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Introduction

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For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Submission of Comments

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 11462-1

Guidelines for implementation of statistical process control (SPC) — Part 1: Statistical Process Management — Elements, Tools and Techniques of SPC

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ISO/TC 69/SC 4

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Foreword

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

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

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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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 edition of (ISO 11462-1:2001) and ISO 11462-2:2010, which have been technically revised.

The main changes are as follows:

— to be included after DIS ballot.

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

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 sampling interval and cost.

This part of ISO 11462 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 ISO 11462-1.

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.

This part of ISO 11462 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 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 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 part 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: Statistical Process Management — Elements, Tools and Techniques of SPC

1 Scope

Statistical process control (SPC) concerns the use of statistical techniques and 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 to 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 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.

This part of ISO 11462 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*

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

Analysis Control Chart

Control chart for post-process analysis

Note 1 to entry: Analysis 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: Analysis control charts are typically process-related control charts.

Note 3 to entry: Analysis 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

The dressing cycle of a tool is the 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

product characteristic in control

product characteristic (3.1.7) 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]

3.5

stable process

process in a state of statistical control

<constant mean> process (3.1.2) subject only to random causes (3.1.19)

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 22514-1:2014, 3.1.21; ISO 3534-2:2006, 2.2.7, modified]

4 Symbols and abbreviated terms

4.1 Symbols

C_p	process capability index
C_{pk}	minimum process capability index
C_{pkU}	upper process capability index
C_{pkL}	lower process capability index
U_{CL}	Upper control limit
L_{CL}	Lower control limit
k	the number of subgroups
n	sample size of a subgroup
N	sample size over all subgroups of a machine or process assessment
P_p	process performance index
P_{pk}	minimum process performance index
P_{pkU}	upper process performance index
P_{pkL}	lower process performance index
U	Upper specification limit
L	Lower specification limit

4.2 Abbreviations

SPC	Statistical Process Control
QFD	Quality Function Deployment
CT-Matrix	Critical To – Matrix (CTF Critical to Function, CTT Critical to Time, CTQ Critical to Quality)
FMEA	Failure Mode and Effect Analysis
SC	Significant Characteristic
YS	Potential Significant Characteristic
CC	Critical Characteristic
YC	Potential Critical Characteristic
CP	Control Plan

5 Statistical process management

5.1 General

The standard ISO 3534-2:2013-12, 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 standard 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 (according to ISO 9001:2015, chap. 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	ISO 9001, organisational and customer-specific requirements
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:

- 1) Process documentation and control plan;
- 2) Definition of process or characteristic target values and their limits and specifications;
- 3) Measuring system and measurement process capability;
- 4) Documented work instructions;
- 5) Employee training and involvement;
- 6) Data recording and collection;
- 7) Traceability;
- 8) Subcontractor performance evaluation;
- 9) Process input sequencing;
- 10) Process logs;
- 11) Process reliability;
- 12) Process output monitoring system;
- 13) Process control system;
- 14) Machine performance assessment;
- 15) Process performance and capability assessment;
- 16) Communicating results of process analyses;
- 17) Customer information system;
- 18) Internal SPC audits;
- 19) SPC projects and teams;
- 20) Process optimisation and troubleshooting and corrective actions.

5.4 Elements provided in this standard

The following are the 15 elements including subclause reference (tbd) that are executed in this document:

- Process documentation and control plan ([6.4](#), [6.5](#));

- Definition of process/characteristic target values and limits/specifications ([6.1](#), [6.2](#), [6.3](#));
- Measuring system and measurement process capability ([6.7](#));
- Data recording and collection ([12](#));
- Traceability ([11](#));
- Process input sequencing ([12](#));
- Process logs ([12](#));
- Process output monitoring system ([12](#));
- Process control system ([10](#));
- Machine performance assessment ([7.1](#), [8](#));
- Process performance and capability assessment ([7.2](#), [9](#));
- Communicating results of process analyses ([12](#));
- Customer information system ([12](#));
- Internal SPC audits ([5.2](#));
- SPC projects and teams ([5.2](#)).

6 Prerequisites for SPC applications

6.1 General

The SPC applications presented in this standard 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 shall be met. These include above all

- Compliance 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,
- Proof of capability for measuring and testing processes used.

See [Figure 1](#) for a schematic flow of the preliminary work on SPC.

