

SAMPLE METHOD AND QUALITY CONTROL

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Summary

Statistical quality control (SQC) originated in techniques of sampling inspection of lots (statistical lot inspection, SLI) and of manufacturing processes (statistical process inspection, SPI) developed since 1920's. Nowadays, the area of SQC comprises all

applications of statistical methodology for the purpose of assuring or improving the quality of products or services. Nevertheless, techniques of SLI and SPI still form the core of SQC. Both are applications of statistical hypothesis testing to the problem of deciding whether the quality of lots or processes is satisfactory or not. In recent years, the tendency has been growing to adopt SPI techniques for non-manufacturing control purposes, e.g., in service industries, finance, medicine. The present article describes the historical background, the objectives, the design principles, and the operation of SLI and SPI.

1. Introduction: Quality Control and Statistical Quality Control

1.1. Systematic Definition of Quality Control and Statistical Quality Control

The ISO standard 8402 defined *quality as the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs. Quality control* is defined as *the operational activities that are used to fulfill requirements for quality.*

Statistical quality control (SQC) is the application of statistical methodology in quality control. Statistics is concerned with drawing inferences from random samples. Hence SQC includes all those operational techniques in quality control which are concerned with sampling and with evaluating samples in order to take adequate decisions on material, products, manufacturing processes, organization etc.

The profit-and-loss statement of an industrial company is affected substantially by the degree to which its products and services are able to satisfy customers' needs, particularly in the long run. Hence the objective of quality control is basically an economic one. The economic concern of SQC is expressed in a definition given by W.E. Deming in an address to the All India Conference on Quality Control in 1971:

“The Statistical Control of Quality is application of statistical principles and techniques in all stages of design, production, maintenance and service, directed towards the economic satisfaction of demand”

1.2. Historical Origins of Quality Control and Statistical Quality Control

It is important to distinguish between the broad systematic concept of SQC introduced in Section 1.1 and the historically developed concept of SQC. The latter concept is much narrower than the systematic one. For the sake of clarity, the systematic concept might be paraphrased by *statistics in quality control*. In literature the two concepts are used ambiguously. For a better understanding, it is useful to review the history of quality control and SQC in the 20th century.

SQC traces back to the work of a group of engineers and statisticians, including H.F. Dodge and W.A. Shewhart, at Bell Telephone Laboratories in the 1920s. This group laid the foundations of the two major branches of SQC.

- (i) *Statistical lot inspection (SLI)*, often called *acceptance sampling*. Finite lots of material or product are sampled to decide whether to *accept* the lot, e.g., for reselling or processing, or to *reject* the lot, e.g., for returning to the shipper, reworking, scrapping. Earliest publications in statistical lot inspection date back to the late 1920s.
- (ii) *Statistical process control (SPC)* in the sense of *statistical process inspection (SPI)*. Processes of manufacture, service, and organization are sampled to decide whether to let the process continue without intervention or whether to take action on the process, e.g., by repairing or renewing the process. An early and classical publication in SPC is W.A. Shewhart's book *Economic Control of Quality of Manufactured Product* published in 1931.

SQC had its origin in the *parts industry*, i.e., in the industry producing discrete units of products like electric bulbs, transistors, ball bearings etc. The parts industry always remained the domain of application of SQC. Statistical methods were also applied in the *process industry*, i.e., in the industry running continuous processes like chemical industry, for the purpose of maintaining stable production processes by continuous adjustments strategies. Although from a systematic point of view these efforts can be classified as SPC, they became known under different headings like *engineering process control (EPC)*.

The history of SQC from the 1920s on reflects the history of the parts industry. In the Taylorist production environments growing in the first decades of the 20th century production was split up into a number of simple consecutive steps. Quality control was identified with inspection of parts at the end of each production step, terminating in a final inspection of finished product. After World War I, expanding mass production made 100% inspection infeasible and required the application of sampling techniques in quality control. Inspection became more efficient, but the basic *inspection attitude* remained unchanged. Quality control continued to be identified with mere inspection activities at the end of production steps. Accordingly, the early decades of SQC from the 1920s until the 1950s coincide with the zenith of theoretical investigation and practical implementation of statistical lot inspection schemes like the *Dodge-Romig Tables* or the *Military Standard* series, e.g., MIL-STD-105D or MIL-STD-414, which originated in inspection schemes of the American armament industry during World War II.

1.3. Contemporary Quality Control and Statistical Quality Control

From the 1960s on industry had to face new challenges: market globalization, rapid technological progress, increasing complexity of products, increasing cost of material and labor, increasing customer requirements, stricter legal commitments on pollution, safety, and warranty. Reacting on these challenges, industry and industrial quality control had to go through drastic changes. The *inspection principle* had to be replaced by a principle of *defects prevention* for all stages of a product's life cycle, the so-called *quality loop* (see Figure 1). The scope of quality control was extended from the manufacturing department to all levels of an industrial company, and also from manufacturing industries to service industries and to administrative organizations. An early propagator which provided the catchword for the new trend was A.V.

