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Original Article

Theoretical Research in Quality Control in Manufacturing

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Abstract: *In business, quality has proven to be difficult to define. Many individuals associate quality with some degree of greatness or natural superiority, while others see it as simply the absence of manufacturing flaws.*
It is a simple notion to understand that quality control considerations are or ought to be an integral element of all industrial activities. Additionally, this theory is presently getting a lot of attention in the manufacturing industry as a result of the growing difficulty in producing goods that are both cost- and utility-competitive in the global market. This means that virtually always it is undesirable to produce goods that are not suitable for their intended purpose (junk) in today's industrial processes. Numerous options may be put up to address this scenario and regulate the level of completed workpiece quality.
Under pressure from globalization, manufacturing businesses are refocusing their efforts on three important areas of competition: quality, cost, and response. Quality is a global virtue that has drawn interest from all across the world. To stay in business and be able to please their customers, manufacturing companies need to monitor their operations and improve the quality of their products. Manufacturing companies employ a variety of quality control strategies to reduce process variability and improve process quality. There are numerous ways to control the quality of a procedure or a final result. These comprise seven Statistical Process Control (SPC) tools: acceptance sampling, Six Sigma, failure mechanism and effects analysis, quality control implementation, and Design of Experiments (DoE).

Keywords: *Quality, Quality control, Total quality management, Quality system, PDCA.*

I. INTRODUCTION

A) Quality Definition

The term "quality" might have several connotations depending on the situation. There is more to "quality" than merely the standard of manufactured items. It could be a reference to the quality of the process (i.e., the utilization of personnel, supplies, and equipment) or even the quality of the management. Where the phrase "quality of product" refers to the degree to which a manufactured good meets the needs of a consumer. Although it isn't absolute, it may be evaluated or realized by comparing it to certain criteria.

Quality is a relative term and is typically used concerning the end use of the product. It starts with the design of a product by the customer's specifications and goes on to involve the measurement standards that have been established, the use of appropriate materials, the choice of an appropriate manufacturing process, etc. According to Crosby, "Conformance to requirements or specifications" is what quality is.

According to Juran, "Quality is fitness for use." A product or service's "quality" may be defined as its ability to satisfy the needs of the client while also meeting or beyond its intended usage.

II. LITERATURE REVIEW

A) Control

Control is the method used to create standards and ensure that they are met. This procedure entails watching how well our activity is going, comparing it to some standards, and taking action if the observed performance deviates considerably from the norms.

The following universal steps are included in the control process:

1. Select the control object and the unit of measurement first.
2. Choose the benchmark value.
3. Select a sensor that can measure.
4. Evaluate performance in real life.
5. Explain the distinction between the real and the standard.
6. Acting.

The Need for Quality Control Lack of quality has the following consequences.

1. There is no standard for comparing the quality of goods and services.
2. Difficult to maintain consistent quality.
3. Customer dissatisfaction due to increased product/service maintenance and operating costs.
4. Increased rework costs in producing products/providing services.
5. Reduced product/service life. 6. Less flexibility regarding the use of standard spare parts.
6. Quality control is, therefore, an essential activity.

B) Types Of Quality Control

Quality control is not the responsibility of a single department or individual. Providing work of acceptable quality is the primary responsibility of every manager.

Quality control can be categorized into three main sub-areas:

1. Offline quality control,
2. Statistical process control and
3. Acceptance sample plan.

- Offline quality control:

  The procedures cover measures for selecting controllable product and process parameters so that product or process performance and deviations from standards are minimized. The design of processes and products helps to accomplish a large portion of this work. For instance, the Taguchi approach, the experimental design principle, etc.

- Statistical process control:

  SPC involves comparing process or service results to standards and taking corrective action when there is a discrepancy between the two. This involves figuring out if the procedure can result in a product that satisfies the required standards or requirements. Online SPC refers to the collection of data while a service, management, or product is in use. During this stage of the procedure, corrective measures are carried out. It is based on real-time.

- Acceptance rehearsal plan:

  A plan that specifies batch acceptance criteria based on the number of items to sample and meeting certain specified conditions (such as the risk of rejecting good batches or accepting bad batches) is called an acceptable sampling plan.

