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Combined accept-zero sampling systems and process control procedures for product acceptance

Systèmes d'échantillonnage de tolérance zéro-défaut et procédures de maîtrise des processus combinés pour l'acceptation de produits

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 5, *Acceptance sampling*.

This first edition of ISO 28594 cancels and replaces ISO 21247:2005, of which it constitutes a minor revision to change the reference number from 21247 to 28594.

With the view to achieve a more consistent portfolio, TC 69/SC 5 has simultaneously renumbered the following standards, by means of minor revisions:

Old reference	New reference	Title
ISO 2859-10:2006	ISO 28590:2017	Sampling procedures for inspection by attributes — Introduction to the ISO 2859 series of standards for sampling for inspection by attributes
ISO 8422:2006	ISO 28591:2017	Sequential sampling plans for inspection by attributes
ISO 28801:2011	ISO 28592:2017	Double sampling plans by attributes with minimal sample sizes, indexed by producer's risk quality (PRQ) and consumer's risk quality (CRQ)
ISO 18414:2006	ISO 28593:2017	Acceptance sampling procedures by attributes — Accept-zero sampling system based on credit principle for controlling outgoing quality
ISO 21247:2005	ISO 28594:2017	Combined accept-zero sampling systems and process control procedures for product acceptance

ISO 14560:2004	ISO 28597:2017	Acceptance sampling procedures by attributes — Specified quality levels in nonconforming items per million
ISO 13448-1:2005	ISO 28598-1:2017	Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 1: Guidelines for the APP approach
ISO 13448-2:2004	ISO 28598-2:2017	Acceptance sampling procedures based on the allocation of priorities principle (APP) — Part 2: Coordinated single sampling plans for acceptance sampling by attributes

Cross references between the above listed documents have been corrected in the minor revisions.

A list of all documents in the new ISO 28590 - ISO 28599 series of International Standards can be found on the ISO website.

Introduction

Enlightened quality-based management practices encourage industry innovation and provide flexibility to achieve the benefits of continuous improvement. There is an evolving industrial product quality philosophy that recognizes the need for quality policy changes that will provide suppliers with opportunities and incentives toward improvement of product quality and cooperative relationships between the supplier and the customer.

Properly employed, process controls and statistical control methods are effective means of preventing nonconformities, controlling quality, and generating information for systematic improvement. An effective process control system may also be used to provide information to assess the quality of deliverables submitted for acceptance. This International Standard encourages suppliers to use process control and statistical control procedures for their internal control and to submit effective process control procedures to the customer for approval, so that the need for acceptance sampling procedures can be reduced or even eliminated.

Sampling inspection by itself can be an inefficient industrial practice for demonstrating conformance. The application of sampling plans for acceptance involves both consumer and producer risks; increased sampling is one way of reducing these risks, but it also increases costs. Suppliers can reduce risks by employing efficient processes with appropriate process controls. To the extent that such practices are properly employed and are effective, risk is controlled and, consequently, inspection and testing can be reduced.

This International Standard supports those whose preference is to move away from an acceptance quality limit (AQL)-based inspection (detection) strategy to implementation of an effective prevention-based strategy including a comprehensive quality management system, continuous improvement and partnering. The underlying theme is cooperation between customer and supplier, with the requisite competence of both parties, and a clear mutual benefit from processes capable of consistently high quality products and services. The objective is to create an atmosphere where every non-compliance is an opportunity for corrective action and improvement, rather than one where AQLs are the contractually sufficient goals.

The following points provide the basis for this International Standard:

a) suppliers are required to submit deliverables that conform to requirements and to generate and maintain sufficient evidence of conformance;

b) suppliers are responsible for establishing their own manufacturing and process controls to produce results in accordance with requirements;

c) suppliers are expected to use recognized prevention practices such as statistical process control.

