Quality and Quality Control in Production: A Review

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ABSTRACT

Quality control is a process employed by companies all over the globe to ensure a certain level of quality in a product or service. With companies controlling a number of operations to manufacture a particular product batch, it is imperative to verify certain characteristics of a product or service. With proper quality control department setup, a company can ensure that the product meets specific requirements and is dependable, satisfactory, and fiscally sound. Because of this reason, many companies are now relying on the services of quality management software solutions to meet their needs when doing business in regulatory environments.

(Keywords: production, quality, quality control, quality assurance, reliability)

INTRODUCTION

Many companies have realized that with proper quality control, a drastic decrease in variation of processes and lesser reliance on resources becomes a distinct possibility. Just as a majority of processes have intricate, multiple steps, quality control is also applicable to the evaluation of products, services, or processes on different tiers.

Usually quality control operations are carried out by a well-trained team of professionals who are specifically hired to identify products and services that don't meet the company's standards of quality. These standards are devised by the company, regulatory agencies, or international standards organizations such as ISO, to ensure that the business enterprise is conducted according to industry standards.

The primary objective of quality control solutions is to identify problems. Once a problem is identified, the quality control team may demand a temporary halt in production. This allows managers the time to figure out the occurrence of problems and devise solutions.

In some cases, quality control teams may not take the extreme step of stopping production of the entire batch; the team can decide on putting a stop on executing only a certain set of processes in which a problem has occurred. Quality management software is particularly used by the corporate management to ensure that the research, analysis, manufacturing, release, and implementation cycle of a product is tailored within the boundaries of specific standards. This helps companies maintain and build upon their existing systems.

While in business, engineering, and manufacturing, quality has a pragmatic interpretation as the non-inferiority or superiority of something; it's also defined as being suitable for its intended purpose (fitness for purpose) while satisfying customer expectations. Quality is a perceptual, conditional, and somewhat subjective attribute and may be understood differently by different people. Consumers may focus on the specification quality of a product or service, or how it compares to competitors in the marketplace. Producers might measure the conformance quality, or degree to which the product/service was produced correctly. Support personnel may measure quality in the degree that a product is reliable, maintainable, or sustainable.

There are many aspects of quality in a business context, though primary is the idea the business produces something, whether it be a physical good or a particular service. These goods and/or services and how they are produced involve many types of processes, procedures, equipment, personnel, and investments, which all fall under the quality umbrella. Key aspects of quality and how it's

diffused throughout the business are rooted in the concept of quality management

1. Quality planning - Quality planning is implemented as a means of "developing the products, systems, and processes needed to meet or exceed customer expectations. This includes defining who the customers are, determining their needs, and developing the tools (systems, processes, etc.) needed to meet those needs.

2. Quality assurance – Quality assurance is implemented as a means of providing enough confidence that business requirement and goals (as outlined in quality planning) for a product and/or service will be fulfilled. This error prevention is done through systematic measurement, comparison with a standard, and monitoring of processes.

3. Quality control – Quality control (QC) is implemented as a means of fulfilling quality requirements, reviewing all factors involved in production. The business confirms that the good or service produced meets organizational goals, often using tools such as operational auditing and inspection. QC is focused on process output.

4. Quality improvement - Quality improvement is implemented as a means of providing mechanisms for the evaluation and improvement of processes, etc. in the light of their efficiency, effectiveness, and flexibility. This may be done with noticeably significant changes or incrementally via continual improvement.

While quality management and its tenets are relatively recent phenomena, the idea of quality in business is not new. In the early 1900s, 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, implementing quality control, inspection, and standardization procedures in their work. Later in the twentieth century, the likes of William Edwards Deming and Joseph M. Juran helped take quality to new heights, initially in Japan and later (in the late '70s and early '80s) globally.

