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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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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.

d) Defining expectations for how the three sets of parameters (process, in-process product and final-product parameters) may be related to help identify omissions in the control plan.

e) Identifying what parameters are effective to measure, where, when, how often; identifying how the data should be used; identifying how the data should be retained, if applicable; and by what job function's responsibility; and understanding why certain parameters are chosen. For example, in automatic control, indirectly and directly controlled variables are distinguished.

f) Identifying what remaining parameters can only be measured with attribute or count data as the result, or not measured at all, to help rank improvements to the measurement system.

g) Stating in an out-of-control action plan what to do about out-of-control signals and/or process disturbances: reaction mechanisms, corrective actions, and responsibilities for action by specific job functions.

7.2 Definition of process targets and limits

The supplier should document the target values and limits (and/or method(s) used to arrive at them) of the process (or in-process product) parameters beyond which the process will produce unacceptable or uneconomic process outputs or final product parameters. This should include, but is not limited to, the following:

a) Quantifying target values and operating limits, or identifying them with a qualitative description or other appropriate sensory mechanism, for example a picture, photograph, master sample or reference sample.

b) Reviewing target values and/or operating limits, including evaluating their adequacy with respect to both customer needs and an understanding of the process.

c) Identifying problems that affect the setting of targets and limits. Such identification helps the supplier rank improvements to the customer feedback system or to the system that measures the accelerated life of a product.

d) Drawing on cross-functional job experiences to set targets and limits, especially those job functions involved in setting or adjusting process control parameters or in responding to process disturbances.

7.3 Measurement system evaluation and control

The supplier should periodically monitor and evaluate the measurement system and as appropriate control or compensate for its variability. This action helps minimize the risks that measurement system inadequacies may lead either to false out-of-control signals to the supplier or to nonconforming product received by the customer. Measurement systems include but are not limited to, automatic monitoring and control systems, manual tracking systems such as survey instruments, fixturing and test set equipment, automated transaction record-keeping systems, and physical and chemical property equipment. Drawing on cross-functional job experiences, this should include, but is not limited to, the following:

a) Evaluating the adequacy of the measurement system's uncertainty under the range of conditions within which the system operates. This includes, but is not limited to:

- discrimination;
- accuracy;
- repeatability;
- intermediate precision;
- reproducibility;
- linearity;
- stability under the range of conditions under which the system operates;

and should include, for example:

— the use of SPC methods such as control charts and time series analyses to evaluate the measurement system;

— the evaluation of test set and test operator differences in bias and precision.

b) Establishing criteria for acceptable uncertainty in the measurement system.

c) Periodically auditing or verifying calibration of measurement system facilities.

d) Documenting the conditions requiring periodic verification of calibration.

e) Where appropriate, maintaining historical data of the measurement results taken just before calibration, and analysing the history to adjust calibration intervals.

f) Where appropriate, adjusting calibration intervals; and if appropriate, having procedures to identify when to quarantine or recall product that may severely deviate from target because of a miscalibrated or uncalibrated instrument.

g) Where appropriate, supplementing the measurement system evaluation with tolerance analyses based on specification data supplied with the measuring system.

h) Documenting limitations on measurement system evaluation and control. Care should be taken to avoid calibrating the measurement system beyond the physical limits of the technology or the equipment, as this can add to the measurement system uncertainty.

7.4 Documented work instructions

The supplier should document work instructions and should draw on cross-functional job experiences initially to prepare and periodically to evaluate instructions' adequacy. This should include, but is not limited to, the following:

a) documenting procedures for production, measurement, inspection, test and maintenance processes;

b) documenting procedures and/or control algorithms for the following:

1) setting up the process;

2) operating, monitoring and controlling the process;

3) detecting deficiencies in process inputs, control variables, and process outputs;

4) reacting to out-of-control conditions;

5) troubleshooting process disturbances;

c) periodically reviewing work instructions for adequacy and employee understanding.

