



BSI Standards Publication

Aerospace Series — Quality Management Systems — Statistical Product — Acceptance Requirements

National foreword

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English Version

Aerospace Series - Quality Management Systems - Statistical Product - Acceptance Requirements

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qualité - Exigences d'acceptation statistique des
produits

Luft- und Raumfahrt - Qualitätsmanagementsysteme -
Statistische Produktannahmeanforderungen

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CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN 9138:2019) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

After enquiries and votes carried out in accordance with the rules of this Association, this Standard has received the approval of the National Associations and the Official Services of the member countries of ASD, prior to its presentation to CEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Rationale

This standard is an upgrade and replacement for the Aerospace Recommended Practice (ARP) 9013-series of documents (i.e., ARP9013, ARP9013/1, ARP9013/2, ARP9013/3, ARP9013/4) prepared and published by the Americas Aerospace Quality Group (AAQG) in 2005. Technically equivalent standards are published in all International Aerospace Quality Group (IAQG) sectors (i.e., Americas, Asia-Pacific, Europe). Reasons for publishing this standard include the following:

- 1) Quality Engineers and planners within many organizations which utilized sampling standards, prior to the publishing of the ARP9013-series of documents, found previous standards difficult to interpret and/or to implement correctly. The IAQG recognized this situation and chartered a committee in 2001 to develop a new sampling standard. The assignment to write a new statistical standard was given to the Americas sector of the IAQG with the stated strategy that once the new document was published and tested in the AAQG, it would be brought back to the IAQG for global implementation.
- 2) The ARP9013-series of documents was published in 2005 to be simpler than existing legacy standards. It also marked a transition from legacy statistical product acceptance requirement documents that were organized around a measure of producer protection rather than consumer protection. To accomplish this without extreme increases in inspection required the simultaneous introduction of new statistical tools and tables.
- 3) After experience gained from the initial release of the ARP9013-series of documents, the IAQG believed that the goals of simpler and more effective statistical methods for Quality Engineers and planners had been achieved, but that further improvements were possible, both in the development of new tools and in providing further detail/clarifications within the writing.
- 4) Furthermore, there have been changes in the EN 9100/EN 9110/EN 9120 quality management system standards relative to the language associated to statistical product acceptance. This EN 9138 standard incorporates those changes.

Foreword

To assure customer satisfaction, the aviation, space, and defence industry organizations produce, and continually improve, safe, reliable products that meet or exceed customer and regulatory authority requirements. The globalization of the aerospace industry and the resulting diversity of regional/national requirements and expectations have complicated this objective. End-product organizations face the challenge of integrating and assuring the quality of product purchased from suppliers throughout the world and at all levels within the supply chain, while suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

The aerospace industry established the IAQG for the purpose of achieving significant improvements in quality and safety, and in reduced costs throughout the value stream. This organization includes representation from aerospace companies in the Americas, Asia/Pacific, and Europe. This standard has been prepared by the IAQG. This document standardizes and streamlines, to the greatest extent possible, the requirements and flexible resources on statistical techniques for product acceptance across the diversity of aerospace industry processes. The establishment of common requirements, for use at all levels of the supply-chain by organizations around the world, should result in improved quality and safety, and decreased costs due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.

Introduction

This standard establishes the general requirements applicable to any method of statistical product acceptance to reduce inspection costs while still assuring acceptable quality. There is no single specific plan that can be considered best suited for all applications or processes.

This document applies only to statistical methods used for product acceptance and does not apply to statistical methods that are not related to product acceptance. Many companies use excellent statistical methods solely to monitor and to improve their product quality, and those methods are not subject to the requirements of this document.

Products which are eligible for the methods defined in this standard include, but are not limited to: end items, cast, forged, wrought, machined, fabricated, plastic, moulded, powdered metal, or stamped components and raw material; electronic, electrical, and mechanical components.

0.1 Paradigm of quality requirements and product acceptance plans

Figure 1 shows how requirements and acceptance strategies come together to develop a product acceptance plan.

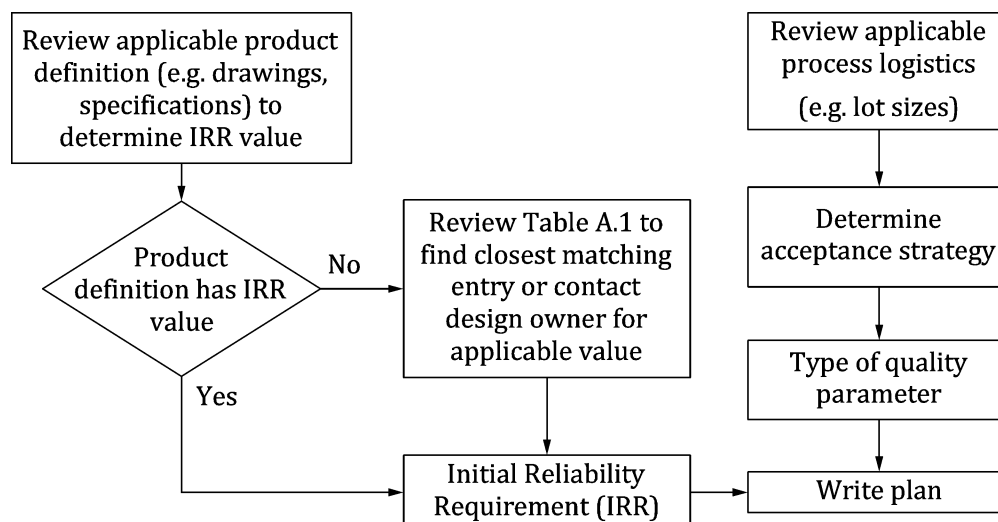


Figure 1 — Engineering and operations inputs into product acceptance plan

0.1.1 Engineering

Each product is engineered to meet functionality and reliability goals. Engineering provides requirements that are needed to meet the goals. Assessment of the goals involves statistics. To compare the goals with engineering requirements requires a statistical benchmark. This document expresses the engineering requirement as an Initial Reliability Requirement (IRR) or Inspection Reliability Requirement. The IRR defines a minimum acceptable outgoing yield or probability of conformance.

