Statistics, SPC and SQC, Standards and Plans for Sampling Inspection and Considerations from Customer's Point of View

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This article is intended for everyone, but mainly for people who are involved in the inspection and testing of elements, for managers responsible for inspection and testing, and for Quality Managers who are responsible, among other things, for Quality Procedures and inspection and testing of elements.

Forward/preface

Quality Management Systems which are manifested in Quality Standards refers to controls of processes, products and services (paragraph 8.4 in ISO 9001:2015 and paragraph 8.4 in AS9100:2016 and relevant paragraphs in IATF 16949, ISO 13485 and TL9000). Basically, the control of the supplier (sub-contractor) is performed in two major areas:

1. **Control of Quality Management System** – does it suitable to the organization's (the buyer) requirements and conform to supplier's commitment according to his Quality Management System? – Those are administrative (managerial) issues and are held mostly by trained auditors specialized for auditing of Quality Management Systems (according to ISO 19011 - Guidelines for auditing management systems).
2. **Control of the processes, products and services** – can refer to administrative (managerial) referring to products and services but also to technical processes of products, stating with raw materials, manufacturing specific element, coating, inspection (in process, source and incoming) and decisions according to findings. In this article we shall focus on inspection (test) of Optical Elements, but it can also refer to other elements as well.

For understanding well our concept of Sampling Inspection we shall refer first to the roots of it which are important. They are the basis for the inspection of controlling processes, products and services of all kinds that are performed today and based on Sampling Standards which are the results of what was developed in early days.

Definitions

Statistics - the science of collecting, analyzing, presenting, and interpreting data.

Statistical Quality Control (SQC)* - a methodology used by statistical methods to monitor and control the quality of products or services. Statistical Quality Control is often used interchangeably with Statistical Process Control (SPC).

Statistical Process Control (SPC)* - statistical method/technique/methodology to measure, monitor, and control and improve manufacturing processes. Statistical Process Control is often used interchangeably with Statistical Quality Control (SQC).

* Despite the similar definitions of SQC and SPC, SQC mostly refers to Quality issues like managerial procedures that includes SPC while SPC refers to technical manufacturing procedures by statistical methods. (Look for good and more explanation in: "What is the Difference between SPC and SQC?" by Hinal Modi, July 26, 2024 on website: https://foodready.ai/blog/what-is-the-difference-between-spc-and-sqc/).

Process Control (PC) – for our matter it is a way to monitor and manage the products to ensure conformity and quality, limit waste and increase efficiency. Process Control is common in manufacturing and continuous production environments.

Sampling - a technique of selecting individual members or a subset of the population to make statistical inferences from them and estimate the characteristics of the whole population.

Random Sampling - a process used to select a sample in a random way, so that the units of the sample are chosen independently, without regard to one another.

Sampling Inspection** **-** a method/technique based on the evidence of a small sample to decide if a population, batch of components, materials, or products, are to be accepted or rejected.

Statistical Sampling Inspection** **-** a method/technique based on samples that are taken from a target lot (population) for testing to determine the acceptability (accept or reject) of the lot according to quality procedures or sampling standards.

** While **Sampling Inspection** is basically referred just for kind of test/inspection of a sample from a kind of population, the **Statistical Sampling Inspection** means mostly to test/inspection elements according to Quality Management Plan which refers to some kind of sampling procedures or standards, often only for some product features.

AQL (Acceptable Quality Level/Limit) - The Acceptable Quality Level/Limit (AQL) defines the maximum number of defective items allowed in a batch of products that inspectors can still consider acceptable. Statistical Sampling Standards (ANSI/ASQ Z1.4, MIL-STD-105E, MIL-STD 1916) or "Zero Acceptance Number Sampling Plans" (by Nicholas L. Squeglia) determines the AQL for a product. Quality control uses AQL to decide whether to accept or reject a lot based on the number of defects found in a sample.

Just in Time - an inventory management system in which a company receives goods or materials as closely as possible to when it needs them.

Batch*** - number refers to components produced in the same manufacturing process. For example: Coating Batch.

Lot*** – Number refers to a group of products with a common manufacturing history. For example: Delivering Lot No. 10.

***Lot or Batch** – sometimes meaning the same: quantity of a product produced at a single production facility within a single manufacturing cycle and specifically marked with a date.