Feigenbaum’s book *Total Quality Control* published in 1961. The revised concept of quality control had two major consequences for SQC:

- (i) The field of statistics in quality control was considerably enlarged, exceeding the classical core of SQC. Statistics can be useful at any of the stages of the quality loop.
- (ii) The classical SQC methods came into a new ranking. Lot inspection schemes lost a good deal of their reputation and were even attacked as completely obsolete.

The practice of SQC came much closer to the systematic definition of ISO or to the one of W.E. Deming quoted in Section 1.1., above. ISO 9004 comments on the application of statistics in quality control:

“Correct applications of modern statistical methods is an important element at all stages in the quality loop and is not limited to the post –production (or inspection) stages. Applications may be for purposes such as

- a) market analysis;
- b) product design;
- c) reliability specification, longevity/durability prediction;
- d) process control/ process capability studies;
- e) determination of quality levels/ inspection plans; and
- f) data analysis/ performance assessment / defect analysis.”

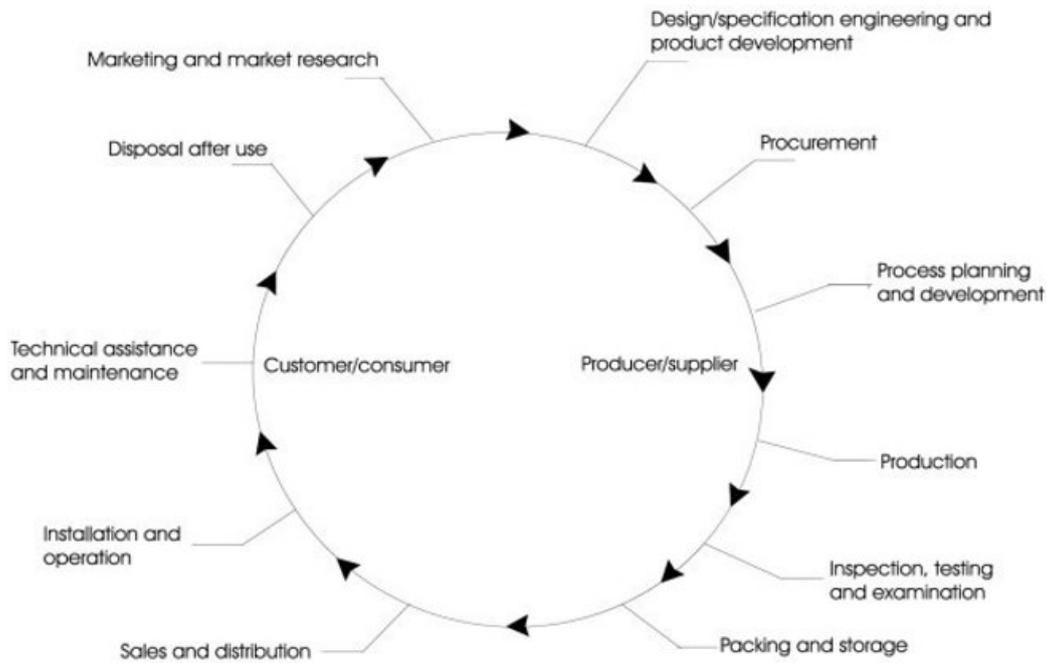


Figure1: ISO 9004 quality loop.

Without claiming completeness ISO 9004 explicitly lists the following statistical techniques: design of experiments, factorial analysis, analysis of variance, regression

analysis, safety evaluation, risk analysis, tests of significance, quality control charts, cusum techniques, and statistical sampling inspection.

At present, applications of statistical methods for purposes of quality control are growing in number as well as in category. Statistical data analysis is simplified and accelerated by statistical computing. Progress in processor and memory technology and global networking through the Internet opened new possibilities for storing, transferring and analyzing large data sets. In turn, this development spurred innovations in statistical methods. A recent example is the rise of data mining in quality control.

Considered as *statistics in quality control*, SQC is an interface which transfers statistical methods to industrial applications for the purpose of assuring quality. A large part of these methods is not specific for SQC; compare the above list given by ISO 9004. For details about these methods the reader is referred to the respective items of the EOLSS. The subsequent sections of the present article are restricted to an exposition of the classical core of SQC: Statistical lot inspection (SLI) and statistical process control (SPC) in the sense of statistical process inspection (SPI). The presentation of Sections 2,...,6 uses the terminology of discrete parts manufacturing where both SLI and SPC originated in. Extension and adaptations to other areas are reviewed in Section 7.

2. Concepts of Quality

SLI and SPC are tools of much more extensive quality control activities. In the terminology of ISO 9004, SLI is a tool of *product control*, in particular of *product verification*, where the overall control objective is to ensure the quality of incoming product, e.g., material, parts, and of outgoing completed products. In this framework, the particular objective of SLI is to discriminate between lots of satisfactory quality and lots of unsatisfactory quality. SPC is clearly a tool of *process control*, where the overall control objective is to ensure the quality of a manufacturing process. In this framework, the particular objective of SPI is to detect whether a process is of satisfactory quality or of unsatisfactory quality.