It is recommended by regulatory authorities that, “Engineering and manufacturing organizations should participate in the review, implementation, and maintenance of statistical quality/process control techniques used for product or article acceptance” [reference Federal Aviation Administration (FAA) Advisory Circular (AC) 21-43].

If Engineering does not provide a specific protection value (e.g., IRR), then the values in Annex A (see Table A.1) are provided as conventional levels of protection.

0.1.2 Operations

The attainment of product functionality and reliability goals involves several kinds of production logistics. Product may be produced in batches, large or small lots, continuous processes, or single-piece flow manufacturing processes. Assessments of the product may occur in receiving inspection, in-process inspections, final inspection, or in-storage inspection. The statistical product acceptance requirements for each kind of production logistics are documented in separate clauses of this document. Each clause cites one or more quality parameters that are used to verify that produced parts meet the Engineering *IRR*.

Manufacturing and/or inspection should provide the range of lot sizes and frequencies that are expected to be used to produce the subject product. Additional information from these organizations should include measurement accuracy (see 4.7), randomization tools (see 4.5), product retrievability limits (see 4.8), and available resources for training, auditing, and records (see 4.2, 4.11, and 4.9 respectively).

Product may be accepted as one or more isolated lots under the instructions of clause 6; sample sizes may be adjusted from lot-to lot based on the history of lot rejections under the instructions of Clause 7; product may be accepted based on process controls under the instructions of Clause 8; and product may be accepted one unit at a time or by other advanced methods under the instructions of Clause 9. Each clause has further explanations and guidance in an associated Annex. There are also guidance and sampling tables relating to these clauses in the Supply Chain Management Handbook (SCMH) published online by the IAQG.

0.2 Acceptance method considerations

Selecting which of EN 9138 clauses 6, 7, 8, or 9 is most appropriate for a statistical product acceptance application depends on the answers to the five decision diamonds (see Figure 2). Each clause covers a family of statistical techniques and their associated quality parameters; Figure 2 presents how the decisions result in the selection of the most appropriate clause.