7.5 Employee training and involvement in process data

The supplier should ensure that all appropriate employees are trained in taking and using process data. The supplier should ensure that those employees are involved in deciding what parameters to measure, and how to measure, collect, interpret, and act on the data. This data training and involvement should include, but is not limited to, the following:

a) preparing a plan and instructions for data collection;

b) procedures for designing, installing and testing control systems and instrumentation, and procedures for sampling, collecting, interpreting and acting on data;

c) identifying and acquiring any controls, processes, inspection or monitoring equipment or software, facilities, resources and skills that may be needed to obtain the required data for process control;

d) updating, as necessary, process control, inspection and testing techniques, including development of new instrumentation or control algorithms, that influence data quality and integrity for process control;

e) identifying any measurement requirement that exceeds the known state of the art in process control, in enough time for the necessary measurement ability to be developed;

f) assessing the inherent capability of the measurement system, and its capability with respect to the system for controlling a particular process;

g) setting standards of acceptability and integrity of process data, including those that contain subjective, unobservable or unmeasurable elements;

h) identifying, preparing and retaining process data records;

i) improving the integrity, interpretation and analysis of process data records.

7.6 Process data recording and collection

The supplier should design, establish, maintain and review an appropriate manual and/or automatic system for recording histories of process data or their summaries. This should include, but is not limited to, the following:

a) Planning the system to let historical data be used to identify causes of variation potentially assignable in the process.

b) Documenting sampling decisions. This should include, but is not limited to:

   1) basis for subgrouping, where appropriate;

   2) sample size;

   3) sampling frequency relative to throughput and cycle time, including quantities processed between successive samples;

   4) sampling stratification;

   5) randomization strategies;

   6) sampling location;

   7) sampling responsibilities;

   8) order of measurement, with respect to the order of production;

   9) periodic review of sampling decisions.

c) Defining what summary data should be retained to identify and correlate patterns of variation with assignable causes, particularly those visible only with longer histories, such as seasonal patterns; and establishing and maintaining retention times and retention systems for those summary data.

d) Periodically auditing the record-keeping system, including adherence to sampling decisions.

7.7 Traceability and production sequence identification

The supplier should define, establish and maintain appropriate mechanisms for product traceability and production sequence identification. Drawing on cross-functional job experiences to do these functions, especially those functions involved in setting or adjusting process control parameters or in responding to process disturbances, this should include, but is not limited to, the following:

a) Identifying as appropriate the sequencing of the product and/or process outputs.

b) Developing as appropriate the ability of the customer to relate suitability of use to the sequence of production.

c) Identifying as appropriate the source of process inputs, such as the materials, labour, and facilities used to produce a quantity of outputs from the process. This may include maintaining the ability to trace sources of process disturbances and/or conditions or settings of the facilities in use at the time the output was produced, and establishing associated record retention.

d) Maintaining a system for documenting deviations of practice from this requirement, to help identify assignable causes of variation not currently being monitored.

e) As appropriate, maintaining a sample or summary data of process outputs, at least until suitability for use can be verified, or for a defined retention period deemed appropriate by the supplier.

f) As appropriate, requiring traceability and identification of production sequences in subcontractors' supply streams.

7.8 Subcontractor performance evaluation

The supplier should define, establish and maintain a system for acquiring information about variation of parameters within incoming product. This should include, where appropriate and economically practical:

a) Evaluating the subcontractor's process performance and assuring the subcontractor's process control system satisfies appropriate elements of this part of ISO 11462.

b) Tracing performance measures to specific deliveries of products, services or transactions.

c) Evaluating and communicating the subcontractor's control plan, and changes in the subcontractor's process, to the supplier. Care should be taken to maintain and update the control plan.

d) Determining the subcontractor's process capability.

7.9 Process input sequencing

The supplier should establish and maintain as appropriate a system for using inputs to the process, such as materials and/or data, in the same time order or sequence in which they were produced. This should include, but is not limited to, the following:

a) Documenting when resource inputs are known or suspected to be mixed together in an inseparable way. Knowing what ***is*** in order of production and what ***is not*** in order of production is important, because a common or apparently random cause of variation at the early stage of a process may turn out to be a special or assignable cause of variation.

b) Setting up a system to document and review deviations of practice from the established system, to help identify potential sources of repetitive process disturbances and significant process events.