C) Steps In Quality Control

The quality control process steps are:

1. Formulate a quality policy.
2. Setting standards or specifications based on customer preferences, costs and benefits.
3. Select an inspection plan and set the inspection procedure.
4. Identify deviations from established standards or specifications.
5. We make the required adjustments or take corrective action to meet our standards.
6. Decide how to recycle. H. Decide how to dispose of defective parts, whether to scrap entirely or rework.
7. Coordination of quality issues.
8. Increased quality awareness inside and outside the organization.
9. Develop procedures for good supplier-buyer relationships.

D) Objectives Of Quality Control

The goals of quality control are:

1. Improve the company's profitability by producing products acceptable to customers. d. H. Longer life, improved usability, improved maintainability, etc. 2. Reduce losses due to defects and reduce operating costs.
2. Achieving manufacturing compatibility in large-scale production
3. Optimal quality at a low price. 5. Ensuring customer satisfaction with products and services or high-quality levels, and building the goodwill, trust and reputation of the manufacturer among customers.
4. Conduct timely inspections to ensure quality control.
5. To check for manufacturing errors. Quality control is applied in a wide range of fields, including incoming inspection, process control, and product inspection.

E) Benefits Of Quality Control

Improving the quality of our products and services. Improve productivity in manufacturing processes, trading houses and enterprises. Reduce manufacturing and business costs. Determine and improve the marketability of products and services.

Lowering consumer prices for products and services. Improve and/or ensure punctuality and availability. Let us help you run your business, as presented in Figure 1.

F) Quality Control Tools

Certain graphical tools are used by businesses to make rational decisions based on the data they receive about their products, processes, or consumers. These methods help you learn more about your process characteristics, operating conditions, and the types of results you can expect from your process. The graphical approach is easy to understand and provides comprehensive information. They are practical tools for analyzing product and process data. These tools affect quality improvement.

The seven quality control tools are:

1. Pareto Chart
2. Test Sheet
3. Fishbone Diagram
4. Scatter plot
5. Histogram
6. Graph or flow chart
7. Control chart.

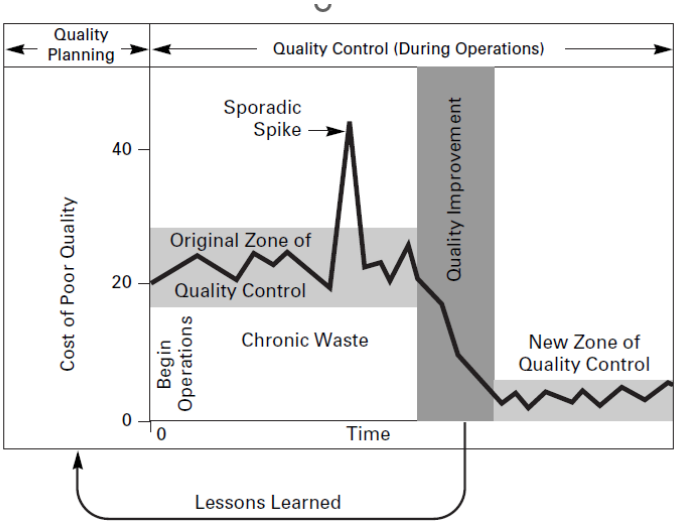

Figure 1. Juran trilogy of quality

G) Total Quality Management

Today's customers demand durable, reliable and affordable products/services. This means that from the creation of products to shipping and installation, producers must adhere to strict quality control protocols. Therefore, the goal of a highly competitive industry is to provide products and services at the most economical cost while ensuring complete customer satisfaction presented in Figure 2. This can be achieved through Total Quality Management (TQM), as quality is not a technical feature but a systematic process that spans all stages of the company. B. Marketing, Design, Development, Technology, Purchasing, Production and Operations. According to Feigebaum, "Total quality management integrates the quality development, quality maintenance and quality improvement efforts of different groups within an organization, enabling marketing, engineering, production and service at the most It is an effective system that allows the complete satisfaction of "satisfaction".