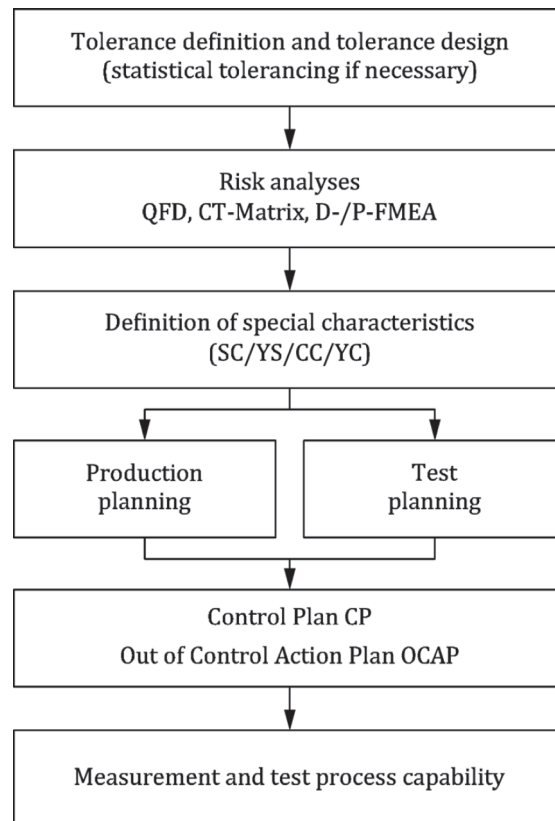


Figure 1 — Schematic flow of the preliminary work on SPC

The tools presented in the following subclauses are intended to clarify whether quality characteristics and manufacturing processes have sufficient capability or performance and can be considered to be stable. Often, when identifying the relevant quality characteristics and manufacturing processes, the question is asked whether they can actually be controlled, or whether control by the employee on site is not possible at all. This question is only relevant to a limited extent in this context, because it relates to the reactions to be selected to identified insufficient skills or performance, and instabilities that have occurred. These reactions can vary across the different control loops, from direct on-site control to changing tools and materials to process shutdown and further safeguarding measures or containment activities.

6.2 Tolerancing principles and responsibility principles

Characteristic tolerances shall be clearly defined in a way that is suitable for function, production and testing.

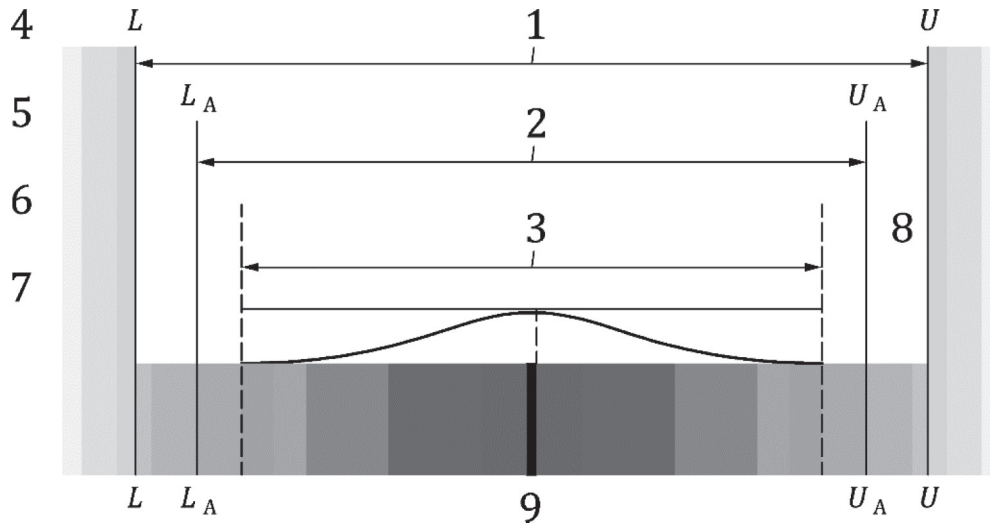
In the following, reference is made to geometric features for simplicity, although the principles and principles naturally also apply to non-geometric features, insofar as they are applicable.

