



SLOVENSKI STANDARD SIST EN 9138:2020

01-januar-2020

Aeronavtika - Sistemi vodenja kakovosti - Statistični proizvod - Zahteve za sprejem

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

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Statistische Produktannahmeanforderungen

Série Aérospatiale - Système de management de la qualité - Exigences d'acceptation statistique des produits

iTeh STANDARD PREVIEW
(standards.itteh.ai)

[SIST EN 9138:2020](#)

Ta slovenski standard je istoveten z: **EN 9138:2019**
<http://standards.itteh.ai/catalog/standards/sist/en-9138-2020/02f-4334-b128-9da6ef8edf39/sist-en-9138-2020>

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

SIST EN 9138:2020

en,fr,de

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 9138:2020

<https://standards.iteh.ai/catalog/standards/sist/ca629e5-e02f-4334-b128-9da6ef8edf39/sist-en-9138-2020>

EUROPEAN STANDARD

EN 9138

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Contents

	Page
0.1	Paradigm of quality requirements and product acceptance plans..... 11
0.1.1	Engineering 11
0.1.2	Operations 12
0.2	Acceptance method considerations 12
1	Scope 15
1.1	Purpose 15
1.2	Application 15
2	Normative references 15
2.1	International Aerospace Quality Group publications 15
2.2	American National Standards Institute publications 16
2.3	International Organization for Standardization publications 16
2.4	Japanese standards 17
2.5	Published books and periodicals 17
2.6	SAE International publications 18
2.7	Standardization Administration of China publications 18
2.8	United States Military standards 18
3	Terms and definitions 19
4	General requirements 30
4.1	Introduction to general requirements 30
4.2	Trained personnel 30
4.3	Safety/critical characteristics 31
4.4	Quality requirements and parameters 31
4.4.1	Quality parameter 31
4.4.2	Quality parameter value 31
4.4.3	Alternative quality plans 32
4.4.4	Regulatory requirements 32
4.5	Selection of samples 32
4.6	Consideration of product and process characteristics 32
4.7	Evaluation systems 32
4.8	Non-conformances (within the sample) 33
4.9	Statistical product acceptance plans and records 33
4.10	Alternate statistical techniques for product acceptance 33
4.11	Auditing of statistical techniques for product acceptance 33
5	Required information to be documented 34
5.1	Documented procedure requirements 34
5.2	Initial Reliability Requirement or quality parameter values for product acceptance 34
5.3	Assigning responsibilities 34
5.4	Assigning where applied 34
5.5	Establishing a training program 34
5.6	Controlling non-conformances 34
5.7	Monitoring performance and effectiveness 34
5.8	Defining adjustments to inspection frequency 35
5.9	Customer approval of procedures and plans 35

6	Requirements for accepting product by individual lots.....	35
6.1	General requirements for individual lot sampling	35
6.2	Quality parameters for individual lot sampling.....	35
6.2.1	Delivered product conformance probability parameters	35
6.2.2	Probability of acceptance parameters	35
6.3	Sample sizes for individual lots.....	35
7	Requirements for accepting product under switching rules.....	35
7.1	General requirements for switching rules	35
7.2	Background information for switching rules	36
7.3	Quality parameter with switching rules.....	36
7.4	Requirements for accepting product with switching rules	36
7.4.1	Sampling documentation.....	36
7.4.2	General conditions	36
7.4.3	Sampling plan criteria.....	37
7.4.4	Qualification criteria for sampling.....	37
7.5	Requirements for accepting product by variables sampling plans using switching rules.....	37
7.5.1	Variable sampling application limits	37
7.5.2	Evaluating lot quality	37
7.5.3	Related requirements	37
8	Requirements for accepting product produced under process controls	38
8.1	General process control requirements.....	38
8.1.1	Data.....	38
8.1.2	Reducing inspection with process controls	38
8.1.3	Measurement systems	38
8.1.4	Training program	38
8.1.5	Process control points	39
8.1.6	Process control acceptance plans and records	39
8.1.7	Unbiased sampling.....	39
8.1.8	Time or production order sequence.....	39
8.1.9	Data retention plan.....	39
8.1.10	Periodic internal audits.....	39
8.1.11	Retrievability system	39
8.1.12	Limiting errors in measurement and recording	39
8.1.13	Evaluating effects of corrective actions.....	39
8.2	Statistical Process Control.....	39
8.2.1	Methods.....	40
8.2.2	Location and dispersion.....	40
8.2.3	Basis for control limits.....	40
8.2.4	Basis for stability	40
8.2.5	Investigation.....	41
8.2.6	Violation of stability	41
8.2.7	Re-evaluation of stability and capability	41
8.2.8	Capability and process control	41
8.2.9	Process monitoring frequency.....	42
8.3	Variation restrictions.....	42
8.4	Process parameter controls.....	42
9	Additional requirements for accepting products based on continuous sampling, skip-lot sampling, or methods for special cases.....	43
9.1	Continuous sampling.....	43
9.1.1	Quality parameters for continuous sampling	43
9.1.2	Inspection sequence	43

