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Statistical methods — Process performance and capability statistics for measured quality characteristics

Méthodes statistiques — Performances de processus et statistiques d'aptitude pour les caractéristiques de qualité mesurées

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 21747 was prepared by Technical Committee ISO/TC 69, *Application of Statistical Methods*, Subcommittee SC 4, *Application of Statistical Methods and Process Management*.

Introduction

Many standards have been created concerning the quality capability/performance of processes by international, regional and national standardization bodies and also by industry. However, all of them assume that the process is in a state of statistical control, with stationary, normal processes behaviour. However, a comprehensive analysis of production processes shows that it is very rare for processes to remain in a normally distributed, stationary state. In recognition of this fact, this International Standard provides a framework for estimating the quality capability/performance of industrial processes for an array of standard processes. These standard processes are categorized by the stability of the first and second distributional moments, as to whether they are constant, change systematically, or randomly. As such, the quality capability/performance can be assessed for very differently shaped distributions with respect to time.

Statistical methods — Process performance and capability statistics for measured quality characteristics

1 Scope

This International Standard describes a procedure for the determination of statistics in order to estimate the quality capability of product and process characteristics. The process results of these quality characteristics are tabularized into eight possible distribution types. Calculation formulae for the statistical values are placed with every distribution.

These statistics relate to continuous quality characteristics exclusively. This International Standard is applicable to processes in any industrial or economical sector.

NOTE This method is usually applied in case of a great number of serial process results, but it can also be used for small series (a small number of process results).

2 Normative references

The following referenced documents are indispensable for the application 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 9000:2005, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in ISO 9000 and the following apply.

3.1
quality characteristic
inherent characteristic of a product, process or system related to a requirement

NOTE 1 Inherent means existing in something, especially as a permanent characteristic.

NOTE 2 A characteristic assigned to a product, process or system (e.g. the price of a product, the owner of a product) is not a quality characteristic of that product, process or system.

[ISO 9000:2005, 3.5.2]

3.1.1 Variation-related concepts

3.1.1.1
variation
difference between values of a characteristic

NOTE Variation is often expressed as a variance or standard deviation.

[ISO 3534-2:—[1], 2.2.1]

1) To be published. (Revision of ISO 3534-2:1993)

3.1.1.2
inherent process variation
variation (3.1.1.1) in a process when the process is operating in a state of statistical control

NOTE 1 When it is expressed in terms of standard deviation, the subscript "w" is applied, (e.g. σ_w, S_w, or s_w), indicating inherent. See also 3.1.4.1, NOTE 2.

NOTE 2 This variation corresponds to "within subgroup variation".

[ISO 3534-2:—, 2.2.2]

3.1.1.3
total process variation
variation (3.1.1.1) in a process due to both **special causes** (3.1.1.4) and **random causes** (3.1.1.5)

NOTE 1 When it is expressed in terms of standard deviation, the subscript "t" is applied (e.g. σ_t, S_t or s_t), indicating total.

See also 3.1.3.1, Note 3.

NOTE 2 This variation corresponds with the combination of the "within-subgroup variation" and the "between-subgroup variation".

[ISO 3534-2:—, 2.2.3]

3.1.1.4
special cause
⟨process variation⟩ source of process variation other than **inherent process variation** (3.1.1.2)

NOTE 1 Sometimes "special cause" is taken to be synonymous with "assignable cause". However, a distinction is recognized. A special cause is assignable only when it is specifically identified.

NOTE 2 A special cause arises because of specific circumstances that are not always present. As such, in a process subject to special causes, the magnitude of the variation from time to time is unpredictable.

[ISO 3534-2:—, 2.2.4]

3.1.1.5
random cause
common cause
chance cause
⟨process variation⟩ source of process variation that is inherent in a process over time

NOTE 1 In a process subject only to random cause variation, the variation is predictable within statistically established limits.

NOTE 2 The reduction of these causes gives rise to process improvement. However, the extent of their identification, reduction and removal is the subject of cost/benefit analysis in terms of technical tractability and economics.

[ISO 3534-2:—, 2.2.5]

3.1.1.6
stable process
process in a state of statistical control
⟨constant mean⟩ process subject to only **random causes** (3.1.1.5)

NOTE 1 A stable process will generally behave as though the samples from the process at any time are simple random samples from the same population.

NOTE 2 This state does not imply that the random variation is large or small, within or outside of specification, but rather that the **variation** (3.1.1.1) is predictable using statistical techniques.

NOTE 3 The **process capability** (3.1.4.1) of a stable process is usually improved by fundamental changes that reduce or remove some of the random causes present and/or adjusting the mean towards the preferred value.

NOTE 4 In some processes, the mean of a characteristic can have a drift or the standard deviation can increase due, for example, to wear out of tools or depletion of concentration in a solution. A progressive change in the mean or standard deviation of such a process is considered due to systematic and not random causes. The results, then, are not simple random samples from the same population.

[ISO 3534-2:—, 2.2.7]

3.1.1.7
out-of-control criteria
set of decision rules for identifying the presence of **special causes** (3.1.1.4)

NOTE Decision rules may include those relating to points outside of control limits, runs, trends, cycles, periodicity, concentration of points near the centre line or control limits, unusual spread of points within control limits (large or small dispersion) and relationships among values within subgroups.

[ISO 3534-2:—, 2.2.8]

3.1.2 Fundamental process performance and process capability related terms

3.1.2.1
distribution
⟨of a characteristic⟩ information on the probabilistic behaviour of a characteristic

NOTE 1 The distribution of a characteristic can be represented, for example, by ranking of the values of the characteristic and showing the resulting pattern of measures or scores in the form of a tally chart or histogram. Such a pattern provides all of the numerical value information on the characteristic except for the serial order in which the data arises.

NOTE 2 The distribution of a characteristic is dependent on prevailing conditions. Thus, if meaningful information about the distribution of a characteristic is desired, the conditions under which the data is collected should be specified.

NOTE 3 It is important to know the class of distribution, for instance, normal or log-normal, before predicting or estimating process capability and performance measures and indices or fraction nonconforming.

[ISO 3534-2:—, 2.5.1]

3.1.2.2
class of distributions
particular family of **distributions** (3.1.2.1) each member of which has the same common attributes by which the family is fully specified

EXAMPLE 1 The two-parameter, symmetrical bell-shaped, normal distribution with parameters mean and standard deviation.

EXAMPLE 2 The three-parameter Weibull distribution with parameters location, shape and scale.

EXAMPLE 3 The unimodal continuous distributions.

NOTE The class of distributions can often be fully specified through the values of appropriate parameters.

[ISO 3534-2:—, 2.5.2]

3.1.2.3
distribution model
specified **distribution** (3.1.2.1) or **class of distributions** (3.1.2.2)

EXAMPLE 1 A model for the distribution of a product characteristic, the diameter of a bolt, might be the normal distribution with mean 15 mm and standard deviation 0,05 mm. Here the model is a fully specified one.

EXAMPLE 2 A model for the diameter of bolts as in Example 1 could be the class of normal distributions without attempting to specify a particular distribution. Here the model is the class of normal distributions.

[ISO 3534-2:—, 2.5.3]

3.1.2.4
upper fraction nonconforming

p_U

fraction of the **distribution** (3.1.2.1) of a characteristic that is greater than the **upper specification limit** (3.2.1.3), U

EXAMPLE In a normal distribution, with mean, μ, and standard deviation, σ:

$$p_U = 1 - \Phi\left(\frac{U-\mu}{\sigma}\right) = \Phi\left(\frac{\mu - U}{\sigma}\right) \tag{1}$$

where

p_U is the upper fraction nonconforming;

Φ is the distribution function of the standard normal distribution;

U is the upper specification limit.

NOTE 1 Tables (or functions in statistical computer packages) of the standard normal distribution are readily available which give the proportion of process output expected beyond a particular value of interest, such as a **specification limit** (3.2.1.2), in terms of standard deviations away from the process mean. This obviates the need to work out the statistical distribution function given in the example.

NOTE 2 The function relates to a theoretical distribution. In practice, with empirical distributions, the parameters are replaced by their estimates.

[ISO 3534-2:—, 2.5.4]

3.1.2.5
lower fraction nonconforming

p_L

fraction of the **distribution** (3.1.2.1) of a characteristic that is less than the **lower specification limit** (3.2.1.4), L

EXAMPLE In a normal **distribution** (3.1.2.1), with mean, μ, and standard deviation, σ:

$$p_L = \Phi\left(\frac{L-\mu}{\sigma}\right) \tag{2}$$

where

p_L is the lower fraction nonconforming;

Φ is the distribution function of the standard normal distribution;

L is the lower specification limit.

NOTE 1 Tables (or functions in statistical computer packages) of the standard normal distribution are readily available which give the proportion of process output expected beyond a particular value of interest, such as a **specification limit** (3.2.1.2), in terms of standard deviations away from the process mean. This obviates the need to work out the statistical distribution function given in the example.

NOTE 2 The function relates to a theoretical distribution. In practice, with empirical distributions, the parameters are replaced by their estimates.

[ISO 3534-2:—, 2.5.5]

3.1.2.6
total fraction nonconforming
p_t
sum of **upper fraction nonconforming** (3.1.2.4) and **lower fraction nonconforming** (3.1.2.5)

EXAMPLE In a normal distribution, with mean, μ, and standard deviation, σ:

$$p_t = \Phi\left(\frac{\mu - U}{\sigma}\right) + \Phi\left(\frac{L - \mu}{\sigma}\right) \tag{3}$$

where

p_t is the total fraction nonconforming;

Φ is the distribution function of the standard normal distribution;

L is the lower specification limit;

U is the upper specification limit.

NOTE 1 Tables (or functions in statistical computer packages) of the standard normal distribution are readily available which give the proportion of process output expected beyond a particular value of interest, such as a **specification limit** (3.2.1.2), in terms of standard deviations away from the process mean. This obviates the need to work out the statistical distribution function given in the example.

NOTE 2 The function relates to a theoretical distribution. In practice, with empirical distributions, the parameters are replaced by their estimates.