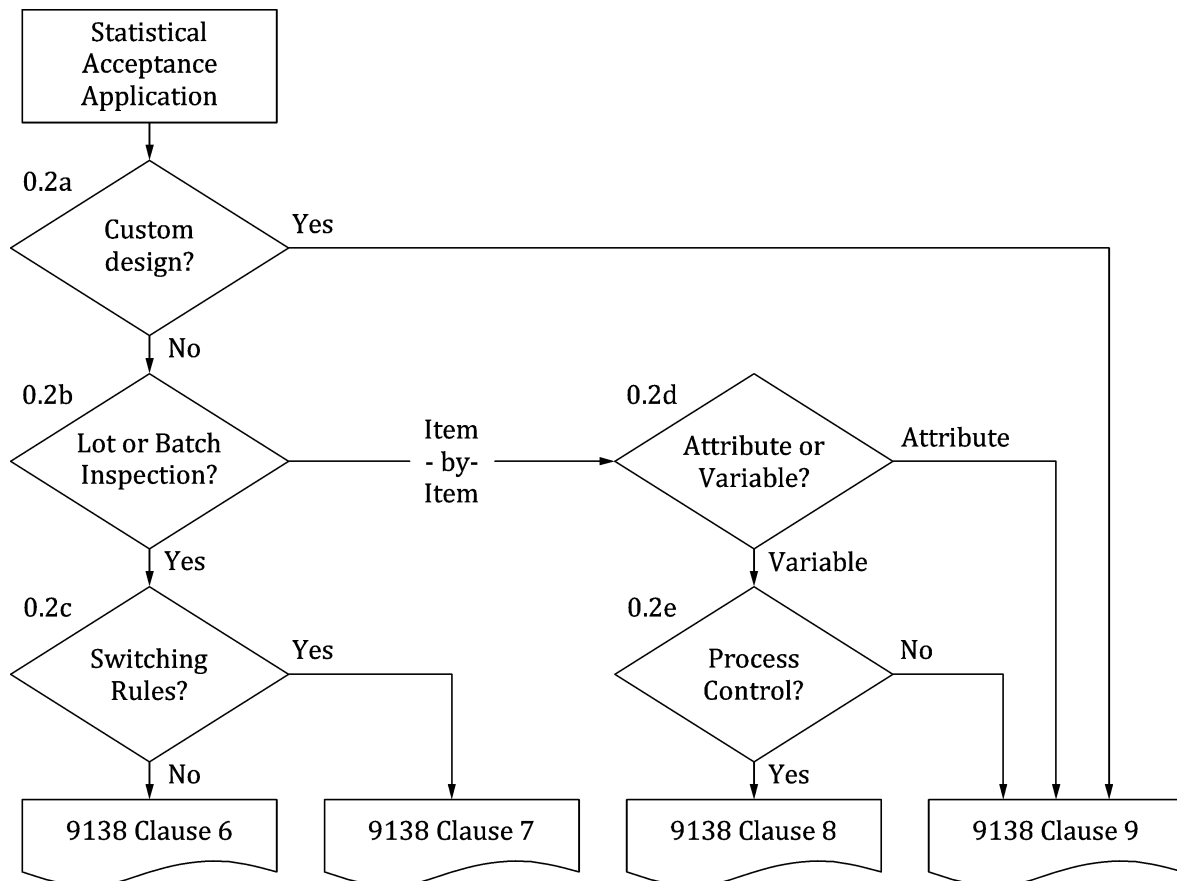


Figure 2 — EN 9138 clause selection guide

- a) In the first decision diamond, the question is whether the specific statistical tool is drawn from published sources (e.g., SCMH) or whether the organization intends to develop their own method; this recognizes that the EN 9138 standard allows for the development of new methods. The skill level for doing this requires competency with the mathematical tools in the definitions clause of this document, support from individuals knowledgeable about the measurement or evaluation processes, and support from individuals who understand the consequences of non-conformances (these should include design authority individuals).
- b) In the second decision diamond, the question is whether the product in question is to be accepted one unit at a time versus being accepted in lots or batches. This decision may be affected by “Economic Order Quantity” mathematics or by direct contractual stipulation.
- c) In the third decision diamond, the question is associated with the use of switching rules. For many years, most sampling standards required users to keep track of their records of previous accepted and rejected lots from each sampled process, and to increase or to decrease the sample sizes in response to the process history. The rules for increasing or decreasing the amount of inspection were called “switching rules”. Switching rules may be helpful in processes that have long production runs, stable quality, relatively large lots, and good computing support to handle the administrative details. Switching rules are also sometimes required by contractual reference to legacy standards. In other cases, the simplicity of individual lot sampling plans may offset the potential savings of using more complicated switching rules.

- d) The fourth decision diamond asks whether the product quality is evaluated on an attribute or variables basis. This question depends primarily on the level of computing and administrative resources available, because variables data involves collecting the detailed measurements of every accepted feature. The additional information from variables sampling does allow for fewer inspections to be performed, so the tradeoff would usually apply variables inspection to products with few characteristics and very high inspection costs per unit.
- e) The last decision diamond asks whether process controls alone will control the probability of an escape to the customer.

1 Scope

1.1 Purpose

This European standard establishes requirements when implementing statistical product acceptance methods to meet defined risk requirements. This standard also establishes the minimum content required to be covered in an organization's documented procedures that govern their application of statistical product acceptance methods.

These general requirements and documented procedures apply the requirements of the EN 9100/EN 9110/EN 9120 quality management system standards, in addition to establishing requirements for retrievability, safety/critical characteristics, and quality parameters that protect the customer.

1.2 Application

This standard is applicable when invoked in a purchasing contract or specification, contractual document, customer agreement, or adopted by the organization. The purchase contract/agreement may or may not identify the appropriate EN 9138 clause(s) to be applied by the organization. All statistical methods of product acceptance require the use of Clause 4 and Clause 5.

To accept product produced:

- by individual lots, see Clause 6;
- under switching rules, see Clause 7;
- under process controls, see Clause 8; and
- by continuous sampling or special case methods, see Clause 9.

2 Normative references

The following referenced documents are valuable for the application of specific tools presented in this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. When a conflict in requirements between this document and the referenced standards/related writings exists, the requirements of this document shall take precedence; however, nothing in this document supersedes applicable laws, regulations, and contractual requirements.

2.1 International Aerospace Quality Group publications

EN 9100, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*¹

EN 9110, *Quality Management Systems — Requirements for Aviation Maintenance Organizations*¹

EN 9120, *Quality Management Systems — Requirements for Aviation, Space and Defence Distributors*¹

¹ As developed under the auspice of the IAQG and published by various standards bodies [e.g., Aerospace and Defence Industries Association – Standardization (ASD-STAN), SAE International, European Committee for Standardization (CEN), Japanese Standards Association (JSA)/Society of Japanese Aerospace Companies (SJAC), Brazilian Association for Technical Norms (ABNT)].

Supply Chain Management Handbook²

NOTE References to specific EN 9100/EN 9110/EN 9120 revision dates are included in this document in order to allow for the corresponding standard clause numbers to be identified and to recognize the potential for future changes to these standards; however, the applicable clause(s) from the latest revision have precedence.

2.2 American National Standards Institute publications

ANSI/ASQ Z1.4, *Sampling procedures and tables for inspection by attributes*³

ANSI/ASQ Z1.9, *Sampling procedures and tables for inspection by variables for percent nonconforming*³

ANSI/ASQC B1, *Guide for Quality Control Charts*³

ANSI/ASQC B2, *Method of Analyzing Data*³

ANSI/ASQC B3, *Controlling Quality during Production*³

ANSI/ASQC S1, *An Attribute Skip-Lot Sampling Program*³

2.3 International Organization for Standardization publications

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*⁴

ISO 3951-1, *Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*⁴

ISO 9000, *Quality management systems — Fundamentals and vocabulary*⁴

ISO 11462-1, *Guidelines for implementation of statistical process control (SPC) — Part 1: Elements of SPC*⁴

ISO 11462-2, *Guidelines for implementation of statistical process control (SPC) — Part 2: Catalogue of tools and techniques*⁴

ISO/IEC Guide 98-1, *Uncertainty of measurement — Part 1: Introduction to the expression of uncertainty in measurement*⁴

ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*⁴

ISO/IEC Guide 98-4, *Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessment*⁴

² See <http://www.sae.org/iaqg/>

³ Available from American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, Tel: 212-642-4900, www.ansi.org

⁴ Available from International Organization for Standardization, ISO Central Secretariat, 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, Tel: +41 22 749 01 11, www.iso.org

2.4 Japanese standards

JISZ9003:1979, *Single sampling inspection plans having desired operation characteristics by variables (standard deviation known)*⁵

JISZ9004:1983, *Single sampling inspection plans having desired operating characteristics by variables (standard deviation unknown and single limit specified)*⁵

JISZ9010:1999, *Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)*⁵

JISZ9015-0:1999, *Sampling procedures for inspection by attributes — Part 0: Introduction to the JISZ9015 attribute sampling system*⁵

JISZ9015-1:2006, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*⁵

JISZ9015-3:1999, *Sampling procedures for inspection by attributes — Part 3: Skip-lot sampling procedures*⁵

JISZ9020-1:2011, *Control charts — Part 1: General guidelines*⁵

JISZ9021:1998, *Shewhart control charts*⁵

JISZ9041-1:1999, *Statistical interpretation of data — Part 1: Statistical presentation of data*⁵

JISZ9041-2:1999, *Statistical interpretation of data — Part 2: Techniques of estimation and test relating to means and variances*⁵

