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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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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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.

3.1.33
verification level
VL
level of importance or utility of a characteristic to the user

Note 1 to entry: The amount of effort to assure conformance can be allocated on the basis of importance to the user. (Major characteristics require more verification effort than minor characteristics.) VL-7 requires the highest level of effort, and the effort decreases as the VL decreases to the lowest level, VL-1. Verification levels T and R have been included to allow for tightened inspection for VL-7 and for reduced inspection for VL-1.

3.2 Symbols

c	number of nonconforming items in sample
C_{p}	process capability index (see 3.1.19)
C_{pk}	minimum process capability index (see 3.1.13)
C_{pk_L}	lower process capability index (see 3.1.9)
C_{pk_U}	upper process capability index (see 3.1.31)
F	acceptability constant for standardized sample standard deviation, $\hat{F}$
$\hat{F}$	standardized sample standard deviation, i.e. $\hat{F} = s / (U - L)$
f	sampling frequency in continuous sampling (see D.2.4)
f_{c}	correction factor in determining S_{c} (see D.2.2 and D.2.3)
i	clearance number in continuous sampling (see D.2.4)
k	acceptability constant for quality index
L	lower specification limit
n_{a}	sample size for sampling by attributes
$n_{\mathrm{a}}(\mathrm{N})$	sample size for sampling by attributes under normal inspection
$n_{\mathrm{a}}(\mathrm{T})$	sample size for sampling by attributes under tightened inspection
n_{v}	sample size for sampling by variables
P_{a}	probability of acceptance
p	process fraction nonconforming
Q	quality index
Q_L	quality index for lower specification limit (see D.2.2 and D.2.3)
Q_U	quality index for upper specification limit (see D.2.2 and D.2.3)
q	complement with respect to unity of process fraction nonconforming (i.e. $q = 1 - p$)
S_{c}	corrected sum of squares (see D.2.2 and D.2.3)
s	sample standard deviation (see D.2.2 and D.2.3)
s^2	sample variance (see D.2.2 and D.2.3)
U	upper specification limit

$\bar{x}$	sample mean (see D.2.2 and D.2.3)
$\tilde{X}$	process median
$X_{0,001\ 35}$	process 0,001 35-fractile
$X_{0,998\ 65}$	process 0,998 65-fractile
μ	process mean
σ	process standard deviation

4 General requirements

4.1 Product requirements

The supplier is required to submit product that meets all contract and specification requirements. The application of the sampling systems or procedures of this International Standard does not relieve the supplier of responsibility from meeting all contract product requirements. The supplier's quality management system, including manufacturing processes and quality control measures, shall be established and operated to produce products that consistently meet all requirements. Absence of any inspection or process control requirements in the contract does not relieve the supplier of responsibility for assuring that all products meet or exceed the customer's requirements.

4.2 Acceptance by tables

4.2.1 Preferred sampling systems

This International Standard presents three types of matched sampling systems for the sampling inspection of product submitted to the customer for acceptance. These sampling systems provide for inspecting the samples from lots by measurement of attributes or variables and for continuous sampling by measurement of attributes. The three types of matched sampling systems are indexed by seven specified verification levels (VL) and five sample-size code letters (CL). Approximately the same level of protection is provided by each of the three types, when using the same code letter and verification level. The supplier has the option to utilize the type of sampling system, at the same verification level, that best complements the production process.

4.2.2 Formation and identification of lots

The product shall be assembled into identifiable lots or sub-lots or in such other manner as may be prescribed. Each lot shall, as far as practicable, consist of items of product of a single type, grade, class, size and composition, manufactured under essentially the same conditions and at essentially the same time. The lots shall be identified by the supplier and shall be kept intact in adequate and suitable storage space. Although lot size is not used to select a continuous sampling plan, the formation of lots may remain desirable for reasons of homogeneity, shipping convenience and facilitation of payment.

4.2.3 Determination of sampling plan

A sampling plan in accordance with this International Standard is determined by all of the following:

a) verification level (VL);

b) type of quality characteristic (i.e. attributes or variables);

c) type of sampling (i.e. single sampling or continuous sampling);

d) sample-size code letter (CL);

e) inspection severity (normal, tightened, reduced).

4.2.4 Sampling of lots

4.2.4.1 Selection of items

Using simple random sampling, items of product shall be drawn from the lot without regard to their quality. Simple random sampling requires that each item in the lot or production interval has the same probability of being selected for the sample. It is recommended that random number tables, computer programs or other suitable means be used for obtaining randomness in sampling rather than relying solely on human selection.

4.2.4.2 Proportionate stratified random sampling

When appropriate, the number of items in the sample shall be selected in proportion to the size of sub-lots or parts of the lot, identified by some rational criterion. When stratified sampling is used, the items from each sub-lot or part shall be selected using simple random sampling.

4.2.4.3 Process of sampling

A sample may be drawn after all items comprising the lot have been assembled, or sample items may be drawn during assembly of the lot, in which case the size of the lot shall be determined before samples are drawn. When the lot satisfies the acceptance criteria of the sampling plan, such lots are acceptable and may be submitted to the customer.

4.2.4.4 Nonconforming product

When sample items are drawn from a lot or during lot assembly and nonconforming items are found, the supplier shall withhold from acceptance that lot or portion of the lot completed and all additional production occurring prior to the initiation and verification of corrective action. The supplier shall take steps to preclude the submission of known nonconforming product to the customer. The customer reserves the right to withhold acceptance of any nonconforming item found, whether that item was part of the sample or not and whether the lot as a whole was accepted or not.

4.2.4.5 Disposition of nonconforming lots

For lots withheld from acceptance, the supplier shall take all of the following actions.

a) Screen the lots and remove all nonconforming items.

b) Take steps to preclude submission of any known nonconforming items to the customer for acceptance.

c) Determine the cause of the nonconformities and implement appropriate process changes and corrective action.

d) Follow the switching requirements of 5.1.1.6.

e) Rework or repair nonconforming items if permitted by contract provisions. The supplier shall advise the customer representative of actions taken. Repaired product shall be treated in accordance with associated contract provisions, documented and reported to the customer on a request for deviation, waiver or concession.

f) Inspect corrected product in accordance with the supplier's quality plan or documented procedures prior to submission to the customer for acceptance.

When continuous sampling is in effect, the occurrence of a nonconforming item while in a sampling phase results in withholding acceptance of that item, a return to screening, and initiation of corrective

action. If a nonconforming item is found while in a screening phase, acceptance is withheld for that item and screening is continued until the requirements of 5.1.2.4.3 are satisfied.

4.3 Acceptance by supplier-proposed provisions

4.3.1 General

This International Standard, when referenced in the contract or product specifications, requires the supplier to perform sampling inspection in accordance with 4.2 and the product specification. However, it is recognized that sampling inspection alone does not control or improve quality. Product quality comes from proper product and process design and process control activities. When such activities are effective, sampling inspection is a redundant effort and an unnecessary cost. Suppliers that have an acceptable quality management system and proven process controls on specific processes are encouraged to consider submitting alternative acceptance methods for one or more contractually specified characteristics. In addition, suppliers that have a successful quality management system, and a history of successful process controls relevant to the products/services being procured in this contract, are encouraged to consider submitting a systemic alternative acceptance method for all the contractual sampling inspection requirements associated with 4.2.

Such submissions shall describe the alternative acceptance methods, the sampling inspection provision to be replaced, and an evaluation of the protection provided by the alternative methods as compared with the inspection requirement to be replaced. The alternative acceptance method shall include evidence of process control and capability during production, together with adequate criteria, measurement and evaluation procedures to maintain control of the process. The acceptability of the alternative acceptance methods is dependent upon the existence of a quality management system, the demonstration of its process focus, and the availability of objective evidence of effectiveness (see 5.2).