EN 9138:2019 (E)

9.1.3	General conditions.....	43
9.1.4	Supply Chain Management Handbook continuous sampling tables.....	43
9.2	Skip-lot sampling.....	44
9.2.1	General conditions for skip-lot sampling.....	44
9.2.2	Quality protection equivalency.....	44
9.2.3	Considerations for subsequent lots.....	44
9.3	Sampling strategies for special cases.....	44
9.3.1	Special sampling customer approvals.....	44
9.3.2	Special case statistical validity.....	44
9.3.3	Predicting quality from correlated variables.....	45
9.3.4	Continuous manufacturing process – First and last unit for a lot produced.....	45
9.3.5	Sequential sampling.....	45
9.4	Other methods for special cases.....	45
Annex A (informative) Guidelines for assigning Initial Reliability Requirement quality levels.....		
	levels.....	46
A.1	Introduction.....	46
A.2	Assigning quality levels.....	46
A.3	Initial Reliability Requirements.....	46
Annex B (informative) Acronym log.....		
		49
Annex C (informative) Mathematics for accepting product under lot-by-lot inspection.....		
		52
C.1	Yield estimation.....	52
C.1.1	Yield estimates.....	53
C.1.2	Confidence limits on yield estimates.....	53
C.2	Probability of acceptance mathematics.....	55
C.2.1	Hypergeometric probability of acceptance.....	55
C.2.2	Legacy <i>Pa</i> lot acceptance mathematics.....	56
C.2.3	Yield rates, discrete units, and conformance probabilities.....	57
C.2.4	Impact lot sampling methods on delivered yield.....	58
C.3	Controlling the probability of conformance for delivered product.....	60
C.3.1	Average Outgoing Quality Limits.....	60
C.3.2	Average Outgoing Quality Limit sample sizes.....	61
C.3.3	Outgoing Quality Confidence Limit sample sizes.....	62
C.3.4	Lot sampling with deliveries from the sample of failed lots.....	63
C.3.5	Probability of acceptance sample sizes.....	64
C.3.6	Lot sampling with destructive tests.....	64
C.4	Mathematics to control clustering.....	65
C.4.1	Formulation for cluster control.....	65
C.4.2	Fixed number of maximum escapements.....	66
C.4.3	Controlling clusters in increasing lot sizes.....	66
Annex D (informative) Guidelines and recommendations for successful implementation of statistical product acceptance methods.....		
		67
D.1	Guidelines for 4.2 — Trained personnel.....	67
D.1.1	General training.....	67
D.1.2	Training for lot sampling.....	67
D.1.3	Training for product acceptance based on process controls.....	68
D.1.4	Training for continuous sampling, lot sampling with switching rules, skip-lot sampling, or process control methods.....	68
D.1.5	Non-published statistical methods.....	68
D.2	Guidelines for 4.3 — Safety/critical characteristics.....	68
D.3	Guidelines for 4.4 — Quality requirements and parameters.....	69
D.3.1	Guidelines for Initial Reliability Requirement assignment.....	69