Customers recognize that quality is an important attribute in products and services, and suppliers recognize that quality can be an important differentiator between their own offerings and those of competitors (the quality gap). In the past two decades this quality gap has been gradually decreasing between competitive products and services. This is partly due to the contracting (also called outsourcing) of manufacturing to countries like China and India, as well internationalization of trade and competition. These countries, among many others, have raised their own standards of quality in order to meet international standards and customer demands. The ISO 9000 series of standards are probably the best-known international standards for quality management, though specialized standards such as ISO 15189(for medical laboratories) and ISO 14001 (for environmental management) also exist.

QUALITY

Determinants of Quality

1. Design, *planned quality:* Intension of designers to include or exclude features in a product or Service. *Designed size, actual durability.* Customer input is addressed.

2. Conformance to design (standards), *executed quality:* The degree to which goods or services conform to the intent of the Designers. *Actual size, actual durability*. Design for quality: Design with quality in mind.

3. Ease of use: This is the need for the design Engineer to include features such as direction for the use of the product or machines. Also the manual written by the designer should play an important role here paving way for better usage without much problem. Directions, instructions, training

4. Service after delivery.

The Consequences of Poor Quality

- Loss of business
- Liability
- Productivity
- Loss of business: Customer quietly stops buying. Customer complaints rarely reach to the upper management.

- Liability: Due to damages or injuries resulting from poor quality (design, conformance, ease of use, service)
- Low productivity: Rework or scrap. More input but does not increase the output.
- High costs

Dimensions of Quality

- Performance - main characteristics of the product/service
- Aesthetics - appearance, feel, smell, taste
- Special features - extra characteristics
- Conformance - how well product/service conforms to customer's expectations
- Safety - Risk of injury
- Reliability - consistency of performance
- Durability - useful life of the product/service
- Perceived Quality - indirect evaluation of quality (e.g. reputation)
- Service after sale - handling of customer complaints or checking on customer satisfaction

Examples of Quality Dimensions

Dimension	(Product) Automobile	(Service) Auto Repair
1. Performance	Everything works, fit & Finish	All work done, at agreed Price
2. Aesthetics	Ride, handling, grade of materials used Interior design, soft touch	Friendliness, courtesy, Competency, quickness Clean work/waiting area
3. Special Features Convenience High-Tech		Location, call when ready, Computer diagnostics
4. Safety	Antilock brakes, airbags	Separate waiting area
5. Reliability	Infrequency of breakdowns	Work done correctly, ready when promised
6. Durability	Useful life in miles, resistance to rust & corrosion	Work holds up over Time
7. Perceived Quality	Top-rated car	Award-winning service Department
8. Service after Sale	Handling of complaints and/or requests for information	Handling of complaints

Service Quality

- Tangibles
- Convenience
- Reliability
- Responsiveness
- Time
- Assurance
- Courtesy

Examples of Service Quality

Dimension	Examples
1. Tangibles	Were the facilities clean, personnel neat?
2. Convenience	Was the service center conveniently located?
3. Reliability	Was the problem fixed?
4. Responsiveness	Were customer service personnel willing and able to answer questions?
5. Time	How long did the customer wait?
6. Assurance	Did the customer service personnel seem knowledgeable about the repair?
7. Courtesy	Were customer service personnel and the cashier friendly and courteous?

Costs of Quality

- Failure Costs - costs incurred by defective parts/products or faulty services.

– Internal Failure Costs
- Costs incurred to fix problems that are detected before the product/service is delivered to the customer.

– External Failure Costs
- All costs incurred to fix problems that are detected after the product/service is delivered to the customer.

- Appraisal Costs

– Product and/or service inspection costs.
- Time and effort spent for course evaluations

- Prevention Costs

– Quality training, planning, customer assessment, process control, and quality improvement costs to prevent defects from occurring
- Instructor training for better course presentation

Why Do We Need Quality?

- Quality makes customer happy

– Companies exist to "delight the customer"

- Poor Quality reduces productivity and increases costs.

– "It is not quality that costs, it is all the things you do because you do not have quality in the first place." [Crosby 1979]

- Quality is no longer an order winner, it is merely an order qualifier.