4.3.2 Requirements and procedures

Suppliers currently operating quality management systems, for example ISO 9001, that are deemed satisfactory to the customer representative, are qualified to apply for alternative acceptance methods if demonstration of process focus and objective evidence of effectiveness exists.

The supplier shall include in his request for approval of an alternative acceptance method an assessment plan to periodically verify process stability, capability, and other conditions under which the alternative acceptance method was developed. The current suggested minimum values of process capability are equivalent to a C_{pk} of 2,00 for critical characteristics, 1,33 for major characteristics, and 1,00 for minor characteristics. These are historically dynamic goals. Contractual minimum or target capability levels should be thoroughly reviewed and agreed upon by both customer and supplier. Upon approval of the assessment plan, verification sampling inspection in accordance with the tables of 5.1.2 may be reduced or eliminated as long as the acceptance criteria of the assessment plan are met. In the case of a critical characteristic, automated screening or the mistake-proof process will continue to be performed, and only the VL-7 sampling inspection will be reduced or eliminated (see 4.4).

4.3.3 Submission and incorporation of alternative acceptance methods

4.3.3.1 Submission of alternative acceptance methods

There are two ways to submit alternative acceptance methods:

a) submission of individual alternative acceptance methods for one or more contractually specified sampling inspection requirements to the customer or the customer's representative, as specified in the contract, for approval at any time during the contract period of performance; or

b) submission of a systemic alternative acceptance method to the customer or the customer's representative, as specified in the contract, either prior to or after award of contract. Approval prior to contract award allows the supplier to adopt alternative acceptance methods throughout the length of the contract.

4.3.3.2 Incorporation of alternative acceptance methods

All approved alternative acceptance methods shall be incorporated into the supplier's manufacturing and quality program plans or other vehicles acceptable to the contracting agency, as applicable.

4.3.4 Withdrawal of approval of alternative acceptance methods

The customer reserves the right to withdraw approval of alternative acceptance methods that are found, in practice, to provide a lower level of protection than the inspection sampling scheme of this International Standard or when the inability to maintain process stability and capability over time becomes apparent.

4.4 Critical characteristics

Unless otherwise specified in the contract or product specifications, the supplier is required for each critical characteristic to do the following:

a) implement an automated screening or a process that prevents the occurrence of a critical nonconforming item (also known as a mistake-proof process); and

b) apply VL-7 to verify the performance of the screening operation or mistake-proof process on every lot.

Approval of an alternative method for acceptance only eliminates or reduces the VL-7 inspection, but not the 100 % screening or mistake-proof process.

In the event that visual screening is permitted by the contract or the specification, VL-7 is still required. In fact, no matter how the screening is performed, VL-7 is required for verification unless otherwise specified in the contract or specification.

The occurrence of one or more critical nonconformities requires corrective action and verification of its effectiveness as specified in 4.5.

4.5 Special reservations for critical nonconformity

When a critical nonconformity is discovered at any phase of production or during any inspection, the following immediate actions are all required:

a) prevent delivery of critical nonconforming items to the customer;

b) notify the customer;

c) identify the cause;

d) take corrective action and verify its effectiveness;

e) screen all available suspect items, if suspect items may contain the same critical nonconformity.

NOTE "All available suspect items" could include an entire lot or batch or all items produced during the last production interval.

Records of corrective actions and conclusions concerning their effectiveness verification shall be maintained and made available to the customer.

5 Detailed requirements

5.1 Acceptance by tables

5.1.1 Sampling inspection

5.1.1.1 General

When acceptance shall be accomplished using the sampling tables provided in this document, the following considerations apply.

5.1.1.2 Code letter determination

The code letter is found by entering Table 1 with both the lot size and the verification level. The sampling plan is then found by entering Table 2, 3 or 4 with both the verification level and the code letter.

Table 1 — Code letters (CLs) for entry into the sampling tables

Lot or production interval size	Verification levels (normal inspection)						
	7	6	5	4	3	2	1
2 – 170	A	A	A	A	A	A	A
171 – 288	A	A	A	A	A	A	B
289 – 544	A	A	A	A	A	B	C
545 – 960	A	A	A	A	B	C	D
961 – 1 700	A	A	A	B	C	D	E
1 701 – 3 072	A	A	B	C	D	E	E
3 073 – 5 482	A	B	C	D	E	E	E
5 483 – 9 720	B	C	D	E	E	E	E
9 721 – 17 408	C	D	E	E	E	E	E
17 409 – 30 960	D	E	E	E	E	E	E
30 961 and larger	E	E	E	E	E	E	E

Table 2 — Sampling by attributes plans

Code letter	T	Verification levels							R
		7	6	5	4	3	2	1	
	Sample size (n_a)								
A	3 250	1 290	512	200	80	32	12	5	3
B	4 096	1 625	645	256	100	40	16	6	3
C	5 160	2 048	810	320	128	50	20	8	3
D	6 500	2 580	1 024	400	160	64	25	10	4
E	8 192	3 250	1 290	512	200	80	32	12	5

NOTE 1 When the lot size is less than or equal to the sample size, 100 % attributes inspection is required.

NOTE 2 One verification level (VL) to the left/right of the specified normal VL is the respective tightened/reduced plan. Tightened inspection of VL-7 is T, reduced inspection of VL-1 is R.

Table 3 — Sampling by variables plans

Code letter	T	Verification levels							R
		7	6	5	4	3	2	1	
	Sample size (n_v)								
A	81	65	49	35	24	16	9	4	3
B	86	68	53	39	27	18	11	5	3
C	91	73	56	41	29	20	12	7	3
D	100	79	59	44	32	22	14	8	3
E	104	81	65	49	35	24	16	9	4
	k **values** (one- or two-sided)								
A	3,55	3,29	3,02	2,72	2,40	2,02	1,54	1,18	0
B	3,61	3,36	3,09	2,80	2,48	2,12	1,69	1,22	0
C	3,67	3,42	3,16	2,88	2,57	2,21	1,81	1,29	0
D	3,72	3,48	3,23	2,95	2,65	2,31	1,91	1,44	1,14
E	3,78	3,55	3,29	3,02	2,72	2,40	2,02	1,54	1,18
	F **values** (two-sided)								
A	0,136	0,145	0,157	0,174	0,193	0,222	0,271	0,370	0,707
B	0,134	0,143	0,154	0,168	0,188	0,214	0,253	0,333	0,707
C	0,132	0,140	0,152	0,165	0,182	0,208	0,242	0,301	0,707
D	0,130	0,138	0,148	0,162	0,177	0,199	0,233	0,283	0,435
E	0,128	0,136	0,145	0,157	0,174	0,193	0,222	0,271	0,370

NOTE 1 When the lot size is less than or equal to the sample size, 100 % attributes inspection is required.

NOTE 2 One verification level (VL) to the left/right of the specified normal VL is the respective tightened/reduced plan. Tightened inspection of VL-7 is T, reduced inspection of VL-1 is R.

Table 4 — Continuous sampling plans

Code letter	T	Verification levels							R
		7	6	5	4	3	2	1	
	Screening phase: clearance numbers (*i*)								
A	4 091	2 224	1 134	549	264	125	55	27	*N/A*
B	7 061	3 599	1 767	842	388	180	83	36	*N/A*
C	11 426	5 609	2 662	1 237	572	256	116	53	*N/A*
D	17 802	8 477	3 957	1 785	815	368	162	73	*N/A*

NOTE 1 Use of other combinations of *i* and *f* are permitted provided they are computed in accordance with D.2.5.

NOTE 2 During the screening phase, one verification level (VL) to the left of the specified normal VL is the tightened plan. Tightened inspection of VL-7 is T. There is no reduced plan while in the screening phase since the reward for good performance during screening is switching to sampling, and the penalty incurred while on reduced sampling is switching to normal screening.

During the sampling phase, one verification level (VL) to the left/right of the specified normal VL is the respective tightened/reduced plan. Tightened inspection of VL-7 is T, reduced inspection of VL-1 is R.

