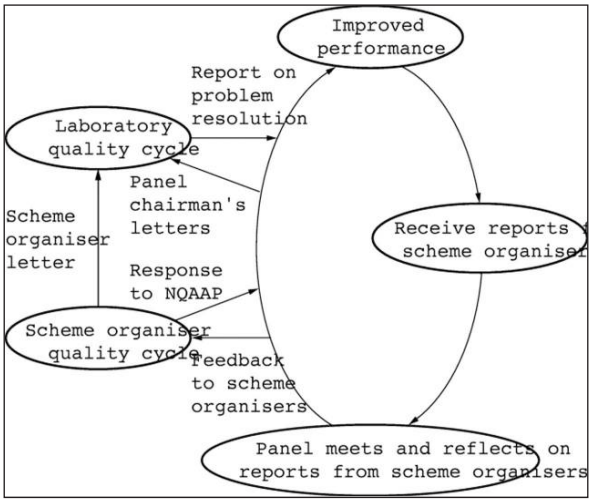


Scheme organiser quality cycle. EQA, external quality assurance; NQAAP, National Quality Assurance Advisory Panels; QA, quality assurance.

Any interpretation of such a definition implies an audit cycle of continuous improvement. Each stage in the process of EQA can be held to have its own cycle.



Laboratory quality cycle. EQA, external quality assurance; NQAAP, National Quality Assurance Advisory Panels.



National Quality Assurance Advisory Panels' (NQAAP) quality cycle.

Common to all schemes is the circulation of material to enable interlaboratory comparisons. This material may be derived entirely or partially from human or other mammalian sources, and is typically in lyophilised or liquid form. The interpretation of data generated from measurements on this material may itself be treated by some schemes as EQA material. A scheme is being piloted that circulates clinical and laboratory data for interpretation by laboratories or individuals. This raises important clinical governance issues, which will be dealt with later.

The responsiveness and relevance of any scheme to clinical practice is dependent on the dynamics between those involved in the day to day running of the scheme (which for convenience we will wrap up in the title of "scheme organiser") and, in the case of

the UK, the steering group composed of independent experts who guide the scheme and help to provide professional accountability. The scheme organiser quality cycle) incorporates those elements of direct laboratory contact with the scheme, namely the receipt of EQA material and of the report after data processing. These points of contact are the yardstick by which the laboratory judges the value of the scheme as a tool for performance improvement and education. Most scheme organisers are only too happy to be proactive in helping their users through these processes.

The laboratory quality cycle is more reactive in that the user awaits prompts from the scheme organiser, awaiting either EQA material for analysis or the scheme's report, which may require remedial action.

The NQAAP quality cycle is also reactive, in that the panels rely on the candour of the scheme organisers when identifying poor performers in situations where the panels need to exercise judgement as to the corrective response required. The confidential nature of these relationships, a feature of EQA schemes in the UK since their inception, has never been challenged, and is an obvious source of sensitivity within the laboratory community. With increasing moves towards transparency and visible public accountability, there will be pressure to relinquish this feature in the future.

One can describe further cyclical interactions at each end of the chain. Thus, the laboratory cycle should link in with directorate of pathology and thence trust level clinical governance procedures. The NQAAP cycle reports to the Joint Working Group on Quality Assurance (JWG), a body composed principally of panel chairs, with its own chair appointed by the Royal College of Pathologists. The panels interact with accrediting bodies in their approval of the schemes themselves.

Effective EQA is clearly not just a matter of accuracy and precision at the bench, nor simply one of application of interlaboratory data to improve these parameters. It requires integrity (in every sense) in all the elements of its organisation. We need to look at the audit cycles more closely to see how variations in different parts of the process can affect the perception of laboratory performance and its contribution to patient care.

Scheme Organiser Quality Cycle

Many aspects of scheme design can affect the external assessment of laboratory performance. Although it is usually impracticable for the frequency of distribution of specimens to reflect clinical practice, it should be frequent enough to identify problem trends in seldom requested analytes, such as trace metals and vitamins. EQA schemes need to circulate material with sufficient frequency to identify those laboratories that perform poorly because infrequent batches are giving them insufficient opportunity to maintain the analytical skills required in these often challenging assays. A good scheme will also circulate material with concentration pitched to examine clinical decision levels, in addition to technical issues that inform clinical usefulness, such as linearity and detection limits.

The scheme should ensure that despatch arrangements are appropriate for preservation of specimens. Schemes should allow laboratories sufficient time for analysis and reporting, and have a clear policy on accepting late submissions and amendments for whatever reason.

Scheme organisers need to provide clear reports to users as to their performance and resist the temptation to overload users with information simply because the technology exists to provide enormous amounts of data. Web based solutions are proving a popular tool to shorten lines of communication and reduce the cost of reporting by conventional mail. However, they are not always as easy to use as might be anticipated, particularly where hard copy is required. Laboratories should check that they have the processing and printing technology to reproduce the reports correctly before committing to such a system.

> "Scheme organisers need to provide clear reports to users as to their performance."