[ISO 3534-2:—, 2.5.6]

3.1.2.7
reference interval
interval bounded by the 99,865 % distribution quantile, $X_{99,865\ \%}$, and the 0,135 % distribution quantile, $X_{0,135\ \%}$

NOTE 1 The interval can be expressed by ($X_{99,865\ \%}$, $X_{0,135\ \%}$) and the length of the interval is $X_{99,865\ \%} - X_{0,135\ \%}$.

NOTE 2 This term is used only as an arbitrary, but standardized, basis for defining the **process performance index** (3.1.3.2) and **process capability index** (3.1.4.2).

NOTE 3 For a normal **distribution** (3.1.2.1), the length of the reference interval can be expressed in terms of six standard deviations, 6σ, or $6S$, when estimated from a sample.

NOTE 4 For a non-normal distribution, the length of the reference interval can be estimated by means of appropriate probability papers (e.g. log-normal) or from the sample kurtosis and sample skewness using the methods described in ISO/TR 12783 [2)].

NOTE 5 A quantile or fractile indicates division of a distribution into equal units or fractions, e.g. percentiles. Quantile is defined in ISO 3534-1.

[ISO 3534-2:—, 2.5.7]

3.1.2.8
lower reference interval
interval bounded by the 50 % distribution quantile, $X_{50\ \%}$ and the 0,135 % distribution quantile, $X_{0,135\ \%}$

NOTE 1 The interval can be expressed by ($X_{50\ \%}$, $X_{0,135\ \%}$) and the length of the interval is $X_{50\ \%} - X_{0,135\ \%}$.

2) Under preparation.

NOTE 2 This term is used only as an arbitrary, but standardized, basis for defining the **lower process performance index** (3.1.3.3) and **lower process capability index** (3.1.4.3).

NOTE 3 For a normal **distribution** (3.1.2.1), the length of the lower reference interval can be expressed in terms of standard deviations as 3σ, or an estimated $3S$, and $X_{50\,\%}$ represents both the mean and the median.

NOTE 4 For a non-normal distribution, the 50 % distribution quantile, $X_{50\,\%}$, namely the median, and the 0,135 % distribution quantile, $X_{0,135\,\%}$, can be estimated by means of appropriate probability papers (e.g. log-normal) or from the sample kurtosis and sample skewness using the methods described in ISO/TR 12783 [2)].

[ISO 3534-2:—, 2.5.8]

3.1.2.9
upper reference interval
interval bounded by the 99,865 % distribution quantile, $X_{99,865\,\%}$, and the 50 % distribution quantile, $X_{50\,\%}$

NOTE 1 The interval can be expressed by $(X_{99,865\,\%}, X_{50\,\%})$ and the length of the interval is $X_{99,865\,\%} - X_{50\,\%}$.

NOTE 2 This term is used only as an arbitrary, but standardized, basis for defining the **upper process performance index** (3.1.3.4) and **upper process capability index** (3.1.4.4).

NOTE 3 For a normal **distribution** (3.1.2.1), the length of the upper reference interval can be expressed in terms of standard deviations as 3σ, or an estimated $3S$, and $X_{50\,\%}$ represents both the mean and the median.

NOTE 4 For a non-normal distribution, the 50 % distribution quantile, $X_{50\,\%}$, namely the median, and the 99,865 % distribution quantile, $X_{99,865\,\%}$, can be estimated by means of appropriate probability papers (e.g. log-normal) or from the sample kurtosis and sample skewness using the methods described in ISO/TR 12783 [2)].

[ISO 3534-2:—, 2.5.9]

3.1.3 Process performance — Measured data

3.1.3.1
process performance
statistical measure of the outcome of a characteristic from a process which may not have been demonstrated to be in a state of statistical control

NOTE 1 The outcome is a **distribution** (3.1.2.1), the class of which needs determination and its parameters assessed.

NOTE 2 Care should be exercised in using this measure as it may contain a component of variability due to **special causes** (3.1.1.4), the value of which is not predictable.

NOTE 3 For a normal distribution described in terms of the standard deviation, S_t, assessed from only one sample of size N, the standard deviation is expressed thus:

$$S_t = \sqrt{\frac{1}{N-1}\sum\left(X_i - \bar{X}_t\right)^2} \quad (4)$$

where

$$\bar{X}_t = \frac{1}{N}\sum X_i \quad (5)$$

This descriptor, S_t, takes into account the variation due to **random (common) causes** (3.1.1.5) together with any special causes that may be present. S_t is used here instead of σ_t as the standard deviation is a statistical descriptive measure. The sample size N can be made up of m subgroups, each of size n.

NOTE 4 For a normal distribution, process performance can be assessed from the expression:

process performance $= \bar{X}_t \pm (zS_t)$

and, "z" is dependent on the particular parts per million performance requirement. Typically "z" takes the value of 3, 4 or 5. If the process performance coincides with the specified requirements, a z value of 3 indicates an expected 2 700 parts per million outside of specification. Similarly, a z of 4 indicates an expected 64 parts per million and a z of 5 an expected 0,6 parts per million outside of specification.

NOTE 5 For a non-normal distribution, process performance can be assessed using, for example, an appropriate probability paper or from the parameters of the distribution fitted to the data. The expression for process performance takes the form:

$$\text{process performance} = \bar{X}_{\text{t}}\ {}^{+a}_{-b}$$

The notation, ${}^{+a}_{-b}$, is in the same style as standard drawing office practice for expressing specified tolerances about a nominal, or preferred, value for a characteristic, when the preferred value is not equidistant from each limit. The equivalent notation for limits symmetrical about the preferred value is $\pm$. This enables a direct comparison to be made between the dimensional performance of a characteristic and its specified requirements in terms of both location and dispersion.

[ISO 3534-2:—, 2.6.1]

3.1.3.2
process performance index

P_{p}

index describing **process performance** (3.1.3.1) in relation to specified tolerance

NOTE 1 Frequently, the process performance index is expressed as the value of the specified tolerance divided by a measure of the length of the **reference interval** (3.1.2.7), namely as:

$$P_{\text{p}} = \frac{U - L}{X_{99,865\,\%} - X_{0,135\,\%}} \tag{6}$$

NOTE 2 For a normal **distribution** (3.1.2.1), the length of the reference interval is equal to $6S_{\text{t}}$ (see 3.1.3.1, Note 3).

NOTE 3 For a non-normal distribution, the length of the reference interval can be estimated using, for example, the method described in ISO/TR 12783 [2)].

[ISO 3534-2:—, 2.6.2]

3.1.3.3
lower process performance index

$P_{\text{pk}L}$

index describing **process performance** (3.1.3.1) in relation to the **lower specification limit** (3.2.1.4), L

NOTE 1 Frequently, the lower process performance index is expressed by the difference between the 50 % distribution quantile, $X_{50\,\%}$, and **lower specification limit** (3.2.1.4) divided by a measure of the length of the **lower reference interval** (3.1.2.8), namely as:

$$P_{\text{pk}L} = \frac{X_{50\,\%} - L}{X_{50\,\%} - X_{0,135\,\%}} \tag{7}$$

NOTE 2 For the symmetrical normal **distribution** (3.1.2.1), the length of the lower reference interval is equal to $3S_{\text{t}}$ (see 3.1.3.1, Note 3) and $X_{50\,\%}$ represents both the mean and the median.

NOTE 3 For a non-normal distribution, the length of the lower reference range can be estimated using the method described in ISO/TR 12783 [2)] and $X_{50\,\%}$ represents the median.

[ISO 3534-2:—, 2.6.3]

3.1.3.4
upper process performance index
$P_{\text{pk}U}$
index describing process performance (3.1.3.1) in relation to the upper specification limit (3.2.1.3), U

NOTE 1 Frequently, the upper process performance index is expressed as the difference between the upper specification limit and the 50 % distribution quantile, $X_{50\,\%}$, divided by a measure of the length of the **upper reference interval** (3.1.2.9), namely as:

$$P_{\text{pk}U} = \frac{U - X_{50\,\%}}{X_{99{,}865\,\%} - X_{50\,\%}} \tag{8}$$

NOTE 2 For a normal **distribution** (3.1.2.1), the length of the upper reference interval is equal to $3S_{\text{t}}$ (see 3.1.3.1, Note 3) and $X_{50\,\%}$ represents both the mean and the median.

NOTE 3 For a non-normal distribution, the length of the upper reference interval can be estimated using the method described in ISO/TR 12783 [2)] and $X_{50\,\%}$ represents the median.

[ISO 3534-2:—, 2.6.4]

3.1.3.5
minimum process performance index
P_{pk}
smaller of **upper process performance index** (3.1.3.4) and **lower process performance index** (3.1.3.3)

[ISO 3534-2:—, 2.6.5]

3.1.4 Process capability — Measured data

3.1.4.1
process capability

statistical estimate of the outcome of a characteristic from a process which has been demonstrated to be in a state of statistical control and which describes that process's ability to realize a characteristic that will fulfil the requirements for that characteristic

NOTE 1 The outcome is a **distribution** (3.1.2.1), the class of which needs determination and its parameters estimated.

NOTE 2 For a normal distribution, the process overall standard deviation, σ_{t}, can be estimated using the formula for S_{t} (see 3.1.3.1, Note 3).

Alternatively, in certain circumstances, the standard deviation, S_{w}, which represents only within-subgroup variation, can replace S_{t} as an estimator.

$$S_{\text{w}} \approx \frac{\overline{R}}{d_2} \text{ or } \frac{\sum S_i}{mc_4} \text{ or } \sqrt{\frac{\sum S_i^{\,2}}{m}} \tag{9}$$

where

$\overline{R}$ is the average range calculated from a set of m subgroup ranges;

S_i is the observed sample standard deviation of the ith subgroup;

m is the number of subgroups of the same size, n;

d_2, c_4 are constants based on subgroup size, n (see ISO 8258).

The value of the estimators S_{t} and S_{w} converge for a process in a state of statistical control. So, a comparison of the two gives an indication of the degree of stability of the process. For an out-of-control process about a constant mean, or, for a process that is subject to systematic change in the mean (see 3.1.1.6, Note 4), the value of S_{w} is likely to significantly underestimate the process standard deviation.

Hence S_w should be used with extreme caution. Sometimes, too, the estimator S_t is preferred to S_w because it has more tractable statistical properties (e.g. facilitating the calculation of confidence limits).

