
Sampling procedures for inspection by variables —

Part 6:
Specification for single sampling plans for isolated lot inspection indexed by limiting quality (LQ)

Règles d'échantillonnage pour les contrôles par mesures —

Partie 6: Spécification pour les plans d'échantillonnage simples pour les contrôles de lots isolés, indexés d'après la qualité limite (QL)

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Contents

	Page
Foreword.....	v
Introduction.....	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Symbols	6
5 Choice of a sampling plan	7
5.1 Choice between variables and attributes.....	7
5.2 General.....	7
5.3 Choice between the s -method and the σ -method.....	8
5.4 Choice of the limiting quality (LQ).....	8
6 Standard procedures for the s-method	9
6.1 General.....	9
6.2 Single specification limits.....	9
6.3 Double specification limits.....	9
7 Standard procedures for the σ-method	10
7.1 General.....	10
7.2 Single specification limits.....	10
7.3 Double specification limits.....	10
8 The p^*-method	11
9 Relation to ISO 2859-2	12
9.1 Similarities.....	12
9.2 Differences.....	12
10 Allowing for measurement uncertainty	13
11 Normality, data transformations and outliers	13
11.1 Normality.....	13
11.2 Data transformations.....	14
11.3 Outliers.....	14
12 Tables	14
12.1 Information about the tables.....	14
13 Examples	28
13.1 General.....	28
13.2 Examples for the s -method.....	28
13.3 Examples for the σ -method.....	33
13.4 Examples for the p^* -method.....	36
Annex A (informative) Procedures for obtaining s and σ	40
Annex B (normative) Accommodating measurement error	43
Annex C (informative) Sampling strategies	51
Annex D (informative) Operating characteristics for the s-method	53
Annex E (informative) Operating characteristics for the σ-method	54
Annex F (informative) Consumer's risks	55
Annex G (informative) Producer's risk quality	56
Annex H (informative) Construction of acceptance diagrams for double specification limits	57
Annex I (informative) Use of the underlying software	67

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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of 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 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*.

A list of all parts in the ISO 3951 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document specifies an acceptance sampling system of single sampling plans for inspection by variables. It is indexed in terms of the limiting quality (LQ) for the inspection of lots where switching rules as used in ISO 3951-1 are not applicable. These switching rules provide protection to the consumer (by the prospect of switching to tightened inspection and discontinuation) and also provide an incentive to the supplier to improve the quality level. However, there are various cases where the switching rules of ISO 3951-1 are not applicable, such as isolated lots or a short series of lots.

This document is designed for the inspection of a single quality characteristic that is measurable on a continuous scale and is normally distributed, under conditions where ISO 3951-1 is not applicable, and is complementary to the attributes standard ISO 2859-2. The operating characteristic curves (OC curves) of the variables plans in this document are similar but not identical to those of the corresponding attributes plans in ISO 2859-2. The OC curves have been matched by minimizing the difference of the OC curves on condition of getting a comprehensible sample size structure (see [Clause 9](#)).

In this document, the acceptance of a lot is implicitly determined from an estimate of the fraction of nonconforming items in the process, based on a random sample of items from the lot. The objectives of the methods laid down in this document are to ensure that lots of limiting quality have a probability of acceptance about 10 % and that the probability of accepting lots with good quality is as high as practicable.

It is assumed in the main body of this document that measurement error is negligible. For information on accommodating measurement error, see [Annex B](#), which was derived from References [24], [29] and [30].

CAUTION — The procedures in this document are not suitable for application to lots that have been screened for nonconforming items.

Inspection by variables for nonconforming items, as described in this document, includes several possible modes, the combination of which leads to a presentation that can appear quite complex to the user:

- unknown standard deviation, or known since the start of inspection;
- a single specification limit, or combined control of double specification limits.

The choice of the most suitable variables plan, if one exists, requires experience, judgement, and some knowledge of both statistics and the product to be inspected. [Clause 5](#) is intended to help those responsible for specifying sampling plans in making this choice. It suggests the considerations that should be borne in mind when deciding whether a variables plan would be suitable and the choices to be made when selecting an appropriate standard plan.

The basic definitions and notations are provided by [Clauses 3](#) and [4](#). The basic operational rules are contained in [Clauses 5](#) through [8](#). [Clause 9](#) informs about the relations between this document and the attributes sampling standard ISO 2859-2. [Clauses 10](#) and [11](#) provide background on accounting for measurement uncertainty and the underlying normality assumption. All tables needed for the sampling procedure can be found in [Clause 12](#), and examples for the s -method and the σ -method for both single and double specification limits can be found in [Clause 13](#).

Nine annexes are provided. [Annex A](#) indicates how the sample standard deviation, s , and the presumed known value of the process standard deviation, σ , should be determined. [Annex B](#) provides procedures for accommodating measurement uncertainty. [Annex C](#) shows five different sampling strategies. [Annex D](#) gives the general formula for the operating characteristics of the s -method. [Annex E](#) gives the general formula for the operating characteristics of the σ -method. [Annex F](#) gives the theory underlying the calculation of consumer's risks. [Annex G](#) gives the theory underlying the calculation of producer's risk quality. [Annex H](#) gives details of how acceptance diagrams for double specification limits are constructed. [Annex I](#) gives a description of the use of the underlying software, R package ISO 3951, to support implementation of this document.

Sampling procedures for inspection by variables —

Part 6:

Specification for single sampling plans for isolated lot inspection indexed by limiting quality (LQ)

1 Scope

This document specifies an acceptance sampling system of single sampling plans for inspection by variables, primarily designed for use under the following conditions:

- a) where the inspection procedure is applied to an isolated lot of discrete products all supplied by one producer using one production process;
- b) where only a single quality characteristic, x , of this process is taken into consideration, which is measurable on a continuous scale;
- c) where the quality characteristic, x , is distributed according to a normal distribution or a close approximation to a normal distribution;
- d) where the quality characteristic can be measured without error or with moderate measurement error;
- e) where a contract or standard defines a lower specification limit, L , an upper specification limit, U , or both; an item is qualified as conforming if and only if its measured quality characteristic, x , satisfies the appropriate one of the following inequalities:
 - 1) $x \geq L$ (i.e. the lower specification limit is not violated);
 - 2) $x \leq U$ (i.e. the upper specification limit is not violated);
 - 3) $x \geq L$ and $x \leq U$ (i.e. neither the lower nor the upper specification limit is violated).

Inequalities 1) and 2) are cases with a single specification limit, whereas inequality 3) is a case with double specification limits.

Where double specification limits apply, it is assumed in this document that conformance to both specification limits is equally important to the integrity of the product. In such cases, it is appropriate to apply a single LQ to the combined fraction of a product outside the two specification limits. This is referred to as combined control.

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

ISO 2859-2, *Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2859-1, ISO 2859-2, ISO 3534-1, and ISO 3534-2 and the following apply.

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

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <https://www.electropedia.org/>

3.1

inspection by variables

inspection by measuring the magnitude of a characteristic of an item

[SOURCE: ISO 3534-2:2006, 4.1.4, modified — "the magnitude(s) of the characteristic(s)" replaced with "the magnitude of a characteristic".]

3.2

sampling inspection

inspection of selected items in the group under consideration

[SOURCE: ISO 3534-2:2006, 4.1.6]

3.3

acceptance sampling inspection

acceptance sampling

sampling inspection (3.2) to determine whether or not to accept a lot or other amount of product, material, or service

[SOURCE: ISO 3534-2:2006, 4.1.8, modified — "acceptance sampling" added as second preferred term; original definition, "acceptance inspection where the acceptability is determined by means of sampling inspection" replaced with the current one.]

3.4

acceptance sampling inspection by variables

acceptance sampling inspection (3.3) in which the acceptance of a lot is determined statistically from measurements on specified quality characteristics of each item in a sample from a lot

[SOURCE: ISO 3534-2:2006, 4.2.11, modified — "the process" replaced by "a lot", and "on specified quality characteristics of each item in a sample from a lot" has been replaced by "from inspection by variables"]

3.5

process fraction nonconforming

rate at which nonconforming items are generated by a process

Note 1 to entry: It is expressed as a proportion.

3.6

quality level

quality expressed as the fraction nonconforming

3.7**consumer's risk****CR**

probability of acceptance when the *quality level* (3.6) has a value stated by the acceptance sampling plan as unsatisfactory

Note 1 to entry: For the purposes of this document, the consumer's risk is approximately 10 %.

[SOURCE: ISO 3534-2:2006, 4.6.2, modified — Deleted symbol β ; original Note 1 to entry replaced with the current one.]

3.8**consumer's risk quality****CRQ**

quality level (3.6) of a lot or process which, in the acceptance sampling plan, corresponds to a specified *consumer's risk* (3.7)

Note 1 to entry: For the purposes of this document, the consumer's risk quality is the *limiting quality* (3.9).

[SOURCE: ISO 3534-2:2006, 4.6.9, modified — Deleted symbol Q_{CR} ; original Note 1 to entry replaced with the current one.]

3.9**limiting quality****LQ**

quality level (3.6), when a lot is considered in isolation, which, for the purposes of *acceptance sampling inspection* (3.3), is limited to a low probability of acceptance

[SOURCE: ISO 3534-2:2006, 4.6.13]

3.10**producer's risk****PR**

probability of non-acceptance when the *quality level* (3.6) has a value stated by the plan as acceptable

Note 1 to entry: For the purposes of this document, the producer's risk is 5 %.

[SOURCE: ISO 3534-2:2006, 4.6.4, modified — Deleted symbol α ; original Notes 1 and 2 to entry replaced with the current one.]

3.11**producer's risk quality****PRQ**

quality level (3.6) of a lot or process which, in the acceptance sampling plan, corresponds to a specified *producer's risk* (3.10)

[SOURCE: ISO 3534-2:2006, 4.6.10, modified — Deleted symbol Q_{PR} ; deleted Notes 1 and 2 to entry.]

3.12**nonconformity**

non-fulfilment of a requirement

[SOURCE: ISO 3534-2:2006, 3.1.11]

3.13**s-method acceptance sampling plan****s-method**

acceptance sampling (3.3) plan by variables using the sample standard deviation.

Note 1 to entry: See [Clause 6](#).

[SOURCE: ISO 3534-2:2006, 4.3.10, modified – “s method” has been replaced by “s-method”, “acceptance sampling plan” has been added; “s-method” left as a second preferred term; in the definition, “acceptance sampling inspection by variables” replaced with “acceptance sampling plan by variables”; added Note 1 to entry.]

3.14

σ -method acceptance sampling plan

σ -method

acceptance sampling (3.3) plan by variables using the presumed value of the process standard deviation

Note 1 to entry: See [Clause 7](#).

[SOURCE: ISO 3534-2:2006, 4.3.9, modified — “sigma method” has been replaced with “ σ -method”; “acceptance sampling plan” has been added with “ σ -method” left as a second preferred term; in the definition, “acceptance sampling inspection by variables” replaced with “acceptance sampling plan by variables”; added Note 1 to entry.]

3.15

specification limit

conformance boundary specified for a characteristic

[SOURCE: ISO 3534-2:2006, 3.1.3, modified — “limiting value stated” replaced with “conformance boundary specified”.]

3.16

lower specification limit

L

specification limit (3.15) that defines the lower conformance boundary

[SOURCE: ISO 3534-2:2006, 3.1.5, modified — “limiting value” replaced with “conformance boundary”.]

3.17

upper specification limit

U

specification limit (3.15) that defines the upper conformance boundary

[SOURCE: ISO 3534-2:2006, 3.1.4, modified — “limiting value” replaced with “conformance boundary”.]

3.18

combined control

requirement when both upper and lower limits are specified for the quality characteristic and an *LQ* (3.9) that applies to the combined fraction nonconforming beyond the two limits is given

Note 1 to entry: The use of combined control implies that *nonconformity* (3.12) beyond either *specification limit* (3.15) is believed to be of equal, or at least roughly equal, importance to the lack of integrity of the product.

3.19

form k acceptance constant

k

constant depending on the specified value of the *limiting quality* (3.9) and the sample size, used in the criteria for accepting the lot in an *acceptance sampling* (3.3) plan by variables

Note 1 to entry: See [Clauses 6](#) and [7](#).

[SOURCE: ISO 3534-2:2006, 4.4.4, modified – “acceptability constant” has been replaced with “form k acceptance constant”; “value of the acceptance quality limit” replaced with “value of the limiting quality”; added Note 1 to entry.]

3.20**form p^* acceptance constant** **p^***

constant depending on the specified value of the *limiting quality* (3.9) and the sample size, used in the criteria for accepting the lot in an *acceptance* (3.3) plan by variables

Note 1 to entry: See [Clause 8](#).

[SOURCE: ISO 3534-2:2006, 4.4.4, modified — “acceptability constant” has been replaced with “form p^* acceptance constant”; “value of the acceptance quality limit” replaced with “value of the limiting quality”; added Note 1 to entry.]

3.21**lower quality statistic** **Q_L**

function of the *lower specification limit* (3.15), the sample mean, and the sample or process standard deviation

Note 1 to entry: For a single lower specification limit, the lot is sentenced on the result of comparing Q_L with the *form k acceptance constant* (3.19) k .

Note 2 to entry: See [Clauses 6](#) and [7](#).

[SOURCE: ISO 3534-2:2006, 4.4.11, modified — In the Note 1 to entry, “acceptability constant” has been replaced with “form k acceptance constant”; Note 2 to entry added.]

3.22**upper quality statistic** **Q_U**

function of the *upper specification limit* (3.17), the sample mean, and the sample or process standard deviation

Note 1 to entry: For a single upper specification limit, the lot is sentenced on the result of comparing Q_U with the *form k acceptance constant* (3.19) k .

Note 2 to entry: See [Clauses 6](#) and [7](#).

[SOURCE: ISO 3534-2:2006, 4.4.10, modified — In the Note 1 to entry, “acceptability constant” has been replaced with “form k acceptance constant”; Note 2 to entry added.]

3.23**maximum process standard deviation****MPSD** **σ_{\max}**

largest process standard deviation for a given sample size and *LQ* (3.9) for which it is possible to satisfy the acceptance criterion for double *specification limits* (3.15) with a combined *LQ* (3.9) when the process variability is known

[SOURCE: ISO 3534-2:2006, 4.4.8, modified — Added symbol σ_{\max} ; “or a given sample size code letter and AQL” replaced with “for a given sample size and LQ”; “for a double specification limit under all inspection severities (i.e. normal, tightened and reduced) when the process variability is known” replaced with “for double specification limits with a combined *LQ* when the process variability is known”; Note 1 to entry deleted.]

3.24**measurement**

set of operations to determine the value of some quantity

[SOURCE: ISO 3534-2:2006, 3.2.1, modified – “having the object of determining a value of a quantity” replaced with “to determine the value of some quantity”.]

4 Symbols

f_σ	factor that relates the maximum process standard deviation to the difference between U and L (see Table 3)
$F_{BETA(\alpha,\beta)}(x)$	the distribution of the standard beta distribution with parameters α and β . In this document $\alpha = \beta = n/2 - 1$ throughout.
$F_{t(v,\delta)}(x)$	the distribution function of the non-central t -distribution with v degrees of freedom and non-centrality parameter δ
K_p	the upper p -quantile of the standardized normal distribution, i.e. x such that $1 - \Phi(x) = p$, which corresponds to the process fraction nonconforming p
k	form k acceptance constant for use with a single quality characteristic and a single specification limit (see Table 2 for the s -method or Table 4 for the σ -method)
L	lower specification limit (as a subscript to a variable, it denotes its value at L)
n	sample size (number of items in a sample)
P_a	probability of acceptance
p	lot quality in fraction nonconforming
\hat{p}	estimate of the process fraction nonconforming
\hat{p}_L	estimate of the process fraction nonconforming below the lower specification limit
\hat{p}_U	estimate of the process fraction nonconforming above the upper specification limit
p^*	form p^* acceptance constant, i.e. the maximum acceptable value for the estimate of the process fraction nonconforming (see Table 5)
$\Phi(x)$	the distribution function of the standardized normal distribution.
Q_L	lower quality statistic NOTE Q_L is defined as $(\bar{x} - L)/s$ when the process standard deviation is unknown, and as $(\bar{x} - L)/\sigma$ when it is presumed to be known.
Q_U	upper quality statistic NOTE Q_U is defined as $(U - \bar{x})/s$ when the process standard deviation is unknown, and as $(U - \bar{x})/\sigma$ when it is presumed to be known.
s	sample standard deviation of the measured values of the quality characteristic (also an estimate of the standard deviation of the process), i.e.

$$s = \sqrt{\frac{\sum_{j=1}^n (x_j - \bar{x})^2}{n-1}}$$

(see [Annex A](#))

σ	standard deviation of a process that is under statistical control NOTE 1 σ^2 , the square of the process standard deviation, is known as the process variance.
σ_{\max}	maximum process standard deviation (MPSD) (see Table 3)

U	upper specification limit (as a subscript to a variable, it denotes its value at U)
x_j	measured value of the quality characteristic for the j^{th} item of the sample
\bar{x}	Sample arithmetic mean of the measured values of the quality characteristic in the sample, i.e.

$$\bar{x} = \frac{\sum_{j=1}^n x_j}{n}$$

(see [Annex A](#))

5 Choice of a sampling plan

5.1 Choice between variables and attributes

The first question to consider is whether it is desirable to inspect by variables rather than by attributes. The following points should be taken into account.

- In terms of economics, it is necessary to compare the total cost of the relatively simple inspection of a larger number of items by means of an attributes scheme with the generally more elaborate procedure required by a variables scheme, which is usually more time consuming and costly per item.
- In terms of the knowledge gained, the advantage lies with inspection by variables as the information obtained indicates more precisely how good the product is.
- An attributes scheme can be more readily understood and accepted; for example, it may at first be difficult to accept that, when inspecting by variables, a lot can be rejected on measurements taken of a sample that does not contain any nonconforming items and vice versa (see [13.2](#) Example 2 a and Example 2 b).
- From a comparison of the size of the samples required for the same LQ from standard plans for inspection by attributes, such as from ISO 2959, and the standard plans in this document, the smallest samples are generally required by the σ -method (used when the process standard deviation is presumed to be known). The sample sizes for the s -method (used when the process standard deviation is presumed to be unknown) are larger than for the σ -method but are, in general, substantially smaller than for sampling by attributes.
- Variables sampling has a substantial advantage when the inspection process is expensive, for example, in the case of destructive testing.
- For two or more quality characteristics, ISO 3951 series does not contain specifications for sampling plans indexed by LQ.

5.2 General

The following procedures shall be followed in advance of the inspection by variables.

- Specify the limiting quality (LQ) in accordance with [5.4](#).
- Determine the lot size (N).
- Determine the quality characteristic x and an upper limit U and/or a lower limit L for x .
- For a quality characteristic with double specification limits, check that nonconformities beyond each limit are of equal importance.

- e) Check whether the *s*-method (Clause 6) should be used or whether the standard deviation is stable and known, in which case the σ -method (Clause 7) should be used (see 5.3);
- f) for the σ -method and a quality characteristic with double specification limits, a process capability study in the following sense should be done:
 - 1) enter Table 3 with the LQ to determine the value of the factor f_σ ;
 - 2) calculate the maximum allowable value of the process standard deviation using the formula $\sigma_{\max} = (U - L)f_\sigma$;
 - 3) If σ exceeds σ_{\max} , the process is not capable and sampling inspection is pointless until it is demonstrated that the process variability has been adequately reduced.

With the specified lot size and the limiting quality as indexing values, the sample size n and the acceptance constant k are given in Table 2 (*s*-method) or Table 4 (σ -method).

Although the primary index is the limiting quality, the producer/supplier needs guidance on the quality level required if lots are to have a high probability of acceptance.

5.3 Choice between the *s*-method and the σ -method

If it is desired to apply inspection by variables as proposed in this document, the decision shall be made whether to use the *s*-method or the σ -method. The σ -method is the more economical in terms of sample size, but before this method can be applied, it is necessary to have a reliable value of σ , usually obtained from previous process analyses.

In case no reliable assumptions on the value of σ can be made, it is necessary to use the *s*-method.

5.4 Choice of the limiting quality (LQ)

The purpose of this document is to guard against unsatisfactory quality. The determination of unsatisfactory quality is generally a decision that should be made by quality management. The choice of the LQ is governed by a number of factors, but is mainly a balance between the total cost of inspection and the consequences of nonconforming items passing into service. In this document, the LQ is the parameter used to protect against unsatisfactory quality. The sampling plans in this document have a probability of accepting the lot at the LQ of about 10 %. In this document, the sampling tables are indexed by a set of specified LQ values.

If the user's chosen LQ value is not among those specified in Table 1, then an applicable LQ value shall be the specified LQ corresponding to the range containing the user's chosen LQ, which is the closest specified LQ below the user's chosen LQ (see Example).

Table 1 — Specified LQ values

Limiting quality (LQ) in percent nonconforming					
range	$0,05 \leq LQ < 0,08$	$0,08 \leq LQ < 0,125$	$0,125 \leq LQ < 0,2$	$0,2 \leq LQ < 0,315$	$0,315 \leq LQ < 0,5$
specified	0,05	0,08	0,125	0,2	0,315
range	$0,5 \leq LQ < 0,8$	$0,8 \leq LQ < 1,25$	$1,25 \leq LQ < 2$	$2 \leq LQ < 3,15$	$3,15 \leq LQ < 5$
specified	0,5	0,8	1,25	2	3,15
range	$5 \leq LQ < 8$	$8 \leq LQ < 12,5$	$12,5 \leq LQ < 20$	$20 \leq LQ < 31,5$	$31,5 \leq LQ$
specified	5	8	12,5	20	31,5

Where both upper and lower specification limits are given, this document addresses only the case of an overall LQ applying to the combined fraction nonconforming beyond both specification limits; this is known as combined control.

EXAMPLE

For a product, the limiting quality has been set at 3,5 % nonconforming. This is not one of the specified values and the applicable LQ shall be that for range $3,15 \% \leq LQ < 5 \%$, which is the specified value of 3,15 %, since this is the closest specified LQ below 3,5 %.