The supplier is recommended to draw on cross-functional job experiences, especially those involved in purchasing, ordering, storing, receiving, handling, scheduling and putting resources into the process.

7.10 Process logs

The supplier should establish, maintain and document process logging systems for recording significant process disturbances as they occur, appropriate process adjustments, and operational changes made to the process. This is intended to help identify longer run patterns in the process and to understand patterns of adjustments to and interventions in the process. This should include, but is not limited to, the following:

a) recording significant process disturbances in the sequences that they occurred and, where appropriate, associating them with the timing or sequence of process outputs;

b) recording operational changes or adjustments to the process (or where appropriate, the magnitude of adjustment to manipulated variables or of in-process parameters), adjustments to the measurement system, or adjustments to the control system, in the sequences that they occurred;

c) where appropriate, associating changes to the process with the timing or sequence of process outputs, and with any potential change in final-product parameter(s);

d) using the data from process logs to identify what causes of process disturbances might possibly be minimized, and to evaluate the potential gains from minimizing particular causes of disturbances;

e) using the data from process logs to identify and reduce process over-adjustments, defined as compensations for variations in the process that themselves increase the variation in the process.

7.11 Process reliability

The supplier should establish and maintain a process maintenance and reliability system for designing, testing, validating and repairing equipment and documenting supporting procedures. In the sub-elements listed below, “equipment” includes machines, tools, gages, measuring systems, electronic systems and software. The supplier’s process reliability system should begin with the concept and system requirements phase, continue in the design/development phase, and persist through the equipment build, operation and support phases. This should include, but is not limited to, the following:

a) Defining requirements for equipment durability, reliability, maintainability and availability, and specifying appropriate indices for monitoring failure and repair performance, such as mean time to failure, mean time between failures, and mean time to restoration or repair.

b) Performing failure modes and effects analysis (FMEA) and failure or fault analysis for equipment, systems, designs, and processes, as appropriate, repeating the analyses as changes are made to them. These efforts involve:

   1) identifying potential failure modes and their effects on the performance of production facilities used in the process, such as systems and subassemblies or components;

   2) rating the severity of their effects;

   3) identifying parameters that are significant characteristics and/or reliability-affecting parameters;

   4) rank-ordering potential design and process deficiencies;

   5) helping personnel focus on eliminating product and process concerns, and preventing problems from occurring that repeatedly disturb the process;

c) Collecting reliability data during acceptance testing of equipment, and using those data to develop a reliability baseline, or starting point for process reliability growth through continuous improvement;

d) Implementing an appropriate data collection and feedback system for recording failure and repair performance indices; analysing that system for root causes of process disturbances and product variation; setting up procedures for acting on the results of analysis; conducting equipment design review and taking appropriate corrective action.

7.12 Process output monitoring system

The supplier should define, establish and maintain a system for monitoring process outputs. This should include, but is not limited to, the following:

a) tracking process outputs over time, and noting in the process data-collection system any significant process disturbances and, if appropriate, process adjustments;

b) investigating apparently favourable process output measurements, and, if validated, considering a process adjustment that captures and capitalizes on chance excellence (a highly favourable process output);

c) comparing process output with target values, and specification and/or operating limits (the latter sometimes statistically determined);

d) initiating a reaction to any important deviation found;

e) analysing histories of process outputs with feedback of the results to those who can effect change.

7.13 Process control system

The supplier should establish and maintain a statistical, algorithmic, and/or model-based process control system for monitoring and controlling appropriate process parameters, in-process product parameters, and final product parameters. This should include, but is not limited to, the following:

a) making operational the control plan and its supporting systems for data collection and recording, process input sequencing, process monitoring, and process logging;

b) defining who has responsibility for reacting to out-of-control conditions;

c) if a parameter is outside its limits of control (these may be statistical, algorithmic, or model-based) or if undesirable patterns are detected, taking a corrective or control action;

d) taking action to prevent nonconforming outputs from reaching the customer;

e) analysing historical data on process parameters, in-process product parameters, and final-product parameters, with feedback of the results to those who can effect change;

f) using results from this system to review periodically the control plan and its supporting system, and to improve its ability to reduce variation and its suitability to satisfy customer needs.