Problems arise as a result of failures of the "manufacturer quality cycle" for reagents or the EQA material itself, outside the control of the schemes and their users. These can be method related (the result of a reagent manufacturing defect) or matrix related (the result of differences between the EQA material and human samples). Both users and schemes need to be aware of these pitfalls, which by their nature can take some time to become evident and longer to investigate and resolve. Method related changes are clinically important when the variation crosses decision cutoff points; hence the importance of schemes addressing performance in these areas. The performance in some assays, particularly immunochemical methods, has given sufficient concern for guidelines to be drawn up whereby a poorly performing method can be drawn to the attention of The Medicines and Healthcare Products Regulatory Agency. The guidelines have been ratified by the JWG for further promulgation. Problems can arise as a result of single assay manufacturing failure or problems inherent in the assay technology used. These second types of problem are particularly intractable, which is not surprising in view of the enormous sums invested in developments that manufacturers are unwilling to recognise as flawed after they reach the commercial market.

Matrix issues may not just be limited to the difference between circulated EQA and human material, but may be dependent on the interaction between the EQA sample and its container. Thus, unexpectedly low salicylate results in one scheme were found to result from interactions between the EQA material and the O ring sealing the cap of the container in which the material was circulated.

Schemes should agree criteria for poor performance for ratification by the NQAAP. The application of these criteria will always be subject to judgement based on assay characteristics and clinical usefulness. For example, there is an obvious requirement for the criteria for sodium to be tighter than—for example, those for vitamin E. Automation

has improved the performance of assays over the years. Wider limits are to be expected with newer assays or where multistep methodology, often not lending itself to automation, is inherently less accurate and precise.

One criterion is that of non-participation. A laboratory that fails to return results can clearly be held to be in breach of performance limits after failure to return the results of two or three successive distributions, dependent on the frequency of these distributions. Reasons for this can vary from staff illness or poor communication to equipment failure, and require attention from the scheme organiser at an early stage if the clinical service is not to be compromised. Migration between schemes is a recognised ploy for maintaining the semblance of acceptable performance ("we've only just joined, so that's why our performance is substandard"). Clearly, in such cases performance will constantly be substandard, hence the existence of monitoring mechanisms at scheme organiser/NQAAP level for addressing these problems.

Finally, part of the activity of scheme organisers is to promote participation in schemes so that laboratories that offer a clinical service for any given analyte subscribe to the EQA scheme for that analyte where one exists.

NQAAP Quality Cycle

The principal functions of an NQAAP involve elements of both professional self regulation (in respect of scrutiny of laboratory performance) and public accountability (in respect of poor performance).

The panel relies on detailed scheme organiser reports. The quality of the information exchange between the scheme organiser and the panel in this cycle is vital to the outcome.

Assay performance has to fail to meet established performance criteria before the panel becomes involved. Where reporting arrangements are robust and these criteria are clear and explicit, the panel is able to ensure a continued quality service to patients. Sometimes this involves communication between panels, particularly where a single diagnostic procedure involves more than one discipline, such as establishing best practice for the examination of cerebrospinal fluid for haem pigments, which is performed in some microbiology and chemical pathology departments after lumbar puncture.

> "Assay performance has to fail to meet established performance criteria before the panel becomes involved."

EQA in the UK has from its outset been based on educational support from scheme organisers for users with problems, made easier by the confidentiality afforded by the relationships between the laboratories, the schemes, and the panel. Professional misconduct and negligence, particularly in pathology, has in recent years attracted unprecedented media interest and government scrutiny. As a result of this, the challenge

to professional self regulation is to increase the transparency of EQA procedures while keeping laboratories involved. Although very few of the schemes are run as profit centres, they are all businesses that have an understandable interest in preserving and expanding their customer base to ensure continued viability. One way of doing this might be to shield the panel from individual problems. This runs counter to current trends and the result would be inadequate panel input into problems, with an increased risk of their being prolonged and a concomitant risk to patient care.

For their part, the panels have to respond to scheme organisers comprehensively and in an appropriate time frame. An important panel function is to spot method failure across schemes and laboratories measuring the same analyte by the same method. The panel is in a unique position to do this, and this can serve as an early warning system for method related changes in performance.

Quality Standards

CHAPTER 6

Quality management standards are the guidelines, requirements and specifications needed by a product to ensure its quality. It includes ISO 9000, ISO 9001, ISO 9002, ISO 14001, IATF 16949, etc. This chapter sheds light on these different quality standards for a thorough understanding of the subject

Quality standards are defined as documents that provide requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose.

Standards provide organizations with the shared vision, understanding, procedures, and vocabulary needed to meet the expectations of their stakeholders. Because standards present precise descriptions and terminology, they offer an objective and authoritative basis for organizations and consumers around the world to communicate and conduct business.

Who uses Quality Standards?

Organizations turn to standards for guidelines, definitions, and procedures that help them achieve objectives such as:

- Satisfying their customers' quality requirements.

- Ensuring their products and services are safe.
- Complying with regulations.
- Meeting environmental objectives.
- Protecting products against climatic or other adverse conditions.
- Ensuring that internal processes are defined and controlled.

Use of quality standards is voluntary, but may be expected by certain groups of stakeholders. Additionally, some organizations or government agencies may require suppliers and partners to use a specific standard as a condition of doing business.

Importance of Standards

For businesses: Standards are important to the bottom line of every organization. Successful companies recognize standards as business tools that should be managed alongside quality, safety, intellectual property, and environmental policies. Standardization leads to lower costs by reducing redundancy, minimizing errors or recalls, and reducing time to market.

For the global economy: Businesses and organizations complying to quality standards helps products, services, and personnel cross borders and also ensures that products manufactured in one country can be sold and used in another.

For consumers: Many quality management standards provide safeguards for users of products and services, but standardization can also make consumers' lives simpler. A product or service based on an international standard will be compatible with more products or services worldwide, which increases the number of choices available across the globe.