NOTE 3 Sample items are chosen with probability *f* so as to give each item of product an equal chance of being inspected. A consequence of this is that the interval between sample items varies somewhat rather than being of constant size.

EXAMPLE — Suppose $f = 1/6$. In the first 30 items produced, if each item of production is given a chance of 1 in 6 of being chosen for inspection, the following items might be randomly selected: 2, 10, 19, 22, and 29. Notice that in the first six items produced, one item was randomly selected (i.e. item 2) for inspection. In the second set of six items produced, one item was selected (i.e. item 10). In the third set of six items produced (i.e. items 13 through 18), none was selected by chance. In the fourth set of six items produced, two items were selected (items 19 and 22) by chance. In the last group of six items, one item was selected (item 29) for inspection.

Table 4 *(continued)*

Code letter	T	Verification levels							R
		7	6	5	4	3	2	1	
	Screening phase: clearance numbers (i)								
E	26 912	12 556	5 754	2 605	1 147	513	228	96	*N/A*
	Sampling phase: frequencies (f)								
A	1/3	4/17	1/6	2/17	1/12	1/17	1/24	1/34	1/48
B	4/17	1/6	2/17	1/12	1/17	1/24	1/34	1/48	1/68
C	1/6	2/17	1/12	1/17	1/24	1/34	1/48	1/68	1/96
D	2/17	1/12	1/17	1/24	1/34	1/48	1/68	1/96	1/136
E	1/12	1/17	1/24	1/34	1/48	1/68	1/96	1/136	1/192

NOTE 1 Use of other combinations of i and f are permitted provided they are computed in accordance with D.2.5.

NOTE 2 During the screening phase, one verification level (VL) to the left of the specified normal VL is the tightened plan. Tightened inspection of VL-7 is T. There is no reduced plan while in the screening phase since the reward for good performance during screening is switching to sampling, and the penalty incurred while on reduced sampling is switching to normal screening.

During the sampling phase, one verification level (VL) to the left/right of the specified normal VL is the respective tightened/reduced plan. Tightened inspection of VL-7 is T, reduced inspection of VL-1 is R.

NOTE 3 Sample items are chosen with probability f so as to give each item of product an equal chance of being inspected. A consequence of this is that the interval between sample items varies somewhat rather than being of constant size.

EXAMPLE — Suppose f = 1/6. In the first 30 items produced, if each item of production is given a chance of 1 in 6 of being chosen for inspection, the following items might be randomly selected: 2, 10, 19, 22, and 29. Notice that in the first six items produced, one item was randomly selected (i.e. item 2) for inspection. In the second set of six items produced, one item was selected (i.e. item 10). In the third set of six items produced (i.e. items 13 through 18), none was selected by chance. In the fourth set of six items produced, two items were selected (items 19 and 22) by chance. In the last group of six items, one item was selected (item 29) for inspection.

5.1.1.3 Verification level specification

The verification levels (VLs) are specified in the contract or product specifications. A VL may be specified for individual characteristics, for a group of characteristics, or for subgroups of characteristics within the group. The VL and code letter (CL) from Table 1 determine the sampling plan required to assess product compliance with contract and specification requirements. Suppliers are expected to produce and submit product in full conformance to all requirements. Lots or production intervals of product that consistently meet or exceed all requirements will be accepted by the sampling plans of this International Standard and will result in qualifying for reduced sampling levels.

5.1.1.4 Selection of verification levels

For critical characteristics, VL-7 should always be used. This inspection is a verification of the automated screening or mistake-proof process implemented in accordance with 4.4. For major characteristics, VLs from 3 to 6 should typically be used. For minor characteristics, VLs from 1 to 3 should typically be used. The more important the characteristic, the higher the VL. Lower VLs may also be considered where relatively small sample sizes are necessary and large sampling risks can or must be tolerated as, for example, when inspection costs are high. If no VL is specified, then VL-4 for major characteristics and VL-2 for minor characteristics should be used.

The tables in Annex E can help the consumer decide which VL to choose. Although this International Standard has a goal of acceptance of product at no worse than parts per million quality levels, sometimes the consumer is guided in the selection of a VL by inspection of the risks associated with individual plans. For example, suppose an attributes plan is desired and code letter A is expected to apply. Suppose further that the consumer is trying to decide between VL-3 and VL-4, which require sample sizes of 32 and 80 respectively. Table E.4 b) of Annex E reveals that the VL-3 plan has a 10 % risk of accepting a lot if the actual percent nonconforming is 6,94 % while the VL-4 plan has a 10 % risk of accepting a lot

if the percent nonconforming is 2,84 %. The consumer may decide to select the VL-4 plan if the risk of accepting product at a 6,94 % nonconforming rate is considered to be intolerable.

5.1.1.5 Sampling procedures

Sampling is performed at one of three inspection severities called normal, tightened and reduced. Unless otherwise specified, the VL stated in the contract shall be considered the normal severity of inspection and shall be used at the start of inspection. The tightened and the reduced severities are then defined as the VLs to the immediate left and right, respectively, of the initial severity of Table 2, 3 or 4. The sampling inspection severity in effect shall continue unchanged for each group of characteristics or individual characteristic except where the switching procedures given in 5.1.1.6 require change. The switching procedures shall be applied separately to each individual characteristic except where characteristics are specified as belonging to a group with a single VL that applies to the entire group.

5.1.1.6 Switching rules and procedures

5.1.1.6.1 General

The procedures for switching among normal, tightened, and reduced inspection are given in Note 2 in Tables 2, 3 and 4. Annex C provides additional guidance for following the switching procedures.

The switching procedures are independent of the results of any remedial action, such as screening, additional samples, etc., resulting from the occurrence of sample nonconformities and withholding of acceptance.

Some Table 4 switching criteria depend upon a corresponding Table 2 entry. These entries have been denoted by n_a(N) and n_a(T) in the descriptions that follow. n_a(N) represents the Table 2 sample size used for normal sampling at the VL and CL currently in effect. Likewise, n_a(T) represents the sample size under tightened inspection.

5.1.1.6.2 Normal to tightened

When normal inspection is in effect, tightened inspection shall be instituted when one of the following conditions occurs, depending on the type of sampling being used.

a) In the case of lot sampling (Tables 2 and 3):

   two lots have been withheld from acceptance within the last 5 or fewer lots.

b) In the case of continuous sampling (Table 4):

   while on either normal screening or normal sampling, two nonconforming items are found within a period of inspections (including all inspected items whether on sampling or screening) totalling no more than 5 times n_a(N). In this case the switch shall be from either normal screening or normal sampling to tightened screening.

5.1.1.6.3 Tightened to normal

When tightened inspection is in effect, normal inspection shall be instituted when the following conditions are both satisfied.

a) The cause for producing the nonconformities is corrected.

b) In the case of lot sampling (Tables 2 and 3):

5 consecutive lots are accepted.

or, in the case of continuous sampling (Table 4):

while on tightened sampling, no nonconforming items have been found within a period of inspections (including all inspected items whether on sampling or screening) totalling at least 5 times n_a(T) items. In this case the switch shall be from tightened sampling to normal sampling.

5.1.1.6.4 Normal to reduced

When normal inspection is in effect, reduced inspection shall be instituted when the following conditions are all satisfied.

a) In the case of lot sampling (Tables 2 and 3):

10 consecutive lots are accepted while on normal inspection;

or, in the case of continuous sampling (Table 4):

while on normal sampling, no nonconforming items have been found within a period of inspections (including all inspected items whether on sampling or screening) totalling at least 10 times n_a(N) items. In this case the switch shall be from normal sampling to reduced sampling).

b) Production is at a steady rate.

c) The supplier's quality management system is considered satisfactory by the responsible authority.

d) Reduced inspection is considered desirable by the responsible authority.