Conditions for an adequate geometry description are:

- Functional fulfilment: The component shall fulfil the defined function during its entire service life.
- Assemblability: It shall be possible to assemble the component.
- Manufacturability: It shall be possible to manufacture the component in a process-capable manner.
- Measurability/testability: Characteristics of the component shall be able to be tested or measured as easily and reliably as possible.

The responsibility for considering measurement uncertainty, on the other hand, lies with the party providing evidence of conformity or non-conformity with a specification. ISO 14253-1 shall be observed in this regard.

See [Figure 2](#) for a drawing of the interaction tolerance.



Key

- | | | | |
|---|--|---|-------------------------------------|
| 1 | tolerance limits (drawing) identical to functional limits | 6 | verification/measurement technology |
| 2 | acceptance limits related to U_{MP} of the measurement process | 7 | realisation/production |
| 3 | capable and stable production process | 8 | guard band g_{UA} |
| 4 | responsibility: | 9 | target/setpoint value |
| 5 | specification/design | | |

Figure 2 — Interaction tolerance (drawing), expanded measurement uncertainty of the measurement process U_{MP} and acceptance limits, capable and stable manufacturing process

As a logical consequence, the responsibility for error-free production therefore lies with the production department. This shall minimise the probability of generating non-conforming product characteristics with the help of sufficiently capable and stable manufacturing processes.

SPC can only be implemented meaningfully if these principles of responsibility are observed.

6.3 Risk analysis/FMEA (D-/P-)

Another important step in the implementation of SPC is the risk assessment of the features characterising the product and their tolerances. SPC monitoring of all characteristics often overtaxes the capacities of the companies and does not make sense from a business point of view. Therefore, a sensible reduction to the characteristics relevant in the respective validation stages should take place. In the case of initial inspections and approvals of production equipment, these are naturally more characteristics than are subsequently monitored in the long term with the help of control charts. The method to be used for this is the "Failure Mode and Effects Analysis" FMEA.

6.4 Special characteristics

Special characteristics (Critical/significant characteristics CC/SC or YC/YS) are product characteristics or production process parameters that may have an impact on safety or regulatory compliance, fit, function, performance, or further processing of the product. Categories are defined to distinguish special characteristics, whereby the designations are often defined on a company or association-specific basis, e.g.:

CC/YC/s = Safety-relevant special feature

CC/YC/h = Legal or approval-relevant special feature

NOTE h can also be expressed by g or l.SC/YS/f = Functionally relevant special feature (e.g., all features relevant to form, fit, function and performance that are not cc).

These special characteristics have to be verified by process capability and stability tests, i.e. SPC-relevant characteristics. If sufficient process capability cannot be demonstrated, 100 % controls may have to be introduced.

6.5 Production/test planning

Production planning is the link between design and production or assembly. It is necessary for the future design of production and includes all measures that occur once to ensure economic production. Production planning shall take into account the workplaces and steps necessary for an SPC application, the spatial, logistical and organisational requirements as well as the requirements for operating resources.

Inspection planning focuses on the actual measurement and inspection process and, according to ISO 9001, ensures that resources for monitoring and measurement are traceable and capable for the particular type of monitoring and measurement activities undertaken. The tasks include the preparation of the measurement and testing concepts, specification and procurement of the measurement systems as well as validation of the measurement systems and processes. Test planning can also provide support to ensure ongoing suitability. In this way, test planning ensures that valid data are available for an SPC application.

6.6 Control Plan / Production Plan / Test Plan

The Control Plan CP is a central cross-divisional document and a component of the advanced quality planning, although the name often vary depending on the company or association. It contains all production process steps, product characteristics and process parameters that have an impact on product quality and shall be controlled.

In particular, measurement systems, measurement and inspection processes as well as inspection methods are defined, sampling frequencies and sizes are specified, and reaction plans to violations of control and tolerance limits are established. The Control Plan can also serve as the basis for the creation of the inspection plans. Thus, the Control Plan is the basis for all SPC applications.

6.7 Measurement and test process capability

According to ISO 9001, with regard to the “resources for monitoring and measurement”, the organization shall ensure that the resources provided:

- are suitable for the specific type of monitoring and measurement activities being undertaken;
- are maintained to ensure their continuing fitness for their purpose. Demonstrating measurement and test process capability for all types of tests, measurements and for all test and measurement systems and processes specified in the Control Plan/Production Control Plan ensures that the data required for SPC applications are generated using validated measurement and test processes. Without validated measurement systems and measurement and test processes, trustworthy and reliable SPC applications are not possible.