TRANSLATION-QUALITY STANDARDS

Like any supplier of goods or services, a translator potentially bears ethical and legal obligations toward his patron or employer. This has turned to be of enormous importance with the development of the language industry at global scale. For the protection of both parties, standards have been developed that seek to spell out their mutual duties.

Standards of quality and documentation were originally developed for manufacturing businesses. Codes for all types of services are now maintained by standardization organizations such as the International Organization for Standardization. Standards of this type include those of the ISO 9000 series.

As interest in quality management has grown, specific quality standards have been developed for translation services. These have included the Italian UNI 10574, the

German DIN 2345, the Austrian Önorm D 1200 and Önorm D 1201, and the Canadian CAN CGSB 131.10.

EN 15038

The European EN 15038 translation-services standard went into effect, replacing the previous standards of the 30 individual CEN member countries. It aims to unify the terminology used in the translation field, define basic requirements for language-service providers (human and technical resources, quality control, and project management) and create a framework for the interaction of customers and service providers in terms of their rights and obligations. It also defines certain services, in addition to translation, that may be offered by language-service providers.

A strong focus is on administrative, documentation, review and revision processes, as well as on the functions of different specialists who guide the translation project over its duration. Appendices to the standard provide information and suggestions on how best to comply with the standard.

CAN CGSB 131.10-2008

The Language Industry Association of Canada, AILIA launched the latest standards certification program in the world. The certification is based on CAN/CGSB-131.10-2008, Translation Services, a national standard developed by the Canadian General Standards Board and approved by the Standards Council of Canada. It involved the participation of representatives from AILIA, professional associations, government, academia, purchasers of service, and other stakeholders.

The Canadian Standard for Translation Services CAN CGSB 131.10 - 2008 establishes and defines the requirements for the provision of translation services by translation service providers.

This National Standard of Canada is a modified adoption of the European Committee for Standardization (CEN) standard EN 15038 Translation Services. This document was prepared with the intent to harmonize where possible with the provisions of EN 15038 Translation Services. Variances in wording and content with EN 15038 reflect the Canadian perspective.

Conformity assessment and certification based on this standard are already in place. With the recent development of national and regional standards for translation services, many translation service providers, nationally and internationally, are now in the process of either considering or seeking certification of the services they provide in meeting the demands of the marketplace.

The standard specifies the requirements for the provision of translation services by the translation service provider (TSP).

There are three key points common to all standards:

- Select your human resources with care.
- Come to an agreement on your project specifications before translation begins.
- Follow the specifications at every step of the project.

The CGSB 131.10 discuss the following:

- Scope.
- Definitions.
- Human Resources.
- Technical Resources.
- Quality Management System.
- Client-TSP Relationship.
- TSP Project Management Procedures.
- Translation Process.
- Notes.
- Appendixes:
  - Project Recording.
  - Pre-Translation Processing.
  - Additional Services.

The standard does not apply to interpreting or terminology services.

ASTM F2575-06

The American translation-services standard is the ASTM F2575-06 Standard Guide for Quality Assurance in Translation. It provides a framework for customers and translation-service providers desirous of agreeing on the specific requirements of a translation project. It does not provide specific criteria for translation or project quality, as these requirements may be highly individual, but states parameters that should be considered before beginning a translation project. As the document's name suggests, it is a guideline, informing stakeholders about what basic quality requirements are in need of compliance, rather than a prescriptive set of detail instructions for the translator.

Criticism: Over-dependence on Standards

There is, however, a view within the translation industry that, while not doing any

actual harm, an over-reliance on such standards can give a false sense of security. Blindly following translation standards does not on its own provide real assurance regarding translation quality. The argument is that the path to quality in translation is by focusing more on providing on-going training and feedback to translators.

ISO STANDARDS

ISO 9000

The ISO 9000 family of quality management systems (QMS) is a set of standards that helps organizations ensure they meet customers and other stakeholder needs within statutory and regulatory requirements related to a product or service. ISO 9000 deals with the fundamentals of quality management systems, including the seven quality management principles that underlie the family of standards. ISO 9001 deals with the requirements that organizations wishing to meet the standard must fulfill.

Third-party certification bodies provide independent confirmation that organisations meet the requirements of ISO 9001. Over one million organisations worldwide are independently certified, making ISO 9001 one of the most widely used management tools in the world today. However, the ISO certification process has been criticised as being wasteful and not being useful for all organizations.

ISO 9000 was first published in 1987 by ISO (International Organisation for Standardization). It was based on the BS 5750 series of standards from BSI that were proposed to ISO in 1979. However, its history can be traced back some twenty years before that, to the publication of government procurement standards, such as the United States Department of Defense MIL-Q-9858 standard in 1959, and the UK's Def Stan 05-21 and 05-24. Large organizations that supplied government procurement agencies often had to comply with a variety of quality assurance requirements for each contract awarded, which led the defense industry to adopt mutual recognition of NATO AQAP, MIL-Q, and Def Stan standards. Eventually, industries adopted ISO 9000 instead of forcing contractors to adopt multiple—and often similar—requirements.

Reasons for Use

The global adoption of ISO 9001 may be attributable to a number of factors. In the early days, the ISO 9001 (9002 and 9003) requirements were intended to be used by procuring organizations as the basis of contractual arrangements with their suppliers. This helped reduce the need for "supplier development"by establishing basic requirements for a supplier to assure product quality. The ISO 9001 requirements could be tailored

to meet specific contractual situations, depending on the complexity of product, business type (design responsibility, manufacture only, distribution, servicing etc.) and risk to the procurer. If a chosen supplier was weak on the controls of their measurement equipment (calibration), and hence QC/inspection results, that specific requirement would be invoked in the contract. The adoption of a single quality assurance requirement also leads to cost savings throughout the supply chain by reducing the administrative burden of maintaining multiple sets of quality manuals and procedures.