- High technology and complicated products make quality a necessity. Computerization and automation increases standardization and quality levels.

– "What technology makes possible today, it makes necessary tomorrow." [Kolesar 1991]

DESIGN OF QUALITY CONTROL SYSTEM

Ten Quality System Design Attributes

1.Standards and Site Procedures: These are part of a document hierarchy that collectively comprise the QMS and declare how a company intends to operate in compliance with laws, regulations, and company requirements. Standards establish the requirements, and procedures provide the detail for how they are applied to a specific operation. Together they provide structure for the library of interlinking requirements and instructions. Without standards and procedures, there is no control over the way work is performed and how decisions are made.

2. Process: An orderly process flow facilitates a common understanding of how work is performed. Process flow diagrams commonly appear in procedures, and process mapping is often the first order of business when designing a new QMS, or improving an established one. Process flows also support value-stream analysis and employee training by showing the big picture, key interactions, and decision points. Incomplete, inefficient, and disjointed processes open the door to informal practices to develop over time due to the lack of a fluid, practical, or understandable way of working. Designing the process to be "fit for purpose" and useable is essential for compliance.

3. Decision Processes: Most processes have decision points. Some decisions may be straightforward, but others may require critical thinking skills to weigh available information and assess the risks and implications to be able to make the best-informed decision. Some decisions require participation by other stakeholders, or need to be escalated to higher levels of management, especially when events or conditions arise that create an unacceptable risk. Ensuring that decision processes, the decision maker's level of responsibility, and escalation criteria are clearly described in procedures helps to establish new, appropriate responsibilities, governance, and risk management.

4. Role of Quality Assurance: Quality assurance (QA) has a unique, independent decision-making role codified by the Code of Federal Regulations. It involves review and approval of all current good manufacturing practice (cGMP) matters, as well as the release of product into interstate commerce. Quality assurance also has a role within each quality system that must be procedurally established. This will include QA reviews and approvals, as well as a description of the type of events and conditions where QA personnel must be notified. QA personnel must not be put into a role where there would be a conflict of interest, such as expediting production or approving their own work. Establishing the role of QA personnel ensures the independent oversight and support required by our industry.

5. Records and Documentation: Equally important to procedures are the records created when procedures are followed. Examples of records include batch records, forms, logbooks, drawings, recording charts, and printouts. Procedure instructions are given on how to complete associated records. These are signed and dated by the one performing the work at the time the work is performed. Some records are considered so important that the work and the entries must be witnessed. It's common to have standards and training on good documentation practices to promote clear and consistent written entries, as well as to prevent the perception of fraud. The design and content requirements, as well as storage and archiving of records are significant. Complete, accurate, and timely records provide the batch history, facilitate data mining, and support investigations.

6. Performance Metrics: Performance metrics are at the core of managing the QMS. Performance metrics are designed into system procedures and are intended to help the system owner manage the performance of the system and to detect problems. Metrics also help to identify improvement targets and measure the effectiveness of decisions and actions. The review of quality system performance metrics is the main content of the quality management review (QMR) process. The QMR is at the core of quality governance, because it brings together cross-functional management, system owners, and performance metrics for the purpose of ensuring that risks are identified, effective decisions are made, and that the QMS is continually effective. Performance metrics are essential for becoming an organization that anticipates risk.

7. Infrastructure: Infrastructure is that which supports the effectiveness and efficiency of the QMS. This could include facilities, equipment, software, and co-location of system users. Infrastructure attributes may be mentioned in procedures if they are part of the process (e.g., TrackWise software). Sometimes infrastructure is assumed (e.g., space and computers). Since infrastructure support takes significant lead time to implement, be sure to allow sufficient time in the implementation plan in order to meet commitment dates.

