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Implementation of statistical process control (SPC) —

Part 1: Statistical process management — Elements, tools and techniques of SPC

Mise en oeuvre de la maîtrise statistique des processus (MSP) —

Partie 1: Gestion statistique des processus (MSP) — Élements, outils et techniques de MSP

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Foreword

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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).

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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 4, *Applications of statistical methods in product and process management*.

This second edition cancels and replaces the first editions of ISO 11462-1:2001 and ISO 11462-2:2010, which have been technically revised.

The main changes are as follows:

— The previous editions presented the “Elements of SPC” (ISO 11462-1:2001) and a “Catalog of tools and techniques” (ISO 11462-2:2010). The new revision combines both and integrates the elements, tools and techniques with a description of the processes and control loops for implementing SPC.

  This revision of the standard has therefore been restructured and should now be understood as an overarching framework for the ISO 7870 and ISO 22514 series of standards. It describes and combines the application of the individual parts of these series of standards in control loops and process operations.

A list of all parts in the ISO 11462 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

The ISO 11462 series provides guidelines for the implementation of a statistical process control (SPC) system. These guidelines are aimed primarily at increasing production efficiency and inherent capability and reducing sampling interval and cost.

This document provides guidance on the implementation of a statistical process control (SPC) system and an overview of tools and techniques to assist an organisation in planning, implementing and evaluating an effective statistical process control (SPC) system. These tools and techniques are essential for the successful implementation of the SPC elements specified in this document.

By implementing those elements deemed applicable and appropriate by customer and supplier, an organisation may satisfy a requirement to adopt a comprehensive and effective SPC system. By also deploying a quality system with the aim of ensuring that products and services meet customer requirements (such as the system defined by ISO 9001), an organisation can improve the infrastructure so as to help hold the gains from its SPC system.

The common economic objective of statistical process control is to increase good process outputs produced for a given amount of resource inputs.

This document follows the definition of process control according to ISO 3534-2 in the sense of the definitions of statistical process control as well as the activities focused on reducing dispersion, improving knowledge about the process and controlling the process in the desired way by means of statistical methods, and extends the definition in the sense of statistical process management by further necessary preparatory activities which are prerequisites of statistical process control.

This document also extends the definition and usage of the term parameter to apply to a process parameter or a product parameter; and to recognize that a product parameter can be either an in-process product parameter or a final-product parameter. Under specified conditions of measurement, a product parameter can be equivalent to a product characteristic.

Some considerations given in the formulations of ISO 11462 series are the following:

a) Elements of this document give guidance to an organisation in how to implement an SPC system. Specific tools and techniques that experience has shown useful in applying these elements within processes will be listed in this document.

b) Users of ISO 11462 series should be aware that the use of “should” throughout both parts of ISO 11462 indicates that

   1) among several possibilities, one or more are recommended as being particularly suitable and effective, without mentioning or excluding others;

   2) a certain course of action is preferred but not necessarily required for a process in order to gain the economic control of production.

This choice of language does not indicate requirements which are to be strictly followed in order to conform to this document and from which no deviation is permitted.

Implementation of statistical process control (SPC) —

Part 1: Statistical process management — Elements, tools and techniques of SPC

1 Scope

This document gives guidance on the implementation of a statistical process control (SPC) system and an overview of tools and techniques to assist an organisation in planning, implementing and evaluating an effective statistical process control (SPC) system.

This document specifies SPC system guidelines for use

— when a supplier's capability to reduce variation in processes associated with design or production needs to be proven or improved, or

— when a supplier is beginning SPC implementation to achieve such capability.

This document considers the complete industrial supply chain. It describes some essential statistical methods that can be used to continuously improve capability or performance and stability of production processes.