For further details refer to ISO 22514-7.

7 Method overview

7.1 General

According to ISO 3534-1 and ISO 22514 series, capability indices C_p and C_{pk} and performance indices P_p and P_{pk} are calculated. The term “capability” is to be used if the stability of a specified characteristic is considered to be given. The term “performance” is to be used if stability has not been explicitly investigated, the investigated data do not allow for stability assessment or stability violations have also been explicitly found, e.g., if a manufacturing process has been assessed as unstable.

Capability studies can be carried out in many ways. The presentation in this standard is not comprehensive but concentrates on the most important applications in the SPC environment. If company-specific deviating methods are used, it shall be ensured that the procedures are documented and that both designation and abbreviations (symbols) allow a clear differentiation of the examination objectives.

7.2 Machine Performance

The objective of the machine performance analysis is to record and evaluate exclusively machine-related influences on the production process. Based on the well-known “5M” machine, method, material, man and milieu, the influences of the four remaining M (method, material, man and milieu) shall be kept constant during the machine performance analysis.

In many cases, this means that the study is also a short-term study. However, as this term can be misleading and can also include the short-term variation of further process influences, the term “short-term study” or “short-term capability” should not be used as a synonym for a machine performance study.

According to ISO 22514-3, the indices P_m / P_{mk} are calculated to evaluate machine performance. There is no explicit assessment of stability, but a qualitative assessment of trends is recommended.

A machine performance study requires careful preparation of the machining equipment in order to keep influences of the 4 Ms not taken into account constant. For example

- the tool to be machined shall be run in,
- the production equipment shall have reached operating temperature,
- sufficiently homogeneous raw materials, if applicable from the same batch or production lot, shall be available for machining,
- the production equipment shall be set to the nominal value.

To evaluate the machine performance indices, a representative number of parts N ($N = 100$ according to ISO 22514-3, usually $N = 50$) shall be produced in a continuous, uninterrupted production run. General conditions and deviations from the continuous production flow shall be documented, as well as changes in non-machine-related influencing and interfering parameters, if these cannot be kept constant. This documentation can provide approaches for optimisation measures if suitability criteria are not met. Subsequently, the part characteristics are to be measured and documented according to the production sequence.

If it is not possible to produce the minimum number of parts (often $n = 30$), performance indices can still be calculated and approvals granted, taking into account the changed confidence interval of the characteristic values, as long as it can be assumed that the machine influences are reflected sufficiently representatively in the data.

In special cases, machine performance can also be evaluated by taking several smaller samples (subgroups). For highly complex or time-consuming machining operations, this creates a smooth transition to process capability studies.

In an extended machine performance evaluation variant, the constant 4 M can be set to different factor levels (different raw materials, environmental conditions or process parameters), so that by repeating the machine performance evaluation with these factor levels, it can be demonstrated that the production equipment or the production process has a sufficient performance index in the specified range of these factors.

EXAMPLE Multiple machine performance studies in which dominant process parameters are set to the upper and lower specification limits of the process parameters.

See [Figure 3](#) for a schematic overview of machine performance.