5.1.1.6.5 Reduced to normal

When reduced inspection is in effect, normal inspection shall be instituted when one or more of the following conditions occur.

a) In the case of lot sampling (Tables 2 and 3):

a lot is withheld from acceptance;

or, in the case of continuous sampling (Table 4):

a nonconforming item is found during sampling inspection.

b) Production becomes irregular or delayed.

c) The supplier's quality management system becomes unsatisfactory.

d) Other conditions warrant that normal inspection be re-instituted.

If a switch is made while on continuous reduced sampling, the switch shall be to normal screening.

5.1.1.6.6 Discontinuation of inspection

If either condition a) or b) below occurs, the customer reserves the right to discontinue inspection of the product until the causes of nonconformities are eliminated or other remedies acceptable to

the customer have been instituted. When sampling inspection is restarted after discontinuation of inspection, it shall be at the tightened inspection severity.

a) In the case of lot sampling:

   the cumulative number of lots not accepted in a sequence of consecutive lots on original tightened inspection reaches 5.

b) In the case of continuous sampling:

   during a period of tightened screening, a nonconforming item is found before finding *i* consecutive items and the number of items screened is equal to or greater than 10 times $n_a(T)$.

5.1.2 Preferred sampling inspection tables

5.1.2.1 General

See Annex D for examples, involving the switching rules, of the computations involved in determining compliance with requirements using the attributes, variables and continuous sampling plans given in Tables 2, 3 and 4 respectively.

5.1.2.2 Sampling by attributes plans for lot inspection

5.1.2.2.1 Preferred plans

The preferred sampling by attributes plans for lots are described in Table 2 for normal, tightened, and reduced inspection. The number of sample units inspected shall be equal to the sample size given by the plan even if a nonconforming item is found before all items in the sampling plan are inspected

5.1.2.2.2 Acceptability criteria

The lot shall be considered acceptable only if no nonconforming items are found upon inspection of the random sample of the size listed in Table 2.

5.1.2.3 Sampling by variables plans for lot inspection

5.1.2.3.1 Preferred plans

The preferred sampling by variables plans for lots are described in Table 3 for normal, tightened, and reduced inspection. The number of sample units inspected shall be equal to the sample size given by the plan, even if a nonconforming item is found before all items in the sampling plan are inspected

5.1.2.3.2 Limitations on use

Sampling by variables is not to be used indiscriminately. Its use shall depend upon evidence, provided by graphical or statistical analyses, that the assumptions of independence and normality are being met. See ISO 5479 [[1]] for examples of tests for departure from normality. Attribute sampling shall be used whenever the evidence fails to warrant the use of sampling by variables.

5.1.2.3.3 Nonconforming item

For the purposes of sampling by variables, an item of product shall be considered nonconforming if the measured value of its quality characteristic is outside the specified tolerance.

5.1.2.3.4 Acceptability criteria

The lot shall be considered acceptable if its sample contains no nonconforming items and the applicable *k* and *F* criteria (see Table 3) are met. If the sample contains any nonconforming item, or if the sample

does not meet the k criterion, or if the sample does not meet the F criterion (when applicable), the lot does not meet the acceptability criteria.

a) k criterion, single-sided specification. For a single-sided specification the quantity $(\bar{x} - L) / s$ or, in the case of an upper limit, $(U - \bar{x}) / s$, shall be greater than or equal to the acceptability constant k specified in Table 3 in order to meet the k criterion.

b) k criterion, double-sided specification. For a double-sided specification, each of the quantities $(\bar{x} - L) / s$ and $(U - \bar{x}) / s$ shall be greater than or equal to the acceptability constant k specified in Table 3 in order to meet the k criterion. When the VLs are not the same for both specification limits, the higher-numbered VL, along with its associated sample size and acceptability constant, shall be used for both sides.

c) F criterion (only applicable in double-sided specifications). For a double-sided specification, the quantity $\hat{F} = s / (U - L)$ shall be less than or equal to the specified acceptability constant F in Table 3 in order to meet the F criterion.

5.1.2.4 Continuous sampling by attributes inspection plans

5.1.2.4.1 Preferred plans

The preferred continuous sampling plans for inspection by attributes are described in Table 4 for normal, tightened, and reduced inspection.

5.1.2.4.2 Conditions for continuous sampling procedures

The following conditions shall exist before the continuous sampling by attributes procedures of this section may be used for inspection:

a) a continuing stream of items;

b) ample space, equipment, and manpower at or near the inspection station to permit 100 percent inspection when required;

c) a process that is producing or is capable of producing material whose quality is stable.

5.1.2.4.3 Continuous sampling inspection procedure

At the start of production, all items are inspected. Sampling inspection may be initiated at frequency f when both of the following conditions are satisfied.

a) All items of product are of the same configuration and produced under stable conditions.

b) At least i consecutive items (see clearance numbers in Table 4) inspected are free of nonconformities.

Sampling inspection shall be terminated and 100 % inspection resumed if one or more of the following conditions occur.

— the production process is interrupted for more than three operating days;

— the requirement that all items of product are of the same configuration and produced under stable conditions is no longer satisfied;

— an item having any nonconformity is found during sampling.

Sampling inspection can resume when conditions a) and b) for initiating sampling are satisfied.

5.1.2.4.4 Acceptability criterion

In continuous sampling, items of product are determined to be acceptable or not on essentially an individual basis. While 100 % inspection is being performed, each item is individually inspected and categorized as a conforming or a nonconforming item, and accepted or not accepted accordingly. While inspection is being performed on a sampling basis, each item that is inspected is categorized as acceptable or not acceptable depending on whether it is found to be conforming or nonconforming and each item not inspected is considered to be conforming and hence accepted. (See 5.1.2.4.5.)

5.1.2.4.5 Special reservation for a critical nonconforming item

In addition to the provisions of 4.5, if a critical nonconforming item is found during sample inspection, all product since the last conforming item was found shall be inspected.

5.2 Acceptance by supplier-proposed provisions

5.2.1 General

In order for an alternative acceptance method to be considered, the supplier shall establish and implement 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. The acceptability of the quality management system as part of the request for alternative acceptance method(s) is dependent on its compliance with an industry-accepted quality management system model, demonstration of its process focus, and the availability of objective evidence of its implementation and effectiveness.

5.2.2 Quality management system

The quality management system shall be documented and shall be subject to on-site customer review throughout the contract. It shall include, at a minimum, a description of the organizational structure, responsibilities, and resources and shall reference appropriate processes and procedures. Such documentation is hereinafter called the quality manual. The supplier shall maintain, disseminate, update and improve the quality manual in order to ensure its continued use and accuracy. The design and documentation of the quality manual shall allow for ease of use, review and audit by internal as well as customer personnel.

5.2.3 Prevention-based quality management system

The quality management system shall be prevention-based. Common quality management system models that reflect this philosophy include those described in ISO 9001 and ISO 9004, as well as many industry-specific quality management standards and procedures. The quality management system shall also reflect additional needs in accordance with the requirements of this International Standard. Regardless of the model chosen, the quality management system shall demonstrate its prevention-based outlook by meeting the following objectives throughout all areas of contract performance:

a) the quality management system is understood and executed by all personnel having any influence on product or process quality;

b) products and services meet or exceed customer requirements;

c) quality is deliberately and economically controlled;

d) emphasis is on the prevention of process discrepancies and product nonconformities;

e) discrepancies and nonconformities that do occur are readily detected, and root cause corrective actions are taken and verified;

f) sound problem solving and statistical methods are employed to continuously reduce process variability and, in turn, improve process capability and product quality;

g) records are maintained to indicate implementation of the quality management system and effectiveness of the control procedures.

5.2.4 Process focus of quality management system

To demonstrate a process focus, the supplier shall demonstrate that the manufacturing process and its related processes have been studied and are understood, controlled, and documented to show that they are

a) consistently producing conforming product,

b) controlled as far upstream as possible,

c) robust to variation in equipment, raw materials, and other process inputs, and designed to yield a quality product,

d) operated with the intent to constantly strive to reduce process/product variability,

e) designed to utilize manufacturing equipment with objectives of minimum variability around targeted values,

f) managed for continuous improvement, and

g) designed and controlled using a combination of manufacturing practices and statistical methods in order to ensure defect prevention and process improvement.