NOTE 3 For a normal distribution, process capability can be assessed from the expression:

$$\text{process capability} = \overline{\overline{X}} \pm (zS_t) \tag{10}$$

where

$$\overline{\overline{X}} = \frac{1}{m}\sum \overline{X}_i \tag{11}$$

$\overline{X}_i$ is the observed mean of the ith subgroup. Note that $\overline{\overline{X}}$ gives identical results to $\overline{X}_t$ (see 3.1.3.1, Note 3).

The choice of the value of "z" depends on the particular parts per million capability standard used. Typically "z" takes the value of 3, 4 or 5. If the process capability meets the specified requirements, a z value of 3 indicates an expected 2 700 parts per million outside of specification. Similarly, a "z" of 4 indicates an expected 64 parts per million and a "z" of 5 an expected 0,6 parts per million outside of specification.

NOTE 4 For a non-normal distribution, process capability can be assessed using, for example, an appropriate probability paper or from the parameters of the distribution fitted to the data. The expression for process capability takes the asymmetric form:

$$\text{process capability} = \overline{\overline{X}}\,{}^{+a}_{-b}$$

The notation, ${}^{+a}_{-b}$, is in the same style as standard drawing office practice for expressing specified tolerances about a nominal, or preferred, value for a characteristic when the preferred value is not equidistant from each limit. The equivalent notation for limits symmetrical about the preferred value is $\pm$. This enables a direct comparison to be made between the dimensional performance of a characteristic and its specified requirements in terms of both location and dispersion.

NOTE 5 When $S_w = \dfrac{\overline{R}}{d_2}$ is used, it needs to be appreciated that this estimator:

— becomes progressively less efficient as subgroup size increases;

— is very sensitive to the distribution of individuals;

— makes it extremely difficult to estimate confidence limits.

[ISO 3534-2:—, 2.7.1]

3.1.4.2
process capability index
C_p
index describing **process capability** (3.1.4.1) in relation to specified tolerance

NOTE 1 Frequently, the process capability index is expressed as the value of the specified tolerance divided by a measure of the length of the **reference interval** (3.1.2.7) for a **process in a state of statistical control** (3.1.1.6), namely as:

$$C_p = \frac{U - L}{X_{99,865\,\%} - X_{0,135\,\%}} \tag{12}$$

NOTE 2 For a normal **distribution** (3.1.2.1), the reference interval is equal to $6S$ (see 3.1.4.1, Notes).

NOTE 3 For a non-normal distribution, the reference interval can be estimated using the method described in ISO/TR 12783 [2)].

[ISO 3534-2:—, 2.7.2]

3.1.4.3
lower process capability index
$C_{\text{pk}L}$
index describing **process capability** (3.1.4.1) in relation to the **lower specification limit** (3.2.1.4), L

NOTE 1 Frequently, the lower process capability index is expressed as the difference between the 50 % distribution quantile, $X_{50\,\%}$, and lower specification limit divided by a measure of the length of the **lower reference interval** (3.1.2.8) for a **process in a state of statistical control** (3.1.1.6), namely as:

$$C_{\text{pk}L} = \frac{X_{50\,\%} - L}{X_{50\,\%} - X_{0{,}135\,\%}} \tag{13}$$

NOTE 2 For a normal **distribution** (3.1.2.1), the lower reference interval is equal to $3S$ (see 3.1.4.1, Notes) and $X_{50\,\%}$ represents both the mean and the median.

NOTE 3 For a non-normal distribution, the upper reference interval can be estimated using the method described in ISO/TR 12783 [2)] and $X_{50\,\%}$ represents the median.

[ISO 3534-2:—, 2.7.3]

3.1.4.4
upper process capability index
$C_{\text{pk}U}$
index describing **process capability** (3.1.4.1) in relation to the **upper specification limit** (3.2.1.3), U

NOTE 1 Frequently, the upper process capability index is expressed as the difference between the upper specification limit and the 50 % distribution quantile, $X_{50\,\%}$ divided by a measure of the length of the **upper reference interval** (3.1.2.9) for a **process in a state of statistical control** (3.1.1.6), namely as:

$$C_{\text{pk}U} = \frac{U - X_{50\,\%}}{X_{99{,}865\,\%} - X_{50\,\%}} \tag{14}$$

NOTE 2 For a normal **distribution** (3.1.2.1), the upper reference range is equal to $3S$ (see 3.1.4.1, Notes) and $X_{50\,\%}$ represents both the mean and the median.

NOTE 3 For a non-normal distribution, the upper reference interval can be estimated using the method described in ISO/TR 12783 [2)] and $X_{50\,\%}$ represents the median.

[ISO 3534-2:—, 2.7.4]

3.1.4.5
minimum process capability index
C_{pk}
smaller of **upper process capability index** (3.1.4.4) and **lower process capability index** (3.1.4.3)

[ISO 3534-2:—, 2.7.5]

3.2 Specifications, values and test results

3.2.1 Specification-related concepts

3.2.1.1
specification
document stating requirements

[ISO 9000:2005, 3.7.3]

NOTE 1 A document can be any medium containing information, for example, paper, computer disc or master sample.

NOTE 2 Typically qualifiers are needed for this term. Examples are product specification and process specification, test specification and performance specification.

NOTE 3 In acceptance sampling, a lot may be accepted because it meets the lot acceptance criteria, but some individual items in the sample or lot may not satisfy the item specification.

NOTE 4 As far as is practicable, it is desirable that the requirements be expressed numerically, in terms of appropriate units, together with their limits. When this is not done, an operational definition is required which establishes the criterion to be applied for examination and decision making. The criterion can, for example, take the form of a reference specimen, master sample or photograph. This can illustrate what is preferred, minimum acceptable, and not acceptable, or, type and/or degree of nonconformity which is unacceptable.

3.2.1.2
specification limit
limiting value stated for a characteristic

[ISO 3534-2:—, 3.1.3]

3.2.1.3
upper specification limit
U
specification limit (3.2.1.2) that defines the upper limiting value

[ISO 3534-2:—, 3.1.4]

3.2.1.4
lower specification limit
L
specification limit (3.2.1.2) that defines the lower limiting value

[ISO 3534-2:—, 3.1.5]

3.2.1.5
specified tolerance
difference between the **upper specification limits** (3.2.1.3) and **lower specification limits** (3.2.1.4)

[ISO 3534-2:—, 3.1.6]

4 Symbols and abbreviated terms

The symbols and abbreviated terms used in this International Standard are as follows.

a additional fluctuations

C_p process capability index

C_pk minimum process capability index

$C_{\text{pk}L}$ lower process capability index

$C_{\text{pk}U}$ upper process capability index

c_4 constant based on subgroup size n (see ISO 8258)

Δ dispersion of the process (see Clause 7)

d_2 constant based on subgroup size n (see ISO 8258)

m number of subgroups of the same size n

μ location of the process (see Clause 7)

L lower specification limit

N sample size

p_L lower fraction nonconforming

p_t total fraction nonconforming

p_U upper fraction nonconforming

P_p process performance index

P_pk minimum process performance index

$P_{\text{pk}L}$ lower process performance index

$P_{\text{pk}U}$ upper process performance index

s standard deviation, realized value

σ standard deviation, population

S standard deviation, sample statistic

S_i observed sample standard deviation of the ith subgroup

S_t standard deviation, with the subscript “t” indicating total (see 3.1.1.3)

S_w standard deviation, with the subscript “w” indicating inherent (see 3.1.1.2)

SPC statistical process control

U upper specification limit

X_L lower point

X_U upper point

$X_{50\,\%}$ 50 % distribution quantile

z_α α-quantile of a standardized normal distribution from $-\infty$ to α

Φ distribution function of the standard normal distribution

5 Process analysis

The purpose of process analysis is to obtain sound knowledge of a process. This knowledge is necessary for controlling the process efficiently and effectively so that the products realized by the process fulfil the quality requirement. It is a general assumption of this standard that a process analysis has been carried out and subsequent process improvements have been implemented.

The values of the characteristics under consideration are typically determined on the basis of samples taken from the process flow. The sample size and frequency should be chosen depending on the type of process and the type of product so that all important changes are detected in time. The samples should be representative for the characteristic under consideration.

The behaviour of a characteristic under consideration can be described by the distribution, the location, the dispersion and the shape parameters of which are time-dependent functions, in general. Different models of such output distributions the parameters of which are time-dependent functions are discussed in Clauses 6 and 7. To prove whether a time-dependent distribution model fits, statistical methods [e.g. estimating parameters, analysis of variance (ANOVA)] including graphical tools (e.g. probability plots, control charts) are used.

6 Time-dependent distribution models

The instantaneous distribution characterizes the behaviour of the characteristic under investigation during a short interval. Usually, it is the time interval during which the sample (e.g. the subgroup) can be taken from the process. Observing the process continuously in time for a longer time interval the outcoming distribution is called the output process distribution and it is described by a corresponding time-dependent distribution model that reflects:

— the instantaneous distribution of the characteristic under consideration, and

— the changes of its location, dispersion and shape parameters during the time interval of process observation.

In practice, the outcoming distribution can be represented by the whole dataset, e.g. when SPC is applied, by all subgroups gained during the interval of the process observation.

Time-dependent distribution models can be classified into four groups according to whether the location and dispersion moments are constant or changing.

a) A process whose location and dispersion are constant is in time-dependent distribution model A. In this case only, all of the instantaneous distributions are equal and they are equal to the outcoming distribution.

b) If the dispersion of a process is changing with time, but the location stays constant, the process is said to be in time-dependent distribution model B.

c) If the dispersion is constant, but the location is changing, we have time-dependent distribution model C.

d) Otherwise, we have time-dependent distribution model D.

For changing moments, the models can be further classified according to whether the changes are random, systematic or both.

Table 1 summarizes the basic features of individual time-dependent distribution models; their graphical representations are given in Figures 1 to 8. There are subclasses of time-dependent distribution models A and C which are introduced due to their practical importance. They differ in the shape of the outcoming distribution and in the cause of the process being in an out-of-control state.