8. Organization, skills, and Resources: To effectively execute the process and make appropriate decisions requires skilled system users and a supportive organization structure. Changes to each quality system require that the organization structure, its workers' skills, and available resources be evaluated to ensure that the organization is capable and ready to operate the new system. Each role specified in a

procedure must have identifiable personnel that have the education, experience, and skills to perform the assigned activities. Implementation of the new system requires role-based training and a learning assessment in advance to ensure organization readiness. The bigger the change, the more effort is required to be ready for effective implementation.

9. Dependent Links: The QMS is a network of interrelated systems. When designing a quality system, it is important to consider not only the inputs and outputs within a system, but also between systems. Inadequate links between systems create "short circuits" and can cause the QMS to fail. Ensuring there are effective links can be a challenge when undertaking a comprehensive quality system remediation effort, because the state of the relevant linked systems can be affected consequentially like a moving target, or the sequence of remediation targets may not be optimized. Nonetheless, the identification and continual assessment of dependent links is essential for an integrated and well-functioning QMS.

10. System Ownership: Each quality system must have a designated owner who takes responsibility for the design, procedures, operation, performance, reporting, and improvement of the system. The system owner also ensures that the system continually evolves as regulatory and industry expectations change. And when there are changes to the business portfolio, organization structure and function, the QMS evolves accordingly. Clear system ownership and ownership behavioral expectations are essential to fundamental quality system management. Establishing system owners sets apart key personnel who can work together within and across sites for internal benchmarking and continuous improvement. These system owners also become a subset of company experts where investment of continuous education and development is well placed.

QUALITY ASSURANCE

Quality Assurance (QA) is a management method that is defined as "all those planned and systematic actions needed to provide adequate confidence that a product, service or result will satisfy given requirements for quality and be fit for use". A Quality Assurance program is defined as "the sum total of the activities aimed at achieving that required standard" (ISO, 1994).

Any monitoring program or assessment must aim to produce information that is accurate, reliable and adequate for the intended purpose. This means that a clear idea of the type and specifications of the information sought must be known before the project starts, i.e. there must be a data quality objective. Data quality objectives are qualitative and quantitative specifications that are used to design the system that will limit the uncertainty to an acceptable level within the constraints allowed. These objectives are often set by the end users of the data (usually those funding the project) in conjunction with the technical experts concerned.

Quality Assurance for a recreational water monitoring program will, apart from helping to ensure that the results obtained are correct, increase the confidence of funding bodies and the public. Quality Assurance extends to all aspects of data collection from sanitary surveys to laboratory procedures. Unless the data can be checked they should not be included in any assessment; unconfirmed observations have little value and can result in misclassification.

Quality Assurance can also be Defined in the Following Ways

A. Quality Assurance (QA) is a way of preventing mistakes or defects in manufactured products and avoiding problems when delivering solutions or services to customers; which ISO 9000 defines as "part of quality management focused on providing confidence that quality requirements will be fulfilled". This defect prevention in quality assurance differs subtly from defect detection and rejection in quality control, and has been referred to as a *shift left* as it focuses on quality earlier in the process.

B. QA is any systematic process of determining whether a product or service meets specified requirements.

QA establishes and maintains set requirements for developing or manufacturing reliable products. A quality assurance system is meant to increase customer confidence and a company's credibility, while also improving work processes and efficiency, and it enables a company to better compete with others.

Components of Quality Assurance

The components of a QA program are often grouped into three levels, variously labelled: the strategic or organizational 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).

Comparison of Quality Assurance and Quality Control

The terms "quality assurance" and "quality control" are often used interchangeably to refer to ways of ensuring the quality of a service or product. For instance, the term "assurance" is often used as follows: Implementation of inspection and structured testing.

Quality assurance comprises administrative and procedural activities implemented in a quality system so that requirements and goals for a product, service or activity will be fulfilled. It is the systematic measurement, comparison with a standard, monitoring of processes and an associated feedback loop that confers error prevention. This can be contrasted with quality control, which is focused on process output.