5.2.5 Objective evidence of quality management system implementation and effectiveness

NOTE Detailed information for many of the items in this subclause can be found either in International Standards listed in the Bibliography or in textbooks.

5.2.5.1 Examples of evidence regarding process improvement

a) Process flow charts showing the key control points where action is taken to prevent the production of nonconforming product.

b) Identification of process improvement techniques and tools used, e.g. Plan-Do-Check-Act (PDCA) cycle, failure modes and effects analysis (FMEA), Pareto analysis, cause-and-effect analysis and 6-sigma capability.

c) Identification of the measures used, e.g. trend analysis, cost of quality, cycle time reduction, defect rates and process capability indices.

d) Results of the improvements from the use of these process improvement tools.

e) Results of properly planned experiments that led to reduced common cause variability of a process and improved productivity.

5.2.5.2 Examples of evidence regarding process control

a) Identification of the scope of use of process control techniques, e.g. statistical process control (SPC), automation, gauges, set-up verification, preventative maintenance and visual inspection.

b) Process control plans, including the improvement goals and statements of management commitment to SPC.

c) Approaches and supporting data used to determine if suppliers have adequate controls to assure nonconforming product is not produced and delivered.

d) Descriptions of the required training in SPC and/or continuous improvement, i.e. the number of courses and their content, courses required for personnel at each organizational level and function

associated with the quality management system, the qualifications of the instructors or trainers for SPC classes, support by management to attend such courses, and information demonstrating the effectiveness of the training.

e) Identification and definition of the interrelations of all departments (e.g. production, engineering, purchasing, marketing, administration, etc.) involved in SPC and quality improvement, their responsibilities, and the use of teams.

f) When applying control charts, the reasoning behind establishing rational subgroups and sampling frequency; the procedures for determining and updating control limits; and the criteria for determining out-of-control conditions.

g) Identification of key process parameters that directly affect one or more specified product characteristics, verification of the correlation of such parameters to those characteristics, and description of the manufacturing process steps responsible for these parameters.

h) Identification of personnel responsible for process-related corrective action.

i) Proper measurement system analyses showing measurement variations relative to the total variation.

j) Traceability of the product and traceability of the process corrective action(s) taken when the process exhibits statistical instability, documenting the identification and elimination of root cause(s).

5.2.5.3 Examples of evidence regarding product conformance

a) Control charts showing the process in statistical control in accordance with the criteria suggested in 5.2.5.2 f).

b) Records of product and process corrective action(s) taken when nonconformities occur.

c) Process capability studies consisting of the correct calculation and interpretation of indices, such as C_p and C_{pk}.

d) History of product inspection results reinforced by statistical data and analysis;

e) Results from in-process control methods, such as 100 % automated assembly and/or inspection.

Annex A
(informative)

Why accept-zero?

The accept-zero plans in this International Standard were formulated with a clear understanding of the following points:

a) observance of zero nonconformities in a sample does not imply that the population has no nonconformities;

b) expectation of no nonconformities in an entire population of product can be unreasonable;

c) accept-zero plans may not be as discriminating as plans with accept numbers greater than zero.

It can nevertheless be desirable to use sampling plans that accept zero nonconformities for the reasons given below.

— Customers generally do not like to give the perception that some small level of percent nonconforming product is acceptable or even tolerable. Whether intended or not, when a sampling plan of, for example, $n = 100$, accept-on-one is used, how could a supplier not get the impression that the customer would be perfectly satisfied, if not elated, to receive product that is, say, 1 % nonconforming?

— If the user really expects product whose quality level is nearly perfect (say, for example, 0 to 20 parts per million nonconforming), then allowing one or two nonconformities in a sample of size $n = 50$ or $n = 100$ would be inconsistent with the user's wishes. It would seem to contradict the claim that the population is of a low parts per million nonconforming level.

— Use of plans with accept numbers greater than zero of themselves tend not to foster a desire on the supplier's part to continuously improve. If the supplier knows that a certain percent nonconforming is acceptable, there is little incentive to continuously improve.

It should be understood that if accept-zero plans are used as a "stand-alone act", one could expect that the only possible way higher quality levels would be attained would be because of the supplier's fear of excessive lot rejection. Process controls are needed to stabilize, monitor, and improve processes. Process controls are then accompanied by accept-zero plans, if necessary, to verify or "spot check" that the process controls are indeed working. In this International Standard accept-zero plans are also needed when the process controls are not yet in place or have not yet reached a mature level. The theme of this International Standard is that process control is of primary importance; acceptance sampling plans are secondary.

Annex B
(informative)

Disposition of lot when customer acceptance is withheld

B.1 The decision on what to do with a quantity of goods when the inspection results or the objective evidence fails to meet the acceptance criteria can be a complex process. The most frequent outcome, however, is simple: the customer refuses to take the goods and refuses to make payment and the supplier either scraps the goods or tries to sell them to another customer, usually at reduced prices.

This outcome may not be reasonable for either party in some circumstances. Some examples are:

a) the customer may absolutely need the product and has no other sources that can provide the goods in a timely, economical manner;

b) the supplier may have no other customers for the product and the economic loss from scrapping the goods is too high;

c) the objective evidence may show a deviation from the acceptance criteria small enough to make the product useful to the customer.

B.2 In these situations, there may be negotiations between the customer and the supplier that extend outside of the initial scope of the contract, and the scope of this International Standard. The following paragraph (B.3), lists examples of the types of events/considerations that can occur in the negotiations. They are provided for information, but with a strong caution: the customer's contractual obligations stop when a lot fails the acceptance criteria, and all subsequent actions are, in essence, modifications to the contract.

B.3 (Acceptance/rejection of the lot with known nonconformities.) Disposition actions can depend on the frequency, nature and severity of the nonconformity, and the degree of fitness-for-use of the nonconforming item. Customers often delegate their decision authority to their representatives on minor characteristics, and merely monitor that decision process for adequacy. For major and critical characteristics, the customer rarely permits its representatives to make disposition decisions. A proposed modification to the contract may then take the form of a waiver request, which would be submitted by the supplier for the customer's approval. Disposition actions could include, but are not limited to

a) outright rejection of the lot: if the nonconformity exists throughout the lot and there is no feasible means available to screen the lot or to rework or repair the nonconformity, the entire lot may be scrapped,

b) "use as-is": the degree or frequency of nonconformity is deemed not to impact product utility sufficiently to make it unusable to the customer. Note that when this decision is made routinely, it is likely that the requirement is too tight, and should be reviewed,

c) "repair/rework": corrective actions on nonconforming items. Generally, the customer wants a voice in the rework or repair procedures to assure that product quality is not degraded in any way,

d) full, partial or zero screening of the lot:

   — The screening requirement of this International Standard can also be an area of negotiation.

   — The customer may decide to disallow the supplier's screening and re-presentation of the entire lot if the supplier's screening process is considered suspect by the customer.

   — The customer may decide to allow the supplier to screen and re-present the entire lot only for the characteristic(s) for which acceptance was withheld.

— Alternatively, the customer may allow the supplier to screen and re-present only sub-sets of the lot for the characteristic(s) for which acceptance was withheld. These sub-sets might be isolated nonconforming quantities that have come from identifiable sources. The remainder of the lot could either be accepted outright, or it could be accepted based on the outcome of further sampling.

— When screening is expensive, or the test is detrimental to the product in some way, or if the objective evidence or process trends show minimal deviation from the norm, the customer may be willing to consider waiving this requirement. The modification to the contract then may take the form of a waiver request by the supplier, prior to a decision being made regarding screening. Disposition of such product should then be based upon review by competent authority, generally the contracting officer. Of course, the screening requirement could also be waived and the product accepted via specification provisions/contractual agreements;

e) the sample size, the lot acceptance criteria, and any other requirement of the sampling tables of this document may also be waived or amended by a contract modification when necessary to meet customer needs. Statistical data, if available, should be considered in making decisions concerning modification of the sampling requirements.