Figure 2. Total Quality Management

H) Principles Of Tqm

1. Ongoing process enhancement: That is the most important rule. It is applied in a methodical and controlled manner and penetrates the whole TQM system.
2. Process knowledge: Continuous improvement requires process knowledge. It requires a thorough understanding of all processes within the system and encourages improvement ideas.
3. User-focused: Users are focused both internally and externally. Every product and service in your organization has internal or external users. More significantly, though, internal customers must be happy with the goods or services they receive in order to satisfy external consumers' demands for compliance-compliant goods and services.
4. Commitment: For TQM to work, it requires the involvement of all members of the system. The most important thing is the full commitment of top management. The success of TQM is directly related to system staff belief that management is committed to continuous improvement programs that reduce costs and ensure adherence to schedules, customer satisfaction and personal pride in their work performance, as presented in figure 3.
5. Top-down implementation: Just as a teacher has to learn a new subject before teaching her students, a manager has to learn her TQM as a new management philosophy before she can make her system personnel understand and apply her TQM. it won't work. The difference between TQM and other management approaches is that system workers actively participate in the process.
6. Consistency of Purpose: TQM begins with a vision set by senior leadership and is implemented through a series of goals and objectives. All activities within the system are tailored to your goals and specifications. People who focus on continuous improvement are rewarded. Positive behaviour is rewarded. Negative behaviours that accept adaptation to the current environment need to be remedied.
7. Everyone participates: No person or process is exempt from continuous improvement. This requires that the processes meet compliance requirements and that the employee is well-trained and familiar with her TQM methodology for continuous improvement. Not everyone is on board, "which is an acceptable level of quality, like recognizing that some part of the system will fail, and that's okay."
8. Cooperation: Teamwork leads to efficient use of resources. correct process. And I got great results. Teams support system goals through practical ownership (ownership) of the goals that support the system as a whole. Teams promote better communication. Creativity and support for his TQM principles.
9. Investing in People: Your system's greatest asset and most important investment is your employees. Continuous improvement requires people to improve too. TQM focuses on training System II members.

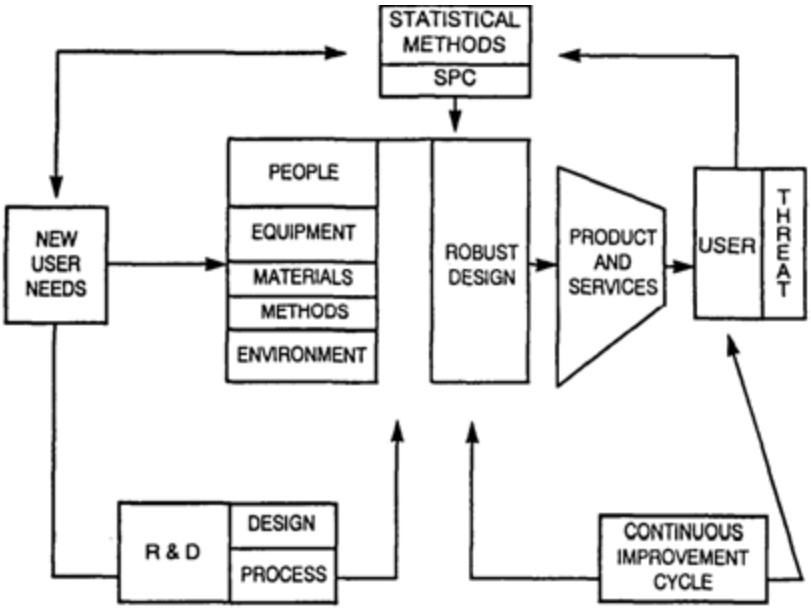

Figure 3. TQM as a system (source: Juran Handbook)

I) Benefits Of Tqm

1. The benefits of TQM fall into two categories:
2. Benefits focused on customer satisfaction.
3. Benefits aimed at improving the economy.

J) Benefits focused on customer satisfaction.

The advantages of this category are:

(a) improving product quality; (b) improving product design; (c) Improving production flow. (d) improve employee morale and quality awareness; (e) improve product service; (f) improve market acceptance.

K) Benefits aimed at improving the economy.

The advantages of this category are:

(a) reduced operating costs; (b) reducing operating losses; (c) reducing field service costs; (d) reducing liability risks.

Total Quality Management (TQM), presented in Figure 4, is an extension of traditional business processes. This is a tried-and-true technology that guarantees survival in fierce competition. The culture and conduct of the entire company can only be altered by altering the actions of the leadership team. TQM is mostly common sense. Analyzing these three words yields a "Total" that consists of the whole. Quality - The degree of excellence that a product or service offers. Management – behaviour, handling, control, direction, etc. TQM, then, is the art of managing the total to get perfection. This can be explained simply but effectively using the Golden Rule.