JISZ9041-3:1999, *Statistical interpretation of data — Part 3: Tests and confidence intervals relating to proportions*⁵

JISZ9041-4:1999, *Statistical interpretation of data — Part 4: Power of tests relating to means and variances*⁵

JISZ9041-5:1999, *Statistical interpretation of data — Part 5: Median — Estimation and confidence intervals*⁵

2.5 Published books and periodicals

Certified Reliability Engineer Primer, 4th Edition (October 1, 2009); Quality Council of Indiana; page VI-21

The Mathematical Background of QSTAG 340; American-British-Canadian-Australian Armies Standardization Program, Quadripartite Advisory Publication 16; pages VI-2 and VI-3

Zero Acceptance Number Sampling Plans; N. L. Squeglia; ASQ Quality Press

⁵ Available from Japanese Standards Association (JSA), Mita MT Bldg., 3-13-13 Mita, Minato-ku, Tokyo, 108-0073, Japan, Tel: +81-3-4231-8503, <http://www.jsa.or.jp/>

2.6 SAE International publications

ARP9013, *Statistical Product Acceptance Requirements*⁶

ARP9013/1, *Statistical Product Acceptance Requirements Using Isolated Lot Sampling Methods*⁶

ARP9013/2, *Statistical Product Acceptance Requirements Using Attribute or Variable Lot Acceptance Sampling Plans*⁶

ARP9013/3, *Statistical Product Acceptance Requirements Using Process Control Methods*⁶

ARP9013/4, *Statistical Product Acceptance Requirements Using Continuous Sampling, Skip-Lot Sampling, or Methods for Special Cases*⁶

2.7 Standardization Administration of China publications

GB/T 2828.1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*⁷

GB/T 2828.3, *Sampling procedures for inspection by attributes — Part 3: Skip-lot sampling procedures*⁷

GB/T 6378.1, *Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*⁷

2.8 United States Military standards

MIL-STD-105, *Sampling Procedures and Tables for Inspection by Attributes*⁸

MIL-STD-414, *Sampling Procedures and Tables for Inspection by Variables for Percent Defective*⁸

MIL-STD-1235C, *Single and Multilevel Continuous Sampling Procedures and Tables for Inspection by Attributes*⁸

NOTE MIL-STD-1235 has been cancelled, but can be used as a guide for derivation and application of continuous sampling plans. The SCMHS contains the essential text and tables of MIL-STD-1235C with some editing, reformatting, and paragraph renumbering.

⁶ Available from SAE International, 400 Commonwealth Drive, Warrendale, PA 15096-0001, Tel: 877-606-7323 (inside USA and Canada) or +1 724-776-4970 (outside USA), www.sae.org

⁷ Available through Standardization Administration of the People's Republic of China (SAC), <http://www.sac.gov.cn/sacn/>, controlled by a Technical Committee of SAC (TC21-Application of Statistical Methods), contact Ding Wenxing, e-mail: dingwx@cnis.gov.cn

⁸ Copies of these documents are available online at <http://quicksearch.dla.mil>

3 Terms and definitions

For the purpose of this document, the terms and definitions provided in ISO 9000 and the following apply. An acronym log for this standard is presented in Annex B.

3.1

Acceptable Quality Level

AQL

acceptance quality limit

maximum percentage or proportion of non-conforming units in a lot or batch that, for purposes of acceptance sampling, would be considered satisfactory as a process average

3.2

acceptance sampling

inspection in which decisions are made to accept or not accept a lot (or other grouping of product or material), based on the results of a sample or samples selected from that lot or grouping

3.3

Analysis of Variance

ANOVA

arithmetic process developed for the purpose of comparing several sample means by partitioning the total variation of a set of data into components associated with recognized sources of variation

3.4

attribute data

qualitative data that counts the presence or absence of a characteristic evaluated to a specified criterion, rather than data from a continuous measurement scale

Note 1 to entry: Attribute data is typically measured on a go/no-go, pass/fail, or yes/no basis.

3.5

Average Outgoing Quality

AOQ

average quality of outgoing product, after sampling inspection, for a given steady value of incoming product quality

3.6

Average Outgoing Quality Limit

AOQL

maximum AOQ over all possible values of incoming product quality level for a given acceptance sampling plan

3.7

Average Run Length

ARL

average number of plotted points on a control chart or the average number of items inspected before a shift in process level can be expected to be signalled (e.g., a point plotting outside the control limits)

3.8

batch

same as a "lot" or "grouping"

3.9

Bernoulli trials model

model where a trial has exactly two possible outcomes (i.e., success and failure) and the probability of success is the same every time the experiment is conducted

$$x_{\text{Bernoulli}} = \begin{cases} 1, & \text{if } x \text{ occurred} \\ 0, & \text{if } x \text{ did not occur} \end{cases} \quad (1)$$

$$\Pr(x_{\text{Bernoulli}}) = \begin{cases} p & , \text{if } x \text{ occurred} \\ 1 - p & , \text{if } x \text{ did not occur} \end{cases} \quad (2)$$

$$\text{Bernoulli}(x; p) = p^x(1 - p)^{1-x}, \quad x = 0, 1 \quad (3)$$

3.10

binomial distribution

distribution of counts of successes (or failures) in a number of trials when there are only two kinds of outcomes and the probability of a success (or failure) is constant for all trials (i.e., the trials are independent)

$$b(k; p, n) = \sum_n x_{\text{Bernoulli}} = \binom{n}{k} (p^k)(1 - p)^{n-k} \quad (4)$$

where

$b(k; p, n)$ is the probability of k non-conforming items in n trials;

n is the fixed number of Bernoulli trials;

k is the number of non-conforming units in n trials;

p is the probability of a non-conforming unit;

$1 - p$ is the probability of a conforming unit.

Note 1 to entry: The binomial distribution results from summing repeated Bernoulli trials.

3.11

$C = 0$ (C is equal to zero)

acceptance sampling plan that requires rejection of the lot, batch, or grouping if the sample contains one or more non-conformances

Note 1 to entry: The variable " C " stands for the number of non-conformances in a sample that allows acceptance of the lot.