6 Standard procedures for the *s*-method

6.1 General

The *s*-method shall be used if information about the standard deviation is missing or unreliable. Under the *s*-method, the standard deviation is estimated directly from each sample. As soon as the conditions for the use of the σ -method are warranted, one may switch from the *s*-method to the σ -method (see 5.3).

6.2 Single specification limits

Before starting the inspection by variables, see [Clause 5](#).

The procedure for a single specification limit is as follows:

- a) Enter [Table 2](#) with the lot size, N , and the LQ to obtain the sample size, n , and the acceptance constant, k .
- b) Take a random sample of size n , measure the characteristic x in each item, and then calculate \bar{x} , the sample mean, and s , the sample standard deviation (see [Annex A](#)).

NOTE Some sampling strategies are provided in [Annex C](#).

- c) Determination of acceptance.
 - 1) If $\bar{x} < L$ or $\bar{x} > U$, reject the lot; or continue with the next step.
 - 2) If $s = 0$ accept the lot; or continue with the next step.

NOTE It is possible to get $s = 0$ when measurement uncertainty is present (see [Clause 10](#) and [Annex B](#)).

- 3) Calculate the quality statistic $Q_U = (U - \bar{x})/s$ or $Q_L = (\bar{x} - L)/s$ and compare it with the acceptance constant k . The lot is accepted if $Q_U \geq k$ or $Q_L \geq k$; or rejected if $Q_U < k$ or $Q_L < k$.

For examples of single lower and upper specification limits, see Example 1, Example 2 and Example 3) in [13.2](#).

6.3 Double specification limits

Before starting the inspection by variables, see [Clause 5](#).

The procedure for double specification limits for the *s*-method is as follows:

- a) Enter [Table 2](#) with the lot size, N , and the LQ to obtain the sample size, n , and the acceptance constant, k .
- b) Take a random sample of size n , measure the characteristic x in each item and then calculate \bar{x} , the sample mean, and s , the sample standard deviation (see [Annex A](#)).

NOTE Some sampling strategies are provided in [Annex C](#).

c) Determination of acceptance.

- 1) If $\bar{x} < L$ or $\bar{x} > U$, reject the lot; or continue with the next step.
- 2) Plot (s, \bar{x}) on the acceptance diagram, which can be obtained using the `acceptance_region` function in the underlying software (see [I.5](#)).

NOTE The standardized values (s_S, \bar{x}_S) where $s_S = \frac{s}{U-L}$ and $\bar{x}_S = \frac{\bar{x}-L}{U-L}$ may be used in which case (s_S, \bar{x}_S) is plotted on the standardized acceptance diagram, which can be obtained using the `acceptance_region` function in the underlying software without providing the standardized lower and upper specification limits $L = 0, U = 1$ (see [I.5](#)).

- 3) If the plotted point is outside the acceptance region the lot is rejected; otherwise the lot is accepted.

For examples of combined control of double specification limits see Example 4 and Example 5 in [13.2](#).

7 Standard procedures for the σ -method

7.1 General

The σ -method shall only be used when there is valid evidence that the standard deviation σ of the process can be considered constant with a known value.

7.2 Single specification limits

Before starting the inspection by variables, see [Clause 5](#).

The procedure for the σ -method for a single limit is as follows.

- a) Enter [Table 4](#) with the lot size, N , and the LQ to obtain the sample size, n , and the acceptance constant, k .
- b) Take a random sample of size n , measure the characteristic x in each item and then calculate \bar{x} .

NOTE Some sampling strategies are provided in [Annex C](#).

- c) Calculate the quality statistic $Q_U = (U - \bar{x})/\sigma$ or $Q_L = (\bar{x} - L)/\sigma$ and compare it with the acceptance constant k . The lot is accepted if $Q_U \geq k$ or $Q_L \geq k$; or rejected if $Q_U < k$ or $Q_L < k$

For examples of single lower and upper specification limits using the σ -method, see Example 1 and Example 2 in [13.3](#).

7.3 Double specification limits

Before starting the inspection by variables, see [Clause 5](#).

- a) For double specification limits, a process capability study in the following sense should be done:
 - 1) Enter [Table 3](#) with the Lot size, N , and the LQ to get f_σ
 - 2) Calculate $U - L$ and multiply this value by f_σ to give σ_{\max} the maximum process standard deviation (MPSD)
 - 3) If the known value of σ is less than or equal to σ_{\max} then acceptance sampling using the σ -method can begin.

- 4) Enter [Table 4](#) with the lot size, N , and the LQ to obtain the sample size, n , and the acceptance constant, k .
- b) Determination of acceptance:
- 1) If $\bar{x} < L$ or $\bar{x} > U$, reject the lot; or continue with the next step.
 - 2) Calculate the quality statistics $Q_L = (\bar{x} - L) / \sigma$ and $Q_U = (U - \bar{x}) / \sigma$. If $Q_L < k$ or $Q_U < k$, reject the lot; or continue with the next step.
 - 3) If $\sigma \leq 0,75 \sigma_{\max}$ accept the lot; otherwise continue with the next step.
 - 4) If neither Q_L or Q_U are close to k accept the lot; otherwise use the p^* -method in [Clause 8](#).

For examples of combined control of double specification limits using the σ -method, see Example 3 in [13.3](#).

8 The p^* -method

The p^* -method is an alternative to the standard procedures in [Clause 6](#) and [Clause 7](#). For the application of this method, distribution functions are calculated.

Before starting the inspection by variables, see [Clause 5](#).

The procedure for the p^* -method for a single specification limit and double specification limits is as follows.

- a) Enter [Table 2](#) for unknown standard deviation or [Table 4](#) for known standard deviation with the lot size, N , and the LQ to obtain the sample size, n .
- b) Enter [Table 5](#) with the lot size, N , and the LQ to obtain the acceptance constant, i.e. the maximum fraction nonconforming, p^* .
- c) Take a random sample of size n , measure the characteristic x in each item and then calculate \bar{x} , the sample mean. For unknown standard deviations, also calculate s , the sample standard deviation (see [Annex A](#)).

NOTE 1 Some sampling strategies are provided in [Annex C](#).

- d) Estimated fraction nonconforming.
 - 1) **Unknown standard deviation:** For a lower specification limit, calculate \hat{p}_L , for an upper limit, calculate \hat{p}_U , and for double specification limits, calculate both.

$$\hat{p}_L = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} - \frac{1}{2} \frac{\bar{x} - L}{s} \frac{\sqrt{n}}{n-1}\right\}\right) = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} \left[1 - Q_L \frac{\sqrt{n}}{n-1}\right]\right\}\right)$$

$$\hat{p}_U = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} - \frac{1}{2} \frac{U - \bar{x}}{s} \frac{\sqrt{n}}{n-1}\right\}\right) = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} \left[1 - Q_U \frac{\sqrt{n}}{n-1}\right]\right\}\right)$$

- 2) **Known standard deviation:** For a lower specification limit, calculate \hat{p}_L , for an upper limit, calculate \hat{p}_U , and for double specification limits, calculate both.

$$\hat{p}_L = \Phi\left(\frac{L - \bar{x}}{\sigma} \sqrt{\frac{n}{n-1}}\right) = \Phi\left(-Q_L \sqrt{\frac{n}{n-1}}\right)$$

$$\hat{p}_U = \Phi\left(\frac{\bar{x} - U}{\sigma} \sqrt{\frac{n}{n-1}}\right) = \Phi\left(-Q_U \sqrt{\frac{n}{n-1}}\right)$$

e) Determination of acceptance:

- 1) **single limit:** A lot shall be accepted if $\hat{p}_L \leq p^*$ for a lower limit, and if $\hat{p}_U \leq p^*$ for an upper limit; if $\hat{p}_L > p^*$ or $\hat{p}_U > p^*$ respectively, the lot is rejected.
- 2) **double limits:** A lot shall be accepted if $\hat{p}_L + \hat{p}_U \leq p^*$; if $\hat{p}_L + \hat{p}_U > p^*$, the lot is rejected.

For an example of single specification limits see Example 7 in [13.4](#). For examples of combined control of double specification limits see Example 8 and Example 9 in [13.4](#).

9 Relation to ISO 2859-2

9.1 Similarities

- a) This document is complementary to ISO 2859-2; the two documents share a common philosophy and, as far as possible, their procedures and vocabulary are the same.
- b) Both use the LQ to index the sampling plans, and the specified values used in this document are identical to those given for percent nonconforming in ISO 2859-2 (i.e. from 0,05 % to 31,5 %).
- c) In both this document and ISO 2859-2, tables give the sample size to be taken and the acceptance constants, indexed by the lot size and the LQ. Separate tables are given for the s -method and the σ -method.

9.2 Differences

- a) **Determination of acceptance.** In ISO 2859-2, acceptance for an attributes sampling plan for nonconforming items is determined by the number of nonconforming items found in the sample. In this document, acceptance for a plan for inspection by variables is based on the distance of the estimated value of the process mean from the specification limit(s) in terms of the process standard deviation. In this document, two methods are considered: the s -method, for use when the process standard deviation, σ , is unknown, and the σ -method, for use when σ is presumed to be known.
- b) **Normality.** In ISO 2859-2, there is no requirement relating to the distribution of the characteristics. However, in this document, it is necessary for the efficient operation of the plans that the measurements be distributed according to a normal distribution (see [11.1](#)) or a close approximation to a normal distribution or the data is appropriately transformed to a normal distribution (see [11.2](#)).
- c) **Sample sizes.** The variables sample sizes for given lot size and LQ are smaller than the corresponding attributes sample sizes. This is particularly true for the σ -method.
- d) **Operating characteristic curves (OC curves).** The OC curves of the variables plans in this document are not identical to those of the corresponding attributes plans in ISO 2859-2. However, the curves have been matched in the sense that the OC curves are as similar as possible. The curves for unknown process standard deviation have been matched by minimizing the difference of the curves on condition of getting a comprehensible sample size structure.

In most cases, the resulting match between the OC curves is so close that, for most practical purposes, the attributes and variables OC curves have the same characteristic. The plans for known process standard deviation were derived by keeping the same form p^* acceptance constant as for the corresponding case for unknown process standard deviation and the same approach for a comprehensible sample size structure, i.e. no parameter was open to choose, so the match was, in general, less perfect. For more details see Reference [\[21\]](#).

- e) **Consumer's risk.** For process quality precisely at the LQ, the producer's risk that a lot will not be accepted in this document is strictly below 10 % for the s -method and about 10 % for the σ -method, whereas in ISO 2859-2 the producer's risk is only about 10 %.

NOTE The consumer's risks of the plans are given in [Table 6](#) and [Table 7](#).

- f) **Producer's risk quality.** The process qualities precisely at the producer's risk of 5 % deviate in some cases from those in ISO 2859-2 to the benefit of a comprehensible sample size structure.

NOTE The producer's risk qualities of the plans are given in [Table 6](#) and [Table 7](#).

10 Allowing for measurement uncertainty

The master, i.e. the tables in [Clause 12](#), are based on the assumption that the quality characteristic, x , of the items in the lots is normally distributed with unknown process mean, μ , and either known or unknown process standard deviation, σ . The assumption is also made that x can be measured without measurement error, i.e. that measurement of an item with the true value, x_i , results in the value x_i . However, the tables in [Clause 12](#) can also be used, with appropriate adjustments, in the presence of measurement error.

Ideally, as a prerequisite for the application of the proposed sampling schemes, the measurement uncertainty, i.e. the measurement standard deviation, is determined by a structured measurement analysis, followed by a measurement system capability assessment (see Reference [14]). If the measurement standard deviation is not higher than 10 % of the process standard deviation and if there is no measurement bias, the measurement system can be considered as capable and no further adjustments on sample sizes are required (see Reference [24]).

For measurement standard deviations higher than 10 % of the process standard deviation, or in case of measurement bias that cannot be simply adjusted, the sample size needs to be increased, although the acceptance constant remains the same. Moreover, if neither the measurement standard deviation nor the process standard deviation is known, more than one measurement needs to be made on each sampled item, and the total variability of the measurements needs to be separated into the components due to the measurements and to the process.

In cases where measurement error is not negligible, the sampling plans of this document shall be used using the adjustments provided in [Annex B](#).

11 Normality, data transformations and outliers

11.1 Normality

The assumption of a normal distribution for the inspected quality characteristic x is the fundamental requirement for the application of the proposed variable sampling plans. Therefore, it is essential to assess the data normality before applying the sampling plans, which could be done by several approaches:

- a) assessment based on practical, engineering experience and expertise;
- b) assessment based on graphical, descriptive methods such as histograms, quantile/quantile or normal probability plots (see ISO 5479 and Reference [18]);
- c) statistical tests for departure from normality, such as those given in ISO 5479.

11.2 Data transformations

For non-normal distributed data, the first approach is usually to try to find a suitable transformation f of the observed data x , so that $Z = f(x)$ follows an (approximate) normal distribution. The most commonly used data transformations are (see ISO 16269-4):

- a) power transformations;
- b) Box-Cox transformations ;
- c) Johnson transformations ;
- d) transformation using Pearson functions.

For the transformed data, the goodness of fit to a normal distribution can be assessed using normal probability plots and/or statistical tests for normality. For subsequent capability analyses and assessments, the targets and specification limits of the quality characteristic x have to be transformed in the same way as the observed process data.

11.3 Outliers

An outlier (or an outlying observation) is one that appears to deviate markedly from other observations in the sample in which it occurs. A single outlier, even when it lies within specification limits, increases variability, changes the mean, and can consequently lead to non-acceptance of the lot (see ISO 16269-4).

Generally, outliers can be a result of

- a) (unexpected high) natural process variability,
- b) presence of special causes not representing the controlled and capable process status.

For case b), one can exclude the outlying observations for the quality assessment, whereas for case a), these values have to be considered in the analysis. Nevertheless, a sensitivity analysis including and excluding the outliers can help to assess the impact of these values on the decision on lot acceptance.

When outliers are detected, the disposition of the lot should be a matter for negotiation between the producer and the responsible authority.

12 Tables

12.1 Information about the tables

[Table 2](#)

With the specified lot size and the limiting quality as indexing values, the single sampling plans of Form k (sample size n and the acceptance constant k) are given for the s -method.

NOTE The cell entry '100 %' denotes that in this case a 100 % inspection has to be done.

[Table 3](#)

The values of f_{σ} for maximum process standard deviation for combined control of double specification limits are given for the σ -method.

The MPSD indicates the greatest allowable magnitude of the process standard deviation when using plans for combined control of double specification limits when the process variability is known. If the process standard deviation is less than the MPSD, then there is a possibility, but not a certainty, that the lot shall be accepted.

The method used to calculate these values is not the same as that used to calculate those in ISO 3951-1:2022, Table 11. More detail is given in [Annex H](#). The two tables should not be used interchangeably.

Table 4

With the specified lot size and the limiting quality as indexing values, the single sampling plans of Form k (sample size n and the acceptance constant k) are given for the σ -method.

NOTE The cell entry '100 %' denotes that in this case a 100 % inspection has to be done.

Table 5

With the specified lot size and the limiting quality as indexing values, the single sampling plans of form p^* (sample size n and acceptance constant, i.e. the maximum fractions nonconforming p^*) are given.

The values of p^* are given to 6 significant figures. This allows the form k acceptance constants, in [Table 2](#) and [Table 4](#), to be calculated from the values of p^* . This is consistent with the fitting process described in [Clause 9 d](#)).

NOTE The formulae for calculating k can be found in [Annex H](#). [Formula \(H.3\)](#) is for the s -method and [Formula \(H.7\)](#) is for the σ -method.

Tables 6 to 11

For a given sampling plan, the consumer's risk (CR) is the probability of accepting a given lot when the fraction nonconforming is equal to the LQ. The producer's risk quality (PRQ) is the quality for which the probability of not accepting a given lot is 5 %.

Both tables are named 'Consumer's risk and producer's risk quality'. The difference is between the s -method and σ -method.

The cell entries display:

- a) upper left: sample size n ;
- b) upper right: acceptance constant k ;
- c) lower left: PRQ in percent nonconforming with <0,001 indicating non-zero values less than 0,001;
- d) lower right: CR in percent;

NOTE The formulae for calculating CR and PRQ can be found in [Annex F](#) and [Annex G](#).

Table 2 — Single sampling plans of Form k: s-method

Lot size	Limiting quality (in percent nonconforming)														
	0,05	0,08	0,125	0,2	0,315	0,5	0,8	1,25	2	3,15	5	8	12,5	20	31,5
16 to 25	n	100 %	100 %	23	22	20	18	17	15	13	12	10	9	7	5
	k	3,665 1	3,665 1	3,745 4	3,507 4	3,363 3	3,210 1	3,028 4	2,856 9	2,685 8	2,448 3	2,235 5	1,949 2	1,675 6	1,388 5
26 to 50	n	32	30	28	26	23	21	19	17	15	13	11	10	8	6
	k	4,004 3	3,872 9	3,745 4	3,604 4	3,464 1	3,293 2	3,130 6	2,970 5	2,789 4	2,604 9	2,402 5	2,177 3	1,887 0	1,683 3
51 to 90	n	36	34	32	30	28	24	21	19	17	15	13	11	9	7
	k	3,953 6	3,818 6	3,686 7	3,540 9	3,394 6	3,238 1	3,069 8	2,923 1	2,735 6	2,542 7	2,329 0	2,088 4	1,863 5	1,551 5
91 to 150	n	41	39	36	34	31	26	24	22	19	17	14	12	10	8
	k	3,902 7	3,764 7	3,639 8	3,490 8	3,353 1	3,193 5	3,036 4	2,865 9	2,672 2	2,493 0	2,272 5	2,086 5	1,886 7	1,716 3
151 to 280	n	47	44	42	39	36	30	28	25	22	19	16	14	11	9
	k	3,854 1	3,721 6	3,584 2	3,441 1	3,297 9	3,145 3	2,981 8	2,807 1	2,623 0	2,469 4	2,247 3	2,042 4	1,864 7	1,432 7
281 to 500	n	55	51	48	45	38	35	32	28	25	22	19	16	13	10
	k	3,803 8	3,673 7	3,540 9	3,394 3	3,254 6	3,097 9	2,929 4	2,777 6	2,614 4	2,520 9	2,275 9	2,047 3	1,678 8	1,461 4
501 to 1 200	n	66	62	58	54	50	42	38	34	30	27	23	19	15	12
	k	3,751 8	3,617 4	3,486 0	3,341 2	3,195 9	3,065 9	2,893 7	2,715 5	2,606 1	2,331 5	2,109 3	1,886 2	1,673 6	1,320 7
1 201 to 3 200	n	85	80	75	69	64	54	49	44	39	34	29	24	19	15
	k	3,689 4	3,554 3	3,422 0	3,305 5	3,142 4	2,988 4	2,822 1	2,691 4	2,455 4	2,272 6	2,047 8	1,808 5	1,557 8	1,253 6
3 201 to 10 000	n	113	106	99	92	85	78	65	58	51	44	38	31	25	20
	k	3,630 3	3,506 7	3,368 8	3,219 8	3,073 1	2,917 7	2,787 2	2,587 3	2,407 2	2,202 4	1,990 3	1,747 9	1,499 0	1,190 0
10 001 to 35 000	n	155	145	135	126	116	106	97	88	78	69	51	42	34	27
	k	3,578 1	3,442 9	3,309 8	3,163 9	3,018 4	2,890 4	2,708 8	2,535 3	2,341 9	2,147 5	1,933 3	1,693 7	1,441 9	1,132 3
35 001 to 150 000	n	213	199	186	173	160	146	120	107	94	82	69	58	47	37
	k	3,531 4	3,397 1	3,264 7	3,119 3	2,995 9	2,827 8	2,660 7	2,482 8	2,295 1	2,101 5	1,886 6	1,648 1	1,392 8	1,083 2
150 001 to 500 000	n	269	252	235	218	201	184	167	151	135	103	87	73	59	47
	k	3,502 9	3,368 2	3,236 0	3,110 8	2,949 7	2,798 2	2,621 5	2,454 2	2,266 1	2,071 8	1,857 8	1,618 6	1,363 5	1,054 4
> 500 000	n	288	269	251	233	215	197	179	162	144	110	93	78	63	50
	k	3,495 3	3,360 9	3,247 6	3,092 3	2,941 1	2,780 5	2,613 6	2,446 2	2,258 8	2,064 4	1,850 2	1,610 8	1,355 8	1,046 9

Table 3 — Values of f_{σ} for maximum process standard deviation for combined control of double specification limits: σ -method

Lot size	Limiting quality (in percent nonconforming)														
	0,05	0,08	0,125	0,2	0,315	0,5	0,8	1,25	2	3,15	5	8	12,5	20	31,5
16 to 25	0,117 595	0,120 519	0,126 170	0,129 888	0,137 225	0,141 951	0,147 312	0,158 291	0,166 082	0,173 845	0,194 739	0,209 992	0,245 538	0,280 291	0,327 321
26 to 50	0,118 145	0,121 939	0,125 749	0,130 333	0,135 143	0,143 506	0,150 590	0,158 035	0,167 667	0,178 510	0,192 224	0,210 299	0,244 745	0,268 789	0,334 105
51 to 90	0,123 234	0,127 586	0,132 058	0,137 477	0,143 305	0,150 142	0,158 283	0,164 483	0,175 444	0,188 151	0,204 541	0,226 612	0,250 834	0,294 755	0,298 264
91 to 150	0,123 812	0,128 435	0,132 310	0,138 029	0,143 016	0,150 152	0,157 033	0,166 169	0,177 957	0,189 009	0,206 386	0,221 411	0,241 859	0,261 409	0,362 089
151 to 280	0,125 177	0,129 390	0,134 394	0,139 660	0,145 390	0,151 845	0,159 552	0,169 239	0,180 086	0,189 758	0,206 529	0,224 222	0,242 529	0,302 107	0,344 763
281 to 500	0,127 103	0,131 229	0,135 930	0,141 559	0,147 019	0,154 043	0,162 372	0,170 485	0,179 715	0,185 014	0,203 165	0,222 986	0,264 318	0,294 477	0,381 251
50 to 1 200	0,129 318	0,133 857	0,138 571	0,144 190	0,150 262	0,156 023	0,164 563	0,174 370	0,180 527	0,199 709	0,218 120	0,239 518	0,263 606	0,315 537	0,391 257
1 201 to 3 200	0,130 747	0,135 411	0,140 279	0,144 709	0,151 668	0,158 801	0,167 216	0,174 405	0,189 355	0,202 454	0,221 179	0,244 880	0,275 073	0,321 819	0,398 426
3 201 to 10 000	0,132 435	0,136 742	0,141 900	0,147 922	0,154 329	0,161 725	0,168 398	0,179 969	0,191 603	0,206 696	0,224 800	0,249 496	0,280 302	0,329 334	0,409 174
10 001 to 35 000	0,133 952	0,138 787	0,143 876	0,149 914	0,156 406	0,162 535	0,172 190	0,182 448	0,195 300	0,210 046	0,228 867	0,253 911	0,286 070	0,336 879	0,419 155
35 001 to 150 000	0,135 315	0,140 203	0,145 368	0,151 484	0,157 046	0,165 316	0,174 399	0,185 161	0,197 945	0,212 957	0,232 301	0,257 846	0,291 409	0,343 868	0,428 643
150 001 to 500 000	0,136 222	0,141 189	0,146 407	0,151 691	0,159 079	0,166 664	0,176 437	0,186 728	0,199 734	0,215 048	0,234 618	0,260 696	0,294 868	0,348 330	0,427 140
>500 000	0,136 454	0,141 420	0,145 872	0,152 460	0,159 434	0,167 538	0,176 825	0,187 165	0,200 165	0,215 547	0,235 219	0,261 442	0,295 772	0,349 492	0,424 719

NOTE The MPSD is obtained by multiplying the standardized MPSD, f_{σ} , by the difference between the upper specification limit, U , and the lower specification limit, L , i.e. $MPSD = (U - L) f_{\sigma}$.