Treat others as you are expected to be treated. TQM is a philosophy and a set of guidelines that form the basis of a continuous improvement organization. It involves utilizing both human resources and quantitative approaches to enhance all organizational processes and surpass both present and future client expectations. TQM integrates basic management practices, existing improvement efforts, and technical tools as part of a disciplined approach

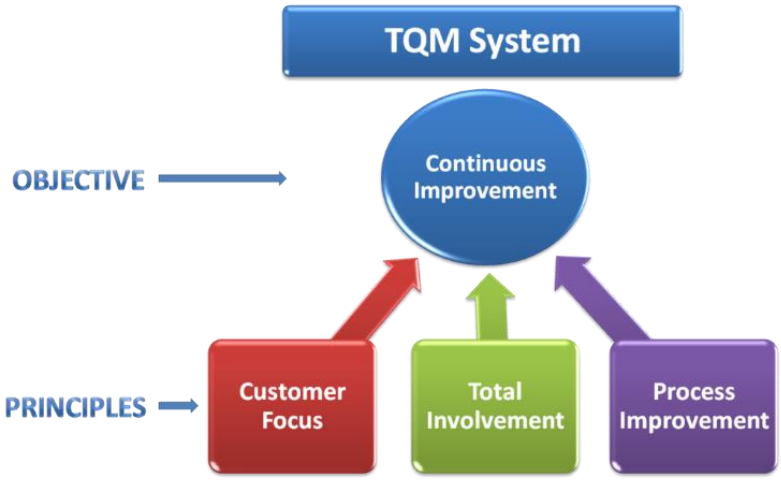

Figure 4. TQM system

Table 1. Quality element, previous state vs. TQM

Quality Element	Previous State	TQM
Definition	Product-Oriented	Customer-Oriented
Priorities	Second to service and cost	First among equals of service and cost
Decisions	Short-term	Long-term
Emphasis	Detection	Prevention
Errors	Operations	System
Responsibility	Quality control	Everyone
Problem-solving	Managers	Teams
Procurement	Price	Life-cycle costs, partnership
Manager's Role	Plan, assign, control and enforce	Delegate, coach, facilitate and mentor

III. RESULTS AND DISCUSSION

A) ISO 9000 Series

ISO stands for International Organization for Standardization. This is an international organization with representatives from more than 90 countries. The national standards bodies of these countries are members of this organization. The Indian Bureau of Standards (BIS) is the Indian representative for ISO and ISO and the International Electrotechnical Commission (IEC) work together as a single system. These are non-governmental organizations tasked with providing common standards for international trade in goods and services. The ISO 9000 standard requires companies to produce quality manuals that comply with ISO policies, documents, quality procedures and work instructions, and external auditors verify that compliance. The ISO 9000 series includes five international standards for quality management. they are:

1. ISO 9000 – Quality Management and Quality Assurance Standards
2. ISO 9001 – Quality System: Design Quality
3. ISO 9002 – Quality Systems: Manufacturing and Installation
4. ISO 9003 – Quality Systems: Final inspection and testing
5. ISO 9004 – Quality Management and Systems.

B) Benefits Of ISO 9000

The following is a list of the various concrete and intangible advantages that the ISO 9000 series offers:

1. It provides a competitive edge in the international market.
2. Consistency in excellence, as ISO aids in the early detection of non-conformity, allowing for the possibility of corrective action.
3. Clarity is added to a quality system through the documentation of quality processes.
4. ISO 9000 guarantees that all employees receive sufficient and consistent high-quality training.
5. ISO assists clients in implementing economical procurement processes.
6. Customers do not have to pay a lot of money for testing and inspection when purchasing products from businesses that hold ISO certifications. Lead time and quality expenses will both decrease as a result.
7. This will contribute to a rise in output.
8. This will help to raise employee involvement and morale.

9. There would be a greater degree of job satisfaction.

C) Role Of Quality Control

Quality control starts after product development is finished, as opposed to the continual process enhancement assurances that were previously discussed. The product, not the production method, is the primary concern of people working in quality control roles.

To complete their jobs, quality control personnel have access to a wide range of equipment. These techniques typically entail testing or examining manufactured goods to ascertain whether they adhere to specified specifications or to identify and separate nonconformities.

Only when a batch or a large number of medical devices are prepared for shipping does testing for products start. Once the product reaches this point, quality control personnel are responsible for batch or lot inspection and final verification to ensure that the equipment within it is indeed ready for sale.