Short historical development of statistical sampling procedures followed by statistical sampling standards

1922[1] - All started at the beginning of the 20th century at the **Western Electric Company** (the AT&T equipment manufacturing arm). Also, according to an article in the *General Electric Review* in 1922, some formal attempts at scientific acceptance sampling techniques were made at the G.E. Lamp Works (Sampling for Test Purposes by Geo. L. Diggles - Electrical Testing Laboratories, New York. General Electric Review, January 1922 – December 1922, VOL XXV No.6, pages 379-402 (published in June 1922). (https://www.worldradiohistory.com/Archive-Company-Publications/General-Electric-Review/General-Electric-Review-1922.pdf)

1924[1] **– "Walter Shewhart**, a physicist and self-made statistician, was assigned to examine and interpret inspection data from the **Western Electric Company**[2] Hawthorn Works **…** he realized that something serious should be done, and he conceived the idea of **Statistical Control**. It was based on the premise that no action can be repeated exactly … the control chart he perceived was founded on sampling during production rather than waiting until the end of the production run".

"The early dissemination of these ideas was limited to the circulation of memos within the Bell Telephone System. However, the soundness of the proposed methods was thoroughly validated by staff at Western Electric and the Bell Telephone Laboratories. The methods worked effectively and were soon made part of the regular procedures of the production divisions".

1927[1] - **Harold F. Dodge** and **Harry G. Romig** developed tables for rectification inspection indexed by the lot tolerance and AOQL (average outgoing quality level)

1931[1] - "Shewhart's ideas were eventually published in his 1931 book "**The Economic Control of Quality of Manufactured Product"** (Shewhart 1931)".

1941[1] **- Dodge** and **Romig**'s sampling tables were published in the Bell System Technical Journal in 1941(Dodge and Romig 1941).

1941[1] – "At the request of the War Department, the American Standards Association developed **American War Standards Z1.1-1941** and **Guide for Quality Control Z.1-2-1941**, **Control Chart Method of Analyzing Data - 1941**, and the **Control Chart Method of Controlling Quality during Production Z1.3-1942**".

1942[1] **-** a course on statistical quality control developed at Stanford by Holbrook Working, **E. L. Grant**, and **W. Edwards Deming** was given at Stanford University to representatives of the war industries and procurement agencies of the armed services. This was followed by:

- "Developing applications of statistical quality control, led the Office of **Production and Research and Development (OPRD)** of the **War Production Board** to establish a nationwide program. The program

combined assistance in developing intensive courses for high-ranking executives from war industry suppliers and direct assistance to establishments on specific quality control problems" ….

- "The plan was to have courses for key quality control personnel from industry given at local educational institutions, which would provide an instructor from their own staff. This plan was implemented with administrative assistance and grants from the Engineering, Science and **Management War Training Program (ESMWT)** funded by the U.S. Office of Education. Much of the training of subordinate quality control personnel was given in their own plants by those previously trained. To stimulate people to actively advance their own education, the OPRD encouraged local groups to form. … The need for literature on statistical quality control was satisfied by publications of the American Standards Association and articles in engineering and technical journals. As a result of all the training and literature, statistical quality control techniques were widely used during the war years. They were instrumental in ensuring the quality and cost effectiveness of manufactured goods as the nation's factories made the great turnaround from civilian to military production…".
- "At the conclusion of the War in 1946, seventeen of the local quality control societies formed during the war organized themselves into the American **Society for Quality Control (ASQC)**. This society has recently been renamed the **American Society for Quality (ASQ)** to reflect the fact that Quality is essential to much more than manufacturing firms".

Following the statistical sampling development from the 1922 year until Second World War and "The development and use of sampling tables and sampling schemes for military procurement continued after the war, resulting in the MIL-STD-105A attributes sampling scheme, which was later revised as 105B, 105C, 105D, and 105E. In addition, variables sampling schemes were developed that eventually resulted in MIL-STD 414[1]".

(For this article our interest is in the Attribute standards and not in Variables standards like MIL-STD 414 or ANSI/ASQ Z1.9).

1959 - MIL-STD-105A - "**Sampling Procedures and Tables for Inspection by Attributes**".

1989 - MIL-STD-1916 - "DoD Preferred Methods for Acceptance of Product" (1 April 1996)

1989 - MIL-STD-105E - "**Sampling Procedures and Tables for Inspection by Attributes**" published on 10 May 1989 and cancelled on 06 February 2008. Future acquisitions may refer to: MIL-STD-1916, "DoD Preferred Methods for Acceptance of Product", or ANSI/ASQ Z1.4, "Sampling Procedures and Tables for Inspection by Attributes".