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Table 4 — Single sampling plans of Form k: σ -method

Lot size	n	Limiting quality (in percent nonconforming)															
		0,05	0,08	0,125	0,2	0,315	0,5	0,8	1,25	2	3,15	5	8	12,5	20	31,5	
16 to 25	3	4,145 6	4,039 9	3,849 2	3,732 6	3,520 5	3,395 2	3,262 5	3,017 9	2,863 3	2,722 5	2,597 1	2,498 6	2,398 8	2,300 0	2,202 2	2,104 4
26 to 50	4	4,112 3	3,977 0	3,850 0	3,704 8	3,563 7	3,440 2	3,169 6	3,006 3	2,815 7	2,624 8	2,412 7	2,273 3	2,180 7	2,088 1	1,995 5	1,902 9
51 to 90	4	3,932 6	3,790 0	3,653 0	3,498 7	3,345 2	3,180 0	3,001 1	2,876 4	2,676 5	2,472 6	2,245 3	2,106 9	2,014 3	1,921 7	1,829 1	1,736 5
91 to 150	5	3,905 0	3,754 9	3,637 0	3,478 8	3,343 3	3,170 1	3,017 4	2,833 4	2,622 8	2,448 0	2,209 2	2,031 2	1,938 6	1,846 0	1,753 4	1,660 8
151 to 280	6	3,854 1	3,719 6	3,570 4	3,424 7	3,279 8	3,124 8	2,957 9	2,768 8	2,580 0	2,429 1	2,199 0	1,991 4	1,883 8	1,791 2	1,700 0	1,608 8
281 to 500	7	3,787 6	3,659 4	3,522 6	3,370 3	3,233 4	3,070 9	2,895 7	2,740 8	2,580 8	2,495 8	2,236 4	1,998 6	1,871 0	1,786 0	1,699 0	1,612 0
501 to 1 200	8	3,714 8	3,578 7	3,446 5	3,299 8	3,153 1	3,024 1	2,848 8	2,667 6	2,563 5	2,278 0	2,048 6	1,823 3	1,685 7	1,600 7	1,515 7	1,430 7
1 201 to 3 200	11	3,665 2	3,528 2	3,394 5	3,280 5	3,114 2	2,958 2	2,790 6	2,659 6	2,417 4	2,233 0	2,004 9	1,762 9	1,617 3	1,532 3	1,447 3	1,362 3
3 201 to 10 000	15	3,610 4	3,486 4	3,347 6	3,197 3	3,049 7	2,893 2	2,768 3	2,559 7	2,378 4	2,171 9	1,958 5	1,713 7	1,568 1	1,483 1	1,398 1	1,313 1
10 001 to 35 000	21	3,562 6	3,426 8	3,293 4	3,146 4	3,000 5	2,873 0	2,689 6	2,515 0	2,320 6	2,125 1	1,909 7	1,669 0	1,523 4	1,438 4	1,353 4	1,268 4
35 001 to 150 000	30	3,520 9	3,386 2	3,253 4	3,107 3	2,984 0	2,815 1	2,647 3	2,468 6	2,280 1	2,085 9	1,870 1	1,630 9	1,485 3	1,400 3	1,315 3	1,230 3
150 001 to 500 000	38	3,493 9	3,358 9	3,226 4	3,101 2	2,939 5	2,787 7	2,610 3	2,442 6	2,253 8	2,059 0	1,844 5	1,604 9	1,459 3	1,374 3	1,289 3	1,204 3
>500 000	41	3,487 1	3,352 4	3,239 3	3,083 3	2,931 7	2,770 6	2,603 3	2,435 4	2,247 5	2,052 6	1,837 9	1,598 1	1,452 5	1,367 5	1,282 5	1,197 5

Table 5 — Single sampling plans of Form p*

Lot size	Limiting quality (in percent nonconforming)														
	0,05	0,08	0,125	0,2	0,315	0,5	0,8	1,25	2	3,15	5	8	12,5	20	31,5
16 to 25	p* 1,914 16E-7	3,751 95E-7	1,212 79E-6	2,421 40E-6	8,101 28E-6	1,603 84E-5	3,225 16E-5	1,094 49E-4	2,268 04E-4	4,275 45E-4	1,663 05E-3	3,543 67E-3	1,263 30E-2	2,890 29E-2	6,137 09E-2
26 to 50	p* 1,024 86E-6	2,193 11E-6	4,381 87E-6	9,431 42E-6	1,935 92E-5	5,741 74E-5	1,261 19E-4	2,588 95E-4	5,743 78E-4	1,219 51E-3	2,668 66E-3	6,044 20E-3	1,832 47E-2	3,171 65E-2	8,397 89E-2
51 to 90	p* 2,799 74E-6	6,034 68E-6	1,231 51E-5	2,673 77E-5	5,605 71E-5	1,203 69E-4	2,647 12E-4	4,479 54E-4	9,990 53E-4	2,151 00E-3	4,762 59E-3	1,084 22E-2	2,135 06E-2	5,014 24E-2	5,290 39E-2
91 to 150	p* 6,330 71E-6	1,345 76E-5	2,388 93E-5	5,118 27E-5	9,276 59E-5	1,968 65E-4	3,710 54E-4	7,677 90E-4	1,681 99E-3	3,100 16E-3	6,756 77E-3	1,157 65E-2	2,081 44E-2	3,247 80E-2	1,226 21E-1
151 to 280	p* 1,211 08E-5	2,304 71E-5	4,591 71E-5	8,787 94E-5	1,635 16E-4	3,096 12E-4	5,971 96E-4	1,210 58E-3	2,354 47E-3	3,896 47E-3	8,000 73E-3	1,457 52E-2	2,392 19E-2	6,983 07E-2	1,121 30E-1
281 to 500	p* 2,147 23E-5	3,864 71E-5	7,094 69E-5	1,361 32E-4	2,393 20E-4	4,550 43E-4	8,807 59E-4	1,535 97E-3	2,654 92E-3	3,511 12E-3	7,855 08E-3	1,543 73E-2	4,102 99E-2	6,665 90E-2	1,566 14E-1
501 to 1 200	p* 3,574 44E-5	6,517 43E-5	1,146 02E-4	2,096 66E-4	3,747 41E-4	6,127 34E-4	1,161 68E-3	2,173 38E-3	3,067 34E-3	7,439 47E-3	1,426 22E-2	2,563 74E-2	4,258 78E-2	9,026 37E-2	1,718 86E-1
1 201 to 3 200	p* 6,050 52E-5	1,076 38E-4	1,852 65E-4	2,902 33E-4	5,450 52E-4	9,590 55E-4	1,712 22E-3	2,639 93E-3	5,615 52E-3	9,590 95E-3	1,774 25E-2	3,223 56E-2	5,659 58E-2	1,032 07E-1	1,881 10E-1
3 201 to 10 000	p* 9,307 79E-5	1,538 03E-4	2,650 39E-4	4,673 56E-4	7,978 52E-4	1,373 43E-3	2,116 59E-3	4,030 39E-3	6,909 97E-3	1,228 29E-2	2,132 04E-2	3,804 45E-2	6,483 43E-2	1,160 66E-1	2,059 20E-1
10 001 to 35 000	p* 1,308 44E-4	2,228 32E-4	3,693 83E-4	6,317 61E-4	1,053 78E-3	1,620 30E-3	2,925 25E-3	4,982 20E-3	8,705 95E-3	1,471 93E-2	2,518 04E-2	4,360 99E-2	7,329 57E-2	1,282 94E-1	2,215 81E-1
35 001 to 150 000	p* 1,711 05E-4	2,864 84E-4	4,681 58E-4	7,876 59E-4	1,202 82E-3	2,096 51E-3	3,545 51E-3	6,023 17E-3	1,019 58E-2	1,693 89E-2	2,858 39E-2	4,857 63E-2	8,096 13E-2	1,391 66E-1	2,354 59E-1
150 001 to 500 000	p* 1,994 20E-4	3,320 82E-4	5,382 24E-4	8,365 46E-4	1,446 14E-3	2,363 25E-3	4,079 91E-3	6,655 07E-3	1,118 30E-2	1,845 93E-2	3,079 32E-2	5,193 28E-2	8,571 75E-2	1,457 56E-1	2,355 08E-1
>500 000	p* 2,074 51E-4	3,442 82E-4	5,199 70E-4	8,992 28E-4	1,498 09E-3	2,515 48E-3	4,199 41E-3	6,838 15E-3	1,143 97E-2	1,884 95E-2	3,139 06E-2	5,283 93E-2	8,699 08E-2	1,475 00E-1	2,333 11E-1

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NOTE The first three entries in the first row are only applicable for the σ -method as the s -method requires 100 % inspection for lot size 16 to 25 at LQ 0,05 %, 0,08 % and 0,125 %.

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Table 6 — Consumer's risk and producer's risk quality: s-method - LQ from 0,05 % to 0,315 %

Lot size	Limiting quality (in percent nonconforming)							
	0,05	0,08	0,125	0,2	0,315			
16 to 25	n PRQ % k CR %	100 % inspection 30 <0,001	100 % inspection 30 <0,001	100 % inspection 28 <0,001	13 <0,001	12 <0,001	2,685 8 9,999	2,448 3 9,998
26 to 50	n PRQ % k CR %	4,004 3 9,998	3,872 9 9,998	3,745 4 9,998	26 <0,001	24 <0,001	3,604 4 10,000	3,464 1 9,997
51 to 90	n PRQ % k CR %	3,953 6 10,000	3,818 6 9,997	3,686 7 9,999	30 <0,001	28 0,001	3,540 9 9,997	3,394 6 9,997
91 to 150	n PRQ % k CR %	3,902 7 9,998	3,764 7 9,997	3,639 8 9,997	34 0,001	31 0,002	3,490 8 9,998	3,353 1 10,000
151 to 280	n PRQ % k CR %	3,854 1 10,000	3,721 6 9,998	3,584 2 9,999	39 0,002	36 0,003	3,441 1 9,998	3,297 9 9,998
281 to 500	n PRQ % k CR %	3,803 8 9,998	3,673 7 9,998	3,540 9 9,998	45 0,003	41 0,005	3,394 3 9,999	3,254 6 9,999
501 to 1 200	n PRQ % k CR %	3,751 8 9,999	3,617 4 9,999	3,486 0 10,000	54 0,005	50 0,008	3,341 2 9,999	3,195 9 9,999
1 201 to 3 200	n PRQ % k CR %	3,689 4 9,998	3,554 3 9,997	3,422 0 9,996	69 0,007	64 0,014	3,305 5 8,695	3,142 4 9,528
3 201 to 10 000	n PRQ % k CR %	3,630 3 9,996	3,506 7 9,318	3,368 8 9,688	92 0,013	85 0,024	3,219 8 9,933	3,073 1 9,995
10 001 to 35 000	n PRQ % k CR %	3,578 1 9,822	3,442 9 9,889	3,309 8 10,000	126 0,022	116 0,037	3,163 9 9,996	3,018 4 9,998
35 001 to 150 000	n PRQ % k CR %	3,531 4 9,912	3,397 1 9,912	3,264 7 9,911	173 0,031	160 0,049	3,119 3 9,903	2,995 9 8,002
150 001 to 500 000	n PRQ % k CR %	3,502 9 9,921	3,368 2 9,919	3,236 0 9,916	218 0,036	201 0,065	3,110 8 8,024	2,949 7 9,413
> 500 000	n PRQ % k CR %	3,495 3 9,919	3,360 9 9,919	3,247 6 8,050	233 0,040	215 0,069	3,092 3 8,994	2,941 1 9,496

Table 7 — Consumer's risk and producer's risk quality: s-method – LQ from 0,5 % to 3,15 %

Lot size	Limiting quality (in percent nonconforming)										
	0,5		0,8		1,25		2		3,15		
16 to 25	n	k	CR %	18	3,210 1	17	3,028 4	15	2,856 9	13	2,685 8
	PRQ %	<0,001	9,999	0,002	10,000	0,004	9,999	0,007	9,998	0,013	9,999
26 to 50	n	k	CR %	21	3,130 6	19	2,970 5	17	2,789 4	15	2,604 9
	PRQ %	0,002	9,998	0,003	9,999	0,006	10,000	0,012	9,998	0,024	9,998
51 to 90	n	k	CR %	24	3,069 8	21	2,923 1	19	2,735 6	17	2,542 7
	PRQ %	0,003	9,999	0,006	9,998	0,009	10,000	0,019	9,998	0,040	9,997
91 to 150	n	k	CR %	26	3,036 4	24	2,865 9	22	2,672 2	19	2,493 0
	PRQ %	0,004	9,997	0,007	9,999	0,015	9,997	0,032	9,998	0,058	9,998
151 to 280	n	k	CR %	30	2,981 8	28	2,807 1	25	2,623 0	22	2,469 4
	PRQ %	0,006	9,999	0,012	9,999	0,024	9,998	0,047	9,997	0,077	8,836
281 to 500	n	k	CR %	35	2,929 4	32	2,777 6	28	2,614 4	25	2,520 9
	PRQ %	0,009	9,997	0,018	9,999	0,032	9,381	0,055	8,858	0,072	5,927
501 to 1 200	n	k	CR %	42	2,893 7	38	2,715 5	34	2,606 1	30	2,331 5
	PRQ %	0,014	8,923	0,026	9,175	0,050	9,734	0,071	6,864	0,184	9,997
1 201 to 3 200	n	k	CR %	54	2,823 1	49	2,691 4	44	2,455 4	39	2,272 6
	PRQ %	0,025	9,430	0,045	9,331	0,071	7,732	0,160	9,996	0,284	9,439
3 201 to 10 000	n	k	CR %	71	2,787 2	65	2,587 3	58	2,407 2	51	2,202 4
	PRQ %	0,042	9,998	0,065	7,952	0,131	9,688	0,233	9,275	0,434	10,000
10 001 to 35 000	n	k	CR %	97	2,708 8	88	2,535 3	78	2,341 9	69	2,147 5
	PRQ %	0,057	8,133	0,108	9,057	0,191	9,484	0,348	9,998	0,614	9,999
35 001 to 150 000	n	k	CR %	133	2,660 7	120	2,482 8	107	2,295 1	94	2,101 5
	PRQ %	0,087	9,041	0,153	9,042	0,269	9,992	0,472	10,000	0,814	9,992
150 001 to 500 000	n	k	CR %	167	2,621 5	151	2,454 2	135	2,266 1	119	2,071 8
	PRQ %	0,109	9,014	0,194	9,995	0,326	9,991	0,568	9,998	0,972	9,997
> 500 000	n	k	CR %	179	2,613 6	162	2,446 2	144	2,258 8	127	2,064 4
	PRQ %	0,119	9,999	0,205	9,999	0,344	9,991	0,595	9,991	1,015	9,991

Table 8 — Consumer's risk and producer's risk quality: s-method – LQ from 5 % to 31,5 %

Lot size		Limiting quality (in percent nonconforming)																	
		5			8			12,5			20			31,5					
		n	PRQ %	CR %	n	PRQ %	CR %	n	PRQ %	CR %	n	PRQ %	CR %	n	PRQ %	CR %			
16 to 25	k	12	2,448 3	0,035	9,999	0,068	2,235 5	9	1,949 2	0,202	9,999	7	1,675 6	0,428	9,999	5	1,388 5	0,806	10,000
26 to 50	k	13	2,402 5	0,049	9,998	0,104	2,177 3	10	1,887 0	0,303	9,998	8	1,683 3	0,499	9,999	6	1,313 6	1,338	8,765
51 to 90	k	15	2,329 0	0,085	9,999	0,190	2,088 4	11	1,863 5	0,374	9,277	9	1,551 5	0,929	9,313	7	1,499 5	0,835	4,159
91 to 150	k	17	2,212 5	0,126	9,997	0,211	2,086 5	12	1,886 7	0,380	7,581	10	1,716 3	0,580	4,809	8	1,151 7	2,960	8,595
151 to 280	k	19	2,247 3	0,160	9,331	0,292	2,042 4	14	1,864 7	0,490	6,265	11	1,432 7	1,670	9,998	9	1,199 9	2,838	6,064
281 to 500	k	22	2,275 9	0,168	6,713	0,343	2,047 3	16	1,678 8	1,050	9,998	13	1,461 4	1,756	7,045	10	1,012 1	5,065	9,999
501 to 1 200	k	27	2,109 3	0,378	9,997	0,713	1,886 2	19	1,673 6	1,222	8,023	15	1,320 7	2,924	9,999	12	0,952 0	6,514	9,999
1 201 to 3 200	k	34	2,047 8	0,556	9,998	1,078	1,808 5	24	1,557 8	2,017	9,997	19	1,253 6	4,009	9,999	15	0,890 3	8,336	10,000
3 201 to 10 000	k	44	1,990 3	0,789	9,995	1,512	1,747 9	31	1,499 0	2,720	9,997	25	1,190 0	5,333	9,994	20	0,825 3	10,673	10,000
10 001 to 35 000	k	60	1,933 3	1,103	9,998	2,023	1,693 7	42	1,441 9	3,594	9,996	34	1,132 3	6,829	9,993	27	0,770 5	13,013	9,999
35 001 to 150 000	k	82	1,886 6	1,438	9,993	2,564	1,648 1	58	1,392 8	4,527	9,994	47	1,083 2	8,353	9,999	37	0,723 7	15,299	9,998
150 001 to 500 000	k	103	1,857 8	1,687	9,994	2,978	1,618 6	73	1,363 5	5,174	9,996	59	1,054 4	9,366	9,999	47	0,722 9	16,124	7,385
> 500 000	k	110	1,850 2	1,759	9,997	3,095	1,610 8	78	1,355 8	5,357	9,997	63	1,046 9	9,640	9,991	50	0,729 9	16,137	6,228

Table 9 — Consumer's risk and producer's risk quality: σ -method - LQ from 0,05 % to 0,315 %

Lot size		Limiting quality (in percent nonconforming)									
		0,05	0,08	0,125	0,2	0,315					
16 to 25	<i>n</i>	3	3	3	13	12					
	PRQ %	<0,001	<0,001	<0,001	<0,001	<0,001					
26 to 50	<i>k</i>	4	4	4	4	4					
	CR %	<0,001	<0,001	<0,001	<0,001	<0,001					
51 to 90	<i>n</i>	4	4	4	4	4					
	PRQ %	<0,001	<0,001	<0,001	<0,001	<0,001					
91 to 150	<i>k</i>	5	5	5	5	5					
	CR %	<0,001	<0,001	<0,001	0,001	0,002					
151 to 280	<i>k</i>	6	6	6	6	6					
	CR %	<0,001	<0,001	0,001	0,002	0,004					
281 to 500	<i>k</i>	7	7	7	7	7					
	CR %	<0,001	<0,001	0,002	0,003	0,006					
501 to 1 200	<i>k</i>	8	8	8	8	8					
	CR %	<0,001	0,002	0,003	0,005	0,009					
1 201 to 3 200	<i>k</i>	11	11	11	11	11					
	CR %	0,002	0,003	0,005	0,008	0,015					
3 201 to 10 000	<i>k</i>	15	15	15	15	15					
	CR %	0,003	0,005	0,008	0,015	0,026					
10 001 to 35 000	<i>k</i>	21	21	21	21	21					
	CR %	0,004	0,008	0,013	0,023	0,039					
35 001 to 150 000	<i>k</i>	30	30	30	30	30					
	CR %	0,007	0,011	0,019	0,033	0,051					
150 001 to 500 000	<i>k</i>	38	38	38	38	38					
	CR %	0,008	0,014	0,024	0,038	0,067					
> 500 000	<i>k</i>	41	41	41	41	41					
	CR %	0,009	0,015	0,024	0,042	0,071					

Table 10 — Consumer's risk and producer's risk quality: σ -method – LQ from 0,5 % to 3,15 %