D.3.2	Guidelines for quality parameter measures.....	69
D.4	Guidelines for 4.5 — Selection of samples.....	69
D.4.1	Sampling recommendations.....	69
D.4.2	Simple random sampling.....	70
D.4.3	Stratification sampling.....	70
D.4.4	Systematic sampling.....	70
D.4.5	Cluster sampling.....	70
D.4.6	Representative sampling without randomization.....	70
D.5	Guidelines for 4.6 — Identification of product characteristics.....	71
D.6	Guidelines for 4.7 — Evaluation systems.....	71
D.6.1	Measurement devices.....	71
D.6.2	Non-Destructive Testing.....	71
D.6.3	Destructive testing.....	72
D.7	Guidelines for 4.8 — Non-conformances (within the sample).....	72
D.7.1	Non-conformance risks.....	72
D.7.2	$C = 0$ sampling.....	72
D.7.3	Retrievability in reduced, continuous, or skip-lot sampling.....	73
D.8	Guidelines for 4.9 — Statistical product acceptance plans and records.....	73
D.8.1	Statistical product acceptance plans.....	73
D.8.2	Acceptance records.....	73
D.8.3	Training records.....	74
D.9	Guidelines for 4.10 — Alternate statistical techniques for product acceptance.....	74
D.10	Guidelines for 4.11 — Auditing of statistical techniques for product acceptance.....	74
D.11	Guidelines for 5.3 — Assigning responsibilities.....	75
D.12	Guidelines for 5.4 — Assigning where applied.....	75
D.13	Guidelines for 5.5 — Establishing a training program.....	76
D.14	Guidelines for 5.6 — Controlling non-conformances.....	76
D.15	Guidelines for 5.7 — Monitoring performance and effectiveness.....	76
Annex E	(informative) Discussion on the technical rationale and history of the relationship of quality parameters to reliability.....	77
E.1	Technical rationale for quality — Reliability relationship in quality parameters.....	77
E.1.1	Minimum probability of conformance.....	78
E.1.2	Probability of non-conformance.....	78
E.1.3	Reliability.....	78
E.2	History of quality — Reliability relationship in quality parameters.....	78
E.2.1	Acceptable Quality Level.....	79
E.2.2	Average Outgoing Quality Limit.....	79
E.2.3	Short run sampling.....	80
E.3	Recommended quality parameter choices.....	80
E.4	Consideration of cluster effects.....	81
Annex F	(informative) Guidelines for choosing a statistical product acceptance technique and quality parameter.....	82
F.1	Guidance for choosing a method of statistical product acceptance.....	82
F.1.1	General guidance.....	82
F.1.2	Clause-specific guidance.....	83
F.2	Directions to match a quality parameter to a statistical acceptance technique.....	84
F.2.1	Guidelines for applying quality parameters.....	84
F.2.2	Overview of quality parameter relationships to Initial Reliability Requirement.....	84
F.2.3	Quality parameters for individual lot sampling.....	84
F.2.4	Quality parameters for lot sampling with switching rules.....	84
F.2.5	Quality parameters for product acceptance using process controls.....	85
F.2.6	Quality parameters for continuous sampling and special methods.....	85

F.3	Assigned by feature and tolerance.....	85
Annex G (informative) Guidelines and recommendations for accepting product by individual lots.....		
		86
G.1	Introduction	86
G.1.1	Process steps for evaluating individual or isolated lots	86
G.1.2	Selecting an appropriate sampling model	87
G.1.3	Screening lots	88
G.2	Guidelines for 6.1.2 — Delivered product conformance probability parameters	89
G.3	Guidelines for 6.2.2 — Probability of acceptance parameters	89
G.4	Guidelines for relating AQL to a quality parameter	90
G.5	Guidelines for 6.3 — Sample sizes for individual lots.....	90
Annex H (informative) Guidelines for some special acceptance methods		
		91
H.1	Continuous sampling extensions.....	91
H.1.1	Guidelines for skip-lot sampling plans.....	91
H.1.2	Guidelines for variables continuous sampling.....	91
H.1.3	Poisson continuous sampling.....	92
H.2	Process characterization	93
H.2.1	Guidelines for 9.3.3 — Predicting quality from correlated variables.....	93
H.2.2	Guidelines for 9.3.4 — Lot acceptance by first and last unit inspections	94
H.2.3	Guidelines for Expected Outgoing Quality	95
H.3	Probability Outgoing Quality Limit.....	97
H.4	Validation of special acceptance methods — Simulation.....	97
H.5	Guidance for small production volumes.....	97
Annex I (informative) Guidelines and recommendations for accepting product produced under switching rules.....		
		98
I.1	Guidelines for Clause 7 — Requirements for accepting product produced under switching rules.....	98
I.2	Guidelines for 7.4 — Requirements for accepting product produced in repetitive lots by attribute sampling plans	98
I.3	Guidelines for 7.5 — Requirements for accepting product produced in repetitive lots by variables sampling plans.....	99
Annex J (informative) Guidelines and recommendations for accepting product produced under process controls		
		100
J.1	Guidelines for 8.1 — General process control requirements	100
J.1.1	Guidelines for 8.1.12 — Limiting errors in measurement and recording.....	100
J.2	Guidelines for 8.2 — Statistical Process Control.....	100
J.2.1	Guidelines for 8.2.1 — Methods.....	100
J.2.2	Guidelines for 8.2.3 — Basis for control limits.....	101
J.2.3	Guidelines for 8.2.5 — Investigation.....	101
J.2.4	Guidelines for 8.2.6 — Violation of stability.....	102
J.3	Guidelines for 8.3 — Variation restrictions.....	102
J.4	Guidelines for 8.4 — Process parameter controls	102
J.5	Step-by-step summary	103
Annex K (informative) Guidelines and recommendations for accepting product based on continuous sampling.....		
		104
K.1	Applicability of continuous sampling	104
K.1.1	Conditions necessary for continuous sampling plans	104
K.1.2	Conditions when continuous sampling inspection might be desirable.....	105
K.1.3	Conditions when sampling plans require approval	105
K.2	Types of continuous sampling plans.....	105
K.3	Implementing continuous sampling	106