3.12

capability

natural limits of a process; typically, the range of six standard deviations of the values in a process having no changes in its mean or any other characteristic of its distribution; inherent variation in a stable process; more precisely, a metric that characterizes the output of a stable process following a statistical distribution

Note 1 to entry: For purposes of establishing a natural variation limit, the distribution is of a continuous variable.

- a) An analysis of a process that compares the output process with some criteria for conformity.

$$C_p \equiv \frac{USL - LSL}{6s} \quad (5)$$

$$C_{pk} \equiv \text{Min} \left(\frac{\bar{x} - LSL}{3\sigma}, \frac{USL - \bar{x}}{3\sigma} \right) \quad (6)$$

Note 2 to entry: Continuous variables analyses compare a model distribution with specifications.

Note 3 to entry: C_p and C_{pk} translations to a probability of conformance commonly depend on a normal distribution. The appropriateness of the normal distribution is to be verified.

- b) For the case of attribute data, it is usually defined as the average proportion or rate of defects or defectives (e.g., centreline of an attribute control chart).

Note 4 to entry: The Bayesian estimator for the defect rate when no defects are observed in the current sample and the prior distribution adds no information is Formula (7).

$$\text{Pr}(d) = \frac{1}{n + 2} \quad (7)$$

where

$\text{Pr}(d)$ is the probability of a defect (the defect rate);

n is the number of representative observations of the process, no defects observed (see "Probability and Statistics for Engineers" by R.L. Scheaffer and J.T. McClave).

3.13 combinations

number of distinct groupings of m distinct objects taken " i " at a time, where order of selection is immaterial (e.g., 123, 321, 213)

$$\binom{m}{i} = \frac{m!}{i! \times (m - i)!} \quad (8)$$

where

$$m! = (m) \times (m - 1) \times (m - 2) \times \dots \times (3) \times (2) \times (1).$$

3.14 conformance

when a characteristic of a product or process meets its requirements; fulfilment of specified requirements

3.15 consumer risk

probability that a lot with a fraction of non-conforming material equal to a stated index value will be accepted by a sampling plan

3.16 continuous sampling

inspection intended for application on the continuous flow of individual items of product that involves acceptance or non-acceptance on a unit-by-unit basis for the applicable characteristics using periods of one-hundred percent (100 %) inspection and periods of sampling, depending on the quality of the observed product (see the SCMH)

3.17

critical characteristic

safety characteristic

safety critical characteristic

characteristic designated with the words “critical” or “safety” by the design authority, where the responsibility for its definition is outside the scope of this standard

3.18

customer

buying entity that is the issuer of a contract to a supplier

Note 1 to entry: All aviation, space, and defence suppliers are also customers to their suppliers. Protection to the customer is the key goal of this standard.

3.19

defect

non-fulfilment of a requirement related to an intended or a specified use; departure of a quality characteristic from its intended level or state that occurs with a severity sufficient to cause an associated product or service not to satisfy intended normal or foreseeable usage requirements

Note 1 to entry: This is different from a non-conformance.

3.20

determine

decide conformity in a way that achieves the level of probability of conformance in accordance with the applicable quality parameter

3.21

Equal Risk Point

ERP

fraction non-conforming at which the probability of rejecting a lot is fifty percent (also noted as $p_{0,50}$)

Note 1 to entry: At this fraction non-conforming, the risk to the producer and consumer are the same. When no integer number of non-conforming units produces exactly 50 % probability of acceptance, the *ERP* for that sample size is computed as the weighted average of the two nearest points on its discrete Operating Characteristic (OC) curve [see Annex C (C.2.2)].

3.22

escapement

escape

non-conformities that were produced, not detected and remedied, and subsequently sent to the customer

3.23

Expected Outgoing Quality

EOQ

probability that a unit accepted by sampling inspection is non-conforming, given both the sampling plan and a statement of what quality patterns have been demonstrated for the process

Note 1 to entry: An *EOQ* can only be computed if there is a distribution, whether based upon parameters or an empirical distribution.

3.24**Gage Repeatability and Reproducibility****Gage R&R**

study used to determine the degree of variability within a measurement system, and to separate this variability into components associated with the gage and the use of the gage

3.25**grouping**

same as a “lot” or “batch”

3.26**homogeneity**

homogeneous

when applied to a process, homogeneity is where there is repetitive production running under the same conditions with similar behaviour. Theoretical homogeneity is distinct from practical homogeneity:

- a) “Practical homogeneity”: where all units of product are made according to the same design requirements under stable consistent conditions of production; a fixed process.

Note 1 to entry: Fixed processes will have identifiable streams or groups of product according to type, grade, class, size, composition, or other conditions of manufacture that could cause inconsistencies.

- b) “Theoretical homogeneity”: the state of having identical cumulative distribution functions or values.

3.27**hypergeometric distribution**

discrete probability distribution that describes the number of items of interest found in a sample taken from a finite population

Note 1 to entry: The probability describes sampling without replacement. Applies whenever one is computing the probability of accepting a single finite lot and it is especially valuable when the sample is large compared to the population.

$$\Pr[X = x] = \frac{\binom{M}{x} \binom{N-M}{n-x}}{\binom{N}{n}} \quad (9)$$

where

x = 0, 1, 2, ..., min. of n or M ;

N = 1, 2, ... (population size);

M = 0, 1, 2, 3, ..., N (occurrences in population);

n = 1, 2, ..., N (sample size);

$$\binom{M}{x} = \frac{M!}{(x!) (M-x)!}$$

3.28

Initial Reliability Requirement

IRR

Inspection Reliability Requirement

minimum probability of conformance for each unit of product accepted through the associated sampling plan for design purposes

3.29

inspection

process of measuring, examining, testing, gauging, or otherwise comparing product or material with requirements and determining conformance

3.30

isolated lot

lot which is accepted solely on the basis of information derived from within itself; separate from the sequence of lots in which it was produced or collected, and not depending on information from any other part of a current sequence of inspection lots

3.31

Limiting Quality

LQ

Lot Tolerance Percent Defective (LTPD)

Lot Quality Protection (LQP)

Unacceptable Quality Level (UQL)

Limiting Quality Level (LQL)

quality parameter that is the fraction non-conforming in a lot where there is a small chance that a lot will be accepted by the specified sampling plan

Note 1 to entry: For use throughout this standard, the term *LQ* is established at the percent non-conforming having probability of lot acceptance equal to 10 %.