Table 1 — Basic features of the time-dependent distribution models

Characteristic	Time-dependent distribution models [c]							
	A1	**A2**	**B**	**C1**	**C2**	**C3**	**C4**	**D**
Location [a]	c	c	c	r	r	s	sr	sr
Dispersion [a]	c	c	sr	c	c	c	c	sr
Instantaneous distribution [b]	nd	1m	nd	nd	nd	as	as	as
Outcoming distribution [b]	nd	1m	1m	nd	1m	as	as	as
See Figure	1	2	3	4	5	6	7	8

[a] Location/dispersion:

"c" = the parameter remains constant;

"r" = the parameter changes randomly only;

"s" = the parameter changes systematically only;

"sr" = the parameter changes systematically and randomly.

[b] Instantaneous/outcoming distribution:

"nd" = normally distributed;

"1m" = not normally distributed, one mode only;

"as" = any shape.

[c] The choice of the model is a result of process analysis.

For each time-dependent distribution model, several instantaneous distributions are shown as a function of time; the related outcoming distribution is shown as well. These distributions are not drawn to scale.

Time-dependent distribution model A1 (see Figure 1) has the following characteristics (e.g. the measured length of an item from a process in a state of statistical control):

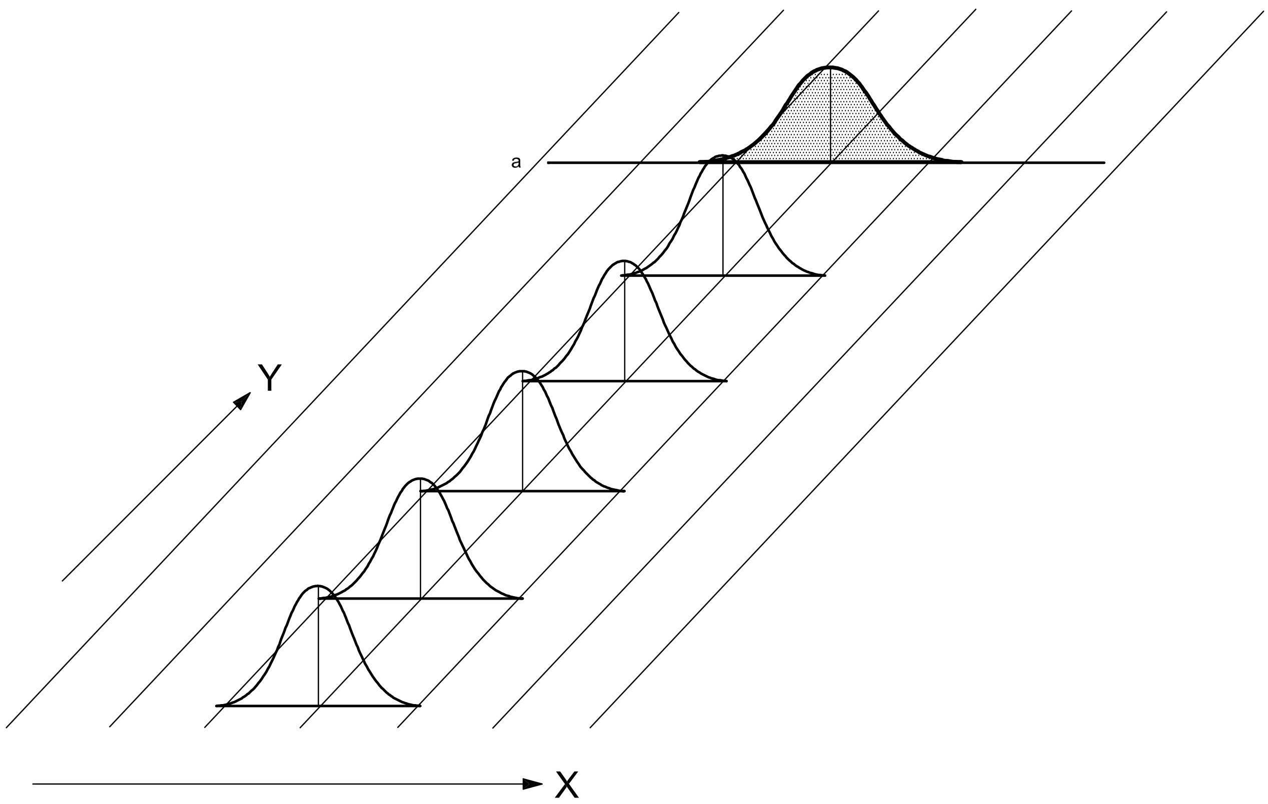
— location: constant;

— dispersion: constant;

— instantaneous distribution: normally distributed;

— outcoming distribution: normally distributed.

This process is under statistical control.



Key

X characteristic value x

Y time

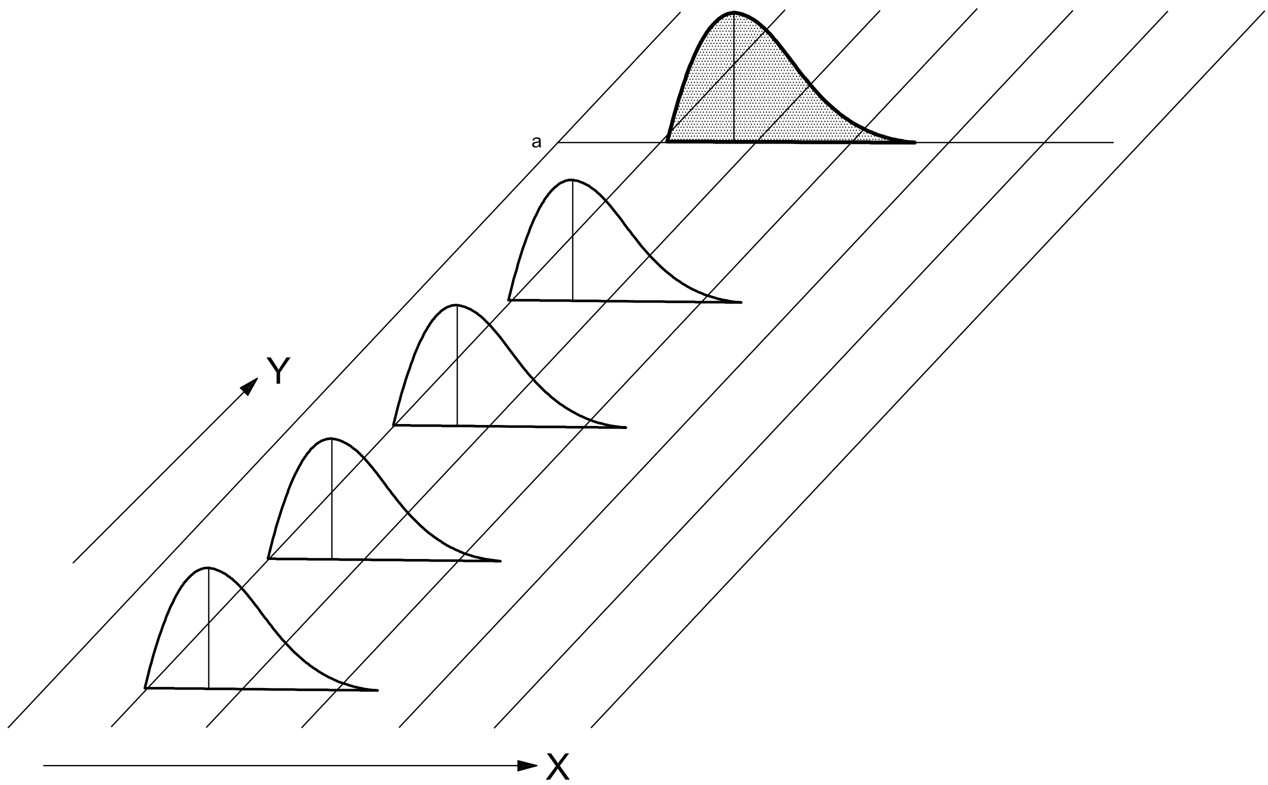
[a] Resulting distribution.

Figure 1 — Graphical representation of time-dependent distribution model A1

Time-dependent distribution model A2 (see Figure 2) has the following characteristics (e.g. the surface roughness of an item as an example for a physically limited characteristic):

- location: constant;
- dispersion: constant;
- instantaneous distribution: not normally distributed, unimodal;
- outcoming distribution: not normally distributed, unimodal.

This process is under statistical control.



Key

X characteristic value x

Y time

[a] Resulting distribution.

Figure 2 — Graphical representation of time-dependent distribution model A2

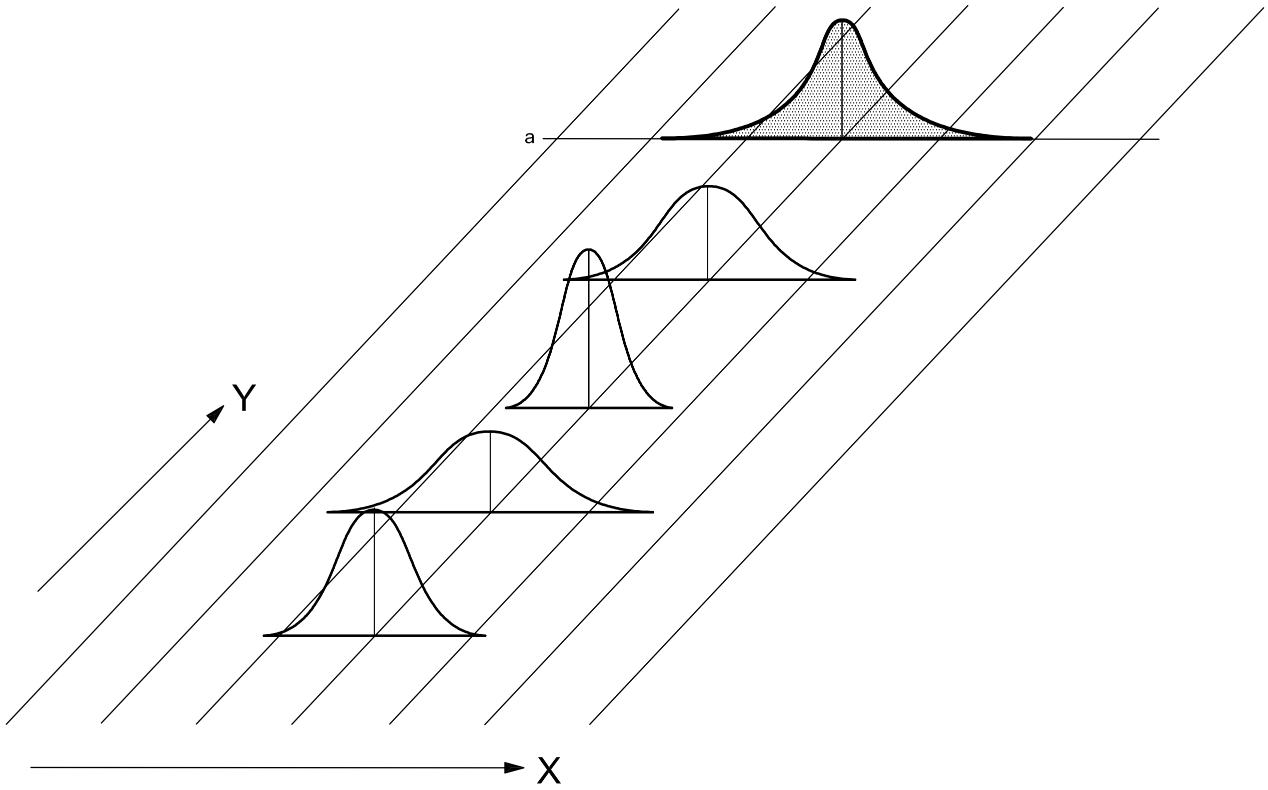
Time-dependent distribution model B (see Figure 3) has the following characteristics (e.g. different wear of the spindles on a multiple-spindle automatic machine with equal centering):