B.4 Usually the customer will require consideration from the supplier for acceptance of a lot that has not passed the acceptance criteria. The consideration is generally financial; however, it can take other forms of "value". In summary, this International Standard covers the process steps up to product acceptance. It uses the phrase "Acceptance withheld" rather than "Rejected" because that point often represents the start of a totally separate process, whereby the customer and the supplier negotiate changes to the basic contractual agreement they have, which was to exchange money for a quantity of totally conforming items.

Annex C
(informative)

Graphical representation of switching rules

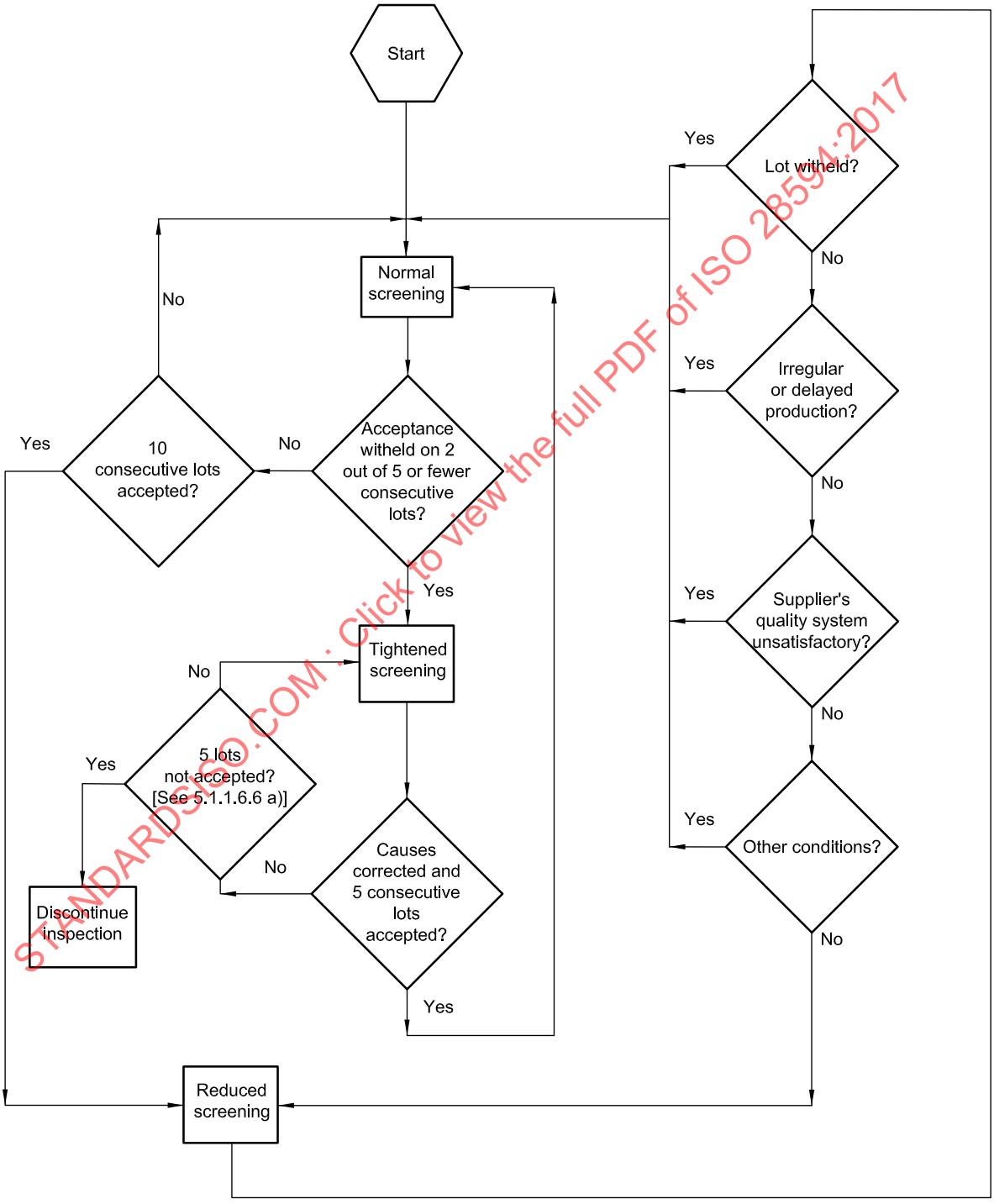
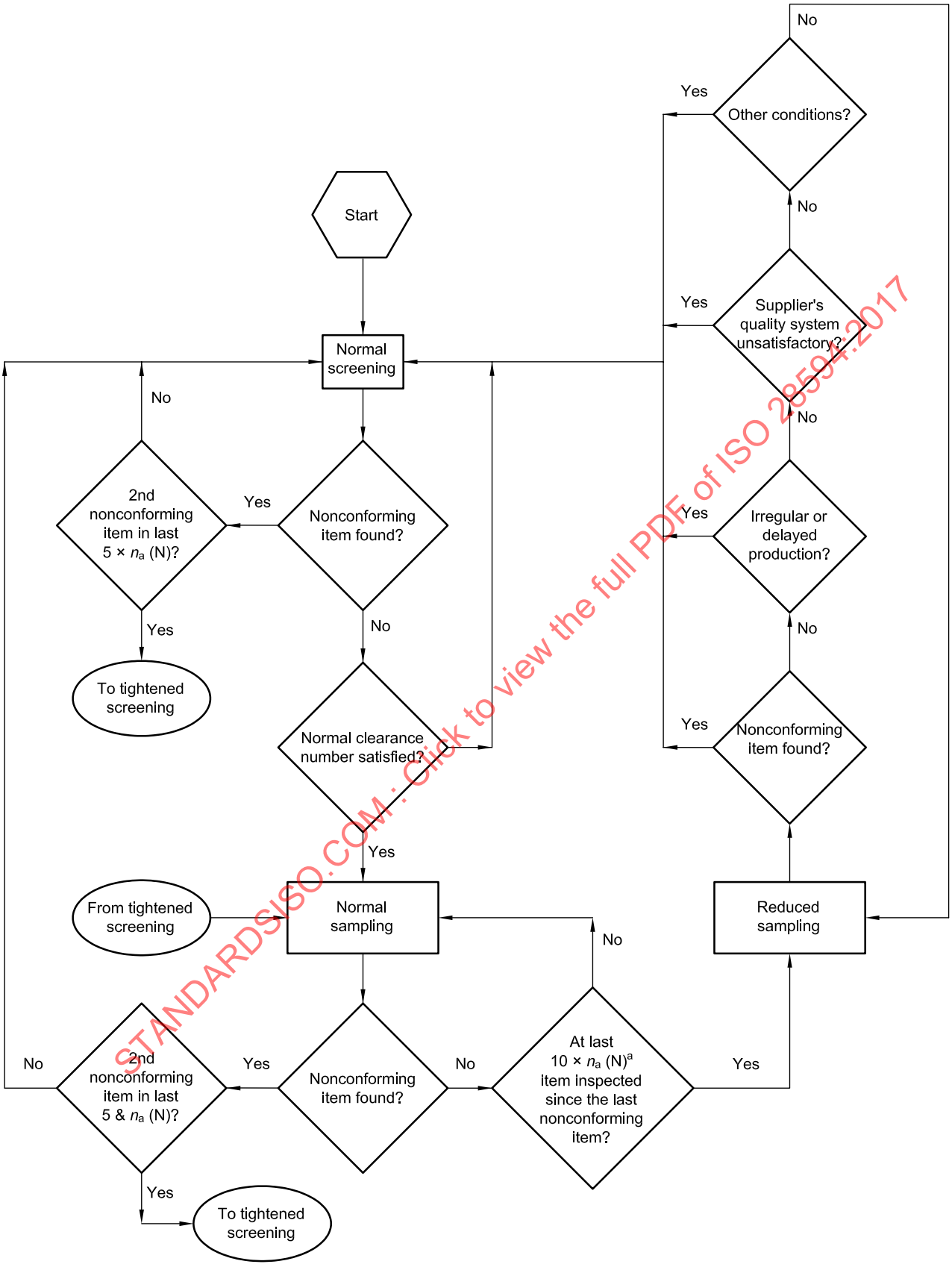