A few years later, the UK Government took steps to improve national competitiveness following publication of cmd 8621, and Third Party Certification of Quality Management Systems was born, under the auspices of the National Accreditation Council of Certification Bodies (NACCB), which has become the United Kingdom Accreditation Service (UKAS).

In addition to many stakeholders' benefits, a number of studies have identified significant financial benefits for organizations certified to ISO 9001, with an ISO analysis of 42 studies showing that implementing the standard does enhance financial performance. Corbett et al. showed that certified organizations achieved superior return on assets compared to otherwise similar organizations without certification.

Heras et al. found similarly superior performanceand demonstrated that this was statistically significant and not a function of organization size. Naveha and Marcus claimed that implementing ISO 9001 led to superior operational performance in the U.S. automotive industry. Sharma identified similar improvements in operating performance and linked this to superior financial performance. Chow-Chua et al. showed better overall financial performance was achieved for companies in Denmark. Rajan and Tamimi showed that ISO 9001 certification resulted in superior stock market performance and suggested that shareholders were richly rewarded for the investment in an ISO 9001 system.

While the connection between superior financial performance and ISO 9001 may be seen from the examples cited, there remains no proof of direct causation, though longitudinal studies, such as those of Corbett et al. may suggest it. Other writers, such as Heras et al. have suggested that while there is some evidence of this, the improvement is partly driven by the fact that there is a tendency for better performing companies to seek ISO 9001 certification.

The mechanism for improving results has also been the subject of much research. Lo et al. identified operational improvements (e.g., cycle time reduction, inventory reductions) as following from certification. Internal process improvements in organizations lead to externally observable improvements. The benefit of increased international trade and domestic market share, in addition to the internal benefits such as customer satisfaction, interdepartmental communications, work processes, and customer/supplier partnerships derived, far exceeds any and all initial investment.

ISO 9000 Series Quality Management Principles

The ISO 9000 series are based on seven quality management principles (QMP). The seven quality management principles are:

- QMP 1 – Customer focus.
- QMP 2 – Leadership.
- QMP 3 – Engagement of people.
- QMP 4 – Process approach.
- QMP 5 – Improvement.
- QMP 6 – Evidence-based decision making.
- QMP 7 – Relationship management.

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 – Engagement 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.

Principle 4 – Process approach: A desired result is achieved more efficiently when activities and related resources are managed as a process.

Principle 5 – Improvement: Improvement of the organization's overall performance should be a permanent objective of the organization.

Principle 6 – Evidence-based decision making: Effective decisions are based on the analysis of data and information.

Principle 7 – Relationship management: An organization and its external providers (suppliers, contractors, service providers) are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Contents of ISO 9001:2015

ISO 9001:2015 Quality management systems — Requirements is a document of approximately 30 pages available from the national standards organization in each country. Only ISO 9001 is directly audited against for third party assessment purposes.

A fish wholesaler in Tsukiji, Japan advertising its ISO 9001 certification.

Contents of ISO 9001:2015 are as follows:

- Section 1: Scope.
- Section 2: Normative references.
- Section 3: Terms and definitions.
- Section 4: Context of the organization.
- Section 5: Leadership.
- Section 6: Planning.
- Section 7: Support.
- Section 8: Operation.
- Section 9: Performance evaluation.
- Section 10: Continual Improvement.

Essentially, the layout of the standard is similar to the previous ISO 9001:2008 standard in that it follows the Plan, Do, Check, Act cycle in a process-based approach but is now further encouraging this to have risk-based thinking. The purpose of the quality objectives is to determine the conformity of the requirements (customers and organizations), facilitate effective deployment and improve the quality management system.

Before the certification body can issue or renew a certificate, the auditor must be satisfied that the company being assessed has implemented the requirements of sections 4

to 10. Sections 1 to 3 are not directly audited against, but because they provide context and definitions for the rest of the standard, not that of the organization, their contents must be taken into account.

The standard no longer specifies that the organization shall issue and maintain documented procedures, however, ISO 9001:2015 requires the organization to document any other procedures required for its effective operation. The standard also requires the organization to issue and communicate a documented quality policy, a quality management system scope, and quality objectives. The standard no longer requires compliant organizations to issue a formal Quality Manual. The standard does require retention of numerous records, as specified throughout the standard. New for the 2015 release is a requirement for an organization to assess risks and opportunities and to determine internal and external issues relevant to its purpose and strategic direction. The organization must demonstrate how the standard's requirements are being met, while the external auditor's role is to determine the quality management system's effectiveness. More detailed interpretation and implementation examples are often sought by organizations seeking more information in what can be a very technical area.

Auditing

Two types of auditing are required to become registered to the standard: auditing by an external certification body (external audit) and audits by internal staff trained for this process (internal audits). The aim is a continual process of review and assessment to verify that the system is working as it is supposed to, to find out where it can improve, and to correct or prevent identified problems. It is considered healthier for internal auditors to audit outside their usual management line, so as to bring a degree of independence to their judgements.