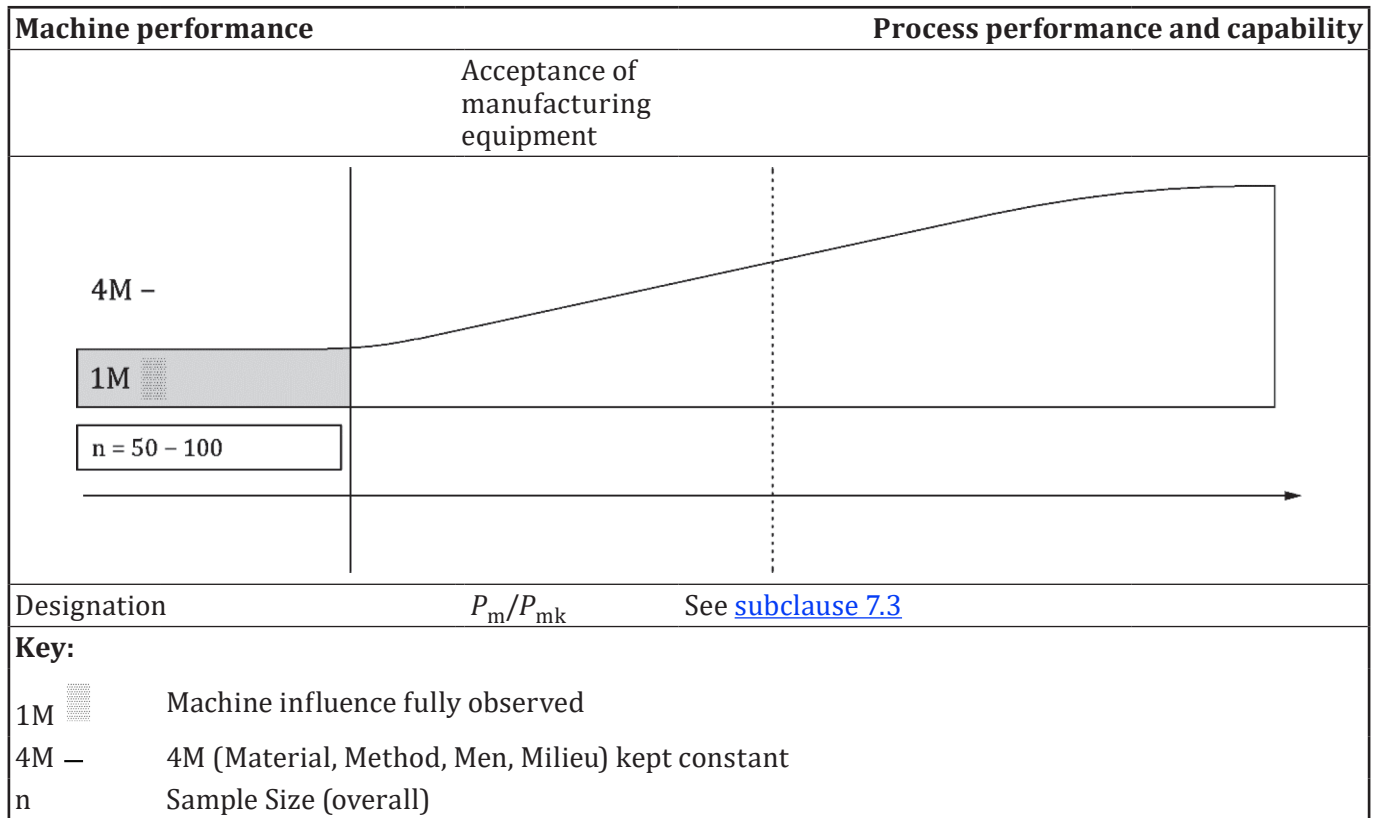


Figure 3 — Machine performance in schematic overview

7.3 Process Capability and Performance

The objective of the process capability/performance analysis is to record and evaluate all influences on a manufacturing process that are to be expected for series production. These influences can be divided into categories by the well-known “5M” machine, method, material, man and milieu.

In many cases, it follows that this study is also a long-term study. However, since this term can be misleading and does not explicitly refer to either the influences studied or the actual objective, the term “long-term study” or “long-term capability” should not be used as a synonym for a Process Capability and Performance Analysis without further detail.

According to ISO 22514-2, the capability indices C_p/C_{pk} or P_p/P_{pk} are calculated to evaluate the process capability or performance. An explicit evaluation of stability decides on the designation of the indices. The indices C_p/C_{pk} may only be used if the process is shown to be stable. If the stability cannot or should not be evaluated, or if the process is explicitly not stable, the indices P_p/P_{pk} are used. Regardless of the name, these indices are calculated numerically the same.

A process capability or performance study requires measured product parts from a larger, representative period of time for series production, so that as far as possible all expected influences on the process have become effective. Therefore, a sampling strategy is to be applied, in which small random samples (mostly samples of 3 to 5) are taken from the production process at sensibly defined time intervals. From the scatter of the individual samples, the current scatter and position of the production process can be determined, as well as the resulting total scatter and total position from the totality of the data. The application of a analysis control chart enables a post-process stability assessment and from the now known process behaviour of a specified characteristic, a meaningful on-site SPC control chart can be derived, with which the process can be controlled in the future.

For the evaluation of the process capability and process performance indices, a representative number of series parts (usually at least $n = 125$ parts in at least $k = 25$ subgroups) taken over a sufficiently long period