ICS 03.120.10, 49.020 SLOVENSKÁ TECHNICKÁ NORMA Máj 2020

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/20

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 9138

November 2019

ICS 03.120.10; 49.020

English Version

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

Série aérospatiale - Systèmes de management de la qualité - Exigences d'acceptation statistique des produits

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Statistische Produktannahmeanforderungen

This European Standard was approved by CEN on 10 December 2018.

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 COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 9138:2019 E

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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.

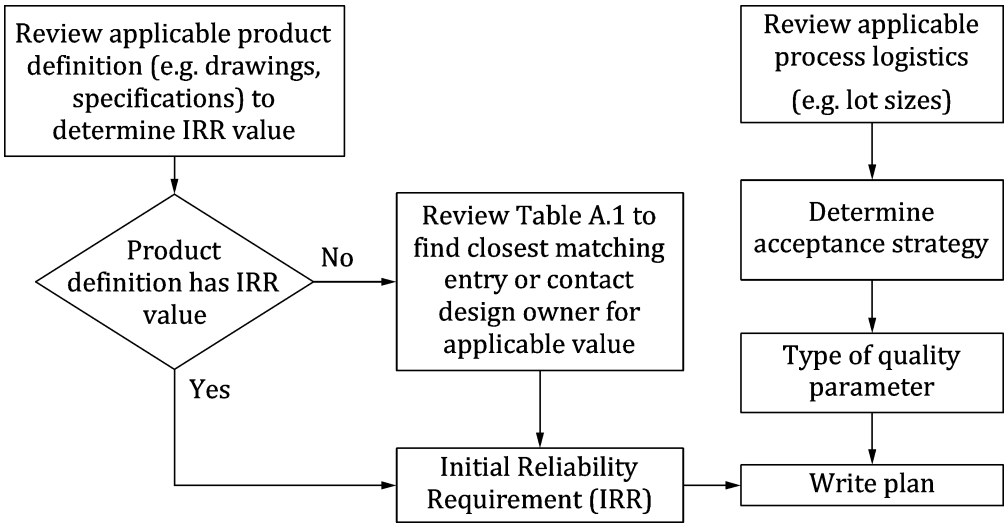

Figure 1 — Engineering and operations inputs into product acceptance plan

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.

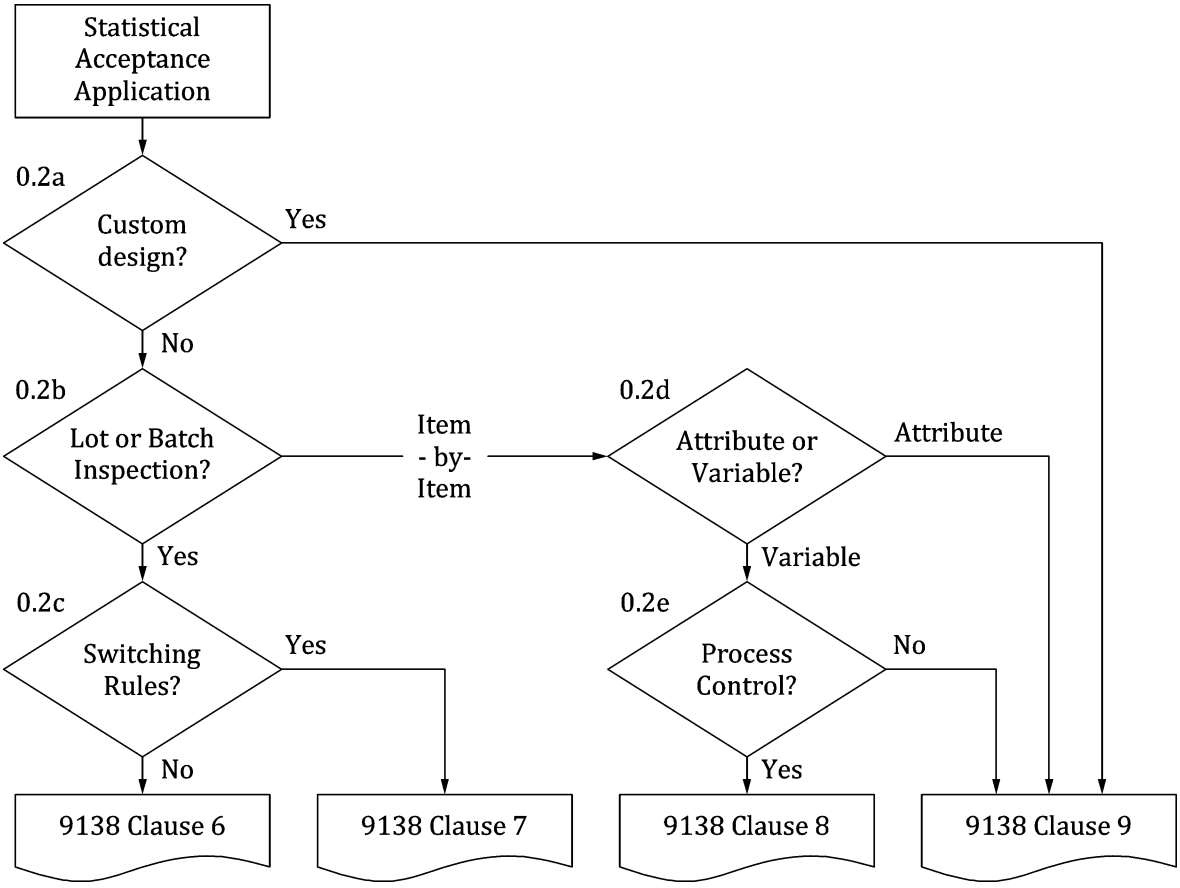

Figure 2 — EN 9138 clause selection guide

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]

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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 Handbook[2]

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]

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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

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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 SCMH contains the essential text and tables of MIL-STD-1235C with some editing, reformatting, and paragraph renumbering.