Industry-specific Interpretations

The ISO 9001 standard is generic; its parts must be carefully interpreted to make sense within a particular organization. Developing software is not like making cheese or offering counseling services, yet the ISO 9001 guidelines, because they are business management guidelines, can be applied to each of these. Diverse organizations—police departments (United States), professional soccer teams (Mexico), and city councils (UK)—have successfully implemented ISO 9001:2000 systems.

Over time, various industry sectors have wanted to standardise their interpretations of the guidelines within their own marketplace. This is partly to ensure that their versions of ISO 9000 have their specific requirements, but also to try and ensure that more appropriately trained and experienced auditors are sent to assess them.

- The TickIT guidelines are an interpretation of ISO 9000 produced by the UK Board of Trade to suit the processes of the information technology industry, especially software development.

- AS9000 is the Aerospace Basic Quality System Standard, an interpretation developed by major aerospace manufacturers. Those major manufacturers include AlliedSignal, Allison Engine, Boeing, General Electric Aircraft Engines, Lockheed-Martin, McDonnell Douglas, Northrop Grumman, Pratt & Whitney, Rockwell-Collins, Sikorsky Aircraft, and Sundstrand. The current version is AS9100D.
- PS 9000 QS 9000 is an interpretation agreed upon by major automotive manufacturers (GM, Ford, Chrysler). It includes techniques such as FMEA and APQP. QS 9000 is now replaced by ISO/TS 16949.
- ISO/TS 16949:2009 is an interpretation agreed upon by major automotive manufacturers (American and European manufacturers); the latest version is based on ISO 9001:2008. The emphasis on a process approach is stronger than in ISO 9001:2008. ISO/TS 16949:2009 contains the full text of ISO 9001:2008 and automotive industry-specific requirements. After the new edition of ISO 9001:2015 the ISO/TS 16949:2009 was also completely revised and reissued by IATF (International Automotive Task Force) IATF 16949:2016 is now a stand-alone standard that doesn't include the ISO 9001:2015 requirements, but still refers to them and works as additional automotive specific requirement to ISO 9001.
- TL 9000 is the Telecom Quality Management and Measurement System Standard, an interpretation developed by the telecom consortium, QuEST Forum. In 1998 QuEST Forum developed the TL 9000 Quality Management System to meet the supply chain quality requirements of the worldwide telecommunications industry. The TL 9000 standard is made up of two handbooks: the QMS Requirements Handbook, and the QMS Measurement Handbook. The current versions of the Requirements and Measurements Handbooks are 6.0. Unlike ISO 9001 or other sector-specific standards, TL 9000 includes standardized product and process measurements that must be reported into a central repository, which allows organizations to benchmark their performance in key process areas against peer organizations. It is important to note that TL 9000 R6.0 contains the full text of ISO 9001:2015.
- ISO 13485:2016 is the medical industry's equivalent of ISO 9001. ISO 13485:2016 is a stand-alone standard. Because ISO 13485 is relevant to medical devices manufacturers (unlike ISO 9001, which is applicable to any industry), and because of the differences between the two standards relating to continual improvement, compliance with ISO 13485 does not necessarily mean compliance with ISO 9001 (and vice versa).
- ISO/IEC 90003:2014 provides guidelines for the application of ISO 9001 to computer software.

- ISO/TS 29001 is quality management system requirements for the design, development, production, installation, and service of products for the petroleum, petrochemical, and natural gas industries. It is equivalent to API Spec Q1 without the Monogram annex.
- ISO 22000 Food Safety Management Systems.
- ISO 17025:2017 is the Quality Management System applicable only to Testing and Calibration Laboratories.

Effectiveness

The debate on the effectiveness of ISO 9000 commonly centres on the following questions:

- Are the quality principles in ISO 9001 of value?
- Does it help to implement an ISO 9001-compliant quality management system?
- Does it help to obtain ISO 9001 certification?

The effectiveness of the ISO system being implemented depends on a number of factors, the most significant of which are:

- Commitment of senior management to monitor, control, and improve quality. Organizations that implement an ISO system without this desire and commitment often take the cheapest road to get a certificate on the wall and ignore problem areas uncovered in the audits.
- How well the ISO system integrates into current business practices. Many organizations that implement ISO try to make their system fit into a cookie-cutter quality manual instead of creating a manual that documents existing practices and only adds new processes to meet the ISO standard when necessary.
- How well the ISO system focuses on improving the customer experience. The broadest definition of quality is "Whatever the customer perceives good quality to be." This means that a company doesn't necessarily have to make a product that never fails; some customers have a higher tolerance for product failures if they always receive shipments on-time or have a positive experience in some other dimension of customer service. An ISO system should take into account all areas of the customer experience and the industry expectations, and seek to improve them on a continual basis. This means taking into account all processes that deal with the three stakeholders (customers, suppliers, and organization). Only then can a company sustain improvements in the customer's experience.
- How well the auditor finds and communicates areas of improvement. While ISO auditors may not provide consulting to the clients they audit, there is the

potential for auditors to point out areas of improvement. Many auditors simply rely on submitting reports that indicate compliance or non-compliance with the appropriate section of the standard; however, to most executives, this is like speaking a foreign language. Auditors that can clearly identify and communicate areas for improvement in language and terms executive management understands facilitate action on improvement initiatives by the companies they audit. When management doesn't understand why they were non-compliant and the business implications associated with non-compliance, they simply ignore the reports and focus on what they do understand.