Principles of Quality Assurance

Quality assurance includes two principles: "Fit for purpose" (the product should be suitable for the intended purpose); and "right first time" (mistakes should be eliminated). QA includes management of the quality of raw materials, assemblies, products and components, services related to production, and management, production and inspection processes. The two principles also manifest before the background of developing (engineering) a novel technical product: The task of engineering is to make it work once, while the task of quality assurance is to make it work all the time.

Historically, defining what suitable product or service quality means has been a more difficult process, determined in many ways, from the subjective user-based approach that contains "the different weights that individuals normally attach to quality characteristics," to the value-based approach which finds consumers linking quality to price and making overall conclusions of quality based on such a relationship.

TOTAL QUALITY MANAGEMENT

Total Quality Management

Total Quality Management (TQM) is a management strategy aimed at embedding awareness of quality in all organizational processes (Siddiqui, Haleem, and Wadhwa, 2009).

TQM was defined by the Deming Prize Committee of the Union of Japanese Scientists and Engineers (JUSE, 2010) as: “a set of systematic activities carried out by the entire organization to effectively and efficiently achieve the organization’s objectives so as to provide products and services with a level of quality that satisfies customers, at the appropriate time and price”. There are many proposed tools and techniques to achieve the TQM promises. Generally, a technique can be considered as a number of activities performed in a certain order to reach the values (Hellsten and Klefsjö, 2000).

Tools for Total Quality Management

Pareto Charts: Pareto charts are useful for separating the important from the trivial. Named after Italian economist and sociologist Vilfredo Pareto (1848-1923). Was promoted by Dr.Josep Juran. Pareto charts are important because they can help an organization decide where to focus limited resources. On a Pareto chart, data are arrayed along an X-axis and a Y-axis.

Example:

In a factory, only 20% of problems will produce 80% of defects.

•80% of defect’s cost will be assigned to only 20% of the total number of defect types occurring.

•So, 80% of defect costs will spring 20% of total cost element.

Purpose of Pareto Chart:

- Pareto can show you where to apply your resources by "revealing few from the trivial many"..
- (Highlight few most important issues out of many)

Cause and Effect Diagrams / Ishikawa Diagrams: Used to identify and isolate causes of a problem. Developed by Dr. Kaoru Ishikawa. (1915-1989) Also called Ishikawa Diagram / Fishbone Diagram.

Benefits of Cause and Effect Diagrams / Ishikawa Diagrams:

- Creating the diagram – enlightened, instructive process.
- Focus a group, reducing irrelevant discussion.
- Separate causes from symptoms
- Can be used with any problems

Flow Charts: A flowchart is a type of diagram that represents an algorithm or process, showing the steps as boxes of various kinds, and their order by connecting these with arrows.

Control Chart - Statistical Process Control (SPC): SPC is a statistical method of separating variation resulting from special causes such as natural causes, to eliminate the special causes, and to establish and maintain consistency in the process, enabling process improvement.

- X-bar chart is used to show the center of the process measurements (accuracy).
- R chart is to show the spread of the data (precision).
- Without Range, it would not be able to understand the PROCESS CAPABILITY of the chart.

Quality Function Deployment (House of Quality): An approach that integrates the "voice of the customer" into the product and service development process.

QFD & House of Quality:

- Identify customer wants
- Identify how the good/service will satisfy customer wants
- Relates the customer's wants to the product
- Identify relationships between the firm's "hows"
- Develop importance ratings
- Evaluate competing products

Benefits of QFD:

- Customer Driven
- Reduces Implementation Time
- Promotes Teamwork
- Provides Documentation

Quality Function Deployment (QFD): QFD seeks to bring the voice of customers into the process of designing and developing a product or service. QFD can point out areas of strength as well as weaknesses in both existing or new products. When a company uses QFD, they stop developing products/services on their own interpretation.