Note 2 to entry: For precise computation of the *LQ* value for finite lots of discrete parts, it is generally the case that no integer number of non-conforming units produces exactly 10% probability of acceptance, so the *LQ* for that sample size can be computed as the weighted average of the two nearest points on the discrete OC curve [see Annex C (C.2.2)].

3.32

lot

batch

grouping

defined quantity of some product, material, or service collected and submitted together for acceptance

Note 1 to entry: It is often expected that a lot be homogeneous in its manufacturing conditions. A lot for product acceptance purposes is not necessarily the same as a lot formed for purposes of a contract, shipment, or anything other than acceptance.

3.33

lot-by-lot inspection

inspection of each sequential lot in a series

3.34

lot homogeneity

quantity of product, material, or service that shows consistent characteristics throughout the quantity within a lot

3.35**Lot Tolerance Percent Defective****LTPD**

level of quality in a lot that the lot-sampling plan will accept 10% of the time [see 3.31, Limiting Quality (*LQ*)]

3.36**material review**

process of determining the disposition of non-conforming material

3.37**multi-level continuous sampling plan**

continuous sampling plan that changes frequency or amount of inspection by a set of rules, based upon the results of past plan inspections

3.38**must**

step that is inherent in meeting obligations from authorities outside this document, especially those of customers, regulatory authorities, or the laws of mathematics

Note 1 to entry: The use of the term “must” in this document is distinct from the use of the term “shall”.

3.39**non-conformance**

parts or materials that do not meet specifications or requirements. The failure of a characteristic to conform to the requirements specified in the contract, drawings, specifications, or other approved product description

3.40**non-conformity**

specific occurrence of a condition that does not conform to a specification or other inspection standard

3.41**Non-Destructive Testing****NDT**

Non-Destructive Inspection (NDI)

technique of testing material properties without impairing their future usefulness

3.42**normal inspection**

default level of lot-by-lot inspection sampling plans with switching rules

Note 1 to entry: Switching rules in sampling standards begin with this level of inspection, and direct the inspection to greater or lesser inspection according to the patterns of quality in the process.

3.43**one-hundred percent (100 %) inspection**

inspection of every item of product or service

3.44

Operating Characteristic curve

OC curve

curve on a graph for a given sampling plan showing the lot fraction defective (x -axis) versus the probability that the sampling plan will accept the lot (y -axis)

Note 1 to entry: This term is also applied to *AOQ*, Average Fraction Inspected (AFI), Average Total Inspected (ATI), and ARL curves.

3.45

organization

entity or party that is performing the work

3.46

Outgoing Quality Confidence Limit

OQCL

computed confidence limit on the probability of conformance for delivered product after sampling

Note 1 to entry: Computations depend on the lot size, sample size, acceptance criteria, screening policy, rectification policy, and Confidence Level (*CL*).

3.47

Poisson distribution

discrete frequency distribution that gives the probability of a number of independent events occurring in a fixed population, where the population can be an interval of time, volume, area, or length

$$\Pr[X = x] = \frac{m^x}{x!} e^{-m} \quad (10)$$

where

x is the number of occurrences (0, 1, 2, ...);

m is the population mean ($m > 0$);

e is the base of natural logarithms (2,71828...).

3.48

Probability Outgoing Quality Limit

POQL

upper confidence limit on the outgoing percent non-conforming in a finite series of lots

Note 1 to entry: This is the maximum of the curve that represents the 90 % upper confidence limit on the Outgoing Quality (*OQ*) and it depends on the sample size, acceptance criteria, the length of the series of lots, and any switching rules that apply.

3.49

process

combination of activities, methods, and resources, including people, material, machines, tools, and environment, that transform inputs into output products or services

3.50**process control**

disciplines of controlling the variables of a process to ensure the resultant characteristic meets requirements

Note 1 to entry: The adequacy of process controls is described in Clause 8.

3.51**process control point**

step (in a process) at which a full or partial control is applied to prevent, eliminate, or reduce the risk of a non-conforming part continuing through the process

3.52**process monitoring**

planned evaluations of the characteristic being accepted via process control to ensure that the process maintains stability

3.53**process stability**

stability

condition or state of behaviour of a process where, through the use of past experience, limits of the process can be predicted for the near future; condition where there is no indication of a special cause of variation, but where only random common cause variation is present

3.54**quality parameter**

statistic of a product acceptance method that indicates the probability of conformance for each accepted unit of product to determine what it takes to ensure that the product conforms to its requirements (e.g., the *IRR*)

Note 1 to entry: Quality parameters include *AOQL*, *OQCL*, *PPM*, *ERP*, and Rejectable Quality Level (*RQL*).

3.55**random sample**

selection of units collected in such a manner that all units being accepted have an equal chance of being selected for inspection or evaluation

3.56**reduced inspection**

one of several levels of inspection connected by switching rules, which involves a lower fraction inspected than one or more of the others

Note 1 to entry: In such a system the quality parameter is usually the *AOQL* and that *AOQL* is maintained, despite the lower fraction inspected, by the fact that the process generally only gets to that level when the quality is as good as or better than the *AOQL* for some period of time.

3.57

Rejectable Quality Level

RQL

minimum percent defective at which a lot will have 5 % or less chance of being accepted when using a sampling plan

Note 1 to entry: For precise computation of the *RQL* value for finite lots of discrete parts, it is generally the case that no integer number of non-conforming units produces exactly 5 % probability of acceptance, so the *RQL* for that sample size can be computed as the weighted average of the two nearest points on the discrete OC curve [see Annex C (C.2.2)].