There are three main tactics that quality control teams use to test and inspect products for conformance or non-conformity.

a. Acceptance criteria:

The FDA requires quality control personnel to develop formal documentation detailing how products are determined to meet product specifications. Quality control personnel are responsible for documenting this acceptance and tracking which products or batches meet these criteria and which do not.

b. Product test:

A method for quality control personnel to inspect, test, and verify that a product is ready for shipment. Under the FDA's quality system regulations, medical device manufacturers are free to develop their quality control tests but must provide detailed documentation demonstrating the effectiveness of their review.

c. Corrective and Preventive Action (CAPA):

As shown in Figure 5, these investigation events are initiated when a nonconforming product is found by quality control staff, who then conduct a root cause analysis to identify the system issue that resulted in the non-compliance.

CAPA is the most important tool for quality control staff. Businesses should not overuse this tool. A common mistake QC teams make is starting their CAPA investigation too early for every problem they find.

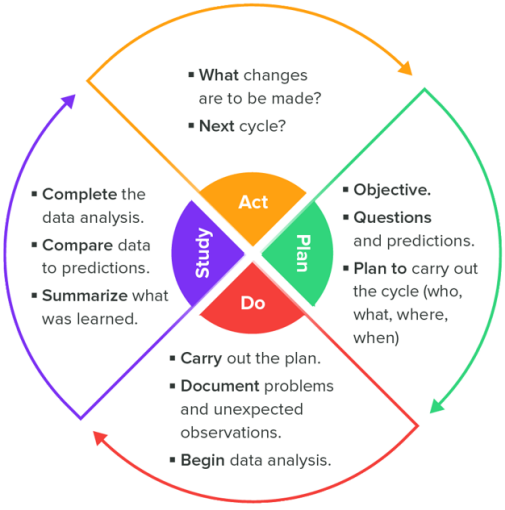

Figure 5. PDSA cycle for improving quality

A component of the quality management system that aids in the maintenance of quality standards by manufacturers is quality assurance. It is centered on methodical actions that guarantee the business upholds manufacturing requirements. Manufacturers must adhere to approved production guidelines and quality standards in order to ensure quality.

There is a small distinction between quality control and quality assurance. The American Society for Quality (ASQ) states that any actions that show a manufacturer's dedication to quality are the focus of quality assurance. Contrarily,

quality control is concerned with providing evidence of quality assurance. This includes testing and inspecting final products as well as monitoring the manufacturing procedure.

Quality assurance is thus defined as an active management task and is process-oriented. Quality control, on the other hand, is reactive and product or object-based, as presented in Figure 6.

Figure 6. Quality control

IV. CONCLUSION

A) The Quality System Overview

a. Quality Leadership:

Delivering on the promise of quality begins with leadership. The Quality Leadership System is designed to help managers implement effective quality programs.

b. Quality Program:

Quality program is the cornerstone of our quality system. Promotes rules and regulations, competence and growth, assessment of performance and constant enhancement, and system and procedure validation. The program includes end-to-end identification and effective management of quality risks across all departments and geographies of the company, from design to raw material sourcing, product manufacturing, distribution, and consumer feedback. Includes assessment tools. Design and development:

This system includes new products, packaging, process design and development, and continuous improvement of existing products. This includes all stages from the early stages of development through to the transition to production and subsequent verification and validation of the design with customers and consumers. This system ensures the creation of innovation protocols, work processes, and physical and technical standards. Design and development support the goal of providing attractive quality products that delight consumers and grow your business, presented in Figure 7,8.

c. Quality Star:

The five integrated quality program systems that ensure the production of fully compliant products that satisfy consumers are:

→ Factory and Facility Systems - Activities that provide suitable physical environments and resources for the development, production and distribution of products. → Production Systems – Activities that support the manufacturing of products, including those used for consumer testing.

→ Packaging and Labeling Systems - Actions that assist with product labeling and packaging, especially consumer trial products.

→ Laboratory Control Systems – Actions and tasks pertaining to laboratory practices, such as testing, developing analytical and microbiological methods, validating and/or validating, and stabilizing programmes.

→ Material Systems - Actions that facilitate the official release, storage, destruction, and delivery of products, as well as the control and use of material resources.

