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Statistical methods in process management — Capability and performance —

Part 2:

Process capability and performance of time-dependent process models

Méthodes statistiques dans la gestion de processus — Aptitude et performance —

Partie 2: Aptitude de processus et performance des modèles de processus dépendants du temps

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Foreword

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

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

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

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

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

The committee responsible for this document is ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 4, *Applications of statistical methods in process management*.

This second edition of ISO 22514-2 cancels and replaces the corrected version of the first edition (ISO 22514-2:2013), of which it constitutes a minor revision.

The changes compared to the previous edition are as follows:

- the symbols and indices in C_{pk_I} , $C_{pk_{II}}$, P_{pk_I} and $P_{pk_{II}}$ have been improved;
- in Table 2, row "Location", column "C", the letter "s" has been replaced by "s/r";
- in Table 2, row "Location", column "D", the capital letter "S" has been replaced by "s/r";
- in <u>Table 3</u>, row "Location method label", rows "3" and "4" in Formulae (13) and (14) the usage of indices has been improved and it is more precise now;
- editorial adjustments have been made to comply with the latest edition of the ISO/IEC Directives, Part 2, 2016.

A list of all parts in the ISO 22514- series, published under the general title *Statistical methods in process management* — *Capability and performance*, can be found on the ISO website.

Introduction

Many standards have been created concerning the quality capability/performance of processes by international, regional and national standardization bodies and also by industry. All of them assume that the process is in a state of statistical control, with stationary, normally distributed processes. However, a comprehensive analysis of production processes shows that, over time, it is very rare for processes to remain in such a state.

In recognition of this fact, this document provides a framework for estimating the quality capability/performance of industrial processes for an array of standard circumstances. These circumstances are categorized based on the stability of the mean and variance, as to whether they are constant, changing systematically, or changing randomly. As such, the quality capability/performance can be assessed for very differently shaped distributions with respect to time.

In other parts of ISO 22514 more detailed information about calculations of indices can be found. It should be noted that where the capability indices given in this document are computed they only form point estimates of their true values. It is therefore recommended that wherever possible the indices' confidence intervals are computed and reported.

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Statistical methods in process management — Capability and performance —

Part 2:

Process capability and performance of time-dependent process models

1 Scope

This document describes a procedure for the determination of statistics for estimating the quality capability or performance of product and process characteristics. The process results of these quality characteristics are categorized into eight possible distribution types. Calculation formulae for the statistical measures are placed with every distribution.

The statistical methods described in this document only relate to continuous quality characteristics. They are 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://standards.iteh.ai)

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 5479, Statistical interpretation of data — Tests for departure from the normal distribution

3 Terms definitions, symbols and abbreviated terms

For the purposes of this document, the terms and definitions given in ISO 3534-2 and ISO 22514-1, and the symbols and abbreviated terms given below, apply.

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1 Symbols

C_{p}	process capability index
$C_{\rm pk}$	minimum process capability index
C_{pk_L}	lower process capability index
C_{pk_U}	upper process capability index
C4	constant based on subgroup size <i>n</i>

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Δ dispersion of the process difference between X_{mid} and $X_{0.135}$ % of the distribution of the product characteristic $\Delta_{\rm L}$ difference between $X_{99.865}$ % and X_{mid} of the distribution of the product characteristic $\Delta_{\rm U}$ d_2 constant based on subgroup size *n* number of subgroups of the same size *n* k average location of the process μ lower specification limit L calculation methods with location method label *l* and dispersion method label *d* $M_{l,d}$ N sample size lower fraction nonconforming p_L total fraction nonconforming p_{t} upper fraction nonconforming p_U process performance index $P_{\rm p}$ minimum process performance index tandards $P_{\rm pk}$ lower process performance index and ards.iteh.ai) P_{pk_L} $P_{pk_{II}}$ range of the *i*th subgroup R_i standard deviation, realized value 75:00-afe8-498e-8250-6343c07de961/iso-22514-2-2017 S standard deviation, population σ S standard deviation, sample statistic observed sample standard deviation of the *i*th subgroup S_i standard deviation, with the subscript "t" indicating total standard deviation S_{t} U upper specification limit *X*_{0,135} % 0,135 % distribution quantile 99,865 % distribution quantile X99,865 % 50 % distribution quantile *X*50 % distribution midpoint X_{mid}

3.2 Abbreviated terms

ANOVA analysis of variance

SPC statistical process control

4 Process analysis

The purpose of process analysis is to obtain 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 document that a process analysis has been carried out and subsequent process improvements have been implemented.

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 resulting distributions the parameters of which are time-dependent functions are discussed in <u>Clauses 6</u> and <u>7</u>. To indicate 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.

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. To asses the stability of the process a control chart should be used. Information on the use of control charts can be found in ISO 7870-2.

5 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 output from the process is called the resulting 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 resulting distribution can be represented by the whole data set, 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 (see <u>Table 1</u>).

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

Table 1- Classification of time-dependent distribution models

Process-standard				Process	Process average μ(t)			
deviation s(t)		Constant		s://s		Not constant		
		A		stan		O		
		A1	A2	dar	C1	C2	C3	C4
				ds.it	Random	Random	Systematic	Systematic and random
			NO.	n.ai/			(e.g. trend)	(e.g. lot to lot)
Constant	Short	Normal	normal	Short time distribu-	Normal	Normal	Normal	Normal
	time	distributed distributed	distributed	alo	distributed	distributed	distributed	distributed
	distribution		– unimodal	g/s		Not		
				Resulting distribution	Normal distributed	normal distrib- uted	Any shape	Any shape (e.g. multimodal)
				O (– unimodal)
Not	Resulting	В	8	Doculting dictailand	Ге //	D		
constant	distribution	Any shape – unimodal	- unimodal	Resulting distribution	h	Any shape	hape	

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