— location: constant;

— dispersion: systematic or random variation;

— instantaneous distribution: normally distributed;

— outcoming distribution: not normally distributed, unimodal.



Key

X characteristic value x

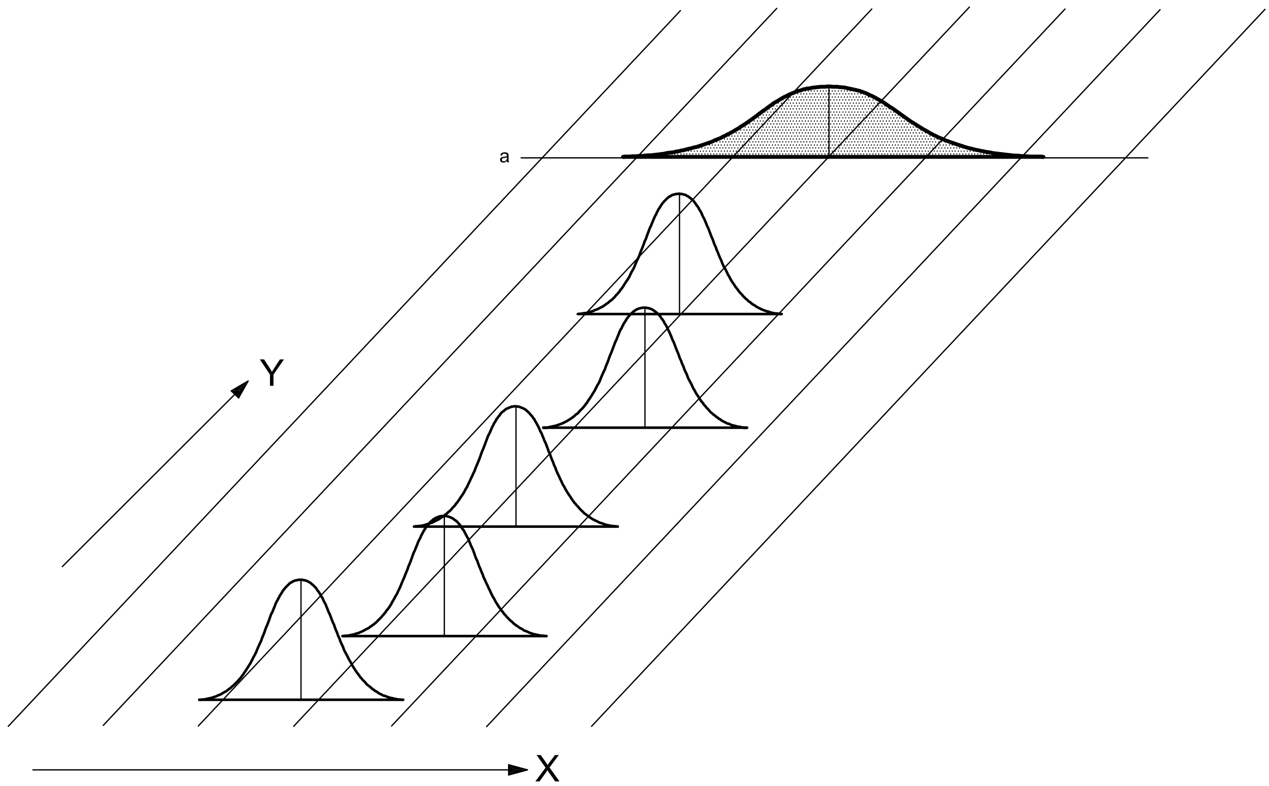
Y time

[a] Outgoing distribution.

Figure 3 — Graphical representation of time-dependent distribution model B

Time-dependent distribution model C1 (see Figure 4) has the following characteristics (e.g. different centering of workholding fixtures):

- location: random (normally distributed);
- dispersion: constant;
- instantaneous distribution: normally distributed;
- outcoming distribution: normally distributed.



Key

X characteristic value x

Y time

[a] Outgoing distribution.

Figure 4 — Graphical representation of time-dependent distribution model C1

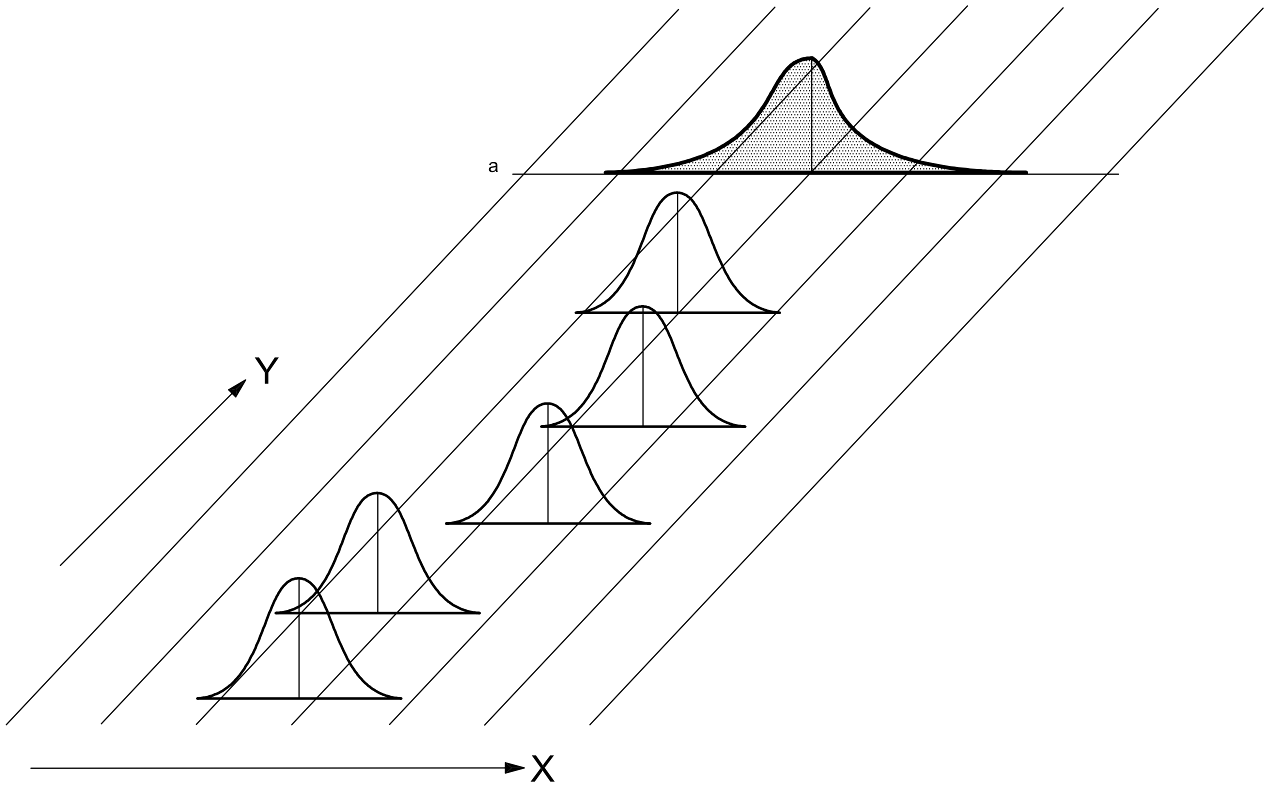
Time-dependent distribution model C2 (see Figure 5) has the following characteristics (e.g. fixed tools):

— location: random (not normally distributed, unimodal);

— dispersion: constant;

— instantaneous distribution: normally distributed;

— outcoming distribution: not normally distributed, unimodal.