Advantages

Proper quality management can improve business, often having a positive effect on investment, market share, sales growth, sales margins, competitive advantage, and avoidance of litigation. The quality principles in ISO 9000:2000 are also sound, according to Wade and Barnes, who says that "ISO 9000 guidelines provide a comprehensive model for quality management systems that can make any company competitive". Sroufe and Curkovic, found benefits ranging from registration required to remain part of a supply base, better documentation, to cost benefits, and improved involvement and communication with management. According to ISO the 2015 version of the standard brings the following benefits:

- By assessing their context, organizations can define who is affected by their work and what they expect. This enables clearly stated business objectives and the identification of new business opportunities.
- Organizations can identify and address the risks associated with their organization.
- By putting customers first, organizations can make sure they consistently meet customer needs and enhance customer satisfaction. This can lead to more repeat customers, new clients and increased business for the organization.
- Organizations work in a more efficient way as all their processes are aligned and understood by everyone. This increases productivity and efficiency, bringing internal costs down.
- Organizations will meet necessary statutory and regulatory requirements.
- Organizations can expand into new markets, as some sectors and clients require ISO 9001 before doing business.

Criticisms of ISO 9001 Certification

A common criticism of ISO 9000 and 9001 is the amount of money, time, and paperwork required for a complete implementation, and later when needed; ISO 9001

certification. Dalgleish cites the "inordinate and often unnecessary paperwork burden" of ISO, and says that "quality managers feel that ISO's overhead and paperwork are excessive and extremely inefficient". The level of minimum documentation for a minimum scope organization has been greatly reduced, going from ISO 9001:2000 to ISO 9001:2008 to ISO 9001:2015.

According to Barnes, "Opponents claim that it is only for documentation. Proponents believe that if a company has documented its quality systems, then most of the paperwork has already been completed". Wilson suggests that ISO standards "elevate inspection of the correct procedures over broader aspects of quality", and therefore, "the workplace becomes oppressive and quality is not improved".

One study showing reasons for not adopting this standard include the risks and uncertainty of not knowing if there are direct relationships to improved quality, and what kind and how many resources will be needed. Additional risks include how much certification will cost, increased bureaucratic processes and risk of poor company image if the certification process fails. According to John Seddon, ISO 9001 promotes specification, control, and procedures rather than understanding and improvement. Wade argues that ISO 9000 is effective as a guideline, but that promoting it as a standard "helps to mislead companies into thinking that certification means better quality, ... [undermining] the need for an organization to set its own quality standards". In short, Wade argues that reliance on the specifications of ISO 9001 does not guarantee a successful quality system.

The standard is seen as especially prone to failure when a company is interested in certification before quality. Certifications are in fact often based on customer contractual requirements rather than a desire to actually improve quality. "If you just want the certificate on the wall, chances are you will create a paper system that doesn't have much to do with the way you actually run your business", said ISO's Roger Frost. Certification by an independent auditor is often seen as the problem area, and according to Barnes, "has become a vehicle to increase consulting services".

Dalgleish argues that while "quality has a positive effect on return on investment, market share, sales growth, better sales margins and competitive advantage," "taking a quality approach is unrelated to ISO 9000 registration." In fact, ISO itself advises that ISO 9001 can be implemented without certification, simply for the quality benefits that can be achieved.

Abrahamson argues that fashionable management discourse such as Quality Circles tends to follow a lifecycle in the form of a bell curve, possibly indicating a management fad.

Pickrell argues that ISO systems merely gauge whether the processes are being followed. It does not gauge how good the processes are or whether the correct parameters are being measured and controlled to ensure quality. Furthermore, when unique

technical solutions are involved in the creation of a new part, ISO does not validate the robustness of the technical solution—a key part of advanced quality planning. It is not unheard of for an ISO-certified plant to display poor quality performance due to poor process selection and/or poor technical solutions.

ISO 9001

The ISO 9000 family addresses various aspects of quality management and contains some of ISO's best known standards.

ISO 9001 is defined as the international standard that specifies requirements for a quality management system (QMS). Organizations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements. It is the most popular standard in the ISO 9000 series and the only standard in the series to which organizations can certify.

ISO 9001 was first published in 1987 by the International Organization for Standardization (ISO), an international agency composed of the national standards bodies of more than 160 countries. The current version of ISO 9001 was released in September 2015.

Who should use the iso 9001:2015 Revision?

ISO 9001:2015 applies to any organization, regardless of size or industry. More than one million organizations from more than 160 countries have applied the ISO 9001 standard requirements to their quality management systems.

Organizations of all types and sizes find that using the ISO 9001 standard helps them:

- Organize processes.
- Improve the efficiency of processes.
- Continually improve.

All organizations that use ISO 9001 are encouraged to transition to ISO 9001:2015 as soon as possible. This includes not only organizations that are certified to ISO 9001:2008, but also any organizations involved in training or certifying others.

What Topics does ISO 9001:2015 Cover?

ISO 9001 is based on the plan-do-check-act methodology and provides a process-oriented approach to documenting and reviewing the structure, responsibilities, and procedures required to achieve effective quality management in an organization. Specific sections of the standard contain information on many topics, such as:

- Requirements for a quality management system, including documented information, planning and determining process interactions.

- Responsibilities of management.
- Management of resources, including human resources and an organization's work environment.
- Product realization, including the steps from design to delivery.
- Measurement, analysis, and improvement of the QMS through activities like internal audits and corrective and preventive action.

Changes introduced in the 2015 ISO 9001 revision are intended to ensure that ISO 9001 continues to adapt to the changing environments in which organizations operate. Some of the key updates in ISO 9001:2015 include:

- The introduction of new terminology.
- Restructuring some of the information.
- An emphasis on risk-based thinking to enhance the application of the process approach.
- Improved applicability for services.
- Increased leadership requirements.