Main benefits of QFD:

- Customer focused – QFD gives information which is then translated into a set of specific customer requirements.
- Time efficient – Time is not wasted on developing features that have no value to customers.
- Teamwork oriented – All decisions are based on consensus and involve in-depth discussion and brainstorming
- Documentation oriented – QFD forces the issue of documentation. This document changes as new information gained. Having up-to-date information about customer requirements, will be very helpful.

Process Maps: One of the important keys to understanding how to improve a process is to map the process. While there are several different approaches to process mapping, the key is to determine who does what at each step of the process. Often, the simple drawing of a process map is sufficient to solve many quality problems because the map makes it so obvious where defects can be introduced.

"Poke-A-Yoke": This concept of the Japanese management philosophy is to make a process foolproof. The idea is to design the process in such a way that it is self-checking or incorporates process steps that cause immediate detection

and possible correction of any defect. Simple examples include color-coding and special keying of parts to ensure that they are assembled the correct way.

Statistical Tools: One of Deming's major contributions to the quality movement was the introduction of statistically grounded approaches to the analysis of defects. Without the use of these tools, one can often make incorrect decisions regarding the cause of a problem. This can often lead to exactly the opposite effect of that being sought. Included in this set of tools are statistical process control (SPC) charts, Pareto Charts, and histograms.

Force Field Analysis: This tool asks one to diagram the forces (policies, culture, and so forth) that are resisting a desired change and the forces that support the change. This assists one in clearly determining the degree of difficulty of making change and exactly where effort will be needed. The supporting forces are places where assistance can be expected.

Root Cause Analysis (Five Whys): The Japanese popularized this tool. It consists of asking a series of questions (whys) until one uncovers the root cause of a defective product. The objective is to determine why a defective product was produced; this is to be contrasted with the usual approach of just fixing the defective product or replacing it.

Obstacles to Implementing TQM

- Lack of:

– Company-wide definition of quality
– Strategic plan for change

- Resistance to a change

– Customer focus
– Real employee empowerment

- Red Tape

– Strong motivation
– Time to devote to quality initiatives
– Leadership.

Reliability Engineering

The objectives of reliability engineering, in decreasing order of priority, are:

1. To apply engineering knowledge and specialist techniques to prevent or to reduce the likelihood or frequency of failures.

2. To identify and correct the causes of failures that do occur despite the efforts to prevent them.

3. To determine ways of coping with failures that do occur, if their causes have not been corrected.

4. To apply methods for estimating the likely reliability of new designs, and for analyzing reliability data.

The reason for the priority emphasis is that it is by far the most effective way of working, in terms of minimizing costs and generating reliable products. The primary skills that are required, therefore, are the ability to understand and anticipate the possible causes of failures, and knowledge of how to prevent them. It is also necessary to have knowledge of the methods that can be used for analyzing designs and data.

Reliability engineering for "complex systems" requires a different, more elaborate systems approach than for non-complex systems. Reliability engineering may in that case involve:

- System availability and mission readiness analysis and related reliability and maintenance requirement allocation
- Functional system failure analysis and derived requirements specification
- Inherent (system) Design Reliability Analysis and derived requirements specification for both Hardware and Software design
- System Diagnostics design
- Fault tolerant systems (e.g. by redundancy)
- Predictive and preventive maintenance (e.g. reliability-centered maintenance)
- Human factors / Human interaction / Human errors
- Manufacturing- and Assembly-induced failures (effect on the detected "0-hour Quality" and reliability)
- Maintenance-induced failures
- Transport-induced failures
- Storage-induced failures

- Use (load) studies, component stress analysis, and derived requirements specification
- Software (systematic) failures
- Failure/reliability testing (and derived requirements)
- Field failure monitoring and corrective actions
- Spare parts stocking (availability control)
- Technical documentation, caution and warning analysis
- Data and information acquisition/organization (creation of a general reliability development Hazard Log and FRACAS system)
- Chaos Engineering

The scope of reliability can be visualized by the following facts in respect of any equipment or system:

- The working environment of the equipment/system.
- The need of safety aspects for men and material.
- Degree of uncertainty about the success of operation and its improvements in system/ equipment performance.
- Need for efficient, economic and continuous running of equipment/system without disturbances.
- A failure of an equipment/system raises the question in the minds of the people regarding its reliability and its further use.
- Improvement in the confidence of the working personnel particularly in the hazardous area because of safety reasons

Factors Affecting Reliability

Maintenance: Maintenance has had a tremendous impact on company's proficiency to optimize its production system in order to meet its long-term objectives. Generally, a production system in which maintenance is not given attention may easily lead to the system producing defective product as a result of machine defect. The result shows that while investment on maintenance implementation might be a cost at the earlier stage of implementation because it is hard to measure and follow up its impact on company's business. Nevertheless, its role in improving company productivity profitability is indispensable. Thus, maintenance is a profit center rather than a cost center.

Maintenance is not just about ensuring proper function of machine and equipment (in order to continue to fulfill its intended purpose) but also play a key role in achieving company's goals and objectives by improving productivity and profitability as well as overall performance efficiency. In generally, not until recently it role has been recognized, maintenance has been considered as a less important activity that only cost money rather than generating profit by most organization's executives or stakeholders, due to the blurred perception about its role in attaining company's goal and objectives.

Reliability Testing and Measurement: Reliability Testing can be performed at the component, subsystem, and system level throughout the product or system lifecycle. Examples of hardware related categories of reliability testing include (Ebeling, 2010, O'Connor 2014).

- Reliability Life Tests: Reliability Life Tests are used to empirically assess the time to failure for non-repairable products and systems and the times between failure for repairable or restorable systems. Termination criteria for such tests can be based on a planned duration or planned number of failures. Methods to account for "censoring" of the failures or the surviving units enable a more accurate estimate of reliability.

- Accelerated Life Tests: Accelerated life testing is performed by subjecting the items under test (usually electronic parts) by increasing the temperature to well above the expecting operating temperature and extrapolating results using an Arhenius relation.

- Highly Accelerated Life Testing/Highly Accelerated Stress Testing (HALT/HASS) subjects units under test (components or subassemblies) to extreme temperature and vibration tests with the objective of identifying failure modes, margins, and design weaknesses.

- Parts Screening: Parts screening is not really a test but a procedure to operate components for a duration beyond the "infant mortality" period during which less durable items fail and the more durable parts that remain are then assembled into the final product or system. Examples of system level testing (including both hardware and software) are (O'Connor 2014, Ebeling 2010).

- Stability tests: Stability tests are life tests for integrated hardware and software systems. The goal of such testing is to determine the integrated system failure rate and assess operational suitability. Test conditions must include accurate simulation of the operating environment (including workload) and a means of identifying and recording failures.

- Reliability Growth Tests: Reliability Growth Testing is part of a reliability growth program in which items are tested throughout the development and early production cycle with the intent of assessing reliability increases due to improvements in the manufacturing process (for hardware) or software quality (for software)

- Failure/recovery tests: Such testing assesses the fault tolerance of a system by measuring probability of switchover for redundant systems. Failures are simulated and the ability of the hardware and software to detect the condition and reconfigure the system to remain operational are tested.

- Maintainability Tests: Such testing assess the system diagnostics capabilities, physical accessibility, and maintainer training by simulating hardware or software failures that require maintainer action for restoration.

Bathtub Curve

Figure 1 shows a typical time versus failure rate curve for equipment. This is the well-known "bathtub curve," which, over the years, has become widely accepted by the reliability community. It has proven to be particularly appropriate for mechanical and electronic equipment and systems. Note that it displays the three failure rate patterns, a decreasing failure rate (DFR), constant failure rate (CFR), and an increasing failure rate (IFR).