Lot size	Limiting quality (in percent nonconforming)											
	0,5		0,8		1,25		2		3,15			
16 to 25	n	k	3	3,395 2	3	3,262 5	3	3,017 9	3	2,863 3	3	2,722 5
	PRQ %	CR %	0,001	7,792	0,001	6,964	0,004	8,932	0,007	8,043	0,012	6,742
26 to 50	n	k	4	3,340 2	4	3,169 6	4	3,006 3	4	2,815 7	4	2,624 8
	PRQ %	CR %	0,002	6,316	0,003	6,408	0,006	6,303	0,014	6,377	0,028	6,286
51 to 90	n	k	4	3,180 0	4	3,001 1	4	2,876 4	4	2,676 5	4	2,472 6
	PRQ %	CR %	0,003	11,346	0,007	11,813	0,011	10,204	0,023	10,647	0,049	10,995
91 to 150	n	k	5	3,170 1	5	3,017 4	5	2,833 4	5	2,622 8	5	2,448 0
	PRQ %	CR %	0,005	9,195	0,009	8,682	0,018	9,279	0,039	10,161	0,073	9,398
151 to 280	n	k	6	3,124 8	6	2,957 9	6	2,768 8	6	2,580 0	6	2,429 1
	PRQ %	CR %	0,007	8,936	0,014	8,936	0,029	9,820	0,057	9,869	0,097	8,136
281 to 500	n	k	7	3,070 9	7	2,895 7	7	2,740 8	7	2,580 8	7	2,495 8
	PRQ %	CR %	0,011	9,513	0,022	9,889	0,039	9,320	0,068	8,159	0,091	4,606
501 to 1 200	n	k	8	3,024 1	8	2,848 8	8	2,667 6	8	2,563 5	8	2,278 0
	PRQ %	CR %	0,016	10,242	0,030	10,672	0,058	11,401	0,083	7,468	0,212	11,809
1 201 to 3 200	n	k	11	2,958 2	11	2,790 6	11	2,659 6	11	2,417 4	11	2,233 0
	PRQ %	CR %	0,028	10,237	0,051	10,477	0,080	8,272	0,179	11,389	0,318	10,753
3 201 to 10 000	n	k	15	2,893 2	15	2,763 3	15	2,559 7	15	2,378 4	15	2,171 9
	PRQ %	CR %	0,045	10,950	0,072	8,495	0,142	10,883	0,253	10,431	0,471	11,293
10 001 to 35 000	n	k	21	2,873 0	21	2,689 6	21	2,515 0	21	2,320 6	21	2,125 1
	PRQ %	CR %	0,061	8,663	0,115	9,918	0,203	10,496	0,369	11,069	0,650	11,151
35 001 to 150 000	n	k	30	2,815 1	30	2,647 3	30	2,468 6	30	2,280 1	30	2,085 9
	PRQ %	CR %	0,092	9,501	0,160	9,583	0,281	10,667	0,493	10,753	0,851	10,717
150 001 to 500 000	n	k	38	2,787 7	38	2,610 3	38	2,442 6	38	2,253 8	38	2,059 0
	PRQ %	CR %	0,113	9,577	0,201	10,723	0,337	10,744	0,586	10,875	1,001	10,903
> 500 000	n	k	41	2,770 6	41	2,603 3	41	2,435 4	41	2,247 5	41	2,052 6
	PRQ %	CR %	0,123	10,617	0,212	10,663	0,355	10,708	0,613	10,737	1,046	10,778

Table 11 — Consumer's risk and producer's risk quality: σ -method - LQ from 5 % to 31,5 %

Lot size		Limiting quality (in percent nonconforming)									
		5		8		12,5		20		31,5	
16 to 25	<i>n</i>	3	2,397 1	3	2,198 6	3	1,826 8	3	1,549 0	3	1,260 2
	PRQ %	0,041	9,630	0,082	8,465	0,275	12,067	0,623	11,025	1,356	8,877
26 to 50	<i>n</i>	4	2,412 7	4	2,173 3	4	1,809 7	4	1,607 5	4	1,194 1
	PRQ %	0,061	6,231	0,137	6,221	0,424	9,363	0,755	6,279	2,187	7,712
51 to 90	<i>n</i>	4	2,245 3	4	1,988 3	4	1,755 1	4	1,423 3	4	1,400 6
	PRQ %	0,108	11,490	0,247	12,171	0,498	11,324	1,236	12,234	1,311	3,305
91 to 150	<i>n</i>	5	2,209 2	5	2,031 2	5	1,822 1	5	1,650 7	5	1,039 3
	PRQ %	0,162	10,349	0,288	8,075	0,527	6,654	0,851	3,521	3,796	10,624
151 to 280	<i>n</i>	6	2,199 0	6	1,991 4	6	1,806 3	6	1,348 4	6	1,109 4
	PRQ %	0,205	8,733	0,387	7,547	0,661	5,406	2,170	10,724	3,746	6,209
281 to 500	<i>n</i>	7	2,236 4	7	1,998 6	7	1,609 9	7	1,389 8	7	0,933 7
	PRQ %	0,213	5,878	0,439	5,817	1,282	11,202	2,214	7,348	5,993	11,589
501 to 1 200	<i>n</i>	8	2,048 6	8	1,823 3	8	1,610 2	8	1,252 6	8	0,885 6
	PRQ %	0,427	12,673	0,809	11,842	1,420	9,669	3,332	12,253	7,117	12,666
1 201 to 3 200	<i>n</i>	11	2,004 9	11	1,762 9	11	1,510 3	11	1,204 7	11	0,843 7
	PRQ %	0,619	11,621	1,195	11,766	2,242	11,627	4,451	11,426	9,018	11,497
3 201 to 10 000	<i>n</i>	15	1,958 5	15	1,713 7	15	1,464 0	15	1,154 4	15	0,792 8
	PRQ %	0,858	11,223	1,624	11,598	2,947	11,223	5,716	11,287	11,171	11,414
10 001 to 35 000	<i>n</i>	21	1,909 7	21	1,669 0	21	1,416 7	21	1,107 2	21	0,748 4
	PRQ %	1,165	11,244	2,128	11,324	3,790	11,112	7,131	11,180	13,407	11,084
35 001 to 150 000	<i>n</i>	30	1,870 1	30	1,630 9	30	1,375 1	30	1,065 9	30	0,708 9
	PRQ %	1,499	10,865	2,673	10,806	4,693	10,916	8,594	10,964	15,644	10,670
150 001 to 500 000	<i>n</i>	38	1,844 5	38	1,604 9	38	1,349 5	38	1,040 8	38	0,711 3
	PRQ %	1,737	10,922	3,062	10,901	5,301	10,979	9,550	10,976	16,400	7,851
> 500 000	<i>n</i>	41	1,837 9	41	1,598 1	41	1,342 8	41	1,034 4	41	0,719 1
	PRQ %	1,810	10,821	3,180	10,823	5,483	10,892	9,830	10,853	16,454	6,426

13 Examples

13.1 General

Examples are included for the *s*-method (13.2), the σ -method (13.3) and the *p**-method (13.4) with details of the calculations and acceptance decisions given. The examples used for the *p**-method are a subset of those used for the *s*-method and the σ -method and this illustrates the equivalence of the methods. The software that supports the use of this standard, described in Annex I, can carry out all the calculations and acceptance decisions and produce the information given here.

13.2 Examples for the *s*-method

EXAMPLE 1 Single, lower specification limit using the *s*-method.

A certain pyrotechnic delay mechanism has a specified minimum delay time of 4,0 s. The process standard deviation is unknown. Production is inspected in lots of 1 000 items and with an LQ of 3,15 % applied to the lower limit. From Table 2, it is seen that the suitable plan is given by sample size 30 and acceptance constant $k = 2,331 5$. A random sample of size 30 is drawn. Suppose the sample delay times, in seconds, are as follows:

5,50 6,95 6,04 6,68 6,63 6,65 6,52 6,59 6,40 6,44 6,34 6,04 6,15 6,29 6,63
 6,50 6,44 7,15 6,70 6,59 6,51 6,80 5,94 6,35 7,17 6,83 6,25 6,96 7,00 6,38

Conformity with the acceptance criterion is to be determined,

Information needed	Values obtained
Sample size: <i>n</i>	30
Form <i>k</i> acceptance constant: <i>k</i>	2,331 5
Sample mean: $\bar{x} = \sum x / n$	6,514 s
Sample standard deviation: $s = \sqrt{\sum_j (x_j - \bar{x})^2 / (n - 1)}$	0,368 s
Lower specification limit: <i>L</i>	4 s
Lower quality statistic: $Q_L = (\bar{x} - L) / s$	6,838
Acceptance criterion: Is $Q_L \geq k$	Yes (6,838 \geq 2,331 5)

The quality statistic is greater than the acceptance constant; therefore, the lot is accepted.

Note that the acceptance test, $Q_L \geq k$, is equivalent to checking that (s, \bar{x}) is above the acceptance region boundary. This is shown in Figure 1.

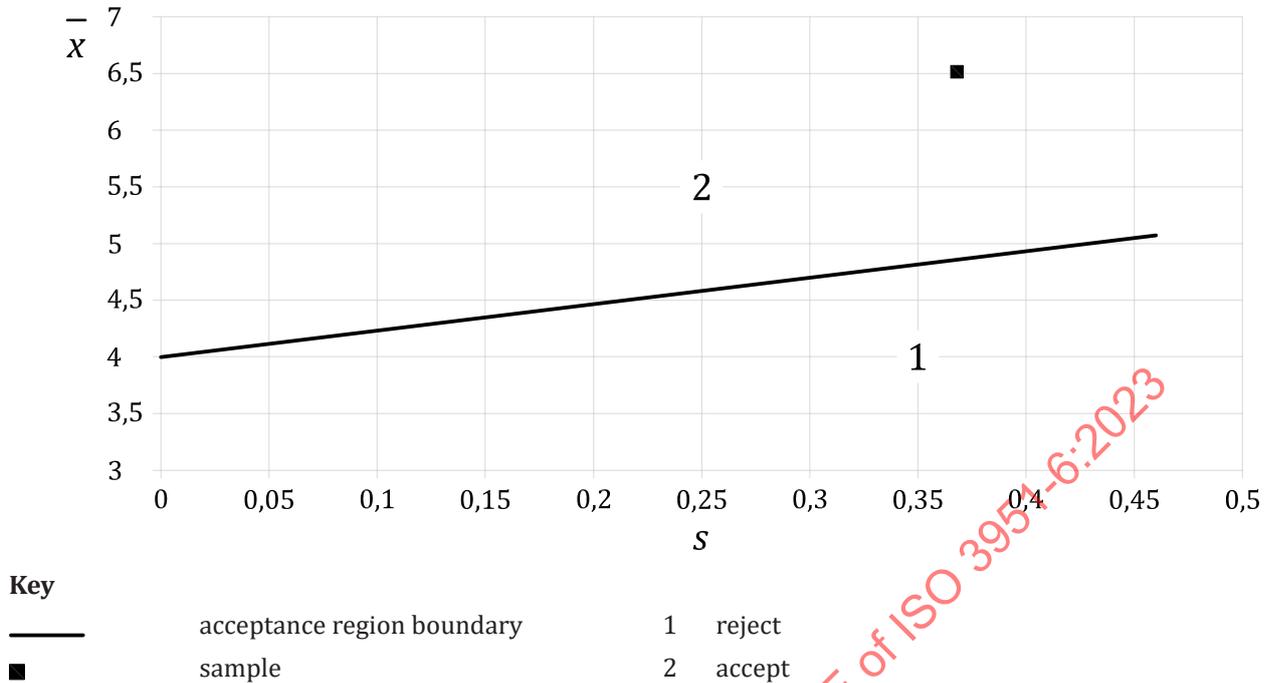


Figure 1 — Example of the use of an acceptance diagram, s-method

EXAMPLE 2 Single, upper specification limit using the s-method.

The maximum temperature of operation for a certain device is specified as 60 °C and the operating temperature is known from previous experience to be normally distributed. Production is inspected in lots of 80 items and the process standard deviation is unknown. Inspection with an LQ of 8 % is to be used. From [Table 2](#), it is seen that a sample size of 13 is required and that the acceptance constant, *k*, is 2,088 4. Suppose that the measurements in °C are as follows:

53 57 49 58 59 54 58 56 50 50 55 54 57

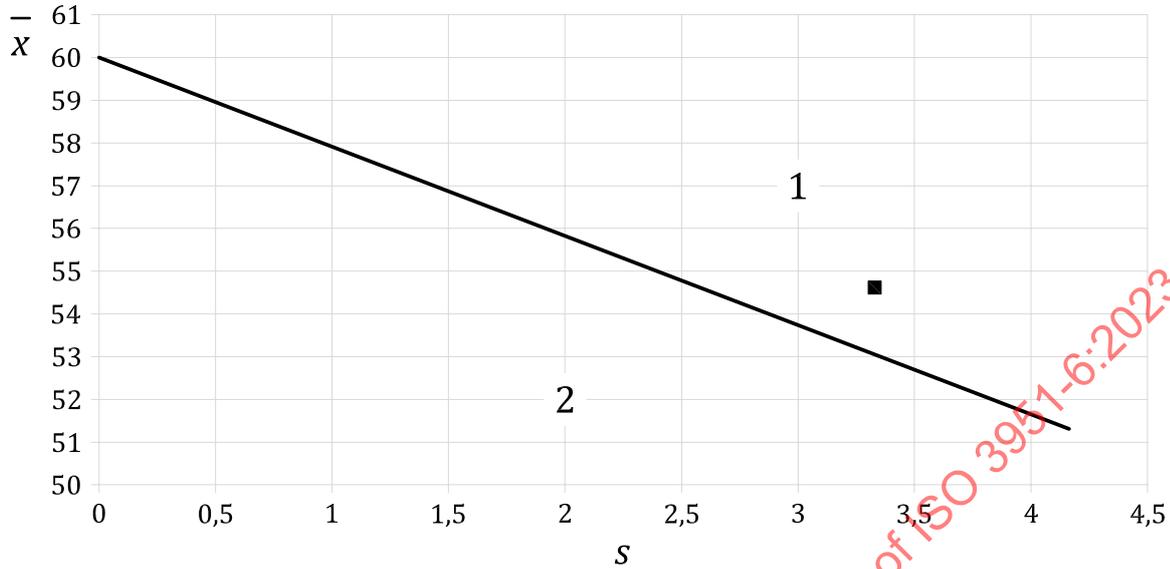
Conformity with the acceptance criterion is to be determined,

Information needed	Values obtained
Sample size: <i>n</i>	13
Form <i>k</i> acceptance constant: <i>k</i>	2,088 4
Sample mean: $\bar{x} = \sum x / n$	54,615 4 °C
Sample standard deviation: $s = \sqrt{\sum_j (x_j - \bar{x})^2 / (n-1)}$	3,330 1 °C
Upper specification limit: <i>U</i>	60 °C
Upper quality statistic: $Q_U = (U - \bar{x}) / s$	1,617
Acceptance criterion: Is $Q_U \geq k$?	No (1,616 9 < 2,088 4)

The quality statistic is less than the acceptance constant; therefore, the lot is rejected.

NOTE This lot is rejected even though all inspected items in the sample are within the specification limit.

Note that the acceptance test, $Q_U \geq k$, is equivalent to checking that (s, \bar{x}) is below the acceptance region boundary. This is shown in [Figure 2](#).



Key		
—	acceptance region boundary	1 reject
■	sample	2 accept

Figure 2 — Example of the use of an acceptance diagram, s-method

EXAMPLE 3 Single, upper specification limit using the s-method.

Example 2 is calculated again with different measurements:

51 62 52 54 50 53 50 45 49 53 50 48 52

Conformity with the acceptance criterion is to be determined,

Information needed	Values obtained
Sample size: n	13
Form k acceptance constant: k	2,088 4
Sample mean: $\bar{x} = \sum x / n$	51,461 5 °C
Sample standard deviation: $s = \sqrt{\sum_j (x_j - \bar{x})^2 / (n-1)}$	3,971 0 °C
Upper specification limit: U	60 °C
Upper quality statistic: Q_U	2,150 2
Acceptance criterion: Is $Q_U \geq k$?	Yes (2,150 2 \geq 2,088 4)

The quality statistic is greater than or equal to the acceptance constant; therefore, the lot is accepted.

NOTE This lot is accepted even though one inspected item in the sample is outside the specification limit. However, a deeper examination of the data using the techniques in ISO 16269-4 show that the highest and out of specification value of 62 °C can be considered an outlier, specifically; on a normal probability plot this value falls a long way off the straight line formed by the other values and the generalized extreme studentized deviate (GESD) procedure (for 1 outlier, equivalent to the Grubbs Test) returns a test statistic $R_0 = 2,561$ which exceeds the critical value ($\alpha=0,05$) of $\lambda_0 = 2,46$. Under the provisions of [11.3](#) the disposition of the lot should be a matter for negotiation between the vendor and the responsible authority.

EXAMPLE 4 Combined control of double specification limits using the *s*-method.

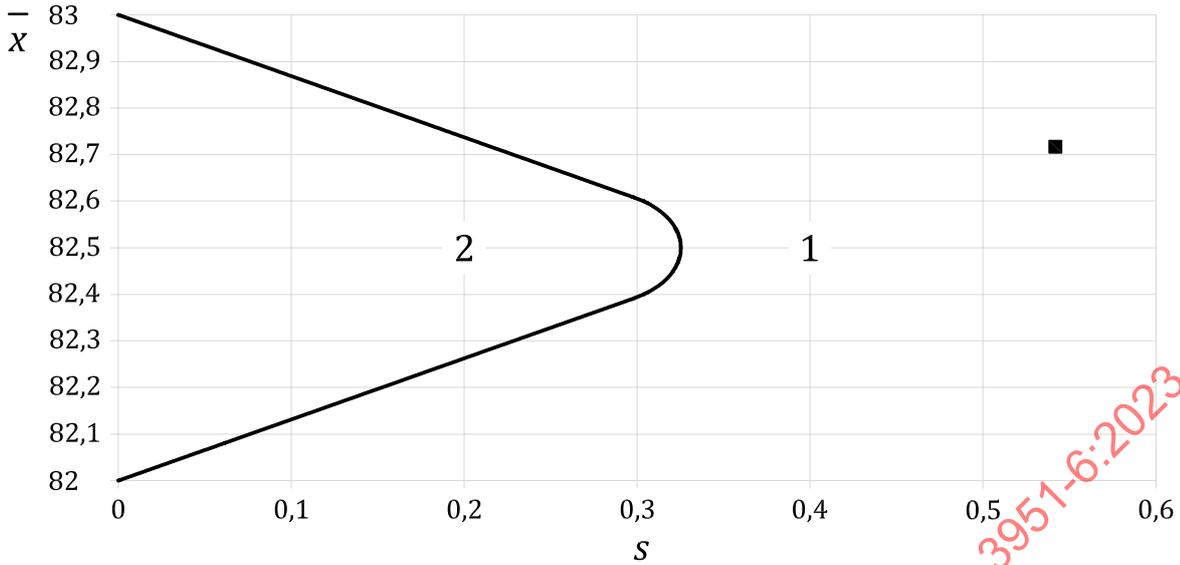
Items are being manufactured in lots of size 30. The lower and upper specification limits on their diameters are 82 mm to 83 mm. Items with diameters that are too large are equally unsatisfactory as those with diameters that are too small, and it has been decided to control the total fraction nonconforming using an LQ of 31,5 %. From [Table 2](#), it is seen that the sample size is 6 and the acceptance constant, *k*, is 1,313 6. The diameters of six items from the first lot are measured, yielding diameters of:

82,4 82,2 83,1 82,3 82,7 83,6 mm

Conformity with the acceptance criteria is to be determined,

Information needed	Values obtained
Sample size: <i>n</i>	6
Form <i>k</i> acceptance constant: <i>k</i>	1,313 6
Sample mean: $\bar{x} = \sum x / n$	82,716 7 mm
Sample standard deviation: $s = \sqrt{\sum_j (x_j - \bar{x})^2 / (n - 1)}$	0,541 9 mm
Lower specification limit: <i>L</i>	82,0 mm
Upper specification limit: <i>U</i>	83,0 mm

Determination of acceptance. Neither $\bar{x} < L$ or $\bar{x} > U$ so can be plotted on the acceptance diagram, as shown in [Figure 3](#). The point is outside the acceptance region; therefore, the lot is rejected.



Key

—	acceptance region boundary	1	reject
■	sample	2	accept

Figure 3 — Example of the use of an acceptance diagram, s-method

EXAMPLE 5 Combined control of double specification limits using the s-method.

Example 4 is calculated again with different specification limits. The lower and upper specification limits on diameters are now 81,5 mm to 84,5 mm,

Information needed	Values obtained
Sample size: n	6
Sample mean: $\bar{x} = \sum x / n$	82,716 7 mm
Sample standard deviation: $s = \sqrt{\sum_j (x_j - \bar{x})^2 / (n-1)}$	0,541 9 mm
Lower specification limit: L	81,5 mm
Upper specification limit: U	84,5 mm
Acceptance constant: k	1,313 6

Determination of acceptance. Neither $\bar{x} < L$ or $\bar{x} > U$ so (s, \bar{x}) can be plotted on the acceptance diagram, as shown in [Figure 4](#). The point is now inside the acceptance region; therefore, the lot is accepted with the new specification limits.