The Seven Principles of ISO 9001:2015.

What are the Benefits of iso 9001?

ISO 9001 helps organizations ensure their customers consistently receive high quality products and services, which in turn brings many benefits, including satisfied customers, management, and employees.

Because ISO 9001 specifies the requirements for an effective quality management system, organizations find that using the standard helps them:

- Organize a quality management system (QMS).
- Create satisfied customers, management, and employees.
- Continually improve their processes.
- Save costs.

In Nevada, the Clark County School District used ISO 9001 to save $174 million over 10 years in actual expenditures and cost avoidance. More than 3,000 employees were trained to the standard, enabling three critical components of the system's success: training, communication and respect, and efficiency.

ISO 9001 Certification

ISO 9001 is the only standard in the ISO 9000 series to which organizations can certify. Achieving ISO 9001:2015 certification means that an organization has demonstrated the following:

- Follows the guidelines of the ISO 9001 standard.
- Fulfills its own requirements.
- Meets customer requirements and statutory and regulatory requirements.
- Maintains documentation.

Certification to the ISO 9001 standard can enhance an organization's credibility by showing customers that its products and services meet expectations. In some instances or in some industries, certification is required or legally mandated. The certification process includes implementing the requirements of ISO 9001:2015 and then completing a successful registrar's audit confirming the organization meets those requirements.

Organizations should consider the following as they begin preparing for an ISO 9001 quality management system certification:

- Registrar's costs for ISO 9001 registration, surveillance, and recertification audits.
- Current level of conformance with ISO 9001 requirements.
- Amount of resources that the company will dedicate to this project for development and implementation.
- Amount of support that will be required from a consultant and the associated costs.

ISO 9002

ISO 9002 refers to company level certification following a standard published by the International Organization for Standardization (ISO). The ISO created guidelines for quality assurance in installation, production, and service provision. The certification went through a few changes, eventually being replaced by ISO 9001: 2000, and finally ISO 9001: 2008. The attributes of ISO 9002 are similar to ISO 9001, though it does not entail the stipulations for new product development. ISO 9002 certification is not industry-specific, but it was meant for those companies which handle processing or production, provided they did not deal with patenting or new products.

What is the ISO 9002 Quality Management System?

The UK government was instrumental in sponsoring the development of the ISO 9000 series. The effort began after the country experienced several disasters in weapons factories resulting from munitions defects. It became paramount to have an independent system, which assured product quality to limit quality-related defects. When ISO standards were first introduced to the market, firms would first ascertain which criteria they would use according to the certifications.

For example, ISO 9001 was oriented to companies in the design field, while ISO 9003 catered for the firms in testing and inspection. ISO 9002 was appealing for the companies that dealt with production.

ISO 9002 guided the practices for quality assurance in production, service, and installation for 13 years from 1987 to the turn of the new century. It entailed nine sets of system requirements to ensure quality in all functions concerning the production and delivery of goods and services. It is worth noting the standard could have been used for the service sector but was instead focused on the processing and manufacturing industries.

ISO 9002 was last amended in 1994 and became the benchmark for quality in production, servicing, and installation, though it mostly had the same tenets as ISO 9001. When it was ISO 9002: 1994, it was quite relevant for contract manufacturing. Companies presently use ISO 9001, and they take exception to particular clauses within the standard involving different designs and service so it would seem ISO 9002: 1994 has become practically obsolete.

According to the ISO 9002 elements, at least 20 clauses detail the different aspects of quality assurance required for the production and installation processes. For example, clause 4.14 is for corrective and preventive action. It provides for appropriate and timely documentation concerning the corrective actions taken. To satisfy this, a company would have to create a system for these corrective actions.

ISO 9004

ISO says standard 9004-2009 "provides organizations with a model for 'sustained success'," which it defines as both producing goods and services to satisfy customers and insuring the economic survival of a business or organization. It is a tool that managers can use to identify strengths and weaknesses in organizations of any size and take specific actions as required.

Offers Suggestions

ISO 9004 is a suggestion document, offering guidance for top managers, the highest level of decision-making authority, in any size or type of organization. It suggests how to structure an enterprise to achieve its goals both in the short term and long term as situations evolve. It includes advice on monitoring and analyzing the organization's environment, external factors that may affect its success or failure. It is up to managers to implement suggestions.

Covers all Areas

The standard covers everything from personnel to financial resources. That includes such things as training, promoting teamwork and sharing of knowledge and ensuring that workers know about and are involved in achieving the objectives. Managing financial resources varies from making sure funds are available when needed to eliminating waste of time and materials or reducing failures of products or services.

Self-assessment

An important element of ISO 9004 is self-assessment, how managers can rate operations, business strategies and other factors so any part of the operation that is not functioning effectively can be corrected. That includes looking at how the organization is structured, analysis of the environment and such internal things as personnel and product or service development.

ISO 22000

ISO 22000 is a standard developed by the International Organization for Standardization dealing with food safety. It is a general derivative of ISO 9000.

Food Safety

Food safety is linked to the presence of food-borne hazards in food at the point of consumption. Since food safety hazards can occur at any stage in the food chain it is essential that adequate control be in place. Therefore, a combined effort of all parties through the food chain is required.

ISO 22000 Standard

The ISO 22000 international standard specifies the requirements for a food safety management system that involves the following elements:

- Interactive communication.
- System management.
- Prerequisite programs.
- HACCP principles.