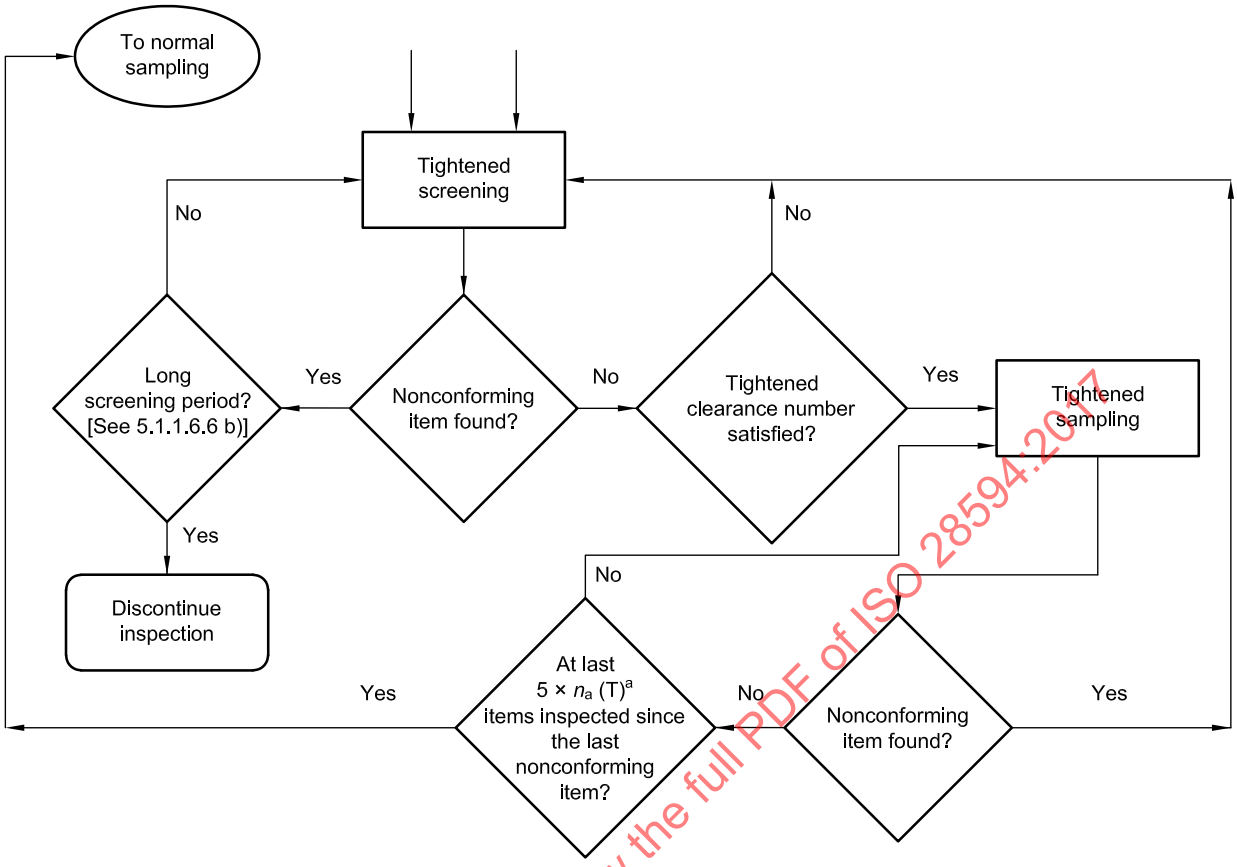
Figure C.1 — Switching procedures for lot sampling



Key

[a] Inspected items from sampling and/or screening.

Figure C.2 — Switching procedures for continuous sampling



Key

[a] Inspected items from sampling and/or screening.

Figure C.2 — (*continue*)

Annex D
(normative)

Examples of use of sampling systems

D.1 Introduction

This annex illustrates how to implement the three types of sampling systems described in Clauses 4 and 5 of this International Standard. The examples explain how to use Tables 1 to 4, how to apply the switching rules, and how to do some of the requisite calculations. In addition, this annex explains how the supplier can modify Table 4 to some extent by calculating and using other values of f and f_t.

D.2 Examples

D.2.1 Sampling by attributes

Wing nuts are to be inspected for missing thread. A verification level 4 (VL-4) has been specified. The producer chooses to use plans for sampling by attributes from Table 2. Lot sizes may vary because of production decisions. A segment of the producer's experience is shown in Table D.1.

Table D.1 — Inspection log for sampling by attributes

Lot number	Lot size	Code letter	Sample size	Nonconformances	Lot disposition	Severity (T/N/R)	Action
1	5 000	D	160	2	Withhold acceptance	N	Begin with normal sampling, VL-4.
2	900	A	80	0	Accept	N	
3	3 000	C	128	1	Withhold acceptance	N	2 lots out of 5 or fewer failed to pass. Switch to tightened VL-4. Check process.
4	1 000	B	256	0	Accept	T	
5	1 000	B	256	0	Accept	T	
6	900	A	200	0	Accept	T	
7	2 000	C	320	0	Accept	T	
8	2 500	C	320	0	Accept	T	Process corrected and 5 consecutive lots accepted. Switch to normal VL-4.
9	3 000	C	128	0	Accept	N	
10	5 000	D	160	0	Accept	N	

D.2.2 Sampling by variables (single-sided specification limit)

The maximum temperature of operation for a certain device is specified as 98 (measured in degrees C). Verification level 1 (VL-1) has been specified. A lot of 40 items is submitted for inspection in accordance with sampling by variables. Table 3 requires a sample size of n_v = 4 for code letter A. Suppose the measurements obtained are as follows: 92, 87, 84 and 96. Compliance with the acceptability criteria is to be determined. The computations are shown in Table D.2. The lot is accepted, as it meets all of the applicable acceptability criteria.

D.2.3 Sampling by variables (double-sided specification limit)

The minimum temperature of operation for a certain device is specified as 82 (measured in degrees Celsius). The maximum is 98. Verification level 1 (VL-1) has been specified. A lot of 40 items is submitted for inspection in accordance with sampling by variables. Table 3 requires a sample of size n_v = 4 for code letter A (CL-A). Suppose the measurements obtained are as follows: 92, 87, 84 and 96. Compliance with the acceptability criteria is to be determined. The computations are shown in Table D.3. The lot is accepted, as it meets all of the applicable acceptability criteria.

D.2.4 Continuous sampling

A visual inspection of stamped metal parts for the presence of a spot weld will be performed immediately after items pass through a spot-welding station. Verification level 2 (VL-2) has been specified. The product will be submitted for continuous sampling-by-attributes inspection. The production interval size is an 8-h shift, which initially will consist of between 700 to 800 welded parts. With VL-2 and code letter C (CL-C) from Table 1, the values of i and f (Table 4) are found to be 116 and 1/48, respectively. A segment of sampling experience is shown in Table D.4.