The bottom line is that production processes are controlled economically, promptly and effectively. As a result, a predefined level of quality can be realised. The improvement of stability and performance or capability of the production processes effectively reduces waste and machine downtime or increases productivity. If defective production parts are found in a random sample, they can be sorted out and, if necessary, further measures can be initiated.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

ISO 22514-1, *Statistical methods in process management — Capability and performance — Part 1: General principles and concepts*

ISO 22514-2, *Statistical methods in process management — Capability and performance — Part 2: Process capability and performance of time-dependent process models*

ISO 22514-3, *Statistical methods in process management — Capability and performance — Part 3: Machine performance studies for measured data on discrete parts*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1, ISO 3534-2 and ISO/IEC Guide 99 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
retrospective control chart
control chart for post-process analysis

Note 1 to entry: Retrospective control charts are used to assess the stability to distinguish between performance and capability indices. In the stability assessment, violations of stability criteria (out of control situations/alarms) up to the number of expected false alarms should not be assessed as instabilities due to the underlying non-interference probability.

Note 2 to entry: Retrospective control charts are typically process-related control charts.

Note 3 to entry: Retrospective control charts are sometimes also called phase 1 control charts.

3.2
SPC control chart
control chart for on-site process control or automatic process control

Note 1 to entry: SPC control charts are used to assess the stability of a process with known performance or capability indices. Any violation of stability criteria applied should be assessed as instability.

Note 2 to entry: SPC control charts are process- or tolerance related control charts.

Note 3 to entry: SPC control charts are sometimes also called phase 2 control charts.

3.3
dressing cycle
<tool> time that a tool can be used for production before it has to be reconditioned or replaced by a new tool due to wear

3.4
non-interference probability
<control chart> probability used as the basis for calculating warning or control limits which indicates the probability that a sample drawn from an in-control process will not exceed the respective limits

Note 1 to entry: Often expressed by z-values in case of control charts based on quantiles of a normal distribution, i.e. $z = 3$ for 3σ charts and 99,73 % non-interference probability, or $z = 2{,}575\ 8$ for charts based on 99 % non-interference probability.

3.5
product characteristic in control
product characteristic parameter of the distribution of the characteristic values of which practically do not change or do change only in a known manner or within known limits

[SOURCE: ISO 22514-1:2014, 3.1.20]

3.6
stable process
process in a state of statistical control
<constant mean> process subject only to random causes

Note 1 to entry: A production in control is a production with processes in control.

Note 2 to entry: 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 3 to entry: This state does not imply that the random variation is large or small, within or outside of specification, but rather that the variation is predictable using statistical techniques.

[SOURCE: ISO 3534-2:2006, 2.2.7, modified — Notes to entry have been modified and renumbered.]

4 Symbols and abbreviated terms

4.1 Symbols

C_{p}	process capability index
C_{pk}	minimum process capability index
$C_{\mathrm{pk}U}$	upper process capability index
$C_{\mathrm{pk}L}$	lower process capability index
U_{CL}	upper control limit
L_{CL}	lower control limit
k	number of subgroups
n	subgroup size
N	total sample size across all subgroups of a machine or process assessment
P_{p}	process performance index
P_{pk}	minimum process performance index
$P_{\mathrm{pk}U}$	upper process performance index
$P_{\mathrm{pk}L}$	lower process performance index
U	upper specification limit
L	lower specification limit

4.2 Abbreviations

CC	critical characteristic
CP	control plan
CT-Matrix	critical to – matrix (CTF critical to function. CTT critical to time, CTQ critical to quality)
EoL	end of line
FMEA	failure mode and effect analysis
LMR	least material requirement
MMC	maximum material condition
MMR	maximum material requirement

QFD	quality function deployment
RPR	reciprocity requirement
SC	significant characteristic
SPC	statistical process control
YS	potential significant characteristic
YC	potential critical characteristic

5 Statistical process management

5.1 General

ISO 3534-2, in which the terms and formula symbols of applied statistics are defined, describes

— “Process control” as process management directed towards the fulfilment of process requirements, and

— “Statistical process control” as activities aimed at reducing dispersion, improving knowledge about the process and controlling the process in the desired way by means of statistical methods.

This document expands the definition in terms of statistical process management to include further necessary preparatory activities that are prerequisites for statistical process control.