7.14 Short-term variability assessment

“Short-term variability” results from changes over a short period of time in the values or levels of one or a few production factors, while other factors remain practically at unchanged values or levels over this same time period.

The supplier should assess short-term process variability of process parameters, in-process product parameters, and final-product parameters, as appropriate. This should include, but is not limited to, one or more of the following:

a) Examining the process data in the sequence in which they were produced, to see how they vary over a short time.

b) Evaluating the distribution of the data and the amount of variation in the data.

c) Exploring the data for patterns of variation within and, as appropriate, between groups in the data (such as those defined by time, shift, setup, operator, batch, material lots, output lots), to help set the best sampling strategy for the process.

d) Identifying relationships between process parameters, in-process product parameters and, where appropriate, final-product parameters, to help choose a process control strategy and to identify assignable causes of variation in the process.

e) Limiting the factors likely to contribute to the process parameter's variation, to isolate the effect of a changed value or level in a single factor (or the few factors) varying in the short term and whose short-term variability is of interest.

Where appropriate, the supplier additionally should consider:

f) Assessing the variability of new process inputs, such as people, machines and materials, for example, as preconditions for acceptance.

g) Conducting systematically designed test runs using small amounts of sample data collected in a short period of time, usually carried out under pre-production or pilot conditions.

NOTE Such test runs are used to observe process and product parameters' changes and interrelationships, assess machine or test equipment capability, or isolate the variability of one or more factors of production.

h) Operating the process under usual production practices and conditions, and with customary adherence to documented operating procedures, to help assess the potential process variability.

i) Recording assignable causes of variation, including identifying those causes whose elimination is currently limited (for example, by technology or contractual agreements).

j) Recording possible factors whose effects are not measured in the data (e.g. because the data were collected in only one shift) or that are not currently measurable (e.g. because of technology or contractual agreements). This is done so as to help identify potential assignable causes of variation missing from the process data routinely collected.

7.15 Long-term variability assessment

Long-term variability means that the values or levels of additional factors can potentially vary over a long period of time, whether they are directly controllable or able to be manipulated by the supplier. Usually, long-term process variability is larger than short-term variability.

Once all known assignable causes of variation have been eliminated and the process is in a state of statistical control, the supplier should assess long-term capability and performance of process parameters, in-process product parameters, and final-product parameters, as appropriate. This requires, where practical, operating the process under conditions that allow factors likely to contribute to process variation to be reflected in process outputs. This should include, but is not limited to, one or more of the following:

a) Examining the data in the sequence that they were produced, to see how they vary over a long period of time when all factors may vary, for example, using a plot, a control chart or a CUSUM (cumulative sum) chart, of parameter values against time produced or time tested.

b) Evaluating the distribution of the data and the amount of variation in the data taken over a long period of time when the process is in a state of statistical control.

c) Identifying patterns of variation within and, as appropriate, between groups observable in the data over a long period of time, to help make long-term process improvements requiring capital investments or technological or contractual changes.

d) Identifying relationships between process parameters, in-process product parameters and, where appropriate, final-product parameters, to help choose a process control strategy and to identify assignable causes of variation in the process observable over the long term.

e) Assessing process capability and performance.

Where appropriate, the supplier additionally should consider:

f) Identifying causes of variation whose elimination is currently limited, for example by technology or contractual agreements.

g) Identifying important factors whose effects are currently unmeasured, or whose operating range is constrained, so as to help identify potential assignable causes of variation missing from the assessment of the long-term process variability.

7.16 Communicating the results of process analyses

To reduce pre-production costs, accelerate new product introduction, and eliminate unnecessary operations, the supplier should design, establish and maintain methods for communicating the results of process monitoring, performance assessment, and analysis:

a) to those who operate and engineer the process;

b) to those in design and development;

c) to customers;

d) to internal suppliers or to subcontractors;

e) to management.