D.2.5 Continuous sampling — Plan tailoring

The producer may opt to use another continuous sampling plan instead of the one specified in Table 4. Certain circumstances make such choices desirable. Sometimes the selection of a clearance number or frequency is application-dependent, e.g. if it matters that i or $1/f$ be a multiple of pallet size. Availability and capability of screening and sampling crews are yet further considerations. The only restrictions on tailoring the sampling plan are the following:

a) a change to the sampling plan shall not be allowed while inside a screening sequence;

b) the AOQL of the new plan shall be no greater than the AOQL of the corresponding attributes plan of Table 2; and

c) the sampling frequency (f) of the new plan shall be no less than the sampling frequency of the Table 4 plan.

Producers willing to sample at rates higher than f can reduce i substantially.

Table D.2 — Example of the computations for a single specification limit

Line	Information needed	Symbol	Formula	Result	Explanation
1	Sample size	n_v		4	See Table 3
2	Sum of measurements		$\sum x$	359	
3	Sample mean	$\bar{x}$	$\sum x / n_v$	89,75	359 / 4
4	Sum of squared measurements		$\sum x^2$	32 305	
5	Correction factor	f_c	$\left(\sum x\right)^2 / n_v$	32 220,25	359^2 / 4
6	Corrected sum of squares	S_c	$\sum x^2 - f_c$	84,75	32 305 – 32 220,25
7	Sample variance	s^2	$S_c / (n_v - 1)$	28,250	84,75 / 3

NOTE 1 The k acceptability constant is the minimum allowable value for the quality index, Q.

NOTE 2 The F acceptability constant is the maximum allowable value for the value F of the sample, $\hat{F}$.

Table D.2 *(continued)*

Line	Information needed	Symbol	Formula	Result	Explanation
8	Sample standard deviation	s	$\sqrt{s^2}$	5,315	$\sqrt{28,25}$
9	Lower specification limit Upper specification limit	L U		Not applicable 98	
10	Lower quality index Upper quality index Quality index	Q_L Q_U Q	$(\bar{x} - L) / s$ $(U - \bar{x}) / s$ $\min(Q_L, Q_U)$	Not applicable 1,552 1,552	(98 – 89,75) / 5,315
11	Sample F value	$\hat{F}$	$s / (U - L)$	Not applicable	
12	Number of nonconforming items k acceptability constant F acceptability constant	c k F		0 1,18 Not applicable	See Table 3 See Table 3
13	c acceptance criterion k acceptance criterion F acceptance criterion		$c = 0$? $Q \geqslant k$? $\hat{F} \leqslant F$?	Yes Yes Not applicable	1,552 > 1,18
NOTE 1 The k acceptability constant is the minimum allowable value for the quality index, Q. NOTE 2 The F acceptability constant is the maximum allowable value for the value F of the sample, $\hat{F}$.					

Table D.3 — Example of the computations for a double specification limit

Line	Information needed	Symbol	Formula	Result	Explanation
1	Sample size	n_v		4	See Table 3
2	Sum of measurements		$\sum x$	359	
3	Sample mean	$\bar{x}$	$\sum x / n_v$	89,75	359 / 4
4	Sum of squared measurements		$\sum x^2$	32 305	
5	Correction factor	f_c	$\left(\sum x\right)^2 / n_v$	32 220,25	359^2 / 4
6	Corrected sum of squares	S_c	$\sum x^2 - f_c$	84,75	32 305 – 32 220,25
7	Sample variance	s^2	$S_c / (n_v - 1)$	28,250	84,75 / 3
8	Sample standard deviation	s	$\sqrt{s^2}$	5,315	$\sqrt{28,25}$
9	Lower specification limit Upper specification limit	L U		82 98	
NOTE 1 The k acceptability constant is the minimum allowable value for the quality index, Q. NOTE 2 The F acceptability constant is the maximum allowable value for the value F of the sample, $\hat{F}$.					

Table D.3 *(continued)*

Line	Information needed	Symbol	Formula	Result	Explanation
10	Lower quality index Upper quality index Quality Index	Q_L Q_U Q	$(\bar{x} - L) / s$ $(U - \bar{x}) / s$ $\min(Q_L, Q_U)$	1,458 1,552 1,458	(89,75 – 82) / 5,315 (98 – 89,75) / 5,315
11	Sample F value	$\hat{F}$	$s / (U - L)$	0,332	5,315 / (98 – 82)
12	Number of nonconforming items k acceptability constant F acceptability constant	c k F		0 1,18 0,370	See Table 3 See Table 3
13	c acceptance criterion k acceptance criterion F acceptance criterion		$c = 0$? $Q \geqslant k$? $\hat{F} \leqslant F$?	Yes Yes Yes	1,458 > 1,18 0,332 < 0,370

NOTE 1 The k acceptability constant is the minimum allowable value for the quality index, Q.

NOTE 2 The F acceptability constant is the maximum allowable value for the value F of the sample, $\hat{F}$.

Table D.4 — Inspection log for continuous sampling

Product item number	Code letter	Frequency or 100 %	Severity T/N/R	Event/Action
1	C	100 %	N	Start production: Begin screening phase with i = 116.
8	C	100 %	N	Find a nonconforming item: reset counter.
124	C	100 %	N	i = 116 consecutive conforming items cleared: Begin sampling phase with f = 1/48.
170	C	1/48	N	First randomly sampled item selected: Found it to conform.
4 024	C	1/48	N	200 consecutive conforming inspected items (116 from screening + 84 from sampling) observed. Since 200 equals 10 times the Table 2 sample size entry for CL-C and VL-2, switch to reduced inspection with f = 1/68.
4 096	C	1/68	R	Next randomly sampled item selected with f = 1/68.
8 309	C	1/68	R	Production interval size tripled (2 100 to 2 400 items instead of 700 to 800 items): End CL-C and begin CL-E sampling phase, f = 1/136, since VL-2 and reduced sampling inspection are in effect.
8 448	E	1/136	R	First randomly sampled item selected with new f = 1/136: Found it to conform. Continue random sampling.
10 617	E	1/136	R	A nonconforming item observed: Switch to normal inspection. Initiate screening phase with i = 228, since CL-E and VL-2 are in effect.
10 845	E	100 %	N	i = 228 consecutive conforming items cleared: Begin sampling phase with f = 1/96.

Suppose the same situation exists as in the beginning of the preceding continuous sampling example (code letter C, VL-2), but the producer desires a smaller i (at the cost of a larger f). Using one of the following two procedures a customized continuous sampling plan with a larger f, a smaller i and an AOQL no larger than the AOQL of the corresponding attributes plan of Table 2 can be determined.

a) Suppose the producer prefers to start with a plan where i = 50 instead of the 116 specified in the preceding continuous sampling example shown in Table D.4. Let $AOQL_a$ be the AOQL of the corresponding attributes plan. Then we can calculate frequency f using the formula

$$f = \frac{q^i (p - \mathrm{AOQL_a})}{\mathrm{AOQL_a} + q^i (p - \mathrm{AOQL_a})} \tag{D.1}$$

where

$$\mathrm{AOQL_a} = \frac{1}{(n_a + 1)\left(1 + \frac{1}{n_a}\right)^{n_a}} \tag{D.2}$$

$q = 1 - p$;

n_a is the corresponding attribute plan sample size, and

p is the process fraction nonconforming, selected at the level that maximizes f via the following formula:

$$p = \frac{1 + (\mathrm{AOQL_a})(i)}{1 + i} \tag{D.3}$$

$\mathrm{AOQL_a}$ should be calculated to at least 6 decimal places for accurate results. Note that the $\mathrm{AOQL_a}$s listed in the tables of Annex E are approximate.

In the above example, the $\mathrm{AOQL_a}$ is 1,79 %, so for $i = 50$, p will be 0,037 and f will equal 0,139 (approximately 1/7). Therefore, an i value of 50 may be used instead of 116 if f is increased from 1/48 to 1/7.

b) If f is preselected instead, i is determined by the formula:

$$i = \frac{\ln[(f)(\mathrm{AOQL_a})] - \ln(p - \mathrm{AOQL_a}) - \ln(1 - f)}{\ln(1 - p)} \tag{D.4}$$

where p is systematically varied until i has been maximized.