For a precise definition of the concepts of *satisfactory* and *unsatisfactory* quality it is necessary to identify the *quality indicators* of the items and of the lot or the process.

2.1. Item Quality Indicators

Each item i is ascribed a measurement ξ_i which is influenced by random events during production, transport, storage. The quality of item i is supposed to be determined exclusively by this value ξ_i , the *quality indicator of item i* . For industrial practice the most important case is a univariate item quality indicator measured in one-dimensional scale. Four major types of univariate item quality indicators are in use.

(IQ1) $\xi_i \in \{0,1\}$ where $\xi_i = 0$ is interpreted as *item i is conforming (nondefective)* and $\xi_i = 1$ is interpreted as *item i is nonconforming(defective)*

(IQ2) $\xi_i = 1, 2, 3, \dots$ interpreted as the *degree of excellence* of item i .

(IQ3) $\xi_i = 0, 1, 2, 3, \dots$ interpreted as the *number of defects (nonconformities)* occurring on item i .

(IQ4) $\xi_i \in \mathbb{R}$ interpreted as a continuous scale measurement, e.g., for weight, length, volume, surface, diameter, pressure, tensile strength, lifetime.

The choice of a suitable item quality indicator is an essential preliminary step towards the implementation of reasonable quality control techniques. Various aspects have to be observed: the physical nature of the product, material properties, engineering specifications, legal requirements, customer's requirements, and finally the economic interest in the product. Clearly (IQ1) has a special status, it is the prototype of a quality scale: requirements fulfilled or not fulfilled.

Finally from the consumer's point of view finally quality is always rated in the conforming/nonconforming scheme. Above all, (IQ1) scales are applied directly above all in the case of simple sensory characteristics like smell, color, consistency, etc. Indirect application of (IQ1) can result from *specifications limits*. Item are rated as conforming, if and only if the associated measurement falls into a prescribed *specification range* R . Thus an (IQ4) model with continuous scale measurement ξ'_i can be transformed into a conforming/ nonconforming scheme by letting

$$\xi_i = \begin{cases} 0, & \text{if } \xi'_i \in R, \\ 1, & \text{if } \xi'_i \notin R. \end{cases}$$

Typical specification ranges are

- $R = (-\infty; U]$ - upper specification limit U ,
- $R = [L; +\infty)$ - lower specification limit L ,
- $R = [L; U]$ - two-sided specification limits L, U .

Multivariate item quality indicators can be defined as vectors of the above univariate ones. From an economic point of view a multivariate item quality indicator $(\xi_i^{(1)}, \dots, \xi_i^{(k)})$ can always be reduced to a univariate one by considering the profit $\xi_i = f(\xi_i^{(1)}, \dots, \xi_i^{(k)})$ incurred from item i as the quality indicator.

Subsequent sections restrict attention to the univariate case. The problem of a formalized algorithm for the definition of quality indicators, in particular for the reduction of multivariate indicators to the univariate case, was recognized in early publications by Dodge and Shewhart. It has received growing interest recently.

2.2. Lot Quality Indicators

A lot of finite set of units (items) $1, \dots, N$ of finished product considered at a fixed time. Hence the quality of the lot is fixed and depends exclusively on the quality of the items in the lot. It is quantified by the *lot quality indicator* \mathcal{G} as a function $\mathcal{G} = T(\boldsymbol{\xi})$, where $\boldsymbol{\xi} = (\xi_1, \dots, \xi_N)$ is the vector of item quality indicators. The choice of the lot quality indicator follows economic reasoning in the following sense: The economic value of the lot should depend on the quality of the items in the lot only through the lot quality indicator. In more detail: Let $G(\boldsymbol{\xi})$ be the profit incurred from a lot with a vector $\boldsymbol{\xi}$ of item quality indicators. Then G should depend on $\boldsymbol{\xi}$ only through $\mathcal{G} = T(\boldsymbol{\xi})$, i.e., $G(\boldsymbol{\xi}) = G(\mathcal{G})$.

The most important lot quality indicator is the arithmetic mean

$$\mathcal{G} = T(\boldsymbol{\xi}) = \frac{1}{N} \sum_{i=1}^N \xi_i$$

of the item quality indicators. Corresponding to the interpretation of the item quality indicators this lot quality indicator has the following interpretations:

- (IQ1) Proportion of nonconforming items in the lot (lot proportion nonconforming).
- (IQ2) Average number of defects (nonconformities) occurring on an item in the lot (lot average number of defects).
- (IQ3) Average measure value per item in the lot (lot average measure value).

Under continuous item quality indicators of type (IQ4), an important lot quality indicator which fits to a loss function of Taguchi type is the average square deviation

$$\mathcal{G} = T(\boldsymbol{\xi}) = \frac{1}{N} \sum_{i=1}^N (\xi_i - a)^2$$

of the item quality indicators from a prescribed target a .

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