7.17 Customer information system

Where economically practical, the supplier should define, establish and maintain an information system or other appropriate mechanism that feeds back to the supplier the product's suitability for use by the customer. This should include, as appropriate:

a) recording consistency, suitability for use, and/or durability, either by direct measurement or by an indirect mechanism (for example, competitive benchmarking, one-time surveying, third-party sampling, use or accelerated testing, or reverse engineering);

b) using information from these records to improve the process and/or product;

c) documenting the system of measurement used.

7.18 Internal SPC audits

The supplier should measure progress made in implementing SPC. This should be achieved by periodically auditing the process against defined, established and documented criteria recommended as elements of SPC in this part of ISO 11462. To avoid conflict of interest, personnel who administer, conduct, or evaluate an internal SPC audit should have responsibilities independent of those that affect the SPC system being audited. The internal SPC audit should include verifying that:

a) the process control plan is being implemented;

b) process data are being collected and used as intended;

c) process controls are effective;

d) corrective or control actions are being taken to prevent repetitive process disturbances, and checks are being done to make sure the actions taken are effective, as appropriate;

e) work instructions exist for every operation, as appropriate;

f) work is being done consistently according to documented instructions.

7.19 SPC projects and teams

To implement SPC most effectively, the supplier should plan and establish projects and, as appropriate, conduct them using teams composed of members with cross-functional job experience. For example, an equipment design improvement may be broken down into projects aimed to reduce variation in final-product parameters of the most critical subassemblies; or a linear production process may be broken down into projects to reduce variation in each stage of the supply chain, even if stages are in different shops or firms.

7.20 Process improvement, optimization and troubleshooting

After removing all known and removable assignable causes of variation from the process and ranking processes for improvement, the supplier should use the results of process monitoring, experimentation, performance assessment, and analysis to make corrective and control actions as well as process improvements, with the aim of achieving the best economic target. This should include, but is not limited to, the following:

a) process improvement to reduce random causes of variation, after preventing assignable causes of variation from affecting the process;

b) process optimization to prevent assignable causes of variation from affecting the process and to set better process parameter values;

c) process troubleshooting and investigation to reduce the effects of special process events and disturbances.

With the completion of all applicable SPC elements, the supplier should check progress toward complete achievement of the three SPC objectives and then re-apply the twenty SPC elements as appropriate.

Annex A
(normative)

Terms and definitions

A.1
accelerated testing
test in which the applied stress level is chosen to exceed that stated in the reference conditions in order to shorten the duration required to observe the stress response of the item, or to magnify the response in a given time duration

NOTE To be valid, an accelerated test shall not alter the basic failure modes and failure mechanisms, or their relative prevalence.

A.2
acceptance testing
test to prove to the customer that the device meets certain conditions of its specification

A.3
algorithmic process control
control of a series of operations which perform a transformation, e.g. physical or chemical, or a series of such transformations, based on a control algorithm for the solution of a control problem in a finite series of steps

A.4
attributes data
recordings of the presence (or absence) of some characteristic or attribute in each of the items in the group under consideration, and counting how many items do (or do not) possess the attribute, or how many such events occur in the item, group or area

NOTE An example of attributes data in acceptance sampling is the proportion of nonconforming items.

A.5
automatic control
system in which deliberate guidance or manipulation is used to achieve a prescribed value of a variable

A.6
conformance test
test made to determine directly or indirectly that relevant requirements for selected performance characteristics of a product (or representative samples thereof) are fulfilled

A.7
control action
within a control element or a controlling system, the nature of change of the output effected by the input

NOTE In the context of control engineering, the output may be a signal or the value of a manipulated variable. The input may be the control loop feedback signal when the command is constant, an actuating signal or the output of another control element. One use of control action is to effect compensation.

A.8
control algorithm
general computational procedure that may include instructions, limits, and equations representing functional relationships in the controlling elements, with the purpose of controlling a series of operations that perform a transformation or a series of such transformations

NOTE In control applications, an algorithm usually defines the functional relationship existing between the manipulated variable and the actuating or error signal.