Key

X characteristic value x

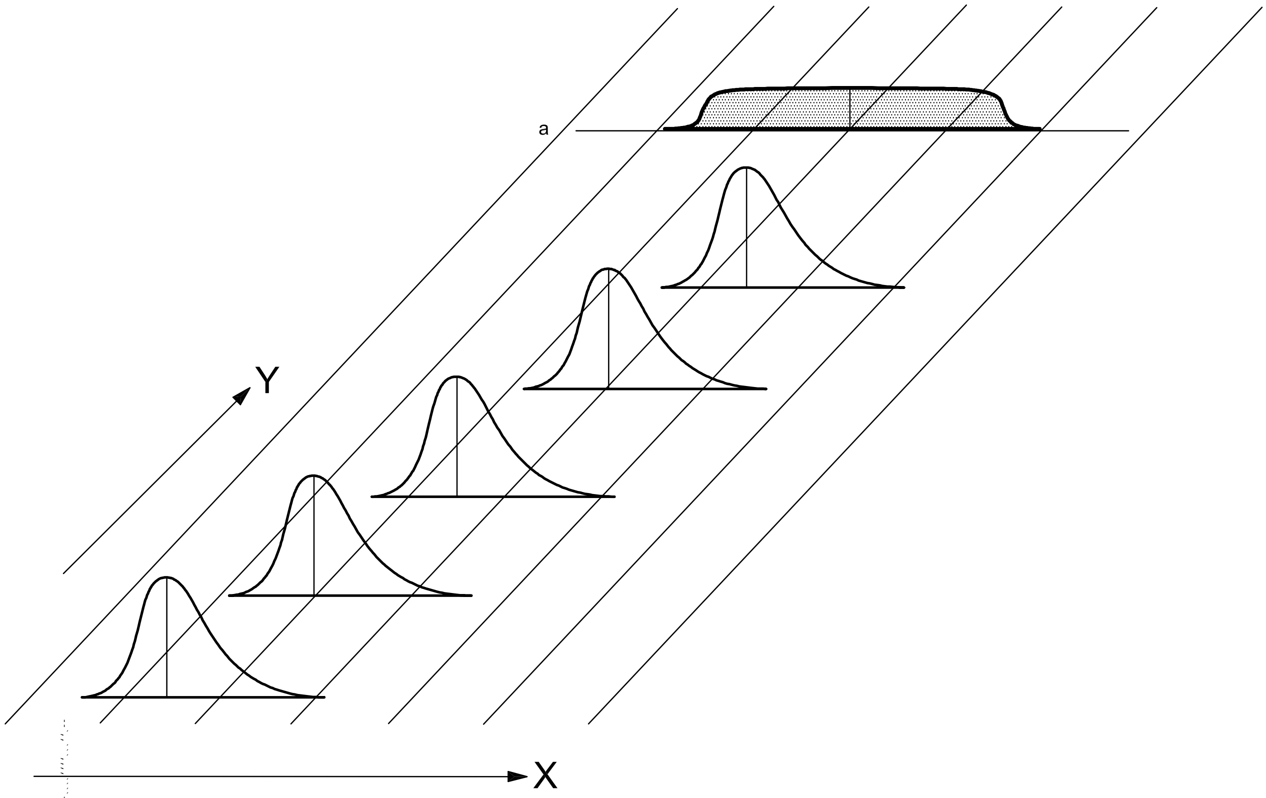
Y time

[a] Outgoing distribution.

Figure 5 — Graphical representation of time-dependent distribution model C2

Time-dependent distribution model C3 (see Figure 6) has the following characteristics:

- location: function oriented (e.g. trend, caused by wear, and cycle);
- dispersion: constant;
- instantaneous distribution: any shape whatever;
- outcoming distribution: any shape whatever.



Key

X characteristic value x

Y time

[a] Outgoing distribution.

Figure 6 — Graphical representation of time-dependent distribution model C3

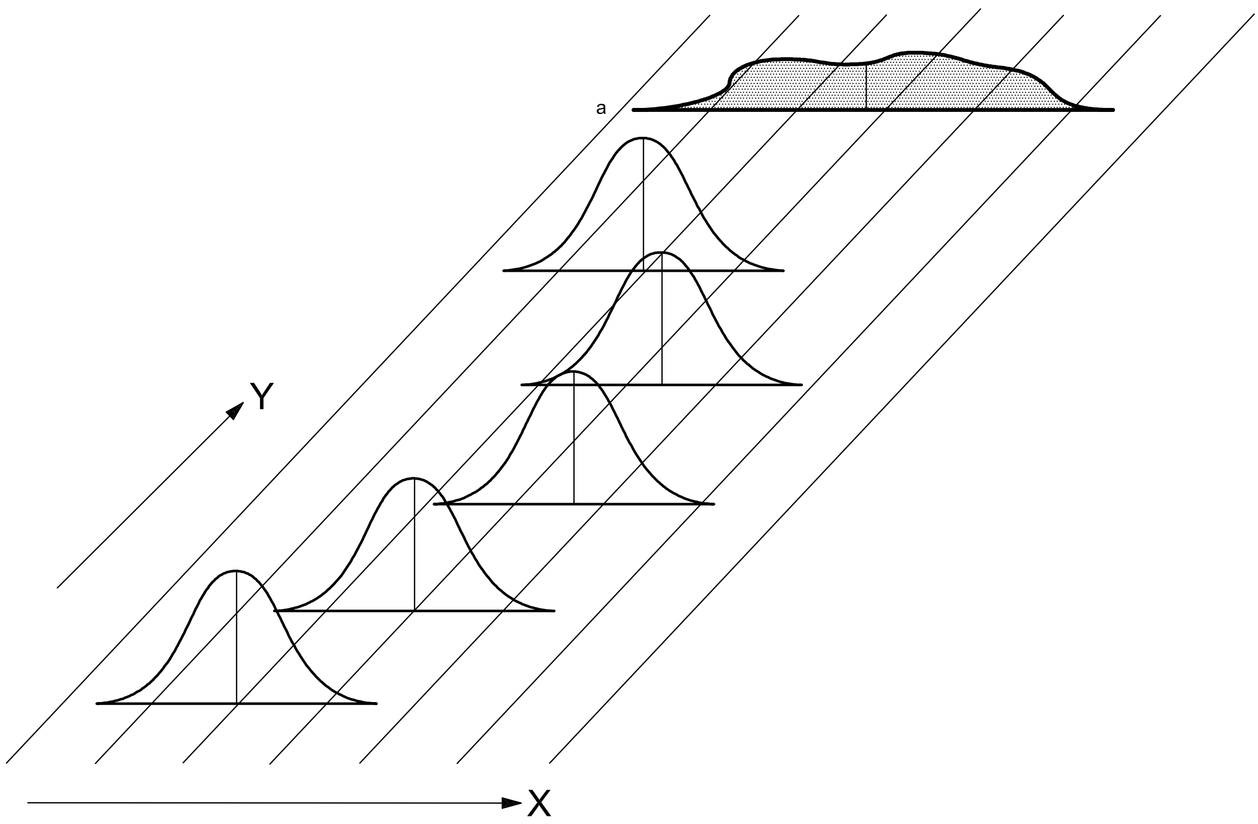
Time-dependent distribution model C4 (see Figure 7) has the following characteristics:

— location: systematic and random change (e.g. change of batches);

— dispersion: constant;

— instantaneous distribution: any shape whatever;

— outcoming distribution: any shape whatever.



Key

X characteristic value x

Y time

[a] Outgoing distribution.

Figure 7 — Graphical representation of time-dependent distribution model C4

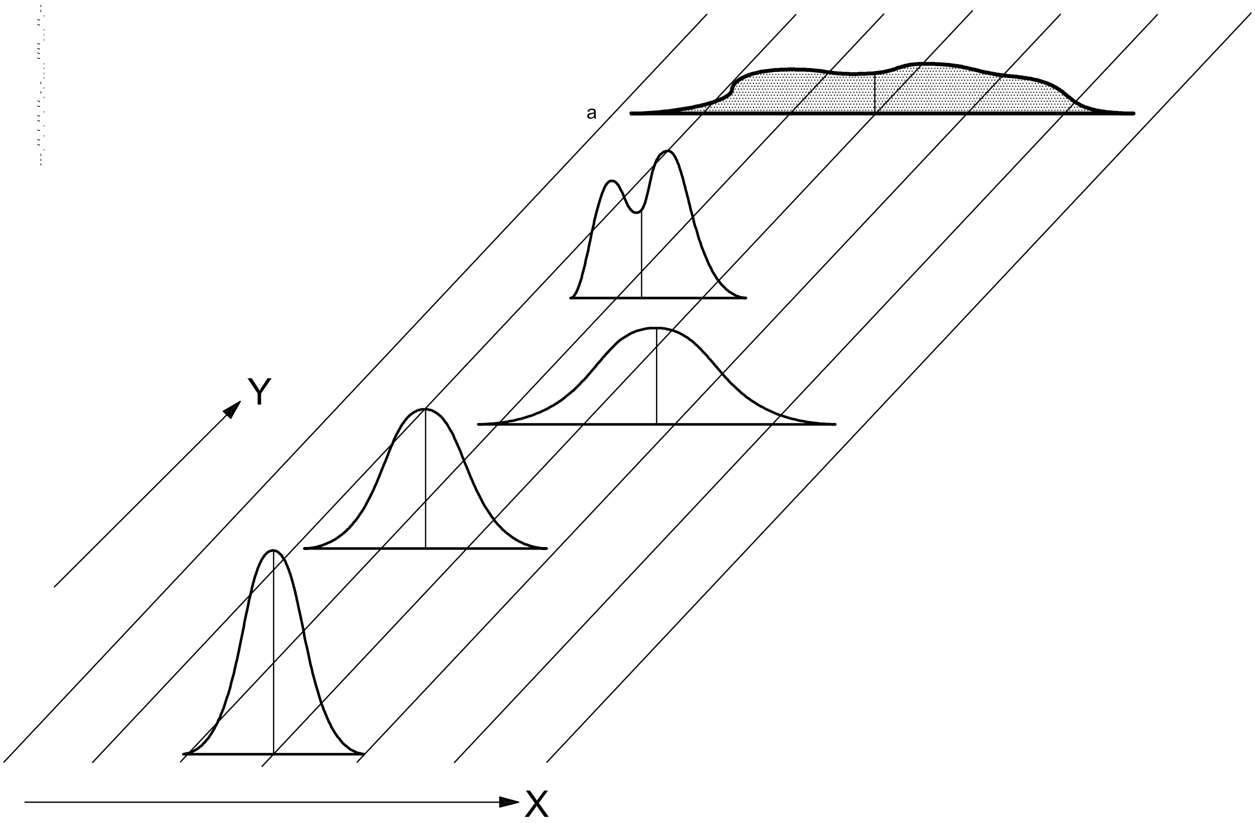
Time-dependent distribution model D (see Figure 8) has the following characteristics (e.g. multi-stream processes):

— location: systematic and random change;

— dispersion: systematic and random change;

— instantaneous distribution: any shape whatever;

— outcoming distribution: any shape whatever.



Key

X characteristic value x

Y time

[a] Outgoing distribution.