Estimation of Hazard Rate

Hazard Rate: The hazard rate refers to the rate of death for an item of a given age (x), and it is also known as the failure rate. It is part of a larger equation called the hazard function, which analyzes the likelihood that an item will survive to a certain point in time based on its survival to an earlier time (t). In other words, it is the likelihood that if something survives to one moment, it will also survive to the next. The hazard rate only applies to items that cannot be repaired. The hazard rate for any time can be determined using the following equation:

h(t) = f(t) / R(t)

f(t) is the probability density function, or the probability that the value (failure or death) will fall in a specified interval (for example, a specific year).

R(t) is the survival function, or the probability that something will survive past a certain time (t).

The hazard rate cannot be negative, and it is necessary to have a set "lifetime" on which to model the equation.

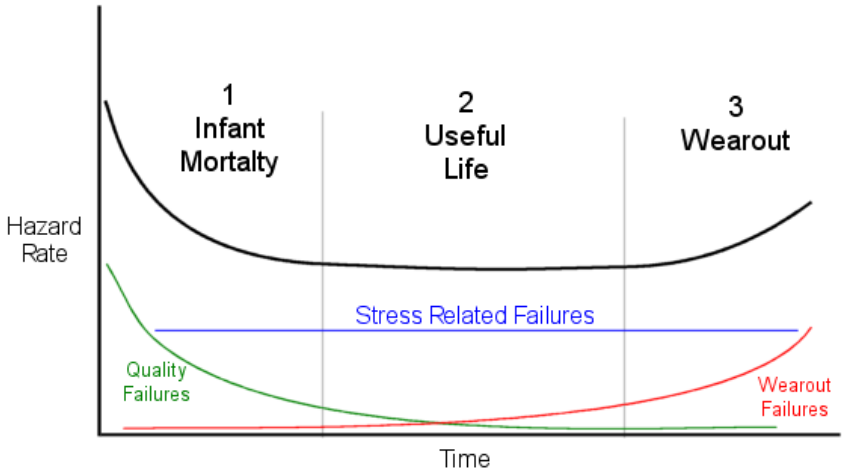

Figure 1: Bathtub Curve for a Mechanical or Electronic Components.

Hazard rate can also be determined with this equation:

Sacher formula for hazard rate estimation (Sacher, 1956; 1966)

$$\underset{\text{Hazard rate}}{\mu_x} = \frac{1}{\Delta x}\left(\ln l_{x-\frac{\Delta x}{2}} - \ln l_{x+\frac{\Delta x}{2}}\right) = \frac{1}{2\Delta x}\ln\frac{l_{x-\Delta x}}{l_{x+\Delta x}}$$

l_x - survivor function at age x; Δx – age interval

Simplified version suggested by Gehan (1977):

The probability density calculates the probability of failure at any given time. For example, a person has a certainty of dying eventually, which is the probability density. As a person age, the person have a greater chance of dying at a specific age, since the average failure rate is calculated as a fraction of the number of units that exist in a specific interval divided by the number of total units at the beginning of the interval.

If we were to calculate a person's chances of dying at a certain age, we would divide one year by the number of years that person potentially has left to live. This number would grow larger each year. A person aged 60 would have a higher probability of dying at age 65 than a person aged 30 because the person aged 30 still has many more units of time (years) left their life, and the probability is less that the person will die during one specific unit of time.

Uses of Hazard Rate

The hazard rate is part of a wider branch of statistics called survival analysis, which predicts the amount of time until a certain event occurs, such as death or failure (as in failure of a mechanical structure). The concept is applied to other branches of research under slightly different names including reliability analysis (engineering), duration analysis (economics), and event history analysis (sociology).

CONCLUSION

The focus on quality and quality control is one of the hallmarks of the production system. Quality is a major enabler of reduced costs, both directly through reductions in the quality assurance function and the cost of rework, and indirectly as it facilitates the reduction of inventory buffers. In this work, we discuss the critical role of quality and quality control in a system and report on efforts to improve quality in the industries, factories and companies. Companies can use a number of tools to enhance quality in the production process. These range from tools that measure quality and make sure processes are standardized to statistical tools that analyze processes and practices to processes on the factory floor.

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