1993 - ANSI/ASQ Z1.4 – "**Sampling Procedures and Tables for Inspection by Attributes**".

The following important sampling plan should be mentioned as well:
1965 - "Zero Acceptance Number Sampling Plans" by Nicholas L. Squeglia. 6th edition published in 2023. (Also called "C = 0 Plans" when C represents the accepted number, meaning that for accept the lot, the number of not conforming elements in the sample is 0).

[1]All this information taken almost completely from "**Chapter 1 Introduction Historical Background - An Introduction to Acceptance Sampling and SPC with R files**".
(https://bookdown.org/lawson/an_introduction_to_acceptance_sampling_and_spc_with_r26/introduction-historical-background.html)

[2]**Western Electric Company** was established in 1869 and operated until 1996. **In 1917** (and years later) **the company employed about 25,000 people!** A few years later, **Walter Shewhart,** at **Western Electric Company** conceived the idea of statistical control. It was based on the premise that no action can be repeated exactly. Therefore, all manufactured products are subject to a certain amount of variation that can be attributed to a system of chance causes.

For such big companies having processes for ongoing (continuous) production, statistical control of production is essential for the quality of the product and general cost for the company. But always remember, time is money and spending more time on inspection means spending more money on it and less financial gain for the company!

Quality and Statistical Sampling Standards during World War II and after

During World War II

All statistical inspection theories and standards referring to statistical inspections were developed and established in U.S.A. They started in 1920, continued at the beginning years of World War II. As those theories and standards found to be very useful for Quality and financial gain for the company, they adopted by the big companies and found to be very useful during World War II as the nation (U.S.A.) has fully enlisted in the war effort. War required a great deal of means, with the speed and quality required and the statistical standards that were available in these years, helped to reach these goals.
According to **"Quality Management in WWII"** from **"The History of Quality"** by **ASQ**: "To ease the problems without compromising product safety, the armed forces began to use sampling inspection to replace unit-by-unit inspection. With the aid of industry consultants, particularly from Bell Laboratories, they adapted sampling tables and published them in a military standard, known as MIL-STD-105. These tables were incorporated into the military contracts, so suppliers clearly understood what they were expected to produce.
The armed forces also helped suppliers improve quality by sponsoring training courses in Walter Shewhart's statistical quality control (SQC) techniques.

See: The History of Quality - https://asq.org/quality-resources/history-of-quality?srsltid=AfmBOoqu6eyEpV4pVJeIZxYGrtY8nMJiBplI8sKIGmwWy9mrcR3PZKEC"

(The MIL-STD-105 was first published after the end of World War II).

But there is no information about which companies adopted the new sampling theories and standards during the years of World War II. If there are such companies, usually the information about adopting the new sampling theories and standards is confidential and these companies do not share the inside information about what they did, how it was implemented and what were the results of this adoption. An exceptional company of course was the Bell Telephone Laboratories where Walter Shewhart worked and implemented his statistical theories.

After the World War II – First 40 Years

As there is no information about how much and by whom, the adoption of statistical methods for inspection/testing elements during production during the years of World War II, there is no information about what happened for these matters after the war. Basically, we refer for these matters about what happened in the U.S.A as the leading country for the production for the World War II needs and as the statistical methods for inspection/testing elements during production have developed and displayed to the industrial organizations in the U.S.A.
These matters of Statistical Process Control (SPC) and Quality publications of **Dodge**, **Romig**, **Deming**, **Shewhart, Juran** and others have not impressed the American industry and things after and things after World War II have been continued as before.

After the World War II – Japan's Awakening

The most influential person in modern quality control was an American who was a hero in Japan but virtually unknown in the United States. W. Edwards Deming worked with Shewhart at Bell Labs and helped apply Shewhart's ideas to American manufacturing processes during World War II. Following the war, American factories returned to the production of consumer goods. Many of the other major manufacturing centers in the world had been damaged by bombing during the war and took time to recover. Without the safety needs of wartime and with little competition, quality control was not a high priority for American companies. Management in the United States focused on increasing production to meet demand and lowering costs to increase profits.
After the war, while the United States occupied Japan, Deming was asked by the U.S. Department of the Army to assist with the statistics of the 1950 census in Japan. Kenichi Koyanagi, the managing director of the Union of Japanese Scientists and Engineers and a very influential industrialist, asked Deming to speak to twenty-one top industrial leaders on the topic of global strategy for Japanese industry. Deming went beyond Shewhart's work and talked about his philosophy of quality manufacturing and how the responsibility for quality begins with management. He explained that a corporate culture devoted to producing high-quality products would result in less waste, lower costs, greater client loyalty, and greater market share. With Koyanagi's support, Deming's ideas were widely adopted by these influential leaders.
Deming described his philosophy as a system of profound knowledge, which has four parts:

1. *Appreciation of a system*. Understanding how suppliers, producers, and clients interact
2. *Knowledge of variation*. Understanding statistical variation
3. *Theory of knowledge*. Understanding what can be known and what cannot
4. *Knowledge of psychology*. Understanding human nature

In 1950, the Japanese created the Deming prize in Deming's honor, which is awarded to an individual and a company for major advances in quality improvements. In 1960, Deming was awarded the Order of the Sacred Treasure, Second Class by the Prime Minister on behalf of Emperor Hirohito.

By the 1970s, Japanese companies had a reputation for high quality and were taking market share from American companies, but Deming's teachings were virtually unknown in his own country. It was not until 1980 that America became aware of Deming when his work was described in an NBC documentary titled ***If Japan Can, Why Can't We*?** By then, Deming was eighty years old, and the producer of the show originally assumed he was dead.

Between 1979 and 1982, Ford Motor Company lost $3 billion, and they were looking for solutions to their problems. They chose to apply Deming's approach to develop the new Taurus-Sable model and by 1986 had become the most profitable American auto company.

In 1982, Deming's book was published and later retitled **"Out of Crisis"**, in 1986. It was aimed at explaining his system to American manufacturers and the American public. In the book, Deming described fourteen principles of management to guide the implementation of his philosophy. Some of them were challenges to Western managers and very different from the thinking that was prevalent at the time.
(see **Deming's 14 Points,** Website: https://www.uthsc.edu/its/business-productivity-solutions/lean-uthsc/deming.php).

This chapter **"After the World War II – Japan's Awakening"** has been taken almost completely from "**Quality Management in America"**,
(See Website: https://www.opentextbooks.org.hk/ditatopic/39288)

Sampling Inspection based on Sampling Standards not for SPC but for PC and Considerations from Customer's Point of View

Sampling Procedures by companies basically are confidential and are not published to the public. The Sampling Procedures as part of the Quality Management System are known to companies that decide what kind of sampling to perform to ensure the quality of the goods to compliance with requirements and satisfy their customers. Companies with Quality Management System that comply with Quality Management Standard (ISO 9001, AS9100, IATF 16949, ISO 13485 and TL9000), their Quality Management System is exposed to auditors of the audit organizations, and they can see the organization's sampling procedures being used.

The existing sampling standards (ANSI/ASQ Z1.4, MIL-STD-105E, MIL-STD 1916 or "Zero Acceptance Number Sampling Plans" by Nicholas L. Squeglia) are widely used for the ongoing mass production but also for small productions. Automated inspection or sampling that developed to specific kind of requirement are used as well. For critical parameters 100% inspection is ascensional.

Let us not forget that Sampling Procedures at the beginning were established in and for **big companies with ongoing mass production**. Using Sampling Standards for SPC (Statistical Process Control) in production for achieving good quality on the one hand but reducing cost of the production on the other hand made good for the **ongoing mass production**. SPC for small quantities is acceptable only if it's an **ongoing production.**

But many companies are small, and they do not produce mass production of goods and their process of producing element is not ongoing. These small companies even get orders from customers for hundreds or more elements, supply the finished elements according to the customer's **Just in Time** methodology. It means that between the finished quantities, the manufacturer is changing the set-up for producing different elements for different suppliers. So, SPC and the rules of the statistical sampling standards in these cases are not relevant but the inspection itself is critical for achieving and delivering good elements to the buyer, the customer. So, for inspection of the produced elements, companies adopting the statistical sampling standards (ANSI/ASQ Z1.4 or MIL-STD-105E or MIL-STD 1916 or "Zero Acceptance Number Sampling Plans" by Nicholas L. Squeglia) for a sampling but not for SPC. This adoption is expressed in companies' **Sampling Procedures** by determining rules for sampling inspection and the **AQL (Acceptable Quality Level/Limit)** as well.

The obligation of the manufacturer to deliver to the customer elements that meet all stated requirements but even then, due to the cost of the inspection, the customer and manufacturer can agree to Sampling Inspection according to some AQL of Statistical Sampling Standard.