Critical reviews of the above elements have been conducted by many scientists. Communication along the food chain is essential to ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain. This implies communication between organizations both upstream and downstream in the food chain. Communication with customers and suppliers about identified hazards and control measures will assist in clarifying customer and supplier requirements.

Recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the chain in order to deliver safe food products to the final consumer.

The most effective food safety systems are established, operated and updated within the framework of a structured management system and incorporated into the overall management activities of the organization. This provides maximum benefit for the organization and interested parties. ISO 22000 has been aligned with ISO 9001 in order to enhance the compatibility of the two standards.

ISO 22000 can be applied independently of other management system standards or integrated with existing management system requirements.

ISO 22000 integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system and application steps developed by the Codex Alimentarius Commission. By means of auditable requirements, it combines the HACCP plan with prerequisite programmes. Hazard analysis is the key to an effective food safety management system, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures. ISO 22000 requires that all hazards that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified and assessed. Thus it provides the means to determine and document why certain identified hazards need to be controlled by a particular organization and why others need not.

During hazard analysis, the organization determines the strategy to be used to ensure hazard control by combining the prerequisite programmes and the HACCP plan.

ISO is developing additional standards that are related to ISO 22000. These standards will be known as the ISO 22000 family of standards. At the present time, the following

standards will make up the ISO 22000 family of standards:

- ISO 22000: Food safety management systems - Requirements for any organization in the food chain.
- ISO 22001: Guidelines on the application of ISO 9001:2000 for the food and drink industry (replaces: ISO 15161:2001).
- ISO/TS 22002: Prerequisite programmes on food safety—Part 1: Food manufacturing; Part 2: Catering; Part 3: Farming; Part 4: Food packaging manufacturing; Part 6: Feed and animal food production.
- ISO TS 22003: Food safety management systems for bodies providing audit and certification of food safety management systems.
- ISO TS 22004: Food safety management systems - Guidance on the application of ISO 22000:2005.
- ISO 22005: Traceability in the feed and food chain - General principles and basic requirements for system design and implementation.
- ISO 22006: Quality management systems - Guidance on the application of ISO 9002:2000 for crop production.

ISO 22000 is also used as a basis for the Food Safety Systems Certification (FSSC) Scheme FSSC 22000. FSSC 22000 is a Global Food Safety Initiative (GFSI) approved scheme.

ISO 9001 vs. ISO 22000

In comparison with ISO 9001, the standard is a more procedural orientated guidance than a principle based one. Apart from that, ISO 22000 is an industrial-specific risk management system for any type of food processing and marketing, which can be closely incorporated with the quality management system of ISO 9001. The detailed similarities and differences of the two standards can be found elsewhere.

Potential Justification

In 2004, the European Office of Crafts, Trades and Small and Medium sized Enterprises for Standardisation noted that the standard is only suitable for large sized companies and small food businesses will not be able to seek such a high standard due to the lack of resources to pursue the certification. The agency suggested creating an alternative for small food businesses to achieve the same objective. EFSA is now making their efforts on the food legislations that are adaptable for the SMEs in food supply chains. A few critics also proposed that organizations which seek the standard certification should also do the same to the ISO 14001 along with the ISO 9001, as they consider that large amounts of risks are mainly from the primary production in the supply chains rather than the later stages of food processing.

IATF 16949

IATF 16949 is a global Quality Management System Standard for the Automotive industry. IATF 16949:2016 incorporates the structure and requirements of the ISO 9001:2015 quality management system standard with additional automotive customer-specific requirements. It was developed by the International Automotive Task Force(IATF), with support from AIAG. This standard requires certification by a 3rd party auditor (Registrar/CB/Certification Body). Here are some key areas of focus:

- Continuous improvement.
- Defect prevention.
- Reducing waste.
- Product safety.
- Risk management.
- Contingency planning.
- Requirements for embedded software.
- Change and warranty management.
- Management of sub-tier suppliers.

Why IATF 16949 and not just ISO 16949?

IATF 16949 was developed by the International Automotive Task Force (IATF). IATF 16949:2016 is an innovative document designed by IATF. It provides strong preference to the customer, with inclusion of a number of consolidated previous customer specific requirements. The IATF maintains strong cooperation with ISO by continuing liaison committee status ensuring continued alignment with ISO 9001.

Why do Companies want to Implement IATF 16949?

Registration to IATF 16949 is not only beneficial but a requirement for any company wanting to supply its products to the Automotive Industry. Companies registered to this Technical Specification are required to develop their suppliers' Quality Management Systems with the goal of the supplier conforming to IATF 16949.

References

- Learn-about-standards, quality-resources: asq.org, Retrieved 18 June, 2020
- Iso-9004-55038: smallbusiness.chron.com, Retrieved 31 March, 2020
- Poksinska, Bozena; Dahlgaard, Jens Jörn; Antoni, March (2002). "The state of ISO 9000 certification: A study of Swedish organisations". The TQM Magazine. 14 (5): 297. doi:10.1108/09544780210439734

- What-is-iatf, iatf-16949-standards-16949: 16949store.com, Retrieved 18 August, 2020
- Quality Management Principles (PDF). International Organization for Standardization. 2015. ISBN 978-92-67-10650-2
- Iso-9001, quality-resources: asq.org, Retrieved 14 May, 2020
- Iso-9002-international-certificate-56932: smallbusiness.chron.com, Retrieved 08 January, 2020

PERMISSIONS

INDEX