This International Standard's goal, ideally, is to have product accepted as a result of control procedures. It also, however, provides a set of accept-zero sampling systems (see Annex A) and procedures for planning and conducting inspections to assess quality and conformance to specified requirements. The intent of including provisions for acceptance sampling is as a verification of the efficacy of process controls, or as an interim measure while such controls are being developed and implemented.

When acceptance sampling is conducted using the tables of this International Standard, the supplier has the option to inspect using any one of three types of sampling: single sampling by attributes; single sampling by variables; continuous sampling by attributes. Switching procedures are also provided to allow movement among normal, tightened and reduced inspection severities.

Some organizations have a policy of not using sampling plans indexed by AQLs. This International Standard complies with that policy.

Combined accept-zero sampling systems and process control procedures for product acceptance

1 Scope

This International Standard provides a set of accept-zero sampling systems and procedures for planning and conducting inspections to assess quality and conformance to specified requirements.

In addition, this International Standard provides requirements for alternative acceptance methods proposed by the supplier. Such alternative methods would be based upon establishing and implementing an internal prevention-based quality management system as a means of ensuring that all products conform to requirements specified by the contract and associated specifications and standards.

This International Standard, when cited in contract, is applicable to the supplier and extends to subcontractors or vendors. The quality plans are to be applied as specified in the contract documents, and deliverables may be submitted for acceptance if the requirements of this International Standard have been met.

Sampling systems and procedures in this International Standard are applicable, when appropriate, to assess conformance to requirements of the following:

a) end items;

b) components or basic materials;

c) operations or services;

d) materials in process;

e) supplies in storage;

f) maintenance operations;

g) data or records;

h) administrative procedures.

NOTE Use of the word “product” throughout this International Standard also refers to services and other deliverables.

The sampling systems and procedures of this International Standard are not intended for use with destructive tests or where product screening is not feasible or desirable. In such cases, the sampling systems to be used will be specified in the contract or product specifications.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3534-1:2006, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

ISO 3534-2:2006, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of document, the terms and definitions given in ISO 9000, ISO 3534-1, ISO 3534-2 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1.1
acceptance
act of an authorized representative of the customer by which the customer, for itself or as agent of another, assumes ownership of existing identified products tendered or approves specific services rendered as partial or complete performance of the contract

3.1.2
average outgoing quality
AOQ
expected average quality level of outgoing product for a given value of incoming product quality

Note 1 to entry: Adapted from ISO 3534-2:2006, definition 4.7.1.

3.1.3
average outgoing quality limit
AOQL
maximum AOQ over all possible values of incoming product quality level for a given acceptance sampling plan and rectification of all non-accepted lots unless specified otherwise

[SOURCE: ISO 3534-2:2006, definition 4.7.2]

3.1.4
acceptance quality limit
AQL
quality level that is the worst tolerable average quality of a process, when a continuing series of lots is submitted for acceptance sampling

3.1.5
contract quality requirements
technical requirements in the contract relating to the quality of the product or service and those contract clauses prescribing inspection, and other quality control procedures incumbent on the supplier, to assure that the product or service conforms to the contractual requirements

3.1.6
critical characteristic
characteristic that judgment and experience indicate must be met to avoid hazardous or unsafe conditions for individuals using, maintaining, or depending upon the product; or that judgment and experience indicate must be met to assure performance of the tactical function of a major product or service

3.1.7
critical nonconforming item
item of product that fails to conform to specified requirements for one or more critical characteristics

3.1.8
inspection
conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging

[SOURCE: ISO 3534-2:2006, definition 4.1.2]

3.1.9
lower process capability index
C_{pk_L}
index describing process capability in relation to the lower specification limit

Note 1 to entry: Frequently, the lower process capability index is designated C_{pk_L} and expressed as the difference between the process median, $\tilde{X}$ and the lower specification limit, L, divided by the length of the lower reference interval for a process in a state of statistical control, namely as:

$$C_{\mathrm{pk}_L} = \frac{\tilde{X} - L}{\tilde{X} - X_{0{,}001\ 35}}$$

where $X_{0{,}001\ 35}$ is the lower 0,001 35-fractile of the distribution of the quality characteristic.