K.3.1 Guidelines for 9.1.1 — Quality parameters	106
K.3.2 Guidelines for 9.1.2 — Inspection sequence	106
K.3.3 Submission of product	106
K.3.4 Sample selection	106
K.3.5 Corrective action indications	106
K.3.6 Example continuous sampling plan	106
Bibliography	109

Figures

Figure 1 — Engineering and operations inputs into product acceptance plan.....	11
Figure 2 — EN 9138 clause selection guide.....	13
Figure 3 — Typical Statistical Process Control chart depicting control limits, warning limits, and zones.....	40
Figure C.1 — Average Outgoing Quality Operating Characteristic curve with Average Outgoing Quality Limit and Initial Reliability Requirement limit.....	62
Figure C.2 — Average Outgoing Quality Operating Characteristic curve where failed lots are scrapped.....	63
Figure C.3 — Points on Average Outgoing Quality Operating Characteristic curve for meeting Initial Reliability Requirement when salvaging sample units from failed lots.....	64
Figure G.1 — Flowchart for identifying lot sampling method.....	88
Figure H.1 — Example graphic Confidence Level to match Initial Reliability Requirements.....	94
Figure K.1 — Illustration of CSP-1 continuous sampling.....	107

Tables

Table 1 — Acceptable Quality Level to Average Outgoing Quality Limit conversion.....	32
Table 2 — True C_{pk} requirements.....	41
Table A.1 — Minimum probability conformance values.....	47
Table C.1 — Table of mathematical variables.....	52
Table C.2 — Minimum sample sizes needed for a yield Confidence Level when no non-conformities are detected.....	55
Table C.3 — Expected escapements and delivered units.....	59
Table C.4 — Average Outgoing Quality formulas for lot sampling categories.....	60
Table C.5 — Average Outgoing Quality formulas for examining lot size limits.....	61
Table C.6 — Expected escapements delivered units when tests are destructive.....	64

EN 9138:2019 (E)

Table E.1 — Formulas for converting quality parameter specifications into an Initial Reliability Requirement.....	80
Table E.2 — Conversion of Acceptable Quality Level specification to Average Outgoing Quality Limit.....	81
Table F.1 — Guidelines to determine inspection logistics.....	82
Table F.2 — Quality parameter value to Initial Reliability Requirement value comparisons	84
Table H.1 — Example computations for Expected Outgoing Quality.....	96
Table I.1 — Example Acceptable Quality Level values to use to meet a required 3 % Average Outgoing Quality Limit.....	99
Table K.1 — Values " <i>i</i> " for choice of " <i>f</i> " and Average Outgoing Quality Limit.....	108

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 9138:2020

<https://standards.iteh.ai/catalog/standards/sist/ca629e5-e02f-4334-b128-9da6ef8edf39/sist-en-9138-2020>

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.

(standards.iteh.ai)

SIST EN 9138:2020

<https://standards.iteh.ai/catalog/standards/sist/ca629e5-e02f-4334-b128-9da6ef8edf39/sist-en-9138-2020>

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.

