SLOVENSKI STANDARD
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Statistiļ ne metode ï Statistike delovanja in sposobnosti procesa za merjene karakteristike kakovosti

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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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

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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 $X_{50\ \%} - X_{0,135\ \%}$.

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2) Under preparation.