Figure 8 — Graphical representation of time-dependent distribution model D

7 Process capability and performance indices

7.1 Methods for the determination of performance and capability indices — Overview

As detailed in the preceding clauses, the basis for determination of process capability and performance statistics is the distribution of characteristic values of a product characteristic.

The calculation of the performance indices, as well as the capability indices is based on the location and dispersion of characteristic values with respect to the tolerance. There are four methods for this calculation (see Table 2).

Table 2 — Methods for the determination of performance and capability indices

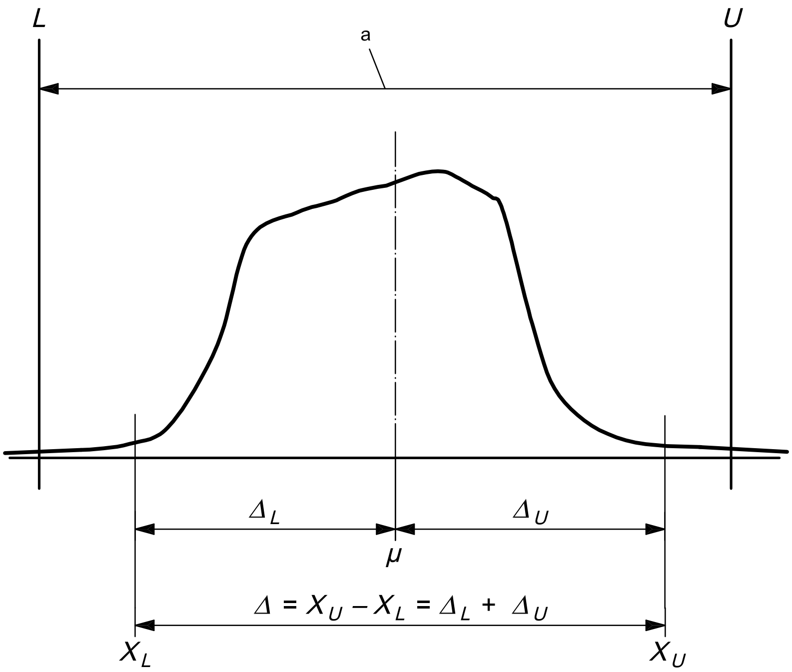
Method [a]	Calculation…
$M1_{l,d}$ General geometric method	… with estimators for location μ and dispersion Δ
$M2_{l,d,a}$ Explicit inclusion of additional variation	… with estimators for location μ, dispersion Δ, and additional fluctuations μ_{add}
$M3_{l,d,a}$ Alternative method of explicit inclusion of additional variation	… with estimators for location μ, dispersion Δ, and additional fluctuations μ_{add}
M4 Excess proportions approach	… with estimators for upper and lower excess proportions

[a] The subscript l refers to an equation for calculation of the estimator for the location μ [Equations (25) to (29)].

The subscript d refers to an equation for calculation of the estimator for the dispersion Δ [Equations (30) to (35)].

The subscript a refers to an equation for calculation of the estimator for the additional variation μ_{add} [Equations (40) and (41)].

7.2 General geometric method ($M1_{l,d}$)



Key

a Specified tolerance $U - L$.

Figure 9 — Graphical representation of the general geometric method M1

In Figure 9, μ indicates the location of the process and Δ indicates the dispersion of the process. Their exact definitions, depending on the method, will be given later. The dispersion is bounded by the lower point X_L, and the upper point X_U. Then we have

$$\Delta_L = \mu - X_L \tag{15}$$

and

$$\Delta_U = X_U - \mu \tag{16}$$

The process performance indices are defined by ratios of length of a geometric parameter of the distribution to the specified tolerance:

Process performance index $$P_\text{p} = \frac{U - L}{\Delta} \tag{17}$$

Lower process performance index $$P_{\text{pk}L} = \frac{\mu - L}{\Delta_L} \tag{18}$$

Upper process performance index $$P_{\text{pk}U} = \frac{U - \mu}{\Delta_U} \tag{19}$$

Minimum process performance index $$P_\text{pk} = \min\left(P_{\text{pk}L}, P_{\text{pk}U}\right) \tag{20}$$

If a process is proven to be in the state of statistical control, a capability index can be assigned. The formulae are the same as for the corresponding performance index:

Capability index $$C_\text{p} = \frac{U - L}{\Delta} \tag{21}$$

Lower capability index $$C_{\text{pk}L} = \frac{\mu - L}{\Delta_L} \tag{22}$$

Upper capability index $$C_{\text{pk}U} = \frac{U - \mu}{\Delta_U} \tag{23}$$

Minimum capability index $$C_\text{pk} = \min\left(C_{\text{pk}L}, C_{\text{pk}U}\right) \tag{24}$$

There are different estimators for the location μ and the dispersion Δ of a given data set.

IMPORTANT — It should be emphasized that a quantitative comparison of the performance and capability indices calculated according to the different methods is not feasible.

The location of the process, μ, can be estimated with one of the following estimators, $\hat{\mu}$

$l = 1$ $$\hat{\mu} = \overline{x} = \frac{1}{n}\sum x_i \tag{25}$$

where

x_i are the individual values; and

n is the number of values.

$$l = 2 \qquad \hat{\mu} = \tilde{x} = \begin{cases} x_{\left(\frac{n+1}{2}\right)} & ; n \text{ odd} \\ \frac{1}{2}\left[x_{\left(\frac{n}{2}\right)} + x_{\left(\frac{n}{2}+1\right)}\right] & ; n \text{ even} \end{cases} \Bigg\} \text{ order statistic } x_i \tag{26}$$

$$l = 3 \qquad \hat{\mu} = X_{50\,\%} \tag{27}$$

$$l = 4 \qquad \hat{\mu} = \bar{\bar{x}} = \frac{1}{m}\sum \bar{x}_i \tag{28}$$

where

$\bar{x}_i$ is the average of the ith subgroup; and

m is the number of subgroups of size n.

$$l = 5 \qquad \hat{\mu} = \bar{\tilde{x}} = \frac{1}{m}\sum \tilde{x}_i \tag{29}$$

where

$\tilde{x}_i$ is the median of the ith subgroup; and

m is the number of subgroups of size n.

The dispersion of the process, Δ, can be estimated with one of the following estimators, $\hat{\Delta}$.

$$d = 1 \qquad \hat{\Delta} = 6\hat{\sigma}_1; \; \hat{\Delta}_L = \hat{\Delta}_U = 3\hat{\sigma}_1 \tag{30}$$

where

$$\hat{\sigma}_1 = \sqrt{\frac{\sum s_i^2}{m}};$$

s_i^2 is the variance of the ith subgroup; and

m is the number of subgroups of size n.

$$d = 2 \qquad \hat{\Delta} = 6\hat{\sigma}_2; \; \hat{\Delta}_L = \hat{\Delta}_U = 3\hat{\sigma}_2 \tag{31}$$

where

$$\hat{\sigma}_2 = \frac{\Sigma s_i}{m c_4};$$

s_i is the standard deviation of the ith subgroup; and

m is the number of subgroups of size n.

See ISO 8258 for tables of c_4 coefficients.

$d = 3 \qquad \hat{\Delta} = 6\hat{\sigma}_3;\ \hat{\Delta}_L = \hat{\Delta}_U = 3\hat{\sigma}_3$ (32)

where

$\hat{\sigma}_3 = \frac{\Sigma R_i}{m d_2}$,

R_i is the range of the ith subgroup;

$R = x_U - x_L$; and

m is the number of subgroups of size n.

See ISO 8258 for tables of d_2 coefficients.

$d = 4 \qquad \hat{\Delta} = 6\hat{\sigma}_4;\ \hat{\Delta}_L = \hat{\Delta}_U = 3\hat{\sigma}_4$ (33)

where

$\hat{\sigma}_4 = \sigma_t = \sqrt{\frac{1}{n-1}\sum\left(x_i - \bar{x}\right)^2}$; and

σ_t is the standard deviation of the whole data set.

$d = 5 \qquad \hat{\Delta} = R;\ \hat{\Delta}_U = \max\left(x_i\right) - \hat{\mu};\ \hat{\Delta}_L = \hat{\mu} - \min\left(x_i\right)$ (34)

$d = 6 \qquad \hat{\Delta} = X_{99,875\,\%} - X_{0,135\,\%};\ \hat{\Delta}_U = X_{99,875\,\%} - \hat{\mu};\ \hat{\Delta}_L = \hat{\mu} - X_{0,135\,\%}$ (35)

NOTE 1 The estimators $\hat{\Delta}$ for d = 1, 2, 3 estimate the subgroup variance only, they neglect the variance between different subgroups. They should be used for process model A1 only.

NOTE 2 The estimators $\hat{\Delta}$ for d = 1, 2, 3, 4 assume that the data is normally distributed. Otherwise, their result is biased depending on the type of distribution.

NOTE 3 The estimator $\hat{\Delta}$ for d = 5 is biased. The bias depends on the distribution and on the subgroup size.

NOTE 4 The estimator $\hat{\Delta}$ for d = 6 is the most general one, it can be used under all conditions.

$\hat{\Delta}$ is also called the reference interval.

7.3 Explicit inclusion of additional variation (M2$_{l,d,a}$)

This method is a modification of the first one, taking explicitly into account additional fluctuations μ_{add}. The dispersion estimators $d = 1, 2, 3$ are estimators of the inherent variation in the subgroups only. μ_{add} can be estimated of the extra variation between the subgroups (process models C and D).

Process performance $P_p = \frac{U - L}{\Delta + \mu_{\text{add}}}$ (36)

Lower process performance index $P_{\text{pk}L} = \frac{\mu - L}{\Delta_L + \frac{1}{2}\mu_{\text{add}}}$ (37)

Upper process performance index $$P_{\text{pk}U} = \frac{U - \mu}{\Delta_U + \frac{1}{2}\mu_{\text{add}}} \tag{38}$$

Minimum process performance index $$P_{\text{pk}} = \min\left(P_{\text{pk}L}, P_{\text{pk}U}\right) \tag{39}$$

The same methods as in approach M1 to estimate the location and the dispersion Δ are used. Additionally, there are two possibilities to estimate the additional variation:

— estimators $\hat{\mu}_{\text{add}}$ for additional variation μ_{add}; and

— the estimators for additional variation estimate the variation between different subgroups.