Figure 7. Construction of Quality Control

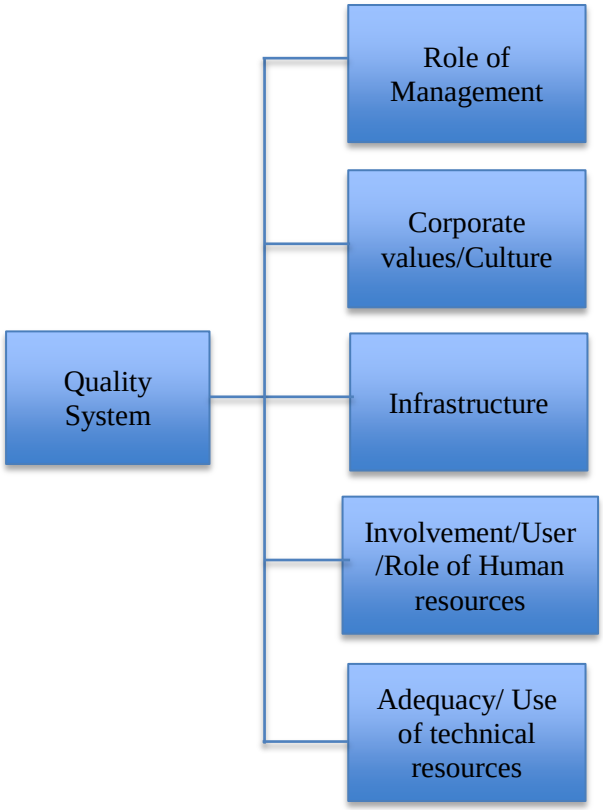

Figure 8. Quality system

B) The Pyramid Of Control

The number of objects to be controlled is large, but the number of "things" to be controlled is much larger. Publicly available catalogs and submitted price charts, multiplied by the quantity of each item, are examples of these things. The amount of products in each sale is then divided by the total sales. Product units produced are multiplied by the number of relevant quality characteristics, such as several items related to employee relationships, supplier relationships, cost control, inventory control, and product and process development, presented in Figure 9.

A common management procedure for taking actions to guarantee stability is quality control. Put another way, to "maintain the status quo" and avoid unfavorable developments. Quality control is done through a feedback loop. Every function of a product or process is subject to control, and feedback loops are built around its core. Whenever possible, human control should be performed by workers such as store clerks, factory workers, and store clerks. Flowcharts are often used in quality control plans. The weakest link in plant control is strict adherence to schedule. Strict adherence to schedules requires independent audits.

Knowing which process variables dominate helps planners allocate resources and priorities. A planner's work is usually summarized in control tables. This table is an important planning tool.

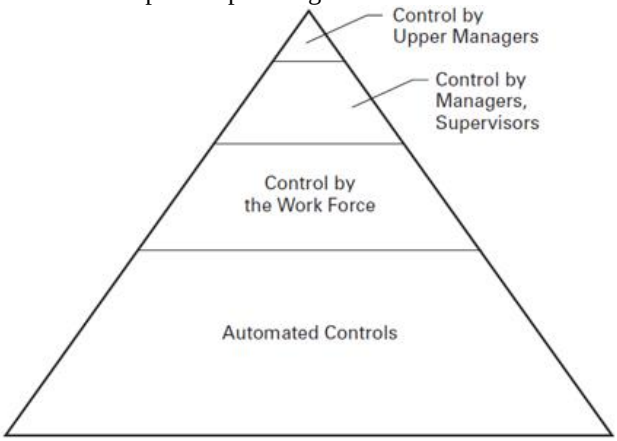

Figure 9. Pyramid of Control

The question "Who is responsible for quality?" is fundamentally unanswerable. But reformulating the question in terms of decisions and actions paves the way for agreeing answers. Real changes and false positives should be distinguished by operators with the aid of tools provided by process control design. Equipping referees with instruments to assist in differentiating between unique and common causes is highly desired. The Shewhart chart, often known as the control chart, is a great tool for this reason. Self-regulatory standards apply to all departments and all levels of processes, from managing directors to non-senior employees. Accountability for results should be based on controllability. Ideally, employees should make decisions about whether a process meets process quality objectives. There are no shorter feedback loops. To be able to use self-regulation, several important criteria must be met.

Quality comes first. Others include mutual trust, self-discipline, training, and certification. Personnel involved in product compliance decisions should be provided with clear definitions of responsibilities and decision-making guidelines. The correct order of management is to set goals first.

Then, plan how to achieve those goals, including choosing the right tools. A quality management plan aims to provide a useful information network for all decision-makers.

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