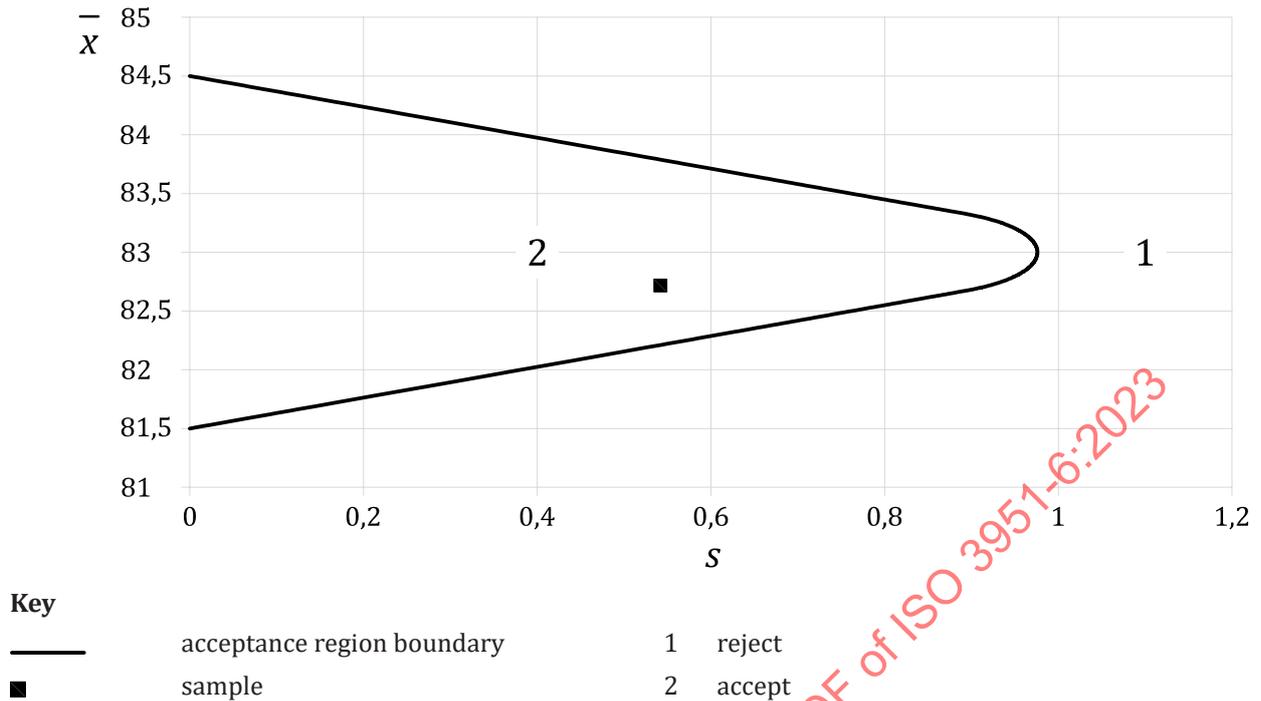


Figure 4 — Example of the use of a combined control double specification limits acceptance diagram, s-method

13.3 Examples for the σ -method

EXAMPLE 1 Single, lower specification limit using the σ -method.

The specified minimum yield point for certain steel castings is 400 N/mm². A lot of 250 items is inspected with an LQ of 8 %. The value of σ is known to be 21 N/mm². From Table 4, it is seen that the sample size, n , is 6 and the acceptance constant, k , is 1,991 4. Suppose the yield points in N/mm² of the sample specimens are:

441 437 460 433 442 452

Conformity with the acceptance criterion is to be determined,

Information needed	Values obtained
Sample size: n	6
Acceptance constant: k	1,991 4
Sample mean: $\bar{x} = \sum x / n$	444,167 N/mm ²
Known Standard deviation: σ	21 N/mm ²
Lower specification limit: L	400 N/mm ²
Lower quality statistic: $Q_L = (\bar{x} - L) / s$	2,103 2
Acceptance criterion: Is $Q_L \geq k$?	Yes (2,103 2 \geq 1,991 4)

The quality statistic is greater than or equal to the acceptance constant; therefore, the lot is accepted.

NOTE Since σ is known the acceptance criterion can also be rearrange to give a limit in terms of \bar{x} :

i.e. accept if $\bar{x} \geq 400 + (1,9911 \times 21) = 441,819$ N/mm² and that the acceptance test, $Q_U \geq k$, is equivalent to checking that (σ, \bar{x}) is above the acceptance region boundary. This is shown in [Figure 5](#).

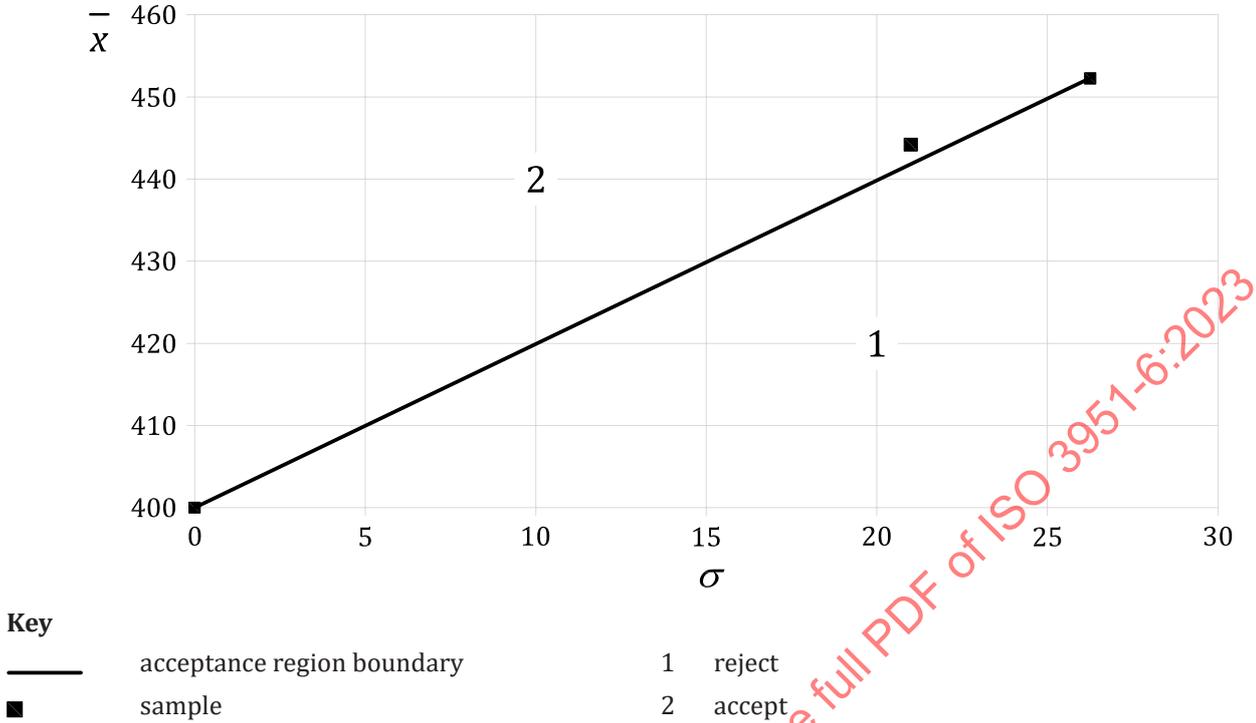


Figure 5 — Example of the use of an acceptance diagram, A-method

EXAMPLE 2 Single, upper specification limit using the σ -method.

The actuation force of a medical inhalation device has to be below the upper specification limit of 20 N in order to guarantee usability. Based on a process validation study, the process standard deviation is assumed to be known at 1,41 N. With average lot size of ~ 200 000 units and an LQ of 3,15 % from [Table 4](#), the sample size of $n=38$ and an acceptance constant of $k = 2,059 0$ is found. The observed measurement values were within a range of 12,41 N to 18,98 N and data normality could be assumed,

Conformity with the acceptance criterion is to be determined,

Information needed	Values obtained
Sample size: n	38
Form k Acceptance constant: k	2,059 0
Sample mean: $\bar{x} = \sum x / n$	15,8 N
Known Standard deviation: σ	1,41 N
Upper specification limit: U	20 N
Upper quality statistic: Q_U	2,978 7
Acceptance criterion: Is $Q_U \geq k$?	Yes ($2,978 7 \geq 2,059 0$)

The sample meets the acceptance criterion and the lot is therefore accepted.

Note that the acceptance test, $Q_U \geq k$, is equivalent to checking that (σ, \bar{x}) is below the acceptance region boundary. This is shown in [Figure 6](#) below.

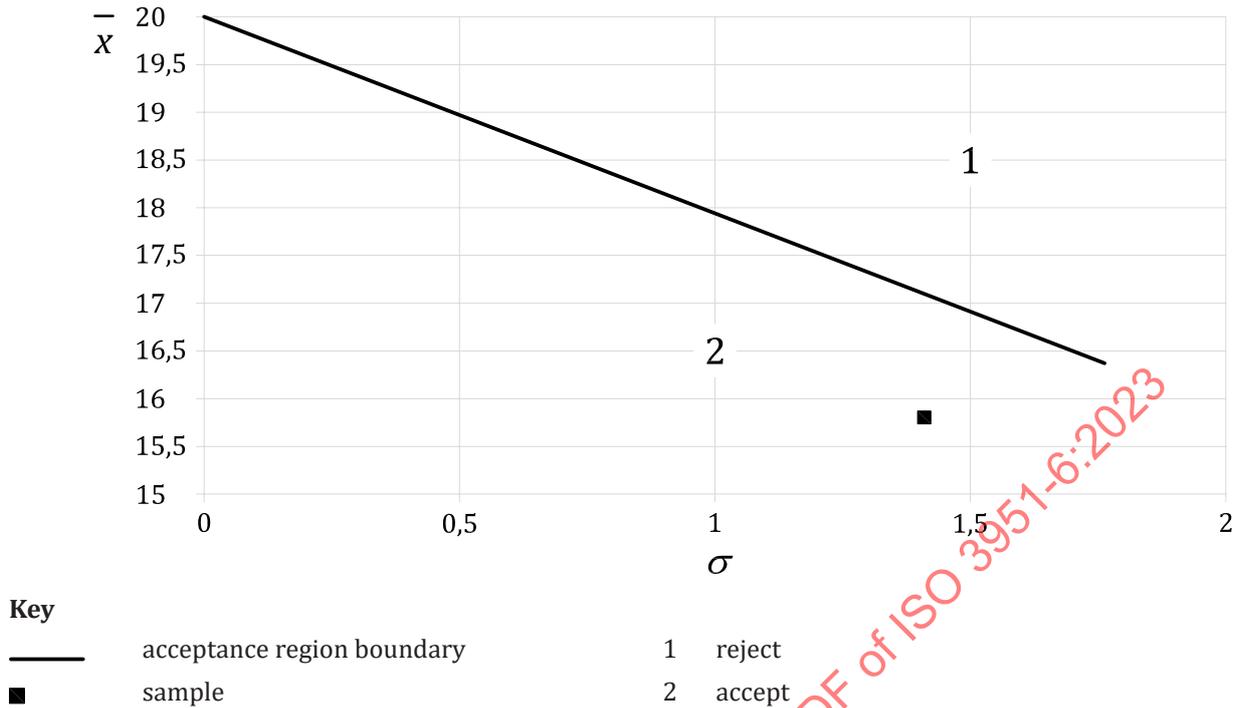


Figure 6 — Example of the use of an acceptance diagram, A-method

EXAMPLE 3 Combined control of double specification limits using the σ -method.

The specification for electrical resistance of a certain electrical component is $(520 \pm 50) \Omega$. Inspection of the 400 items in the lot is done with a single LQ of 12,5 % for the two specification limits (470 Ω and 570 Ω), σ is known to be 18,5 Ω ,

Information needed	Value obtained
Upper specification limit: U	570 Ω
Lower specification limit: L	470 Ω
Factor from Table 3: f_σ	0,264 318
Maximum process standard deviation: $\sigma_{\max} = (U - L) \times f_\sigma$	26,431 8 Ω

It is noted that the known σ of 18,5 Ω is less than the maximum process standard deviation of 26,431 8 Ω so there is evidence that there is a possibility that lots will be accepted so acceptance sampling can be undertaken,

NOTE If $\sigma > \sigma_{\max}$ the lot would be rejected without a sample being taken.

The maximum process standard deviation is, however, not exceeded and a sample is taken.

From Table 4, the sample size of $n = 7$ and an acceptance constant of $k = 1,609 9$ are found

Suppose that the 7 sample values of the resistance, in Ω , are as follows:

532 499 530 512 492 522 488

Conformity with the acceptance criterion is to be determined,

Information needed	Values obtained
Sample size: n	7
Acceptance constant: k	1,609 9
Lower specification limit: L	470 Ω
Upper specification limit: U	570 Ω
Standard deviation: σ	18,5 Ω
Sample mean: $\bar{x} = \sum x / n$	510,714 3 Ω
Lower quality statistic: $Q_L = (\bar{x} - L) / \sigma$	2,200 8
Upper quality statistic: $Q_U = (U - \bar{x}) / \sigma$	3,204 6

Acceptance criterion:

- 1) Is $Q_L \geq k$? Yes (2,200 8 \geq 1,609 9)
- 2) Is $Q_U \geq k$? Yes (3,204 6 \geq 1,609 9)

Both the quality statistics are greater than or equal to the acceptance constant; therefore, the lot is accepted.

Note though that caution is needed if σ is close to the MPSD as when σ is close to the MPSD these acceptance criteria cannot be rearranged to give limits on \bar{x}

13.4 Examples for the p^* -method

EXAMPLE 1 Single upper specification limit using the s-method. Example 1 from [13.2](#).

A certain pyrotechnic delay mechanism has a specified minimum delay time of 4,0 s. The process standard deviation is unknown. Production is inspected in lots of 1 000 items and with an LQ of 3,15 % applied to the lower limit. From [Table 2](#), it is seen that the suitable plan is given by sample size 30 (and acceptance constant $k = 2,331 5$), From [Table 5](#) a p^* value of 7,439 47E-3 is obtained A random sample of size 30 is drawn. Suppose the sample delay times, in seconds, are as follows:

- 5,50 6,95 6,04 6,68 6,63 6,65 6,52 6,59 6,40 6,44 6,34 6,04 6,15 6,29 6,63
- 6,50 6,44 7,15 6,70 6,59 6,51 6,80 5,94 6,35 7,17 6,83 6,25 6,96 7,00 6,38

Conformity with the acceptance criteria based on p^* is to be determined,

Information needed	Values obtained
Sample size: n	30
Form p^* acceptance constant: p^*	7,439 47E-3
Sample mean: $\bar{x} = \sum x / n$	6,514 s

Sample standard deviation

$$s = \sqrt{\sum_j (x_j - \bar{x})^2 / (n-1)} \quad 0,368 \text{ s}$$

Estimated fraction nonconforming

$$\hat{p}_L = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} - \frac{1}{2} \frac{\bar{x} - L}{s} \frac{\sqrt{n}}{n-1}\right\}\right) \quad 0,0$$

Acceptance criterion: Is $\hat{p} \leq p^*$ Yes ($0,0 \leq 7,439 \text{ 47E-3}$)

The sample meets the acceptance criterion; therefore, the lot is accepted.

EXAMPLE 2 Combined control of double specification limits using the s-method. Example 4 from [13.2](#).

Items are being manufactured in lots of size 30. The lower and upper specification limits on their diameters are 82 mm to 83 mm. Items with diameters that are too large are equally unsatisfactory as those with diameters that are too small, and it has been decided to control the total fraction nonconforming using an LQ of 31,5 %. From [Table 2](#), it is seen that the sample size is 6 (and the acceptance constant, k , is 1,313 6). From [Table 5](#) p^* is found to be 8,397 89E-2. The diameters of six items from the first lot are measured, yielding diameters of:

82,4 82,2 83,1 82,3 82,7 83,6 mm

Conformity with the acceptance criterion is to be determined using Form p^* ,

Information needed

Values obtained

Sample size: n

6

Acceptance constant: p^*

8,397 89E-2

Sample mean: $\bar{x} = \sum x / n$

82,716 7 mm

Sample standard deviation:

$$s = \sqrt{\sum_j (x_j - \bar{x})^2 / (n-1)} \quad 0,541 \text{ 9 mm}$$

Lower specification limit: L

82,0 mm

Upper specification limit: U

83,0 mm

Estimated fraction nonconforming

$$\hat{p}_L = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} - \frac{1}{2} \frac{\bar{x} - L}{s} \frac{\sqrt{n}}{n-1}\right\}\right) \quad 8,205 \text{ 76E-2}$$

$$\hat{p}_U = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} - \frac{1}{2} \frac{U - \bar{x}}{s} \frac{\sqrt{n}}{n-1}\right\}\right) \quad 3,121 \text{ 15E-1}$$

$$\hat{p} = \hat{p}_L + \hat{p}_U \quad 3,941 \text{ 73E-1}$$

Acceptance criterion: Is $\hat{p} \leq p^*$ No ($3,94 \text{ 173E-1} > 8,397 \text{ 89E-2}$)

The estimated fraction nonconforming is greater than the acceptance constant; therefore, the lot is rejected.

EXAMPLE 3 Single, upper specification limit using the σ -method. Example 2 from [13.3](#).

The actuation force of a medical inhalation device has to be below the upper specification limit of 20 N in order to guarantee usability, Based on a process validation study, the process standard deviation is assumed to be known at 1,41 N. With average lot size of ~ 200 000 units and an LQ of 3,15 % from [Table 4](#), the sample size of $n = 38$ (and an acceptance constant of $k = 2,059 0$) is found. From [Table 5](#) the corresponding p^* of 1,845 93E-2 is found. The observed measurement values were within a range of 12,41 N to 18,98 N and data normality could be assumed,

Conformity with the p^* acceptance criterion is to be determined,

Information needed	Values obtained
Sample size: n	38
Acceptance constant: p^*	1,845 93E-2
Sample mean: $\bar{x} = \sum x / n$	15,8 N
Known Standard deviation: σ	1,42 N
Upper specification limit: U	20 N
Estimated fraction nonconforming $\hat{p}_U = \Phi\left(\frac{\bar{x} - U}{\sigma} \sqrt{\frac{n}{n-1}}\right)$	1,361 24E-3
Acceptance criterion: Is $\hat{p} \leq p^*$	Yes ($1,361 24E-3 \leq 1,845 93E-2$)

The estimated fraction nonconforming is greater than the acceptance constant; therefore, the lot is accepted.

EXAMPLE 4 Double combined specification limit using the σ -method. Example 3 from [13.3](#).

The specification for electrical resistance of a certain electrical component is $(520 \pm 50) \Omega$. Inspection of the 400 items in the lot is done with a single LQ of 12,5 % for the two specification limits (470 Ω and 570 Ω), σ is known to be 18,5 Ω . The procedure to confirm that sufficiently small to allow a chance of acceptance the same as set out in Example 3 and it is noted that the known σ of 18,5 Ω is less than the MPSD of 26,431 8 Ω so there is evidence that there is a possibility that lots will be accepted so acceptance sampling can be undertaken.

From [Table 4](#), the sample size of $n=7$ (and an acceptance constant of $k = 1,609 9$) are found. From [Table 5](#) a corresponding p^* value of 4,102 99E-2 is obtained.

Suppose that the 7 sample values of the resistance, in Ω , are as follows:

532 499 530 512 492 522 488

Conformity with the acceptance criterion is to be determined,

Information needed	Values obtained
Sample size: n	7
Form p^* acceptance constant: p^*	4,102 99E-2
Lower specification limit: L	470 Ω
Upper specification limit: U	570 Ω
Standard deviation: σ	18,5 Ω
Sample mean: $\bar{x} = \sum x / n$	510,714 3 Ω

Estimated fraction nonconforming

$$\hat{p}_L = \Phi\left(\frac{L - \bar{x}}{\sigma} \sqrt{\frac{n}{n-1}}\right) \quad 8,724\ 52\text{E-}3$$

$$\hat{p}_U = \Phi\left(\frac{\bar{x} - U}{\sigma} \sqrt{\frac{n}{n-1}}\right) \quad 2,686\ 88\text{E-}4$$

$$\hat{p} = \hat{p}_L + \hat{p}_U \quad 8,993\ 21\ \text{E-}3$$

Acceptance criterion: Is $\hat{p} \leq p^*$ Yes (8,993 21E-3 \leq 4,102 99E-2)

The estimated fraction nonconforming is greater than the acceptance constant; therefore, the lot is accepted.

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Annex A (informative)

Procedures for obtaining s and σ

A.1 Procedure for obtaining s

A.1.1 Definition

The observed value of a sample standard deviation is generally denoted by the symbol s . It is defined in [Formula \(A.1\)](#):

$$s = \sqrt{\frac{\sum_{j=1}^n (x_j - \bar{x})^2}{n-1}} \quad (\text{A.1})$$

where

x_j is the value of the quality characteristic of the j th item in a sample of n articles, expressed as a decimal fraction;

\bar{x} is the mean value of the x_j , i.e.

$$\bar{x} = \frac{1}{n} \sum_{j=1}^n x_j \quad (\text{A.2})$$

A.1.2 One-pass formula

[Formula \(A.1\)](#) for s is accurate but requires two passes through the sample data. A number of alternative methods exist and these are analysed in Reference [16] and are described here. An algebraically equivalent formula, which only requires a single pass through the sample data, is given in [Formula \(A.3\)](#):

$$s = \sqrt{\frac{n \sum_{j=1}^n x_j^2 - \left(\sum_{j=1}^n x_j \right)^2}{n(n-1)}} \quad (\text{A.3})$$

A.1.3 Potential numerical inaccuracy

Although [Formula \(A.3\)](#) is well suited for manual calculations it can produce poor results for difficult problems where the variability is very small relative to the mean, i.e. s is very small in comparison with

\bar{x} , Although [Formula \(A.3\)](#) can be improved by subtracting a suitable arbitrary constant, a , from all the values before computing s , i.e.

$$s = \sqrt{\frac{n \sum_{j=1}^n (x_j - a)^2 - \left[\sum_{j=1}^n x_j - a \right]^2}{n(n-1)}} \quad (\text{A.4})$$

it should be noted that there is no generally accepted guidance on how to choose this arbitrary constant and if either of these formulae is used the result may be suspect should s/\bar{x} turn out to be much less than 1.

