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Guidelines for implementation of statistical process control (SPC) —

Part 1:
Elements of SPC

Lignes directrices pour la mise en œuvre de la maîtrise statistique des processus (MSP) —

Partie 1: Éléments de MSP

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Contents

Page

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 3.

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 part of ISO 11462 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11462-1 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 4, *Applications of statistical methods in process management*.

ISO 11462 consists of the following parts, under the general title *Guidelines for implementation of statistical process control (SPC)*:

— *Part 1: Elements of SPC*

A catalogue of tools and techniques will be the future subject of part 2 to ISO 11462.

Annex A forms a normative part of this part of ISO 11462.

Introduction

ISO 11462 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 interval and cost.

This part of ISO 11462 provides *elements* to guide an organization in planning, developing, executing, and/or evaluating a statistical process control system. By implementing those elements deemed applicable and appropriate by customer and supplier, an organization 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 organization can improve the infrastructure so as to help hold the gains from its SPC system.

This part of ISO 11462 extends the definition of process control to integrate the traditional definitions of statistical process control, algorithmic process control, and model-based control methods. These are different approaches with the same purpose of reducing variation in both products and processes.

This part of ISO 11462 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 are the following:

a) Elements of part 1 of ISO 11462 guide an organization 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 part 2 of ISO 11462.

b) Users of ISO 11462 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 International Standard and from which no deviation is permitted.

Guidelines for implementation of statistical process control (SPC) —

Part 1: **Elements of SPC**

1 Scope

Statistical process control (SPC) concerns the use of statistical techniques and/or statistical or stochastic control algorithms to achieve one or more of the following objectives:

a) to increase knowledge about a process;

b) to steer a process to behave in the desired way;

c) to reduce variation of final-product parameters, or in other ways improve performance of a process.

These guidelines give the elements for implementing an SPC system to achieve these objectives. The common economic objective of statistical process control is to increase *good* process outputs produced for a given amount of resource inputs.

NOTE 1 SPC operates most efficiently by controlling variation of a process parameter or an in-process product parameter that is correlated with a final-product parameter; and/or by increasing the process's robustness against this variation. A supplier's final-product parameter may be a process parameter to the next downstream supplier's process.

NOTE 2 Although SPC is concerned with manufactured goods, it is also applicable to processes producing services or transactions (for example, those involving data, communications, software, or movement of materials).

This part of ISO 11462 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.

These guidelines are not intended for contractual, regulatory or certification use.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11462. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11462 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3534-1:1993, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms.*

ISO 3534-2:1993, *Statistics — Vocabulary and symbols — Part 2: Statistical quality control.*

ISO 3534-3:1999, *Statistics — Vocabulary and symbols — Part 3: Design of experiments.*

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary.*

3 Terms and definitions

For the purposes of this part of ISO 11462, the terms and definitions given in ISO 3534-1, ISO 3534-2, ISO 3534-3 and ISO 9000, as well as those given in annex A, apply.

NOTE Annex A provides a glossary of explanatory terms and definitions. Some of these terms and definitions given have been based on those given in references [1] and [2] of the Bibliography.

4 SPC applications

4.1 Process characteristics

It is intended that elements in this part of ISO 11462 be selected based on their applicability and appropriateness to a specific process. The selection of SPC elements, the order in which an organization implements these elements, and the extent to which the elements are adopted and applied by an organization all depend on factors including: customer needs, market being served, nature of product or service, technology, and the nature and speed of production and transaction processes.

It is emphasized that the SPC system guidelines specified in this part of ISO 11462 are complementary (not alternative) to both technical specified requirements (product-, test- or service-specific) and quality system requirements. These guidelines specify the elements that are recommended to be included in SPC systems. It is not the purpose of these SPC system guidelines to enforce uniformity of statistical process control systems.

These guidelines are generic, independent of any specific process, industry or economic sector. These guidelines are intended to be adopted in their present form by organizations implementing SPC. On occasion, they may need to be tailored by adding or deleting certain SPC system elements for specific circumstances. The phrases, “where appropriate”, and “where applicable” are used to highlight those elements whose particular application is expected to be more process-dependent or more market-sensitive.

4.2 Production characteristics

This part of ISO 11462 can be used in circumstances when:

— variation or deviation from either product requirements or performance to a target value may occur;

— confidence in product conformance can be attained by adequate demonstration of a supplier’s capabilities in design, development, production, installation, and/or servicing.