They should be used only in combination with one of the estimators of the dispersion $d = 1, 2, 3$ which neglects this variation:

$a = 1$ $$\hat{\mu}_{\text{add}} = \max\left(\bar{x}_i\right) - \min\left(\bar{x}_i\right) \tag{40}$$

where $\bar{x}_i$ is the mean of the ith subgroup.

$a = 2$ $\hat{\mu}_{\text{add}}$ is calculated by analysis of variance (ANOVA) (41)

7.4 Alternative method of explicit inclusion of additional variation (M3$_{l,d,a}$)

This method is similar to the second, but the additional fluctuations are taken into account differently:

Process performance index $$P_{\text{p}} = \frac{U - L - \mu_{\text{add}}}{\Delta} \tag{42}$$

Lower process performance index $$P_{\text{pk}L} = \frac{\mu - L - \frac{1}{2}\mu_{\text{add}}}{\Delta_L} \tag{43}$$

Upper process performance index $$P_{\text{pk}U} = \frac{U - \mu - \frac{1}{2}\mu_{\text{add}}}{\Delta_U} \tag{44}$$

Minimum process performance index $$P_{\text{pk}} = \left(P_{\text{pk}L}, P_{\text{pk}U}\right) \tag{45}$$

7.5 Calculation of fractions nonconforming (M4)

The distribution model has to be known for this calculation. See Figure 10.

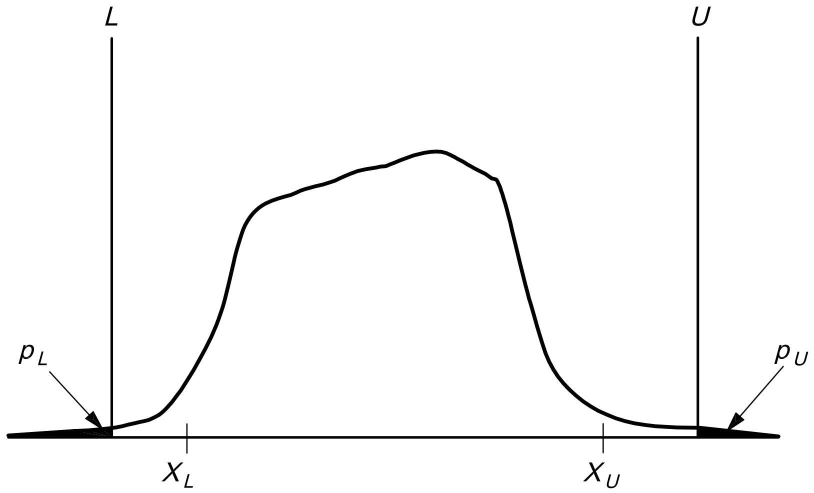


Figure 10 — Graphical representation of the calculation method M4

The lower fraction nonconforming, p_L, and the upper fraction nonconforming, p_U, are the areas under the distribution function outside the lower and upper tolerance.

Lower process performance index $$P_{\text{pk}L} = \frac{z_{(1-p_L)}}{3} \quad (46)$$

Upper process performance index $$P_{\text{pk}U} = \frac{z_{(1-p_U)}}{3} \quad (47)$$

Minimum process performance index $$P_{\text{pk}} = \min\left(P_{\text{pk}L}, P_{\text{pk}U}\right) \quad (48)$$

where z_α is the α-quantile of a standardized normal distribution from $-\infty$ to α.

If a process is proven to be in the state of statistical control, a capability index can be assigned. The formulae are the same as for the corresponding performance index:

Lower capability index $$C_{\text{pk}L} = \frac{z_{(1-p_L)}}{3} \quad (49)$$

Upper capability index $$C_{\text{pk}U} = \frac{z_{(1-p_U)}}{3} \quad (50)$$

Minimum capability index $$C_{\text{pk}} = \min\left(C_{\text{pk}L}, C_{\text{pk}U}\right) \quad (51)$$

There is no possibility to calculate a “process performance index, P_{p}” or a “process capability index, C_{p}” with this method.

7.6 One-sided specification limits

One-sided specification limits can be treated in the same manner as two-sided specification limits. See Figure 11.

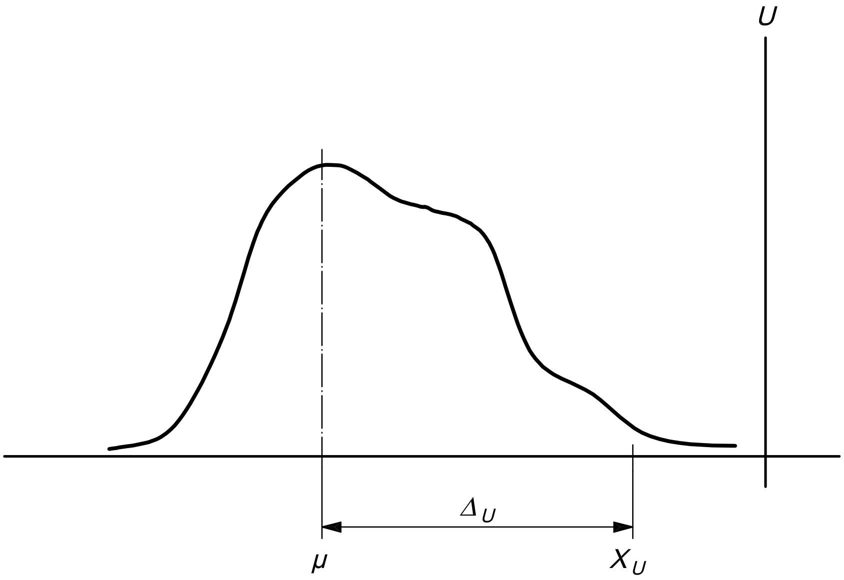


Figure 11 — Graphical representation of the calculation method Δ_U

In the case of an upper specification limit, we have

Upper process performance index $$P_{\text{pk}U} = \frac{U - \mu}{X_U - \mu}$$ (52)

Minimum process performance index $$P_{\text{pk}} = P_{\text{pk}U}$$ (53)

If a process is proven to be in the state of statistical control, a capability index can be assigned. The formulae are the same as for the corresponding performance index:

Upper capability index $$C_{\text{pk}U} = \frac{U - \mu}{X_U - \mu}$$ (54)

Minimum capability index $$C_{\text{pk}} = C_{\text{pk}U}$$ (55)

X_U and μ are estimated as in method M1.

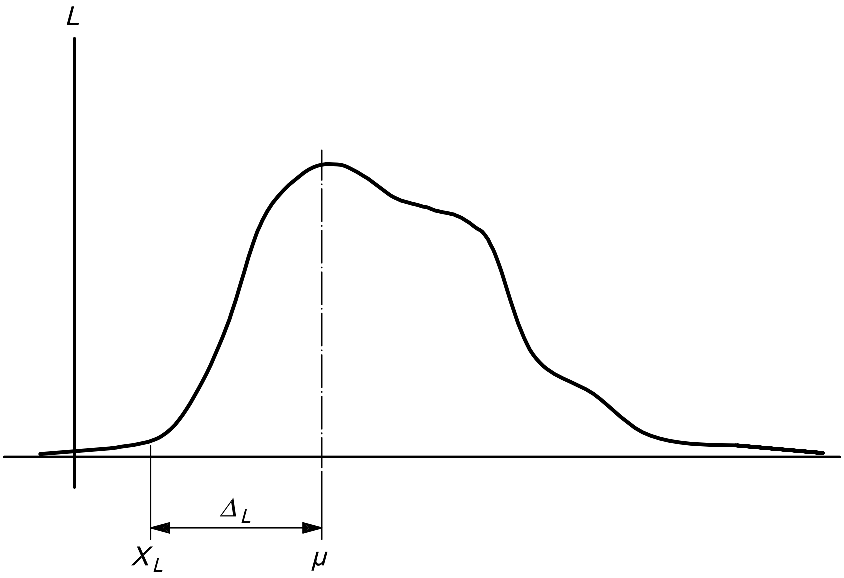


Figure 12 — Graphical representation of the calculation method Δ_L

In the case of a lower specification limit, we have

Lower process performance index $$P_{\text{pk}L} = \frac{\mu - L}{\mu - X_L} \quad (56)$$

Minimum process performance index $$P_{\text{pk}} = P_{\text{pk}L} \quad (57)$$

If a process is proven to be in the state of statistical control, a capability index can be assigned. The formulae are the same as for the corresponding performance index:

Lower capability index $$C_{\text{pk}L} = \frac{\mu - L}{\mu - X_L} \quad (58)$$

Minimum capability index $$C_{\text{pk}} = C_{\text{pk}L} \quad (59)$$

X_L and μ are estimated as in method M1.

8 Reporting process performance/capability indices

If process performance/capability statistics are used for process qualification, they should be reported with relation to this International Standard. The calculation method and the number of values used as basis for the calculation shall be stated.

An example is given in Table 3.

Table 3 — Example — Process capability indices

Process capability index	C_p = 1,68
Minimum process capability index	C_{pk} = 1,47
Calculation method	$M1_{1,6}$ [a]
Number of values used for the calculation	2 000
Optional: — frequency of sampling; — time and duration of data taking; — choice of time distribution model justification; — measurement system gauge capability repeatability and reproducibility uncertainty resolution; — technical conditions (batches, operation, tools).	A2

[a] Calculation method $M1_{1,6}$ means:

Method M1 with estimator $\hat{\mu} = \mu_1$ and $\hat{\Delta} = \Delta_6$.

Another method would be $M2_{1,\,4,\,2}$ where the estimators are $\hat{\mu} = \mu_1, \hat{\Delta} = \Delta_4$, and $\hat{\mu}_{add}$ is calculated by analysis of variance.

Bibliography

[1] ISO/TR 12783[3)], *Process capability and performance measures*

[2] ISO 3534-1[4)], *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

[3] ISO 3534-2:—[5)], *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

[4] ISO 8258, *Shewhart control charts*

3) Under preparation.

4) To be published. (Revision of ISO 3534-1:1993)

5) To be published. (Revision of ISO 3534-2:1993)

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