A.1.4 An updating algorithm for sequential data

Both [Formula \(A.1\)](#) and [Formula \(A.4\)](#) require complete recalculation in situations where additional sample data is to be added to the initial sample, for example in double sampling or sequential sampling. In these situations, an updating algorithm due to West, which makes the sample mean and sample standard deviation at any stage in the updating process and which is almost as accurate as that for [Formula \(A.1\)](#) is preferable:

$$\begin{aligned} M_1 &= x_1, T_1 = 0 \\ M_j &= M_{j-1} + \left(\frac{x_j - M_{j-1}}{j} \right) \quad j = 2, \dots, n \\ T_j &= T_{j-1} + (j-1) \left(\frac{x_j - M_{j-1}}{j} \right)^2 \quad j = 2, \dots, n \\ \bar{x}_j &= M_j \\ s_j &= \sqrt{T_j / (j-1)} \end{aligned} \quad (\text{A.5})$$

A.1.5 Software packages, including spreadsheets

Many software packages, including spreadsheets, have a standard deviation function. Unfortunately, sometimes the sample size, n , is used in the denominator of [Formula \(A.1\)](#) instead of $n - 1$. If it is planned to use a software package, it is important to check that the formula used is equivalent to [Formula \(A.1\)](#). A simple check is to find the standard deviation of the three numbers 0, 1, and 2. The sample size n is 3, the sample mean is 1, the deviations from the mean are -1, 0, and 1, the squares of the deviations are 1, 0, and 1, the sum of squares of the deviations is 2. So from [Formula \(A.1\)](#), one obtains

$$s = \sqrt{\frac{2}{2}} = \sqrt{1} = 1 \quad (\text{A.6})$$

If the software package is erroneously using n instead of $n - 1$ in the denominator, then the result of the calculation is:

$$s = \sqrt{\frac{2}{3}} = 0,816\ 5$$

Use of n in the denominator shall be avoided, for otherwise the acceptance criterion is weakened and any protection to the consumer is lost. The result obtained from the software package shall be scaled by $(n - 1)/n$ to obtain the correct result.

NOTE It is instructive to work through the use of [Formula \(A.3\)](#) for this example. It is found that

$$s = \sqrt{\frac{3 \times (0^2 + 1^2 + 2^2) - (0 + 1 + 2)^2}{3 \times (3 - 1)}} = \sqrt{\frac{3 \times (0 + 1 + 4) - 3^2}{3 \times 2}} = \sqrt{\frac{3 \times 5 - 9}{6}} = \sqrt{\frac{6}{6}} = 1$$

as before.

A.2 Procedure for obtaining σ

A.2.1 Definition

If it appears from the control chart that the value of s is in control, σ can be presumed to be the weighted root mean square of s given by [Formula \(A.7\)](#):

$$\sigma = \sqrt{\frac{\sum_{i=1}^m (n_i - 1) s_i^2}{\sum_{i=1}^m (n_i - 1)}} \quad (\text{A.7})$$

where

m is the number of lots;

n_i is the sample size from the i^{th} lot;

s_i is the sample standard deviation from the i^{th} lot,

A.2.2 Simplification for equal sample sizes

If the sample sizes from each of the lots are equal, then [Formula \(A.7\)](#) simplifies to

$$\sigma = \sqrt{\frac{\sum_{i=1}^m s_i^2}{m}} \quad (\text{A.8})$$

Annex B (normative)

Accommodating measurement error

B.1 General

The master tables of this document, i.e. the tables in [Clause 12](#), are based on the assumption that the true values of the quality characteristic, x , of the items in the lots are normally distributed with an unknown process mean, μ , and either a known or unknown process standard deviation, σ . The assumption is also made that x can be measured without measurement error, i.e. that the measurement of an item with true value, x_i , results in the value x_i . This Annex explains how the tables in [Clause 12](#) can be used when measurement error without bias or with moderate bias is present.

When measurement error is present the measurement of an item with true value, x_i , results in the value y_i , where the difference between y_i and x_i is due to (1) a random error that occurs between repeated measurements performed on presumably identical items in presumably identical circumstances and (2) a systematic error, known as bias, that occurs, for example, when measurements are conducted with different instruments or in different laboratories.

Where bias depends on the sampled item, for example, when different food items are analysed using chemical methods, it is often not possible to correct for the bias completely, although comprehensive calibration procedures are used. As bias varies from laboratory to laboratory or from device to device, it can be considered a random error. Principles of statistical modelling are described in ISO 5725-1.

The standard deviation of the random error within a single device or in a single laboratory is referred to as repeatability standard deviation; whereas the standard deviation across devices or laboratories, i.e. including the bias component, is referred to as the reproducibility standard deviation. Methods for the determination of repeatability and reproducibility standard deviation of a standard measurement method are described in ISO 5725-2 and ISO 5725-3.

Measurement error changes the operating characteristics of the sampling plans (see [B.4.1](#)). The procedures here aim to recover the operating characteristics by increasing the sample size (see [B.4.2](#)) and removing the repeatability standard deviation from the acceptance test when it is known, or can be estimated. Where it is possible to measure items more than once, perform duplicate, or multiple, measurements to estimate the repeatability standard deviation and remove it from the acceptance test (see [B.4.3](#)).

The measurement error could be considered negligible if it has no bias and its standard deviation is such that the required increase in the sample size is not greater than one. For over 80 % of the s -method plans this is equivalent to the standard deviation being less than 10 % of the lot standard deviation. This reduces as the LQ gets smaller and the lot size gets larger, being approximately 4 % for the smallest LQ and the largest lot size, but here the 10 % criterion is used for all LQs and the sampling plans are not adjusted when the standard deviation is less than 10 % of the lot standard deviation.

Bias is more difficult to deal with for two reasons. Firstly, the required sample size grows rapidly as the bias increases to the point where the formula is no longer applicable as it gives infinite sample sizes. Secondly, bias leads to the consumer not having the required LQ protection and it is not feasible to provide simple guidance on how to determine when this is insignificant. For this reason, the sampling plans shall be adjusted when there is any bias.

This Annex addresses four situations, three where there is no bias and the repeatability standard deviation is not negligible and one where there is bias. The three situations where there is no bias are (a) process standard deviation known and non-negligible repeatability standard deviation known (see

B.5), (b) process standard deviation unknown but non-negligible repeatability standard deviation known (see B.6) and (c) process standard deviation unknown and non-negligible repeatability standard deviation unknown (see B.7). The situation where bias is present is (d) process standard deviation unknown but repeatability and reproducibility standard deviations are known (see B.8).

B.2 Statistical model

The measured value of an item with true value, x_i is denoted y_i in the general case of measurement error with bias can be written

$$y_i = x_i + e_i + b \tag{B.1}$$

where

e_i is the random error of the measurement of item i ;

b is the bias, which is constant across all measured items in the sample,

It is assumed that

- x_i is normally distributed with mean μ and variance σ_x^2 ;
- the random error e_i is normally distributed with zero mean and variance σ_e^2 ;
- the bias b is a sample from a normally distribution with zero mean and variance σ_b^2 ;
- measurement error inflates the perceived process variation and is independent of the actual process standard deviation.

The distribution of the sample mean of the n measured values is

$$\bar{y} \sim N\left(\mu, \frac{\sigma_x^2}{n} + \frac{\sigma_e^2}{n} + \sigma_b^2\right) \equiv N\left(\mu, \{1 + \gamma_e^2 + n\gamma_b^2\} \sigma_x^2 / n\right) \tag{B.2}$$

where $\gamma_e = \sigma_e / \sigma_x$ and $\gamma_b = \sigma_b / \sigma_x$.

The distribution of the sample variance of the n measured values, s_y^2 , is

$$s_y^2 \sim (\sigma_x^2 + \sigma_e^2) \frac{\chi^2(n-1)}{n-1}. \tag{B.3}$$

Note that the bias, b , does not affect the sample variance, because it is constant across all measured items in the sample.

B.3 Operating characteristics and the effects of measurement error

The operating characteristic for the s -method with measurement error is given here and the effects of the measurement error is described. The same effects also occur with the σ -method.

The operating characteristic for the s -method with a single specification limit at process fraction nonconforming, p , with measurement error is

$$\begin{aligned}
P_a &= 1 - F_{t(v,\delta)}(t) \\
v &= n - 1 \\
\delta &= K_p \frac{\sqrt{n}}{\sqrt{1 + \gamma_e^2 + n\gamma_b^2}}, \\
t &= k \frac{\sqrt{n}\sqrt{1 + \gamma_e^2}}{\sqrt{1 + \gamma_e^2 + n\gamma_b^2}}
\end{aligned} \tag{B.4}$$

where

- $F_{t(v,\delta)}(\cdot)$ is the distribution function of the non-central t -distribution with v degrees of freedom and noncentrality δ ;
- n is the sample size;
- K_p is the upper p -quantile of the standardized normal distribution;
- k is the s -method acceptance constant,

Note that this is for the case where the sample mean, \bar{y} , and the sample standard deviation, s_y , are used with the s -method. The standard operating characteristic for the s -method, (see [Annex D](#)), is obtained by substituting $\gamma_e = 0$ and $\gamma_b = 0$ in [Formula \(B.4\)](#).

When $\gamma_e > 0$ and $\gamma_b = 0$ the operating characteristic is underneath the standard operating characteristic everywhere, Both the producer's risk quality and the consumer's risk are smaller so the producer is worse off but the consumer still has the required LQ protection.

When $\gamma_e = 0$ and $\gamma_b > 0$ the operating characteristic is underneath the standard operating characteristic at the producer's point but above the standard operating characteristic at the consumer's point. The producer's risk quality is smaller but the consumer's risk is larger so the producer is worse off and the consumer does not have the required LQ protection.

When $\gamma_e > 0$ and $\gamma_b > 0$ the operating characteristic is between the operating characteristic for $\gamma_e > 0, \gamma_b = 0$ and the operating characteristic for $\gamma_e = 0, \gamma_b > 0$.

B.4 General procedures

B.4.1 Negligible repeatability standard deviation

The standard deviation of the mean of a sample of size n , from [\(B.2\)](#) is $\sqrt{(1 + \gamma_e^2 + n\gamma_b^2)} \sigma_x / \sqrt{n}$. If it is known that there is no measurement bias, i.e. $\sigma_b^2 = 0$, and $\gamma_e < 0,1$, the total standard deviation is

$$\sigma_{\bar{y}} < \sqrt{1 + 0,1^2} \sigma_x / \sqrt{n} < 1,005 \sigma_x / \sqrt{n}. \tag{B.5}$$

This is considered negligible and hence, the sampling plans are not adjusted for measurement error.

B.4.2 Increasing the sample size

Formulae showing the derivation of the increased sample size to be used are given here. These apply to both the s -method and the σ -method.

The increased sample size when both repeatability error and bias are present, denoted n_{eb}^* , is chosen so that the variance of the sample mean for the increased sample size is equal to the variance of the sample mean with no measurement error. Hence, it is found by solving [Formula \(B.6\)](#) for n_{eb}^* :

$$\frac{\sigma_x^2 + \sigma_e^2}{n_{eb}^*} + \sigma_b^2 = \frac{\sigma_x^2}{n} \quad (\text{B.6})$$

The solution is given by [Formula \(B.7\)](#):

$$n_{eb}^* = \frac{\sigma_x^2 + \sigma_e^2}{\sigma_x^2/n - \sigma_b^2} = \left(\frac{\sigma_x^2 + \sigma_e^2}{\sigma_x^2 - n\sigma_b^2} \right) n = \left(\frac{1 + \gamma_e^2}{1 - n\gamma_b^2} \right) n. \quad (\text{B.7})$$

Note that as γ_b^2 tends to 1, the increased sample size tends to infinity. Once γ_b^2 reaches 1 there is no sample size that could compensate for the increased variability.

When bias is not present this simplifies to

$$n_e^* = (1 + \gamma_e^2) n \quad (\text{B.8})$$

For both formulae the sample size must be an integer and larger than the original sample size so, in order to provide at least the required LQ protection, n^* is rounded up to the next integer.

Approximate operating characteristics can be derived by substituting n^* from [Formula \(B.7\)](#) into [Formula \(B.4\)](#). This produces

$$\begin{aligned} P_a &= 1 - F_{t(v,\delta)}(t) \\ v &= n - 1 \\ \delta &= K_p \sqrt{n} \\ t &= k \sqrt{n} \sqrt{1 + \gamma_e^2} \end{aligned} \quad (\text{B.9})$$

Where $F_{t(v,\delta)}(\cdot)$, n , K_p and k are as before. The only difference between this operation characteristic and the standard one is the presence of $\sqrt{1 + \gamma_e^2}$ in the expression for t . Hence, the probability of acceptance, P_a is reduced. Rounding n^* up helps to keep the reduction small and in many cases the resulting operating characteristic is almost equivalent to the standard one.

However, there is a difference when tests are carried out, as sample statistics will contain the mean of the repeatability errors. Although it has an expected value of zero, it varies from sample to sample and will add variability to the individual acceptance tests.

B.4.3 Estimation of the measurement and process and standard deviations when both are unknown

Where it is possible to measure items more than once, perform duplicate, or multiple, measurements to estimate the repeatability standard deviation and remove it from the acceptance test. When there is no bias this allows the process standard deviations to be estimated.

The j th measurement on the i th item is denoted by y_{ij} , the mean for the i th item by \bar{y}_i , and the overall mean by $\bar{y}_{..}$. The number of measurements for the i th item is denoted by m . The total sum of squares of the measurements about their overall mean can be partitioned as follows:

$$\sum_{i=1}^n \sum_{j=1}^m (y_{ij} - \bar{y}_{..})^2 = \sum_{i=1}^n \sum_{j=1}^m (y_{ij} - \bar{y}_i)^2 + m \sum_{i=1}^n (\bar{y}_i - \bar{y}_{..})^2$$

Which can be written as $SS_T = SS_W + SS_B$, where SS_W is the within-items sum of squares and SS_B is the between-items sum of squares. The expectations of these sums of squares are

$$E(SS_W) = n(m-1)\sigma_e^2 = v_W \sigma_e^2$$

$$E(SS_B) = (n-1)\sigma_e^2 + m(n-1)\sigma_x^2 = v_B \sigma_e^2 + m v_B \sigma_x^2$$

where

$$v_W = n(m-1) \quad \text{is the degrees of freedom in } SS_W$$

$$v_B = (n-1) \quad \text{is the degrees of freedom in } SS_B.$$

Hence, σ_e^2 , and σ_x^2 can be estimated by

$$s_e^2 = \frac{SS_W}{v_W}$$

$$s_x^2 = \frac{1}{m} \left(\frac{SS_B}{v_B} - \frac{SS_W}{v_W} \right).$$

(B.10)

Note that if an analysis of variance (ANOVA) calculation is used the ANOVA table contains

	SS	ν	MS = SS/ ν
between items	B	$n-1$	$B/(n-1)$
within items	W	$n(m-1)$	$W/\{n(m-1)\}$
total	T	$mn-1$	$T/(mn-1)$

and the estimates may be written in terms of the mean squares

$$s_e^2 = MS_W = \frac{W}{v_W}$$

$$s_x^2 = \frac{1}{m} MS_B - \frac{1}{m} MS_W$$

(B.11)

Because s_e^2 is estimated as the weighted difference between mean squares, the distribution of s_e^2/σ_e^2 is not chi-squared and the true operating characteristic is no longer based on a noncentral t distribution. Reference [29] gives an approximate operating characteristic based on a normal approximation, whilst Reference [30] shows how an approximate noncentral t distribution can be derived.

A comparison of the two different approaches has not been investigated so initially the process in this document uses the estimate based on the weighted difference between the mean squares. It is expected that the results obtained are better than simply taking one measurement for each item and using the process in [Clause 6](#) with sample mean, $\bar{x} = \bar{y}$, and an estimate of the total standard deviation, $s = s_y$.

As when the repeatability error is known the effect the sample statistics will contain the mean of the repeatability errors and this will add variability to the individual acceptance tests.

B.5 No bias, process standard deviation σ_x known and non-negligible repeatability standard deviation σ_e known

Use [Formula \(B.8\)](#) to determine the increased sample size, $n^* = n_e^* = (1 + \gamma_e^2)n$. Follow the standard procedures for the σ -method in [Clause 7](#) with the increased sample size but do not alter the form k acceptance constant or the form p* acceptance constant. Use sample mean, $\bar{x} = \bar{y}$, and process standard deviation, $\sigma = \sigma_x$.

change the operating characteristic so that it is not based on the noncentral t distribution and add the sample mean of the errors, \bar{e} , to one of the terms in it. The precise effect of these changes has not been investigated but, as the expected value of the sample mean of the errors is zero it is expected that the results obtained are better than simply taking one measurement for each item and using the process in [Clause 6](#) with sample mean, $\bar{x} = \bar{y}$, and an estimate of the total standard deviation, $s = s_y$.

B.6 No bias, process standard deviation σ_x unknown but repeatability standard deviation σ_e known

Use [Formula \(B.8\)](#) to determine the increased sample size, $n^* = n_e^* = (1 + \hat{\gamma}_e^2)n$, where $\hat{\gamma}_e$ is an estimated upper bound of $\gamma_e = \sigma_e / \sigma_x$. Follow the standard procedures for the s-method in [Clause 6](#) with the increased sample size but do not alter the form k acceptance constant. Use sample mean, $\bar{x} = \bar{y}$, and an estimate of the process standard deviation, $s = s_x$, given by

$$s_x = \sqrt{s_y^2 - \sigma_e^2} . \tag{B.12}$$

If $s_x < 0$, use $s_x = 0$.

B.7 No bias, process standard deviation σ_x unknown and repeatability standard deviation σ_e unknown

Use [Formula \(B.8\)](#) to determine the increased sample size, $n^* = n_e^* = (1 + \hat{\gamma}_e^2)n$, where $\hat{\gamma}_e$ is an estimated upper bound of $\gamma_e = \sigma_e / \sigma_x$. Perform duplicate (or multiple) measurements on each sampled item, and use the measurement results to estimate the process standard deviation separately from the measurement standard deviation, as shown in [B.4.3](#).

Follow the standard procedures for the s-method in [Clause 6](#) but do not alter the form k acceptance constant. Use sample mean, $\bar{x} = \bar{y}$, and an estimate of the process standard deviation, $s = s_x$, from either [formula \(B.9\)](#) or [\(B.10\)](#).

B.7.1 Example

A manufactured component has a dimension with an upper specification limit of 13,05 cm. The process standard deviation, σ_x , and repeatability standard deviation, σ_e , are unknown, but from previous experience, it is known that the ratio $\gamma_e = \sigma_e / \sigma_x$ is greater than 0,1 but less than 0,2. It is also known that there is no measurement bias. A lot of size 800 of these components is to be inspected with an LQ of 8 %. From [Table 2](#), it is found that the sampling plan in the absence of sampling error has sample size $n = 23$ and form k acceptance constant, $k = 1,886 2$. As γ_e exceeds 0,1, it is necessary to adjust the sample size to allow for measurement uncertainty. In the presence of the worst conceivable measurement error, the appropriate sample size (from [Formula B.8](#)) is given by

$$n^* = n_e^* = (1 + 0,2^2) 23 = 23,92 .$$

NOTE The sample size must be an integer and larger than the original sample size so, in order to provide at least the required LQ protection, n^* is rounded up to 24.

A random sample of 24 of the components is taken from the lot, and, in order to be able to assess the measurement uncertainty, each component is measured twice. The results for the sample from the first lot are as follows:

i	x_{i1}	x_{i2}									
1	12,997 2	12,999 7	7	13,023 1	13,021 9	13	12,962 1	12,956 2	19	12,957 8	12,952 7
2	12,984 8	12,973 1	8	12,993 0	12,993 7	14	12,986 7	12,988 6	20	12,976 5	12,967 4
3	12,964 6	12,963 0	9	12,958 9	12,943 9	15	13,008 3	13,007 1	21	12,999 1	13,001 0
4	12,954 3	12,953 9	10	12,958 9	12,952 4	16	12,978 7	12,978 7	22	13,002 9	13,006 7
5	12,976 3	12,980 2	11	13,015 0	13,016 4	17	12,927 4	12,927 4	23	12,968 8	12,976 2
6	12,999 3	13,000 9	12	12,994 5	13,003 4	18	12,962 5	12,965 1	24	12,985 2	12,986 5

An ANOVA calculation produces the table

	SS	ν	$MS = SS/\nu$
between items (B)	0,025 571 160	23	0,001 111 789 565
within items (W)	0,000 371 960	24	0,000 015 498 333
total (T)	0,025 943 120	47	0,000 551 981 277

The estimates of the variances of measurement error, process variances and the sample standard deviation for the acceptance tests are:

$$s_e^2 = 0,000 015 498 333$$

$$s_x^2 = (0,001 111 789 565 - 0,000 015 498 333)/2$$

$$= 0,000 548 145 616$$

$$s_x = 0,023 412 509 817$$

The quality statistic is:

$$Q_U = \frac{13,05 - 12,980 25}{0,023 412 509 817} = 2,979 176$$

The quality statistic is greater than the acceptance constant; 1,886 2, therefore, the lot is accepted.

B.8 Bias, process standard deviation σ_x unknown but repeatability standard deviation σ_e and bias standard deviation σ_b known

Use [Formula \(B.7\)](#) to determine the increased sample size, $n^* = n_{eb}^* = \left\{ \frac{(1 + \gamma_e^2)}{1 - n \gamma_b^2} \right\} n$. Follow the standard procedures for the s-method in [Clause 6](#) with the increased sample size but do not alter the form k acceptance constant. Use sample mean, $\bar{x} = \bar{y}$, and an estimate of the process standard deviation, $s = s_x$, given by

$$s_x = \sqrt{s_y^2 - \sigma_e^2 - n^* \sigma_b^2} \tag{B.13}$$

If $s_x < 0$, use $s_x = 0$.

Here the effect of the repeatability error is to add the sample mean of the errors, \bar{e} , and the sample bias, b , to the noncentrality of the noncentral t distribution, which will add variability to the individual acceptance tests.

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Annex C (informative)

Sampling strategies

The sampling strategy is an important part of statistical sampling. [Figure C.1](#) illustrates how the n sample units are obtained from the lot.

For industrial applications, the following sampling strategies can be differentiated.

- (Simple) Random sampling (SRS) - Each item in the lot has the same probability to be selected for the sample.
- Convenience sampling (CS) - Items that are most convenient and easy to select are taken.
- Systematic sampling (SyS) - The items in the sample are systematically (by time, number, etc) spread over the lot.
- Stratified sampling (StS) - The lot is divided into sub lots (strata) from which (random) samples are taken. Usually sub lots and sub lot samples have equal size, but also different sizes of sub lots and/or samples are feasible.
- Cluster sampling (ClS) - The lot is divided into sub lots (cluster) from which (randomly) sub lots are selected. For these selected sub lots all items are sampled (100 % inspection).