3.58

retrievability

ability of a production system to identify or trace units, and make them available for appropriate disposition

3.59

sample

one or more units of product drawn from a lot, batch, or grouping to provide information

3.60

sampling plan

statement of sample size(s), frequencies, associated acceptance and rejection criteria, and switching rules (if applied)

3.61

sequential sampling

sampling acceptance where a sequence of samples is taken from a lot or grouping and after each unit a decision is made to accept or reject the lot or grouping, or to continue sampling

3.62

shall

indicates a requirement

3.63

should

indicates a recommendation

Note 1 to entry: If the organization chooses not to follow a “should” or other recommendation, then it is advisable to document the rationale for that decision.

3.64

sigma

Greek letter (σ) symbolizing standard deviation

3.65

single-level continuous sampling

alternating periods of 100 % inspection and sampling inspection wherein the sampling rate is constant

Note 1 to entry: The extent of periods of 100 % inspection depends on the pattern of non-conformances.

3.66**skip-lot inspection**

sampling inspection in which some lots in a series are accepted without inspection, when the sampling results for preceding lots from the same process meet stated criteria and all retrievability requirements for skipped lots have been met

3.67**standard deviation**

measure of the spread or dispersion of the process output that has the same unit of measure as the original observations and the process mean (i.e., square root of the variance in a population); usually identified by the Greek letter (σ) symbolizing standard deviation of the population

3.68**statistical control**

process operating with a constant system of causes that result in a stable probability distribution of outcomes

Note 1 to entry: Evidence of statistical control is provided by observations or observational statistics (e.g., average, range, standard deviation, maximum) appearing within limits calculated from extremes of the estimated stable distribution.

Note 2 to entry: Control charts depict graphically the observations and limits over time. Observational statistics within control limits are equivalent to failing to reject the null hypothesis that the process outputs come from a stable distribution.

Note 3 to entry: Tolerance limits do not enter into calculations of control limits or determination of statistical control.

Note 4 to entry: See clause 8 for more details and the method for determining when to accept a process as being adequately in statistical control.

3.69**statistical principles**

legitimate conclusion, based on samples taken from a defined population, claiming some probability value that is achieved by following a defined procedure; verifiable mathematics exists that shows this probability value is accurate; refers to the phrase “justified on the basis of recognized statistical principles”, as used in quality management system standards

3.70**Statistical Process Control****SPC**

graphical/statistical method by which a process is monitored for patterns of variation

Note 1 to entry: The resulting data is analysed statistically to identify incidents of special causes of variation (see Clause 8 for more details).

3.71**statistically valid**

legitimate conclusion, based on samples taken from a defined population, claiming some probability value that is achieved by following a defined procedure; by definition, verifiable mathematics exists that shows this probability value is accurate

3.72

subgroup

segregation of process output such that it is reasonable to expect the same causal factors are present throughout the subgroup

Note 1 to entry: A subgroup is represented on a control chart by a single point.

3.73

supplier

entity or party that supplies product or services to a customer in accordance with contractual requirements

3.74

switching rules

requirements used to adjust the level of inspection, such as between “Normal”, “Tightened”, and “Reduced” inspections

3.75

tightened inspection

level of sampling with switching rules that has more inspection than a “Normal” inspection level, but generally less than 100 % inspection

3.76

unit

single part or item

Note 1 to entry: For continuous sampling application, this term can also apply to a lot with a small quantity of parts from a fixed process, where the sample size equals the lot size.

3.77

variables data

variables measurement
quantitative measurements taken on a continuous scale

4 General requirements

4.1 Introduction to general requirements

The requirements of this clause are common to the application of methods and techniques defined in Clause 6, Clause 7, Clause 8, and Clause 9 which might be restated therein. Additional requirements specific to each method are defined in its respective clause of the document. Refer to Figure 2 for guidance in determining which method and technique is appropriate for the product being assessed.

Regardless of the use of these statistical product acceptance methods, the organization shall be responsible to ensure that each part conforms to the engineering design requirements.

4.2 Trained personnel

Personnel involved in the planning, application, and execution of statistical product acceptance do affect product quality and therefore shall be subject to the training requirements of the EN 9100/EN 9110/EN 9120 quality management system standards.

NOTE Additional training requirements specific to process control are contained in 8.1.4.

4.3 Safety/critical characteristics

Any characteristics identified in the design documentation as “safety” or “critical” characteristics shall not be accepted using statistical product acceptance methods, unless prior written authorization is granted from the customer (e.g., a customer-approved procedure) such as when the method for acceptance is defined in the design documentation [see Annex D (D.2) for guidance].

NOTE Written authorizations for the use of statistical product acceptance on a “safety” or “critical” characteristic in accordance with the EN 9138 standard do not provide adequate information unless that authorization includes a quality parameter value.

4.4 Quality requirements and parameters

When the organization uses statistical techniques for product acceptance, they shall identify a quality parameter and value for each plan.

NOTE This is an essential part of the EN 9138 standard fulfilment of the EN 9100 and EN 9120 requirement that “the sampling plan is justified on the basis of recognized statistical principles and appropriate for use.” The value of the quality parameter represents the risk level of sampling; when the risk level is acceptable for a statistical product acceptance plan, the “appropriate for use” stipulation is satisfied.

4.4.1 Quality parameter

A statistical technique for product acceptance shall have a quality parameter that controls the probability of conformance of delivered product (see Annex D for guidance).

When engineering specifications require an *AQL*, the consumer protection quality parameter shall be an *AOQL*.

NOTE The column headings in many existing sampling tables are indexed by the *AQL*; however, the *AQL* is not a measure of protection for the customer. This standard requires the defining of a different quality parameter that provides protection for the customer. Along with other statistical acceptance requirements contained in this standard, the *AQL* figures must not be construed as allowing a non-conforming part to be delivered.