5.2 Control loops

Defined quality control loops enable a differentiated view of statistical process management, which, in addition to the interlocking methods of statistical process control (SPC), also defines higher-level goals and designates executing persons (see Table 1 and Table 2).

Table 1 — Control loops 1 to 3

Control loop	Quality		
	Control loop 1	**Control loop 2**	**Control loop 3**
Naming	Direct process control	Quality gates	Post-process control
Objectives	Continuous maintenance of the stability of the ongoing production process (online control), documentation of results and decisions.	Only approved lots (characteristics according to specification) are passed on and processed.	Understand processes by regularly assessing stability and capability, initiating improvement actions where necessary.
Methods, Standards	Each specified characteristic is tested on the basis of a test plan. Stability violations require cause analyses as well as appropriate reactions, e.g. correction of the process settings or, if necessary, a production stop. For documentation and monitoring, SPC control charts are used, for example, which are usually also available directly at the machine. The following are required: the use of approved test equipment (i.e. as mentioned in ISO 9001:2015, 7.1.5), validated measuring and testing processes as well as capable machines and preliminarily capable manufacturing processes.	Defined quality characteristics are checked for each production order, First part / last part and parts in between according to the inspection plan. It is a prerequisite that only calibrated, approved test equipment is used.	Based on data analyses, non-stable or non-capable processes are filtered out on a daily, weekly and monthly basis. If required, individual characteristics of selected parts can be traced back via manufacturing, assembly, EoL processes in order to proactively initiate process optimisations.
Executors	Production	Production	Production, planning, quality

Table 2 — Control loops 4 to 6

Control loop	Quality		
	Control loop 4	**Control loop 5**	**Control loop 6**
Naming	Product audits	Process audits	System audits
Objectives	The evaluation of the quality of the product ready for shipment from the customer's point of view.	The evaluation of compliance with all specifications in manufacturing, assembly and logistics processes.	The assessment of compliance with the QM system requirements.
Methods, Standards	Organisation- and customer-specific requirements	Organisational and customer-specific requirements	Organisational and customer-specific requirements (e.g. ISO 9001)
Executors	Internal auditors	Internal auditors	Internal and external auditors

5.3 Elements of SPC

Typical elements in the field of statistical process management that can be used to increase the knowledge about a process and, ultimately, the performance of a process are:

a) process documentation and control plan (see 6.4, 6.5);

b) definition of process or characteristic target values and their limits and specifications (see 6.1 to 6.3);

c) measuring system and measurement process capability (see 6.7);

d) documented work instructions (not provided in this document);

e) employee training and involvement (not provided in this document);

f) data recording and collection(see Clause 12);

g) traceability (see Clause 11);

h) subcontractor performance evaluation (not provided in this document);

i) process input sequencing (see Clause 12);

j) process logs (see Clause 12);

k) process reliability (not provided in this document);

l) process output monitoring system (see Clause 12);

m) process control system (see Clause 10);

n) machine performance assessment (see 7.1 and Clause 8);

o) process performance and capability assessment (see 7.2 and Clause 9);

p) communicating results of process analyses (see Clause 12);

q) customer information system (see Clause 12);

r) internal SPC audits (see 5.2);

s) SPC projects and teams (see 5.2);

t) process optimisation and troubleshooting and corrective actions (not provided in this document).

6 Prerequisites for SPC applications

6.1 General

The SPC applications presented in this document can be used as stand-alone tools, but experience shows that success does not come as desired. Therefore, the SPC applications need to be integrated into the company-wide quality processes for a meaningful and successful implementation. Above all, it is important to apply the tools in a goal-oriented way. In order to identify the decisive quality features and manufacturing processes and to be able to apply the underlying control concepts, a number of prerequisites should be met. These include above all

— conformity with the principles of responsibility within the framework of tolerance specification,

— risk analyses,

— determination of special characteristics,

— implementation of target-oriented production and test planning,

— preparation of a control or production control plan, and

— proof of capability for measuring and testing processes used.

See Figure 1 for a schematic flow of the preliminary work on SPC.