The drawings in [Figure C.1](#) illustrate the different sampling strategies for a two-dimensional population, e.g, tablets spread open for a drying process.

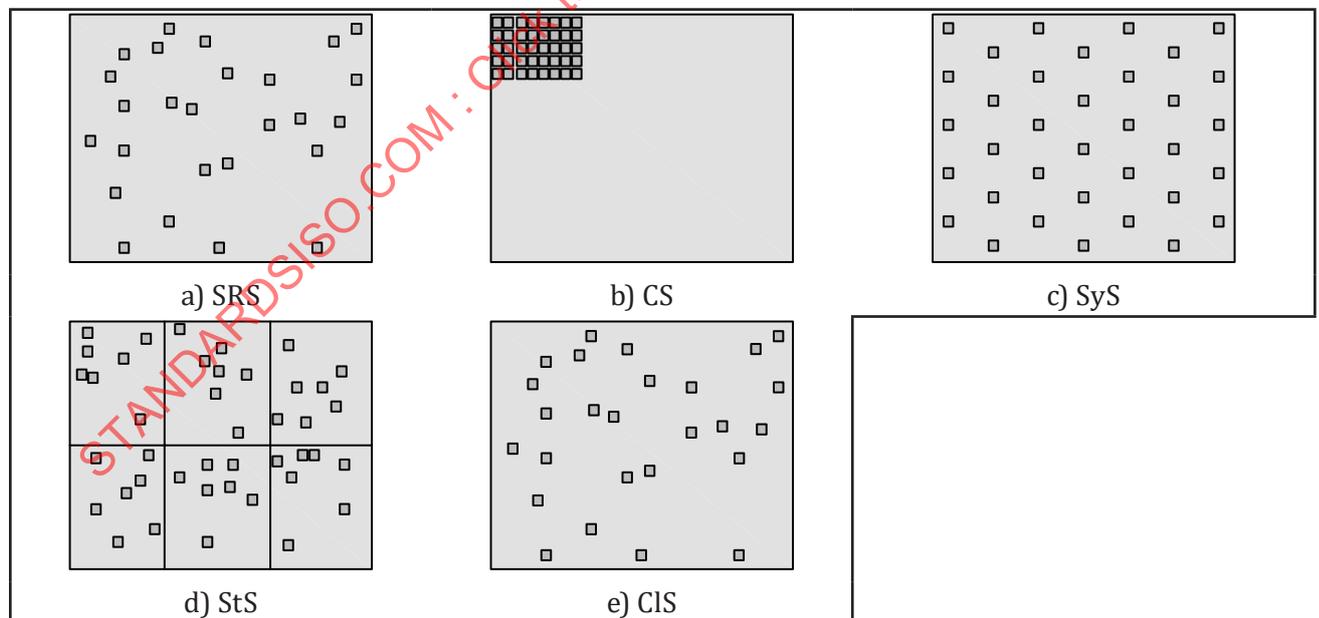


Figure C.1 — Examples of sample strategies for a two-dimensional population

Generally, there is no statistical guidance on which sampling strategy is superior to the others. Some statistical comparisons of different sampling strategies can be found in Reference [17]. However, this standard and associated probabilities does assume that random sampling is being used no matter which sampling strategy is selected. There is risk for the validity of the results if convenience (biased) sampling is used.

ISO 2859-4:2020 specifies: “The items selected for the sample shall be drawn from the lot by simple random sampling However, when the lot consists of sub-lots or strata, identified by some rational criterion, stratified sampling shall be used in such way that the size of the subsample from each subplot or stratum is proportional to the size of that subplot or stratum”.

Under general conditions, i.e. if there are no technically or practically founded assumptions on the existence of specific nonconformity patterns, a sampling strategy, including a systematic as well as a random component, yields satisfactory results in most practical applications.

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Annex D (informative)

Operating characteristics for the *s*-method

D.1 The probability of acceptance for a single specification limit

The exact probability of lot acceptance for a single specification limit at process fraction nonconforming, p , when the process standard deviation is unknown is given by [Formula \(D.1\)](#):

$$P_a = 1 - F_{t(n-1, K_p \sqrt{n})}(k\sqrt{n}) \quad (\text{D.1})$$

where

$F_{t(v, \delta)}(\cdot)$ is the distribution function of the non-central t-distribution with v degrees of freedom and noncentrality δ ;

n is the sample size;

K_p is the upper p -quantile of the standardized normal distribution;

k is the *s*-method acceptance constant,

D.2 Example

Consider the calculation of the probability of acceptance at a process quality of 0,5 % nonconforming for an *s*-method plan with an LQ of 1,25 % and a lot size of 1 000 items. Entering [Table 2](#) with lot size 1 000 and LQ of 0,012 50, it is found that the sample size, n , is 38 and the acceptance constant, k , is 2,715 5. The process fraction nonconforming under consideration is $p = 0,005 0$, and $K_p = -2,575 8$. Hence,

$$P_a = 1 - F_{t(37; 2,5758\sqrt{38})}(2,7155\sqrt{38}) = 1 - F_{t(37; 15,8783)}(16,7395) = 1 - 0,6294 = 0,3706.$$

D.3 The probability of acceptance for double specification limits

The probability of lot acceptance for double specification limits depends on the location of the true standard deviation in the acceptance region. When the true standard deviation is outside the curved nose of the acceptance region the probability of lot acceptance for double specification limits is the same as that for a single specification limit. Otherwise, the probability of lot acceptance double specification limits is approximated by the exact probability of lot acceptance for a single specification limit, with the approximation becoming less accurate as the standard deviation increases.

D.4 Operating characteristics

Using the underlying software, the user can create the OC curve, i.e. a plot of the acceptance probability, P_a , versus the process fraction nonconforming, p , and can create tables of $p(P_a)$ (see [I.3](#)).

Annex E (informative)

Operating characteristics for the σ -method

E.1 The probability of acceptance for a single specification limit

The exact probability of lot acceptance for a single specification limit at process fraction nonconforming, p , when the process standard deviation is known is given by [Formula \(E.1\)](#):

$$P_a = 1 - \Phi\left[\frac{(k - K_p)\sqrt{n}}{\sigma}\right] \quad (\text{E.1})$$

where

$\Phi(\cdot)$ is the distribution function of the standardized normal distribution;

n is the sample size;

K_p is the upper p -quantile of the standardized normal distribution;

k is the σ -method acceptance constant,

E.2 Example

Consider the calculation of the probability of acceptance at a process quality of 0,5 % nonconforming for a σ -method plan with an LQ of 0,012 50 and a lot size of 1 000 items. Entering [Table 4](#) with lot size 1 000 and LQ of 1,25 %, it is found that the sample size, n , is 8 and the acceptance constant, k , is 2,667 6. The process fraction nonconforming under consideration is $p = 0,005 0$, and $K_p = -2,575 8$. Hence,

$$P_a = 1 - \Phi\left[\frac{(2,667 6 - (-2,575 8))\sqrt{8}}{\sigma}\right] = 1 - \Phi[0,259 6] = 1 - 0,602 4 = 0,397 6.$$

E.3 The probability of acceptance for double specification limits

The probability of lot acceptance for double specification limits depends on the location of the true standard deviation in the acceptance region. When the true standard deviation is outside the curved nose of the acceptance region the probability of lot acceptance for double specification limits is the same as that for a single specification limit. Otherwise, the probability of lot acceptance double specification limits is approximated by the exact probability of lot acceptance for a single specification limit, with the approximation becoming less accurate as the standard deviation increases.

E.4 Operating characteristics

Using the underlying software, the user can create the OC curve, i.e. a plot of the acceptance probability, P_a , versus the process fraction nonconforming, p , and can create tables of $P_a(p)$ and $p(P_a)$ (see [L.3](#)).

Annex F (informative)

Consumer's risks

F.1 General

The consumer's risk is the probability of accepting a given lot when the fraction nonconforming is equal to the LQ. When the true standard deviation is outside the curved nose of the acceptance region the consumer's risk for double specification limits is the same as that for a single specification limit. Otherwise, the consumer's risk is approximated by the exact consumer's risk for a single specification limit, with the approximation becoming less accurate as the standard deviation increases.

F.2 The consumer's risk for the *s*-method plans

For the *s*-method, the consumer's risk is given by [Formula \(F.1\)](#):

$$P_a = 1 - F_{t(n-1, K_{LQ} \sqrt{n})}(k \sqrt{n}) \quad (\text{F.1})$$

where

- $F_{t(v, \delta)}(\cdot)$ is the distribution function of the non-central t-distribution with v degrees of freedom and noncentrality δ ;
- n is the sample size;
- K_p is the upper p -quantile of the standardized normal distribution;
- k is the *s*-method acceptance constant,

F.3 The consumer's risk for the σ -method plans

For the σ -method, the consumer's risk quality is given by [Formula \(F.2\)](#):

$$P_a = 1 - \Phi\left[\frac{(k - K_{LQ})\sqrt{n}}{\sigma}\right] \quad (\text{F.2})$$

where

- $\Phi(\cdot)$ is the distribution function of the standardized normal distribution;
- n is the sample size;
- K_p is the upper p -quantile of the standardized normal distribution;
- k is the σ -method acceptance constant,

Annex G (informative)

Producer's risk quality

G.1 General

The producer's risk quality is the quality for which the probability of not accepting a given lot is 5 %. When the true standard deviation is outside the curved nose of the acceptance region the producer's risk quality for double specification limits is the same as that for a single specification limit. Otherwise, the producer's risk quality is approximated by the producer's risk quality for a single specification limit, with the approximation becoming less accurate as the standard deviation increases.

G.2 The producer's risk quality for the s -method plans

For the s -method, the exact producer's risk quality for a single specification limit is the solution in p for [Formula \(G.1\)](#):

$$1 - P_a = F_{t(n-1, K_p \sqrt{n})}(k\sqrt{n}) = 0,05 \quad (\text{G.1})$$

where

- $F_{t(v, \delta)}(\cdot)$ is the distribution function of the non-central t -distribution with v degrees of freedom and noncentrality δ ;
- n is the sample size;
- K_p is the upper p -quantile of the standardized normal distribution;
- k is the s -method acceptance constant,

G.3 The producer's risk quality for the σ -method plans

For the σ -method, the exact producer's risk quality for a single specification limit is the solution in p for [Formula \(G.2\)](#):

$$1 - P_a = \Phi\left[\frac{(k - K_p)\sqrt{n}}{\sigma}\right] = 0,05 \quad (\text{G.2})$$

The solution is given by [Formula \(G.3\)](#):

$$p = 1 - \Phi\left[\frac{k - K_{0,95}}{\sigma/\sqrt{n}}\right] = 1 - \Phi\left[\frac{k + 1,644854}{\sigma/\sqrt{n}}\right] \quad (\text{G.3})$$

where

- $\Phi(\cdot)$ is the distribution function of the standardized normal distribution;
- n is the sample size;
- K_p is the upper p -quantile of the standardized normal distribution;
- k is the σ -method acceptance constant,

Annex H (informative)

Construction of acceptance diagrams for double specification limits

H.1 General

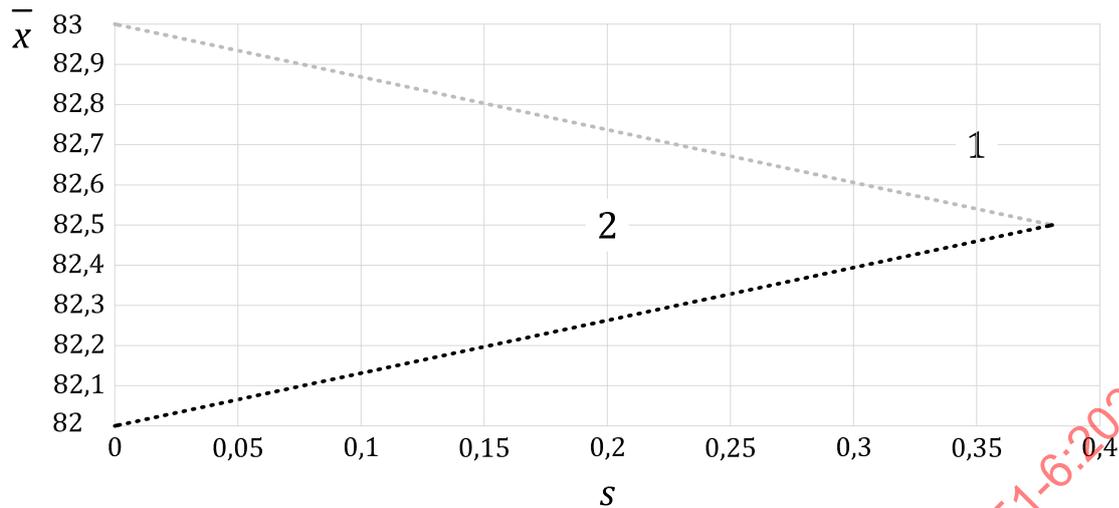
Earlier standards on acceptance sampling contained standardized acceptance diagrams for combined control of double specification limits. A realization that most users would want to have the particular acceptance curves they need to use in an unstandardized form with the specification limits relevant to their application, perhaps presented in a document to be agreed with the responsible authority and perhaps supported by a spreadsheet to calculate results and plot results has led to a decision not to include these standardized curves in this document. It was decided that a software package to support use of the standard generally (see [Annex I](#)) and guidance on how acceptance diagrams are drawn in this Annex would be provided.

H.2 *s*-method acceptance diagrams for double specification limits under separate control

It is instructive to start with an acceptance diagram for double specification limits under separate control. If the same LQ is applied to both limits, then the sample size n and acceptance constant k will be the same for both limits. The acceptance region is the union of the acceptance regions for the lower and upper specification limits and can be constructed by drawing the lines

$$\bar{x} = L + ks \quad \text{and} \quad \bar{x} = U - ks$$

from $s = 0$ to their intersection at $s = (U - L)/(2k)$. Using the same sampling plan as [13.2](#) Example 4, i.e. $U = 83$ mm, $L = 82$ mm, $n = 6$ and $k = 1,313 6$ we obtain the diagram below in [Figure H.1](#).



Key

-----	$\bar{x} = L + ks$	1	reject
.....	$\bar{x} = U - ks$	2	accept

Figure H.1 — acceptance region, s-method, separate control

This standard presents sampling plans in two ways: the k method and the p^* method with equivalent acceptance criteria.

$$Q = \frac{\bar{x} - L}{s} \geq k \text{ or } \hat{p}_L \leq p^* \text{ and } Q = \frac{U - \bar{x}}{s} \geq k \text{ or } \hat{p}_U \leq p^*$$

Note that Q is the slope of a line from the specification limits through \bar{x}, s and k is the slope of the acceptance boundary lines so the acceptance criteria can be thought of in terms of slopes; if Q is steeper than k accept otherwise reject.

H.3 s-method acceptance diagrams for double specification limits under combined control

The equivalence between the k and p^* methods is provided by the formulae at [Clause 8 d\) 1\)](#)

$$\hat{p}_L = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} - \frac{1}{2} \frac{\bar{x} - L}{s} \frac{\sqrt{n}}{n-1}\right\}\right) \tag{H.1}$$

$$\hat{p}_U = F_{BETA\left(\frac{n}{2}-1, \frac{n}{2}-1\right)}\left(\max\left\{0, \frac{1}{2} - \frac{1}{2} \frac{U - \bar{x}}{s} \frac{\sqrt{n}}{n-1}\right\}\right) \tag{H.2}$$

If $(\bar{x} - L)/s$ is set to k in [Formula \(H.1\)](#) then the formula will yield $\hat{p}_L = p^*$ similarly if $(U - \bar{x})/s$ in [Formula \(H.2\)](#) is set to k then the formula will yield $\hat{p}_U = p^*$. This means that for separate control all along the lower acceptance boundary $\hat{p}_L = p^*$ and all along the upper acceptance boundary $\hat{p}_U = p^*$,

At the apex $\hat{p}_L + \hat{p}_U = 2p^*$ but this is alright because each specification limit is under separate control. The relationship between k and \hat{p} is obtained by inverting these cases:

$$k(n, \hat{p}) = \frac{n-1}{\sqrt{n}} \left\{ 1 - 2 F_{BETA}^{-1} \left(\frac{n}{2} - 1, \frac{n}{2} - 1 \right) (\hat{p}) \right\} \quad (H.3)$$

Although in principle the beta distribution has an infinite interval $[-\infty, \infty]$ in practice by limiting $\varepsilon/4 \leq \hat{p} \leq 1 - \varepsilon/4$, where ε is the smallest value such that $1,0 + \varepsilon > 1,0$ in computer arithmetic and $\hat{p} = \varepsilon/4$ should be used when use $\hat{p} = 0$. This limits the normal distribution to approximately $(-8, 29, 8, 29)$.

Although in principle the beta distribution has an infinite $[0, 1]$ in practice it should be limited by limiting $\varepsilon/4 \leq \hat{p} \leq 1 - \varepsilon/4$, where ε is the smallest value such that $1,0 + \varepsilon > 1,0$ in computer arithmetic. When $\hat{p} = 0$ you should use $\hat{p} = \varepsilon/4$ and this ensures that it is numerically symmetric.

Suppose now it is decided to put both specification limits under combined control and the acceptance criterion becomes $\hat{p}_L + \hat{p}_U \leq p^*$. It is clear that the triangular acceptance region we had under separate control has to be adjusted to exclude a region where the combined control acceptance criterion is not met. This is done by using the relationship in [Formula \(H.3\)](#) to construct pairs of lines representing \hat{p}_L and $\hat{p}_U = p^* - \hat{p}_L$

$$\bar{x} = L + k(n, \hat{p}_L) s \equiv L + k_L s \text{ and } \bar{x} = U - k(n, p^* - \hat{p}_L) s \equiv U - k_U s$$

The intersections of these pairs of lines are points (s, \bar{x}) on the acceptance region boundary with $\hat{p} = \hat{p}_L + \hat{p}_U = p^*$ where

$$s = \frac{U - L}{k_U + k_L} \quad (H.4)$$

$$\bar{x} = \frac{U k_L + L k_U}{k_U + k_L}$$

This is illustrated in [Figure H.2](#) where three lines for $\hat{p}_L = 0, p^*/4, p^*/2$ corresponding to $\hat{p}_U = p^*, 3p^*/4, p^*/2$ have been added. Note that the value of s where p^* is shared equally between \hat{p}_L and \hat{p}_U defines the maximum sample standard deviation (MSSD) that was used in previous issues of this document in preliminary screening for unacceptable samples.

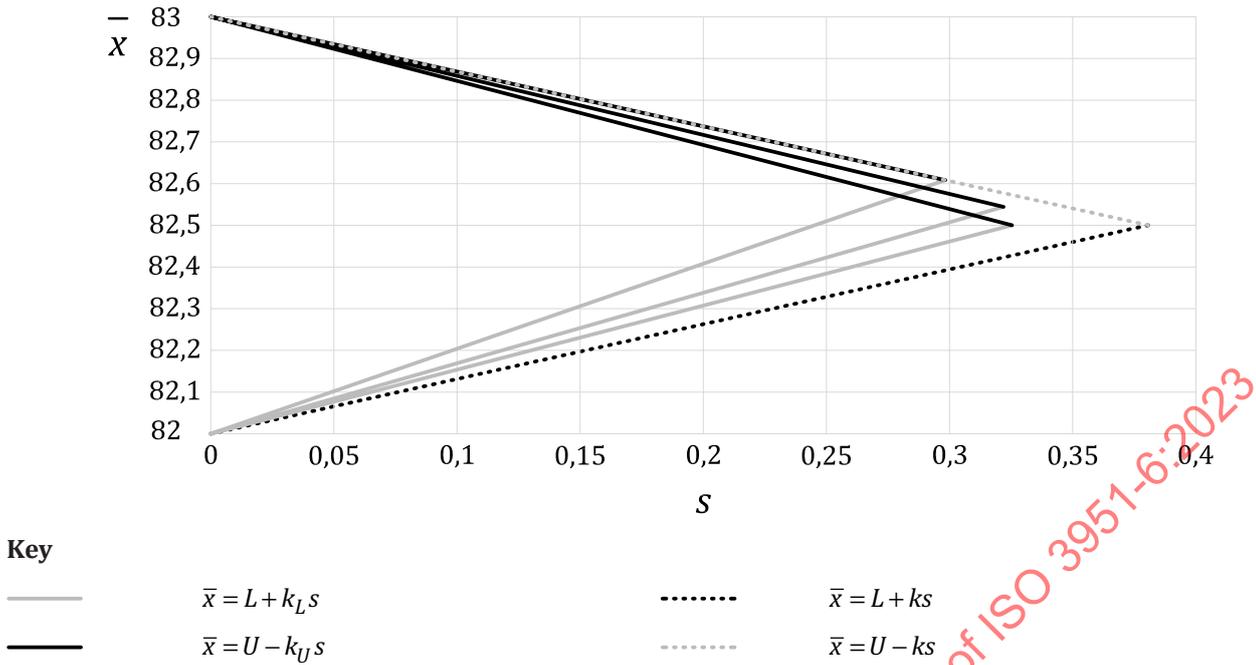


Figure H.2 — acceptance region, s-method, combined control – construction lines
 $\hat{p}_L = 0, p^* / 4, p^* / 2$ and $\hat{p}_U = p^*, 3 p^* / 4, p^* / 2$

The acceptance region for double specification limits under combined control is the union over $0 \leq \hat{p}_L \leq p^*$ of the triangular regions enclosed by the construction lines and the \bar{x} axis. The boundary of this region is the locus over $0 \leq \hat{p}_L \leq p^*$ of the points (s, \bar{x}) . This is illustrated in [Figure H.3](#) where the acceptance region boundary has been added. Note that the horizontal scale has been adjusted.