Production characteristics that benefit from SPC implementation include, but are not limited to:

a) design and development, production, installation, and/or servicing;

b) customized or mass production;

c) short runs or long runs;

d) small, medium or large-scale production;

e) discrete, batch, or continuous processes;

f) transactions, as in services, information or communications;

g) manual or automated technologies for production, assembly, test, or communications;

h) first pass or loops for rework, repair, reprocessing, or purging.

In this part of ISO 11462, references to a *product* include service, hardware, processed material, software, or a combination thereof, such as an information or communications transaction.

4.3 Techniques for control and models of processes

SPC elements extend to techniques applied on-line within the operation of the process; and off-line either outside the operation of the process, or on the outputs at the end of the process. These elements are not limited to traditional control charting techniques, to specific models of process data involving specific distributions or to specific patterns of correlation. The SPC elements can be applied to control processes regardless of the tactics used. Applications include automatic controllers for continuous and batch processes, automated editors for data inputs, control algorithms for timing or spacing of resource inputs, manual maintenance procedures for low volume outputs, and analytical procedures such as control charts. A supplier may use statistical, algorithmic or model-based methods, or a combination of such methods. The choice of these methods will depend on process data availability, model availability, business needs, as well as the relative frequency of random, unknown, and assignable causes of variation.

5 SPC objectives and organization

5.1 SPC objectives

5.1.1 General

Statistical process control as stated in clause 1 has one or more objectives, distinct from those of statistical quality control and important to emphasize:

a) to increase knowledge about the process;

b) to steer a process to behave in the desired way;

c) to reduce variation of final product parameters, or in other ways improve performance of a process.

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

5.1.2 Specific

Depending on the market being served, nature of product, process technology, and customer needs, effective implementation of SPC reduces cost and increases profit in the following ways:

a) by managing the process most economically, with the aim of greater consistency and improvement;

b) by reducing variation around target values in either a final product or process output parameter;

c) by transferring variation in an in-process product parameter to a controllable or manipulated process variable, and compensating for variation in the in-process product parameter (used in some control engineering applications) in order to increase consistency in final-product parameters;

d) by providing signals and evidence of how a process is behaving, and how it is likely to behave;

e) by assessing and quantifying what quality and consistency levels the process is currently capable of producing;

f) by identifying *when to, when not to* and *where to* look for assignable causes of variation or to make preventive process adjustments;

g) by pointing to potential root causes of variation or failure modes and their sources, identifying sources of poor yield or variability, and detecting assignable causes of variation which results in increasing speed of detection and in reducing troubleshooting costs;

h) by providing information that helps identify when assignable causes of variation are present which results in helping to reduce or remove the effects of these assignable causes and in effectively implementing corrective action;

i) by controlling and/or reducing random cause variation through process design changes, and other systematic changes to procedures;

j) by increasing knowledge of how the causes of variation of the system affect the process, improvements can be made to the process.

5.2 Financial motive for SPC

The strongest motive for implementing SPC is financial so as to increase *good* process outputs for a given amount of resource inputs. Ways to measure financial costs and benefits of SPC implementation against an alternative include, but are not limited to:

a) collecting producer costs such as cost of scrap, screening, rework, equipment repair, downtime, and outages;

b) collecting consumer costs incurred over the life cycle of the product;

c) estimating the amount of business and jobs lost because dissatisfied customers turn to competitors or refuse to pay a premium for perceived greater quality;

d) estimating benefits to other parts of the organization (such as design and development, marketing, production, installation and servicing) from the feedback and information that SPC brings;

e) quantifying benefits to all parts of the organization from faster troubleshooting and greater potential for process or product innovation.

5.3 Relationships

5.3.1 Relationship between traditional and automated process control

The general SPC objectives are shared both by traditional Shewhart control methods and by automatic process control based on a more complex model. The SPC elements can be used either to reduce variation in a process parameter or a process output, or to transfer variation to an adjusted or manipulated process input (for example, as in the chemical industry). The objective of reducing variation around target in final-product parameters is the same whether the process and/or product has specification limits.

5.3.2 Relationship to final product conformance-to-specification

SPC helps to minimize efforts required to assure final product conformance-to-specification (such as screening, sorting, sample inspection, 100 % inspection and/or testing) in the following ways:

a) identifying cause-and-effect relationships between final product, in-process product (or process output), and process input parameters;

b) enabling controls to be set up as early in the process as possible;

c) minimizing process variation, based on knowledge acquired from a) and on control actions taken in b) above.