4.4.2 Quality parameter value

The quality parameter value shall be selected or approved by individuals who understand the consequences of non-conformance.

- a) The preferred method to identify the quality parameter value is for the design authority to specify an *IRR* via instructions on the purchase order, contract, engineering drawing, and/or related product definition documents. This *IRR* determines a maximum for the quality parameter value for the production logistics according to Annex A.
- b) The quality parameter(s) chosen shall protect the customer by controlling the probability of conformance for delivered product.
- c) When instructions on the purchase order, contract, engineering drawing, and/or related product definition documents from the customer require a specific quality parameter and value, the statistical method shall provide at least that degree of protection.
- d) Quality can recommend alternative quality parameters or values to the customer authority using guidance in Annex E (see E.3).
- e) If no other authority identifies an *IRR* value, then Annex A (see Table A.1) can be used as a default to demonstrate conventional levels of protection.

- f) When engineering specifications require an *AQL*, Table 1 shall be used to convert the *AQL* value to an *AOQL* value.

Table 1 — Acceptable Quality Level to Average Outgoing Quality Limit conversion

<i>AQL</i>	0,010 %	0,015 %	0,025 %	0,040 %	0,065 %	0,100 %	0,150 %	0,25 %
<i>AOQL</i>	0,018 %	0,033 %	0,046 %	0,074 %	0,113 %	0,143 %	0,198 %	0,33 %

<i>AQL</i>	0,40 %	0,65 %	1,00 %	1,50 %	2,50 %	4,00 %	6,50 %	10,00 %
<i>AOQL</i>	0,53 %	0,79 %	1,22 %	1,90 %	2,90 %	4,94 %	7,12 %	11,46 %

4.4.3 Alternative quality plans

The customer shall retain the right to approve alternative classification methods.

4.4.4 Regulatory requirements

The organization shall be responsible for ensuring that any product acceptance methods comply with regulatory requirements.

4.5 Selection of samples

Samples shall be representative of the unchecked production. Articles presented for acceptance by sample inspection shall share similar variability, quality level, and history as the unchecked production (see Annex D for guidance).

Samples may be predetermined, if it has been determined by an ANOVA, Process Failure Modes and Effects Analysis (PFMEA), or other valid statistical analysis that the predetermined sample shall be over representative of non-conforming product.

4.6 Consideration of product and process characteristics

The statistical product acceptance plan shall identify the product characteristics to be accepted under the plan. The organization shall create a statistical product acceptance plan that covers each applicable characteristic.

In addition to the general requirements of Clause 4 and Clause 5, the plan shall meet the requirements of the supporting Clause 6, Clause 7, Clause 8, or Clause 9. Refer to Figure 2 for guidance in determining which method and technique is appropriate for the product being assessed. See examples of these in Annex F (see Table F.1).

4.7 Evaluation systems

Monitoring and measuring devices used to accept product shall be controlled as required by 7.6 in the EN 9100:2009/EN 9110:2012/EN 9120:2009 quality management system standards. When reliability values are specified in the design, measurement capability shall support those reliability requirements (see Annex D, Annex E, and Annex F for guidance).

Statistical methods for product acceptance may be used in conjunction with NDT, unless disallowed by product engineering. If design drawings or specifications give instructions on destructive testing, those instructions take precedence over this standard.

4.8 Non-conformances (within the sample)

No discretion shall be permitted for measurements or conditions outside of the tolerances. Any deviations from design tolerance shall be reported as non-conforming and the affected production represented by the sample shall be controlled per the organization's quality instructions that govern non-conformances. In the event that any characteristic is rejected by the plan when lot or batch sampling is applied, the entire lot or batch shall be rejected and dispositioned in accordance with EN 9100-series standard requirements for non-conforming material.

NOTE The primary options for disposition are to inspect the remaining product in the lot, scrap the product, or return the product to its source. A material review decision to accept the product as-is with no further inspection is not recommended due to the high probability that other uninspected units contain even more extreme non-conformances than the sample did (see Annex D for guidance). This policy is known as "C=0".

When the sampling is continuous or skip-lot (see Clause 9), or when the sampling uses reduced sampling levels that are less than would be required under isolated lot sampling (see Clause 7), then the sampling plan shall accommodate adequate retrievability. Replacement or rectification of product is required. Production rates and frequencies of inspection shall be linked so that if non-conforming product is found, any product skipped since the previous inspection can be retrieved. Refer to the EN 9100:2009/EN 9110:2012/EN 9120:2009 quality management system standards (see 8.2.4) for instructions on monitoring and measuring of product.

4.9 Statistical product acceptance plans and records

The documentation of the sampling plan shall not provide for the acceptance of characteristics that are inadequately inspected in the samples. A sampling plan shall show the number of units of product from each lot or batch that are to be inspected and the criteria for determining the acceptability of the lot or batch. Both the statistical product acceptance plan and associated acceptance records shall show conformance to design requirements, account for all non-conformities in the sample, and shall be maintained in accordance with established procedures.

Plans for compiling and retrieving statistical acceptance information and acceptance data shall provide for adequate retrievability and shall provide for the verification that the plan is being executed correctly (see Annex D for guidance).

4.10 Alternate statistical techniques for product acceptance

Alternate statistical techniques and unique applications intended for special cases are covered in Clause 9. Techniques, other than those stated in this standard, that are developed and used shall be justified on the basis of recognized statistical principles to meet or exceed the required consumer protection quality parameter value or *IRR* (see 4.4 and 5.2). Reference Clause 5 requirements for documenting these alternatives in written procedures and plans (see Annex D for guidance).

4.11 Auditing of statistical techniques for product acceptance

Any statistical technique for product acceptance shall be reviewed as a part of periodic internal audits conducted in accordance with the EN 9100:2009/EN 9110:2012/EN 9120:2009 quality management system standards (see 8.2.2). A technical review of the statistical application should also be performed regularly. A technical review shall be conducted by individuals who understand the design of the statistical techniques used [see Annex D (D.10) for guidance].