Note 2 to entry: For a normal distribution, the process median, $\tilde{X}$ is the same as the process mean, μ, and $X_{0{,}001\ 35} = \mu - 3\sigma$, thus:

$$C_{\mathrm{pk}_L} = \frac{\mu - L}{3\sigma}$$

Note 3 to entry: Adapted from ISO 3534-2:2006, definition 2.7.3.

3.1.10
lower reference interval

interval bounded by the process median, $\tilde{X}$ and the 0,001 35-fractile, $X_{0{,}001\ 35}$, expressed by the difference

$$\tilde{X} - X_{0{,}001\ 35}$$

Note 1 to entry: For a normal distribution, the lower reference interval $\tilde{X} - X_{0{,}001\ 35} = \mu - (\mu - 3\sigma) = 3\sigma$.

Note 2 to entry: Adapted from ISO 3534-2:2006, definition 2.5.8.

3.1.11
major characteristic
characteristic, other than critical, that must be met to avoid failure or material reduction of usability of the item of product for intended purpose

3.1.12
major nonconforming item
item of product that fails to conform to specified requirements for one or more major characteristics, but conforms to all critical characteristics

3.1.13
minimum process capability index
C_{pk}
smaller of upper process capability index and lower process capability index

Note 1 to entry: Hence $C_{\mathrm{pk}} = \min.\ (C_{\mathrm{pk}_L}, C_{\mathrm{pk}_U})$.

Note 2 to entry: Adapted from ISO 3534-2:2006, definition 2.7.5.

3.1.14
minor characteristic
characteristic, other than critical or major, whose departure from its specification requirement is not likely to reduce materially the usability of the item of product for its intended purpose or whose departure from established standards has little bearing on the effective use or operation of the item

3.1.15
minor nonconforming item
item of product that fails to conform to specified requirements of one or more minor characteristics, but conforms to all critical and major characteristics

3.1.16
nonconformity
non-fulfilment of a requirement

[SOURCE: ISO 9000:2015, definition 3.6.9]

3.1.17
nonconforming item
item with one or more nonconformities

[SOURCE: ISO 3534-2:2006, definition 1.2.12]

3.1.18
process capability
statistical estimate of the outcome of a characteristic from a process which has been demonstrated to be in a state of statistical control

Note 1 to entry: Adapted from ISO 3534-2:2006, definition 2.7.1.

3.1.19
process capability index
C_p
index describing process capability in relation to specified tolerance

Note 1 to entry: Frequently the process capability index is designated C_p and expressed as the value of the specified tolerance divided by a measure of the length of the reference interval for a process in a state of statistical control, namely as:

$$C_p = \frac{U - L}{X_{0,998\ 65} - X_{0,001\ 35}}$$

where $X_{0,001\ 35}$ and $X_{0,998\ 65}$ are respectively the lower and upper 0,001 35-fractiles of the distribution of the quality characteristic.

Note 2 to entry: For a normal distribution, the reference interval is 6σ and the process capability index is given by the equation:

$$C_p = \frac{U - L}{6\sigma}$$

Note 3 to entry: Adapted from ISO 3534-2:2006, definition 2.7.2.

3.1.20
production interval
period of production under continuous sampling, assumed to exhibit essentially homogeneous quality

Note 1 to entry: A production interval is normally a single shift. It can be a day if it is reasonably certain that shift changes do not affect quality of product, but not longer than a day.

3.1.21
quality
degree to which a set of inherent characteristics fulfils requirements

Note 1 to entry: The term “quality” can be used with adjectives such as poor, good or excellent.

Note 2 to entry: “Inherent”, as opposed to “assigned”, means existing in something, especially as a permanent characteristic.