When the system is properly executed, SPC is used to identify and either eliminate or dampen process disturbances. Depending on the process's characteristics and the forces driving deviations from targets, SPC may not completely eliminate the need for some screening or sampling inspection operations to detect accidental disturbances that must be prevented from reaching the customer (e.g. operator error or automatic control system interruptions, or later problems, such as handling errors). Extension of SPC elements to more widely defined processes affecting quality has been shown to minimize costs associated with such screening or inspection.

Depending on the capability and stability of the process, and on the level of nonconformity risk deemed acceptable by the customer, SPC may be used to reduce, for example, sample size and/or sampling frequency associated with process data collection and monitoring. If sample size and/or sample frequency are chosen optimally, and nonconformity risk decreases, SPC may be used to minimize or eliminate screening and inspection of final product. Accumulated knowledge acquired from SPC data can guide the supplier toward a reduction in the operating limits of the process. In turn, this reduction results in less product variation being detectable or measurable at the customer's site. The supplier's organization may use the accompanying cost savings and competitive advantage of SPC to do any remaining screening or inspection in a more efficient way.

Depending on progress made implementing SPC on a particular project, a supplier may prove the product meets specifications with one or a combination of the following:

a) quality conformance evaluations and acceptance sampling with feedback (algorithmic or procedural) to the process;

b) final-product parameter monitoring and control;

c) in-process product parameter monitoring and control;

d) process parameter monitoring and control, for those parameters identified as correlating with final-product parameters.

5.4 SPC organization

5.4.1 Organizing for SPC implementation

SPC implementation activities such as process data collection, process control, parameter correlation and capability assessment/improvement should be performed:

a) through projects selected based on specific criteria;

b) through work on processes linked in a successive stream or linked in a product supply chain. (For example, this may be done by choosing a final product parameter and organizing SPC efforts focusing on one set of parameters, then moving to another set successively upstream in the supply chain.)

6 Conditions for statistical process control

6.1 Management support

The supplier's management should document, implement, and maintain its continuing support for SPC. This includes, but is not limited to, the following:

a) improving the process, based on periodic review of both SPC results and audit reports. The supplier should ensure that management SPC policy is understood, implemented and maintained at all levels in the organization;

b) using and improving data to drive decisions about the process;

c) supporting recording of, and reaction to, process disturbances and/or out-of-control points, without penalty;

d) appointing and supporting SPC coordination responsibility.

6.2 Understanding of SPC tools and methods

The supplier should design, implement and review programs that provide, but are not limited to, the following:

a) awareness in SPC tools and methods for all employees (including management) involved with SPC;

b) training to make SPC skills appropriate to employees' job functions and to their interaction with the process;

c) ensuring sufficient expertise is available to understand the objectives, application, and risks associated with the statistical and algorithmic control techniques chosen.

6.3 Quality management system

To help preserve the benefits of the SPC system, the supplier should seek to establish and maintain the infrastructure of a quality management system, for example, as prescribed by applicable ISO 9001 requirements.

7 Elements of a statistical process control system

7.1 Process documentation and control plan

The supplier should document the process, the system of measurement, and the system of controls in a control plan. This should be done at all important points in the process where form, fit, function or suitability for use are altered. The supplier is recommended to consider cost characteristics (if available) of basic technological operations and to draw on cross-functional job experiences. The documentation should include, but is not limited to, the following:

a) Constructing a flow diagram, or other alternative, that identifies:

   1) process inputs and outputs;

   2) process flows;

   3) process measurement points (with feedforward or feedback control loops, if appropriate);

   4) process return loops (for example, repair, rework, regrinding, reprocessing, purging, or rejections and dropout of transactions);

   5) process boundaries.

b) Identifying potential process parameters, in-process product parameters, and final-product parameters. Process parameters sometimes may affect product performance in ways not measurable or observable immediately after the operation occurs. It is always recommended that the supplier consider using one or more of the following methods:

   1) engineering judgement;

   2) controls applied downstream to measure process parameters whose effects are not immediately visible;

   3) conformance testing, repeated periodically when designs or materials change;

   4) functional testing or accelerated testing;

   5) a system for timely customer feedback of suitability for use on receipt of the product by the customer.

c) Assessing how process and in-process product parameters may affect form, fit, function and suitability for the customer's use; and how time and conditions of use either may interact with these parameters' effects, or may directly affect final product parameters.