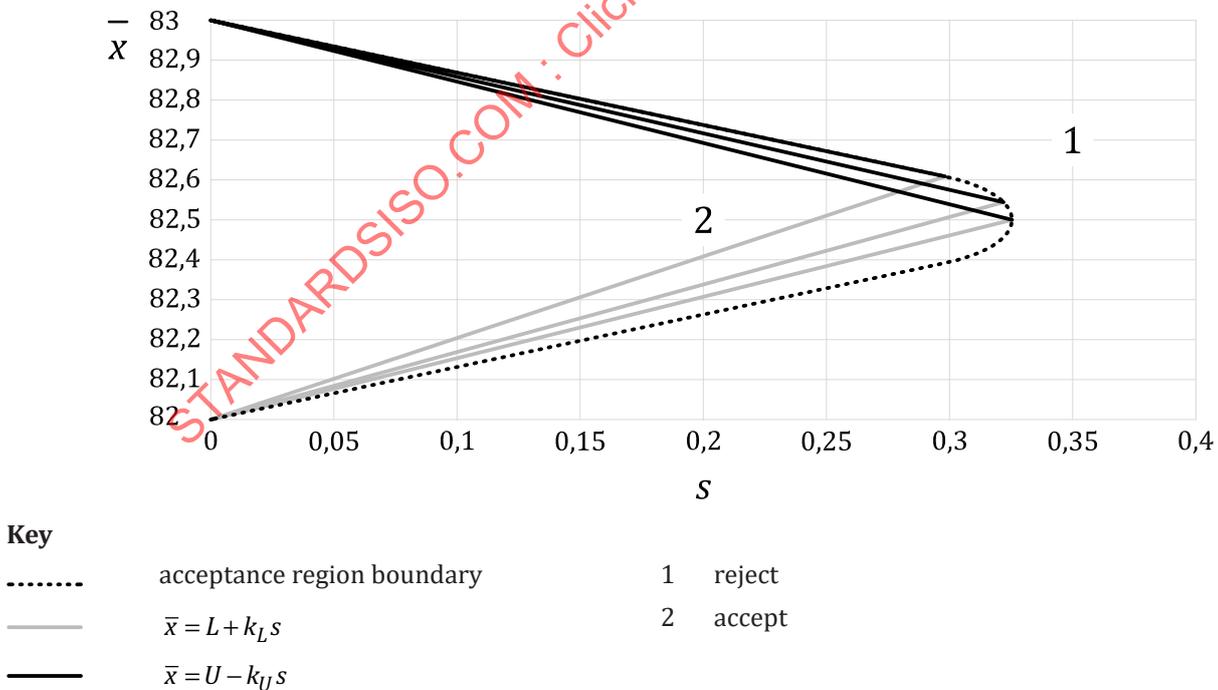


Figure H.3 — acceptance region, s-method, combined control with construction lines
 $\hat{p}_L = 0, p^* / 4, p^* / 2$ and $\hat{p}_U = p^*, 3 p^* / 4, p^* / 2$

The acceptance diagram can be completed as shown in [Figure H.4](#) by removing the construction lines and the sample mean and sample standard deviation for the data in the example can be plotted. The sample mean and sample standard deviation are outside the acceptance region; therefore, the lot is rejected.

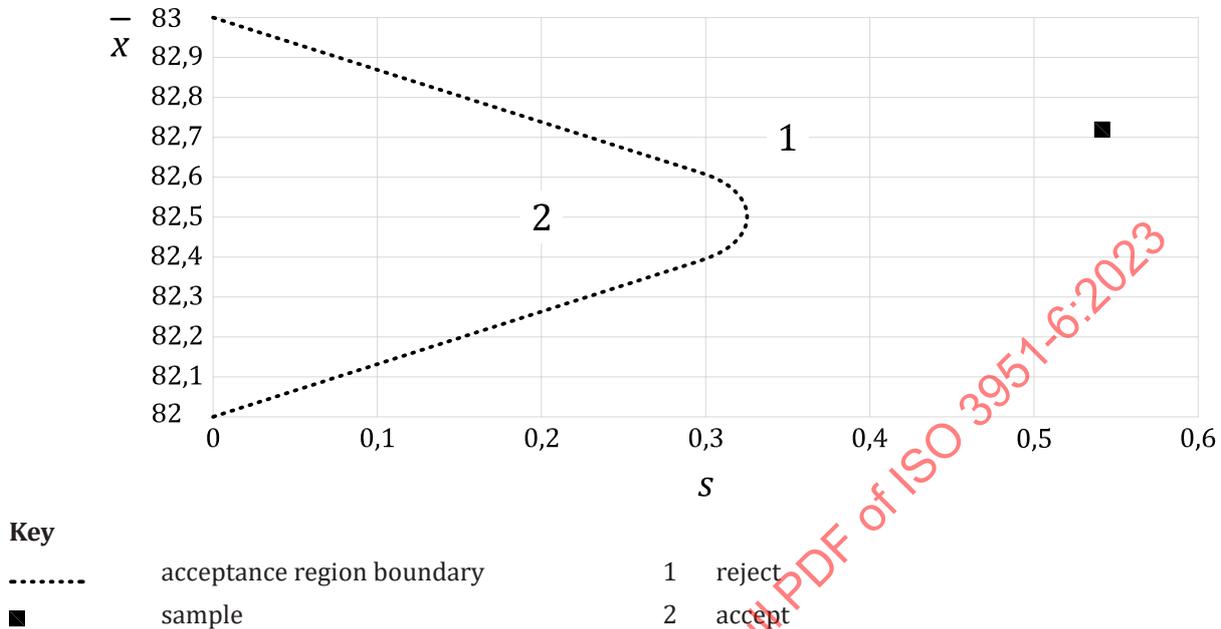


Figure H.4 — acceptance region, s -method, combined control with sample mean and standard deviation

H.4 σ -method – determination of combined specification limits acceptance criteria

The first step in setting up any σ -method sampling scheme is to establish a value of the process standard deviation that can be considered to be known. See [5.3](#). This is best done by collecting data over time, maybe whilst using the s -method, and using Statistical Process Control (see References [\[9\]](#) and [\[10\]](#)) to assess whether this assumption can be justified. If the standard deviation is under control, i.e. there is no more variation in it than can be explained by sampling variation, then an estimate of the process standard deviation can be made (see [Annex A](#)).

Next, for the use of combined specification limits the question of process capability arises i.e. is the estimated process standard deviation sufficiently small to allow for the possibility, but not the certainty of lots drawn from the process being acceptable.

This uncertainty arises from the possibility that the means of lots may be too high or too low to allow acceptance. [Table 4](#) gives values f_σ for Maximum Process Standard Deviation (MPSD) to help make this determination, e.g. in 13.2 Example 2 the lot size is 400 and the LQ is 12,5 % and the specification limits are $520 \pm 50 \Omega$. Entering [Table 4](#) with these values gives $f_\sigma = 0,264\ 318$ and multiplying this by $U - L = 100$ gives 26,431 8 Ω as a MPSD.

Since the known value of sigma given in the example is 18,5 Ω it is concluded that there is the possibility of lots being acceptable. Acceptance sampling using the σ -method can therefore begin,

The calculation of the MSSD relevant to the s -method is described earlier and defines the maximum point on the acceptance region for an s -method combined double specification limit acceptance region. In ISO 3951-1:2022, H.4, it is emphasised that the calculation of the MPSD in that standard is quite different and it does not define the maximum point on an acceptance diagram in the same way. However, this does not hold in this standard which is indexed by limiting quality (LQ) rather than the acceptance quality limit. If the larger LQ is used in those calculations a MPSD larger than the maximum

point on the acceptance diagram results and the acceptance diagram will not be truncated so the MPSD for this document is the maximum point on the σ -method combined control acceptance region.

It is not necessary to draw an acceptance diagram to determine σ -method acceptance criteria but may be useful to determine actions to adjust a process where the sample is close to being rejected. The acceptance region is constructed in the same way as that for the s -method except the equivalence between the k -method and p^* -method is provided by the formulae at [Clause 8 d\) 2\)](#):

$$\hat{p}_L = \Phi \left(\frac{L - \bar{x}}{\sigma} \sqrt{\frac{n}{n-1}} \right) \tag{H.5}$$

$$\hat{p}_U = \Phi \left(\frac{\bar{x} - U}{\sigma} \sqrt{\frac{n}{n-1}} \right) \tag{H.6}$$

and the relationship between k and p^* is obtained by inverting these:

$$k(n, \hat{p}) = -\Phi^{-1}(\hat{p}) \sqrt{\frac{n-1}{n}} = K_{\hat{p}} \sqrt{\frac{n-1}{n}} \tag{H.7}$$

Although in principle the normal distribution has an infinite interval $[-\infty, \infty]$ in practice it should be limited by limiting $\varepsilon/4 \leq \hat{p} \leq 1 - \varepsilon/4$, where ε is the smallest value such that $1,0 + \varepsilon > 1,0$ in computer arithmetic. When $\hat{p} = 0$ you should use $\hat{p} = \varepsilon/4$ and this limits the normal distribution to approximately $(-8,29,8,29)$ and ensures that it is numerically symmetric.

The triangular acceptance region for separate control, together with three pairs of construction lines for $\hat{p}_L = 0, p^*/4, p^*/2$ corresponding to $\hat{p}_U = p^*, 3p^*/4, p^*/2$ is shown [Figure H.5](#).

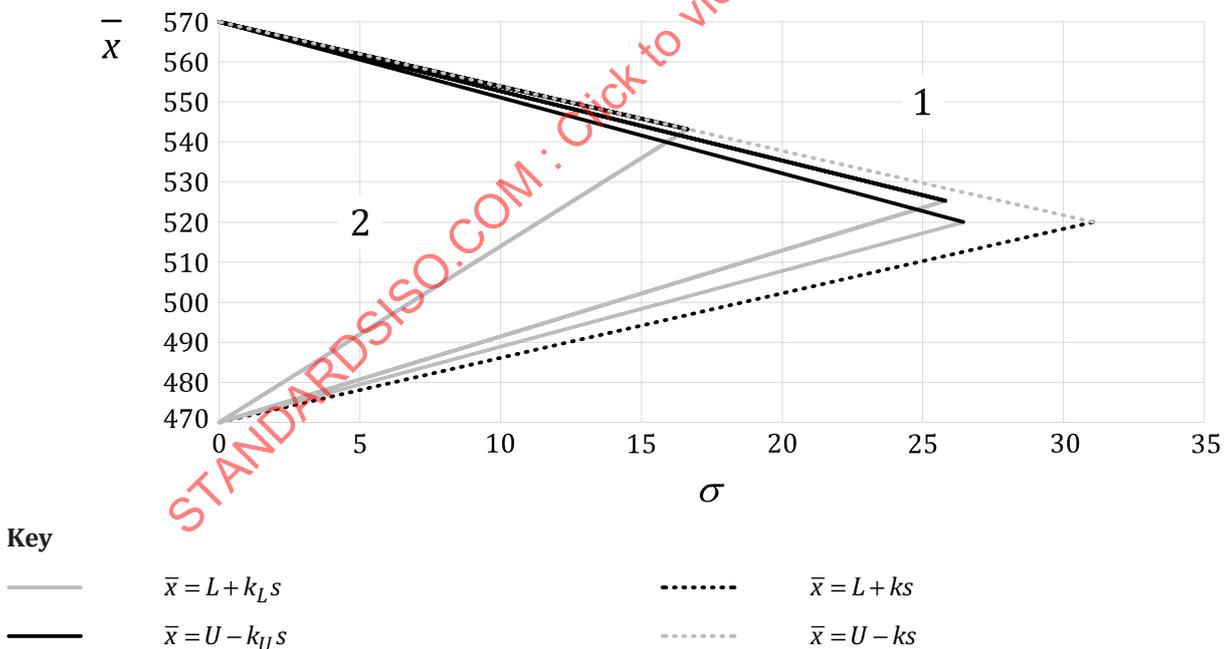


Figure H.5 — acceptance region, σ -method, combined control – construction lines
 $\hat{p}_L = 0, p^*/4, p^*/2$ and $\hat{p}_U = p^*, 3p^*/4, p^*/2$

As for the s -method the acceptance region is the union over $0 \leq \hat{p}_L \leq p^*$ of the triangular regions enclosed by the construction lines and the \bar{x} axis. The acceptance region boundary is the locus over $0 \leq \hat{p}_L \leq p^*$ of the points (σ, \bar{x}) . This is illustrated in [Figure H.6](#).

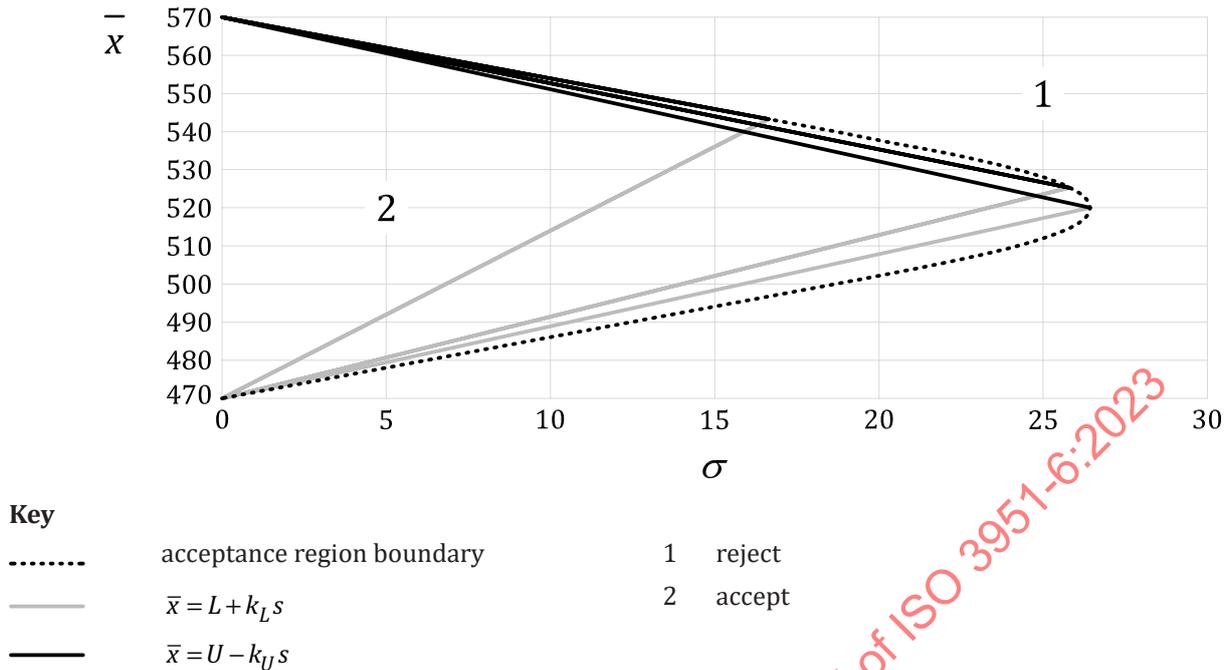


Figure H.6 — acceptance region, σ -method, combined control with construction lines

$$\hat{p}_L = 0, p^* / 4, p^* / 2 \text{ and } \hat{p}_U = p^*, 3 p^* / 4, p^* / 2$$

Note that maximum point on the acceptance region in [Figures H.6](#), [H.7](#) and [H.8](#), which in this document is the MPSD, is at the intersection of the construction lines for $\hat{p}_L = \hat{p}_U = p^* / 2$ and hence the MPSD is given by

$$\sigma = \frac{U - L}{2k(n, p^* / 2)} = \frac{U - L}{2K_{p^* / 2}} \sqrt{\frac{n}{n - 1}} \tag{H.8}$$

and the values of f_σ given in [Table 3](#) are calculated with $U = 1, L = 0$, and with n and σ from [Table 5](#). For this example, $n = 7$ and $p^* = 0,0413$, which gives the values used above:

$$\sigma = \frac{570 - 470}{2K_{0,020515}} \sqrt{\frac{7}{6}} = \frac{109,012345}{2,043227} = 26,4318 \text{ and } f_\sigma = \frac{\sigma}{100} = 0,264318.$$

The acceptance diagram can be completed as shown in [Figure H.7](#) by removing the construction lines and plotting the sample mean and known standard deviation for the data in the example. The sample mean and known standard deviation are within the accept region agreeing with the result of the numerical procedure in [13.3](#).

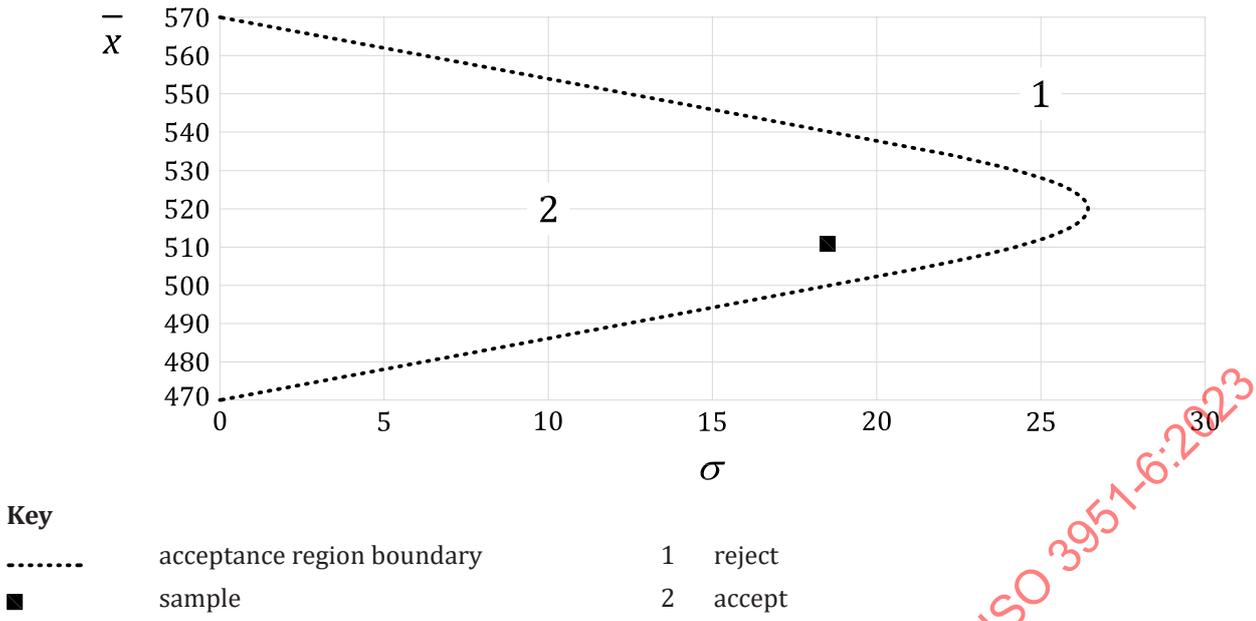


Figure H.7 — Acceptance region, σ -method, combined control with sample mean and standard deviation

With this particular sampling plan, we can also illustrate the use of the approximate method, in 7.3 b) 4), that uses separate limits. The known value of σ and the separate limits are shown in Figure H.8. It can be seen that this is a reasonable assumption. When σ is close to σ_{max} and either Q_L or Q_U is close to k the sample values (σ, \bar{x}) have to be plotted on the acceptance region to make the correct acceptance decision.

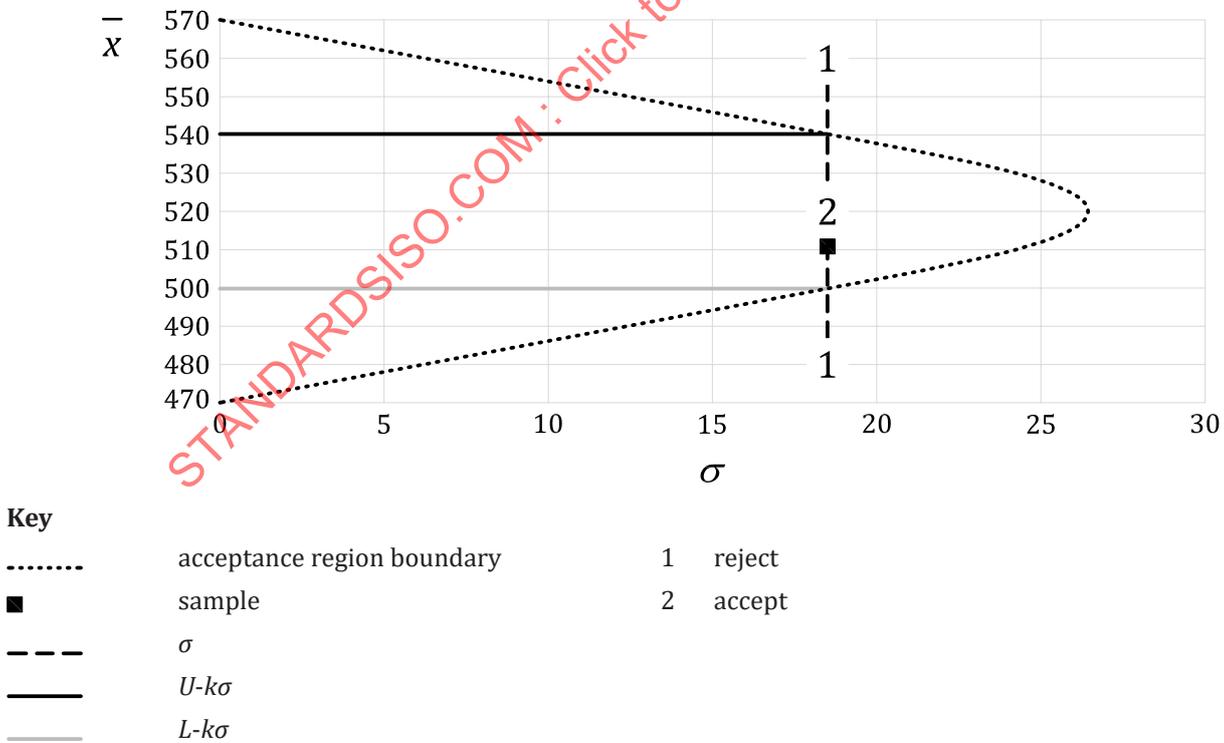


Figure H.8 — Acceptance region, σ -method, combined control with sample mean and standard deviation and separate limits