A.9
control loop
assembly of elements comprising a comparing element, the corresponding feedforward control path and the corresponding feedback control path

NOTE See **feedforward control**; **feedback control**.

A.10
control plan
written description of the system used for controlling product(s) and/or process(es)

NOTE For example, a control plan is written by a supplier to state how important characteristics and engineering requirements of the product are controlled. Each part can have a control plan, but in many cases, family control plans can cover a number of parts produced using a common process. Customer approval of control plans may be required prior to production part submission.

A.11
control system
system in which a desired effect is achieved by operating on the various inputs to the system until the output, which is a measure of the desired effect, falls within an acceptable range of values

A.12
controllable
property of a component of a state whereby, given an initial value of the component at a given time, there exists a control input that can change this value to any other value at a later time

A.13
count data
recordings of numbers of occurrences in some form

A.14
critical characteristic

A.14.1
critical characteristic
⟨general⟩ characteristic applicable to a component, material, assembly or assembly operation designated by the supplier as being critical to the part function and having particular quality, reliability and/or durability performance

A.14.2
critical characteristic
⟨regulatory or safety⟩ product requirements (dimensions, performance tests) or process parameters that can affect compliance with government regulations or safe product function and which require specific supplier, assembly, shipping, or monitoring and inclusion in control plans

A.14.3
critical characteristic
⟨safety or tactical function⟩ characteristic that judgement and experience indicate is necessary to be met so as to avoid hazardous or unsafe conditions for individuals using, maintaining, or depending upon the product; or that judgement and experience indicate is necessary to be met to assure performance of the tactical function of a major item, such as a ship, aircraft, tank, missile, or space vehicle

A.15
cross-functional job experience
knowledge and skills acquired through formal or on-the-job training in different responsibilities, departments or employments that affect or are affected by a process

A.16
design review
formal and independent examination of an existing or proposed design for the purpose of detection and remedy of deficiencies in the requirements and design which can possibly affect such things as reliability performance,

maintainability performance, maintenance support performance requirements, fitness for the purpose and the identification of potential improvements

NOTE Design review by itself is not sufficient to ensure proper design.

A.17
directly controlled variable
variable in a feedback control system whose value is sensed to originate the primary feedback signal

A.18
failure
termination of the ability of an item to perform a required function

A.19
failure modes and effects analysis
FMEA
identification of significant failures, irrespective of cause, and their consequences including electrical and mechanical failures that can conceivably occur under specified service conditions and their effect, if any, on adjoining circuitry or mechanical interfaces displayed in a table, chart, fault tree or other format

NOTE This includes failures in non-electrical and non-mechanical processes, such as software and information transactions.

A.20
failure analysis
logical, systematic examination of a failed item to identify and analyse the failure mechanism, the failure cause and the consequences of failure

A.21
fault analysis
logical, systematic examination of an item to identify and analyse the probability, causes and consequences of potential faults

A.22
feedback control
control in which the control action is made to depend on the measurement of the controlled variable

A.23
feedforward control
sending of a signal from input to output or from one point in the process to a subsequent point

A.24
final-product parameter
any specific variable affecting or describing the measurable or theoretical features of an output to a process

NOTE 1 It may either act independently (e.g. product mass) or depend upon some functional interaction of other variables (e.g. ice cream volume as a function of air content, temperature, and butterfat percentage).

NOTE 2 A supplier's final-product parameter may be treated as a process parameter or in-process product parameter by the next supplier downstream.

NOTE 3 Under specified conditions, “final product parameter” is equivalent to “product characteristic”. An example of “specified conditions” follows, taken from the vehicle industry.

EXAMPLE In any type of vehicle industry, it is stated that the vehicle will have a fuel consumption of 30 km/l (i.e. product characteristic) under “standard testing conditions”. The standard conditions are specified, for example, as follows:

— good road conditions: roads as dry as possible and as well-drained and paved as possible

— surrounding temperature: 10 °C to 25 °C