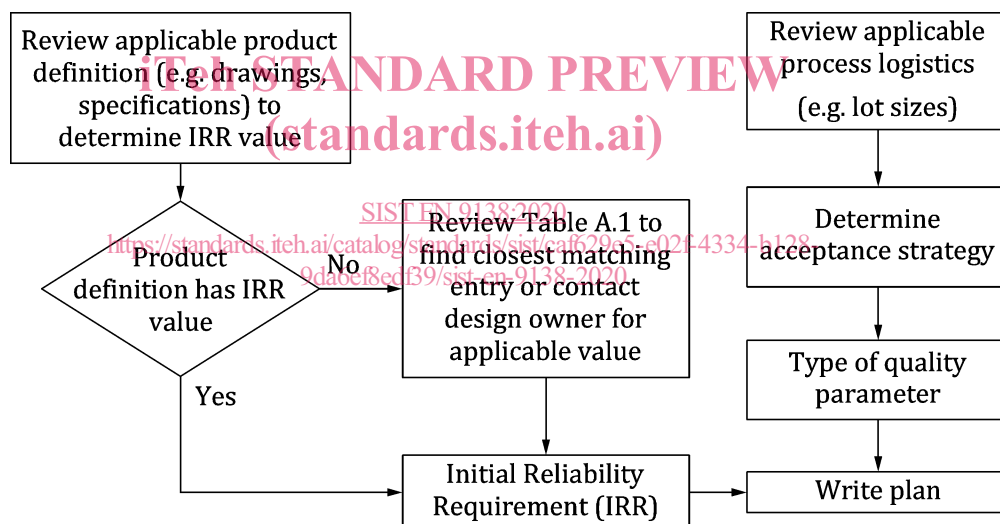


Figure 1 — Engineering and operations inputs into product acceptance plan

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.

EN 9138:2019 (E)**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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

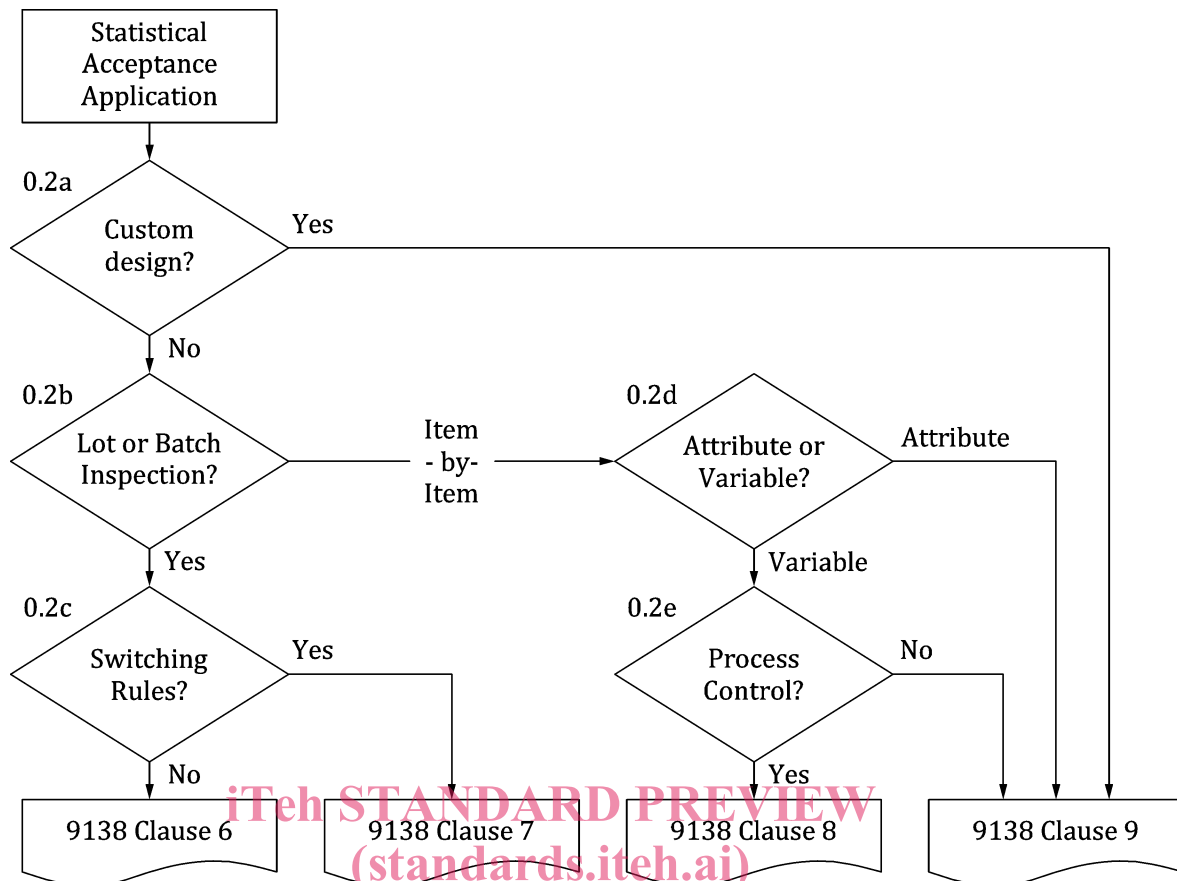


Figure 2 — EN 9138 clause selection guide

- <https://standards.iteh.ai/catalog/standards/sist/ca629e5-e02f-4334-b128-9138-2019/sist-en-9138-2020>
- 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).
 - 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.
 - 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.