[SOURCE: ISO 9000:2015, definition 3.6.2]

3.1.22
quality assurance
part of quality management focused on providing confidence that quality requirements will be fulfilled

[SOURCE: ISO 9000:2015, definition 3.3.6]

3.1.23
quality audit
systematic examination of the acts and decisions with respect to quality in order to independently verify or evaluate the operational requirements of the quality program or the specification or contract requirements of the product or service

3.1.24
quality program
program that is developed, planned, and managed to carry out cost effectively all efforts to effect the quality of materials and services from concept to validation, full-scale development, production, deployment, and disposal

3.1.25
reference interval
interval bounded by the 0,998 65-fractile, $X_{0,998\,65}$, and the 0,001 35-fractile, $X_{0,001\,35}$, expressed by the difference $X_{0,998\,65} - X_{0,001\,35}$

Note 1 to entry: For a normal distribution, the reference interval $X_{0,998\,65} - X_{0,001\,35} = (\mu + 3\sigma) - (\mu - 3\sigma) = 6\sigma$.

Note 2 to entry: Adapted from ISO 3534-2:2006, definition 2.5.7.

3.1.26
sampling plan
combination of sample size to be used and associated lot acceptability criteria

Note 1 to entry: A sampling plan does not contain the rules on how to draw the sample.

Note 2 to entry: For the purposes of this International Standard, a distinction should be made between the terms *sampling plan* (3.1.26), *sampling scheme* (3.1.27) and *sampling system* (3.1.28).

3.1.27
sampling scheme
combination of sampling plans with rules for changing from one plan to another

3.1.28
sampling system
collection of sampling plans, or of sampling schemes, each with its own rules for changing plans, together with sampling procedures including criteria by which appropriate plans or schemes may be chosen

Note 1 to entry: This International Standard contains a set of sampling systems each indexed by verification levels, and either lot size or production interval size ranges.

3.1.29
screening inspection
100 % inspection with rejection of all items or portions found nonconforming

Note 1 to entry: Screening inspection may be concerned only with one particular kind of nonconformity.

[SOURCE: ISO 3534-2:2006, definition 4.1.7]

3.1.30
traceability
ability to trace the history, application or location of that which is under consideration

Note 1 to entry: When considering product, traceability can relate to

— the origin of materials and parts,

— the processing history, and

— the distribution and location of the product after delivery.

Note 2 to entry: In the field of metrology, the definition in ISO/IEC Guide 99 is the accepted definition.

[SOURCE: ISO 9000:2015, definition 3.6.13]

3.1.31
upper process capability index
C_{pk_U}
index describing process capability in relation to the upper specification limit

Note 1 to entry: Frequently, the upper process capability index is designated C_{pk_U} and expressed as the difference between the upper specification limit, U, and the process median, $\tilde{X}$ divided by the length of the upper reference interval for a process in a state of statistical control, namely as:

$$C_{\mathrm{pk}_U} = \frac{U - \tilde{X}}{X_{0,998\,65} - \tilde{X}}$$

where $X_{0,998\,65}$ is the upper 0,001 35-fractile of the distribution of the quality characteristic.

Note 2 to entry: For a normal distribution, the process median, $\tilde{X}$ is the same as the process mean, μ and $X_{0,998\,65} = \mu + 3\sigma$, thus

$$C_{\mathrm{pk}_U} = \frac{U - \mu}{3\sigma}$$

Note 3 to entry: Adapted from ISO 3534-2:2006, definition 2.7.4.

3.1.32
upper reference interval
interval bounded by the 0,998 65-fractile, $X_{0,998\,65}$ and the process median, $\tilde{X}$, expressed by the difference $X_{0,998\,65} - \tilde{X}$

Note 1 to entry: For a normal distribution, the upper reference interval $X_{0,998\,65} - \tilde{X} = (\mu + 3\sigma) - \mu = 3\sigma$.

Note 2 to entry: Adapted from ISO 3534-2:2006, definition 2.5.9.