There are two kinds of Sampling Procedures:
1) customer's procedure for his inspection and for manufacturer's inspection and,
2) manufacturer's procedure.
Good customer Sampling Procedures should consider other possibilities that allow the inspector **not to follow exactly the AQL requirement**. These considerations refer to the history and reliability of the manufacturer, complexity and features of the elements, experience of customer's inspector and even on the authority given to the inspector by higher authority for consideration during the inspection.

What is the meaning of "**not to follow exactly the AQL requirement**"?
For example, if the Inspection Procedure requires AQL of 2.5 and for 30 elements we need according to "Zero Acceptance Number Sampling Plans" to test 5 elements for all stated element's parameters, can the customer's inspector to consider, referring to his experience, the history and reliability of the manufacturer, complexity and features of the elements and even by authority given to him, to test some parameters for **more or less** than AQL of 2.5%? **Things to think about**.

And what happened when nonconformance (deviation from stated requirement) has been found after the consideration that has been taken?

1. If the inspection is based on MIL-STD-105E or ANSI/ASQ Z1.4, refer to Organization's Procedure referring to such cases (MRB, CAR and other needed activities).
2. If the inspection based on "Zero Acceptance Number Sampling Plans" remember that when nonconformance has found, the lot is being **withhold** as written in the "Zero Acceptance Number Sampling Plans":

> This book provides a set of attribute plans for lot-by-lot inspection. The acceptance number in all cases is zero. This means that for some level of protection you select a certain size sample and withhold the lot if the sample contains one or more nonconforming pieces.
>
> The phrase "withhold the lot" is significant in that it does not necessarily mean rejection. Under these plans, the inspector does not automatically reject the lot if one or more nonconformances are found. The inspector only accepts the lot if zero nonconformances are found in the sample. Withholding the lot forces a review and disposition by engineering or management personnel in regard to the extent and seriousness of the nonconformance.

Meaning that, in other words, MRB should decide what will be the next step.

3. Inspection based on customers procedure that don't based on existing sampling standards or plans (ANSI/ASQ Z1.4, MIL-STD-105E, MIL-STD 1916 or "Zero Acceptance Number Sampling Plans" by Nicholas L. Squeglia) has the same importance.
4. Additional consideration should be taken, referring to what kind of deviation was found by the customer's inspector or representative during incoming inspection or source inspection. Is the found deviation being significant or meaningless and can be approved without wasting time and disruption of the continued delivery of items to the next station (local decision by the inspector or by quick MRB decision – both cases according to customer's stated procedures). Is the deviation connected to safety parameters, to functional parameters or to visual parameters? Recommendations on how to act in these cases cannot be given, and each organization must act according to its own discretion and in accordance with written procedures.

And why is the last decision, the lot approved or rejected is so important? It is important because it gives information about manufacturers' quality. For customers that evaluate the quality of the manufacturer, good lot increases manufacturer's score and bad lot, decreases the score. All it can have influence on the next orders from the manufacturer. And of course, let us not forget that bad lot can delete the production of the next stage.

MRB – Material Review Board - a board that consists of authorized supplier quality and engineering members that are needed to review, evaluate, and determine the proper disposition of nonconforming material referred to it.
CAR – Corrective Action Request - a request sent to a supplier or manufacturer to open an investigation into the occurrence of nonconformity or a defect of a specific product.

Sampling Inspection based on Sampling Standards and Considerations from Manufacturer's Point of View

The Quality Management Standards mentioned above (ISO 9001, AS9100, IATF 16949, ISO 13485 and TL9000) do not refer specifically what Inspection Sampling Standard adopt and use. Manufacturing and Service organizations can adopt the relevant standard at their discretion and according to their needs and can establish standard/procedure of their own accordingly. Of course, they should always consider the customers' needs and their explicit requirements and follow what kind of inspection to implement referring to the sector of their activity: health, transportation, communication, electronics, aviation, agriculture, and other sectors.

Summary

What's written in this article is based on my experience in testing and inspection of elements, and the consideration as I refer to that can also be adopted to different technologies that do not use the SPC but PC procedures.
There are many articles and books referring to SPC and explanation of Sampling Standards for Inspection but almost nothing on the real processes and results of inspection by companies. It is understandable without a doubt and must not be distributed to the public and, of course, each company establishes the needed inspection and procedures for inspection depending on the nature of its products, their complexity, the quantities required and of course their accumulated experience. Inspection is important. Following the organization's procedures is important as well and consideration in testing (inspection) serves the organization's needs for delivering the elements in time to the next station and to reduce time (time is money!) of the inspection. Of course, any test and any consideration shouldn't harm the confidence that what is being tested meets the requirements.

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