



## Statistical Process Control

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# SPC Manual

Process Management  
Performance and Capability  
Control Charts

1st edition, February 2026  
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Control Loops  
Performance and Capability  
Control Charts

1st edition, February 2026  
Automotive Industry Action Group (AIAG)  
Verband der Automobilindustrie e. V. (VDA)  
Online download document

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The German Association of the Automotive Industry (VDA) recommends that its members apply the following VDA Handbook when introducing and maintaining QM systems.

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This document will be published in multiple languages. The current status can be obtained from VDA QMC or AIAG.

## **Gender notice**

For reasons of legibility, the masculine form is chosen for personal names, but the feminine form is always meant.

# Contents

1	Foreword.....	8
2	Scope.....	9
3	Standards and Guidelines.....	10
4	Terms and Definitions .....	11
5	Statistical Process Management/Control (SPC) .....	15
5.1	Proactive Prevention over Reactive Detection .....	16
5.2	Process Improvement Cycle and Process Control .....	17
5.3	A Process Control System.....	18
5.4	Quality Control Loops .....	19
6	Requirements for SPC Applications.....	21
6.1	Introduction.....	21
6.2	Clear Product Specifications .....	22
6.2.1	Tolerancing and Responsibility Principles.....	23
6.2.2	Risk Analyses .....	25
6.2.3	Special Characteristics .....	26
6.3	Valid and Capable Measurement and Inspection Processes .....	26
6.4	Process Characterization .....	27
6.5	Production and Inspection Planning .....	27
6.6	Out-of-Control Action Plan (OCAP) .....	27
6.7	Control Plan.....	28
6.8	Roles and Competencies in SPC .....	28
6.8.1	Roles in SPC.....	28
6.8.2	Competencies in SPC .....	30
7	Overview of Methods.....	33
7.1	Preliminary Remark .....	33
7.2	Difference between Performance and Capability .....	33
7.3	Machine Performance .....	35
7.4	Process Capability and Performance Studies .....	37
7.5	Quality Control Charts .....	39
7.6	Outliers: Definition and Handling .....	42
7.7	Overview Table.....	43
7.8	Calculating Capability Indices.....	45
7.8.1	Evaluation of the statistical distribution .....	45
7.8.2	Calculation of Capability and Performance Indices.....	45
7.8.2.1	General Geometric Method .....	45
7.8.2.2	One-Sided Tolerance Limits .....	48

7.8.2.3	Exceedance Proportion Method/z-Score/Bothe Method.....	49
7.8.2.4	Comparison of the Methods .....	50
7.8.2.5	Within Capability.....	51
8	Machine Performance for Releasing Production Facilities .....	53
8.1	Preliminary Remark.....	53
8.2	Preparation.....	54
8.2.1	Sample Size.....	54
8.2.2	Material .....	54
8.2.3	Measuring System and Measurement Process.....	54
8.2.4	Operating and Production Conditions .....	54
8.2.5	Pre-Production Run (optional).....	55
8.2.6	Special Circumstances .....	56
8.3	Execution.....	56
8.3.1	Traceability of Data .....	56
8.3.2	Storage and Blocking of Test Parts.....	57
8.3.3	Data Collection and Storage .....	57
8.3.4	Statistical Analysis of Data.....	57
8.3.4.1	Qualitative Stability Study.....	57
8.3.4.2	Evaluation of the Statistical Distribution.....	57
8.4	Requirements Regarding the Performance Indices to be Achieved .....	57
8.5	Special Cases.....	58
8.5.1	Multi-Stage Machining .....	58
8.5.1.1	Approach.....	58
8.5.1.2	Application Example .....	58
8.5.1.3	Miscellaneous.....	60
8.5.2	Multidimensional/Multivariate Characteristics .....	61
8.5.2.1	Machine Performance Index $Pmk$ Related to Process Location and Variation .....	61
8.5.2.2	Machine Performance Index $Pm$ Related to Variation Only.....	62
8.5.3	Geometric Dimensioning and Tolerancing (GD&T) and Maximum/Least Material Condition (MMC/LMC).....	63
9	Process Performance and Capability for Releasing Manufacturing Processes ...66	66
9.1	Preliminary Remark.....	66
9.2	Data Collection and Sampling Strategies .....	66
9.3	Execution.....	67
9.4	Time-Dependent Distribution Models (according to ISO 22514-2) .....	67
9.5	Requirements .....	75
10	Control Charts for Statistical Process Control and Ongoing Capability .....	77

10.1	Different Control Concepts (Process- vs. Tolerance-Related).....	78
10.2	Out of Control Conditions and Quality Criteria of Control Charts .....	79
10.2.1	Retrospective (Analysis) Control Chart vs. SPC Control Chart .....	79
10.2.2	Stability Criteria.....	80
10.2.2.1	Process Control with SPC Charts.....	81
10.2.2.2	Post-process stability evaluation with analysis control charts.....	81
10.2.3	Corrective Action Plan in Case of Instabilities.....	81
10.2.4	Measures for Evaluating the Effectiveness of Control Charts .....	82
10.2.4.1	Operating Characteristic.....	83
10.2.4.2	Average run length .....	83
10.3	Types of Control Charts .....	84
10.3.1	General Information .....	84
10.3.2	Which Control Chart is Recommended for which Application? .....	86
10.3.2.1	Introduction.....	86
10.3.2.2	Characteristic Type.....	88
10.3.2.3	Type of Observation Approach.....	88
10.3.2.4	Process or Tolerance-Related Control Charts .....	89
10.3.2.5	Control Charts for the Instantaneous Process State or Control Charts with Memory.....	89
10.3.2.6	Control Charts for Non-Normal Distributed Characteristics .....	90
10.3.2.7	Control Charts for Preliminary Control without Process Knowledge or for Targeted Control Based on a Known Process (After Process Analysis).....	90
10.3.2.8	Control Charts for Individual Characteristics or Multivariate Control Charts for Controlling Several Interacting Characteristics .....	91
10.3.2.9	Short-Run Control Charts .....	91
10.3.3	Variable Control Charts (Shewhart Control Charts for Continuous Characteristics) .....	92
10.3.3.1	Introduction.....	92
10.3.3.2	Average and Standard Deviation.....	92
10.3.3.3	Average and Range .....	95
10.3.3.4	Median and Range .....	98
10.3.3.5	Individuals and Moving Range .....	101
10.3.4	Tolerance-Related Control Charts .....	104
10.3.5	Special Control Chart .....	106
10.3.5.1	Introduction.....	106
10.3.5.2	Pearson Control Chart.....	106
10.3.5.3	Shewhart Control Chart with Extended Limits .....	108

10.3.5.4 CUSUM Control Chart (Refer to ISO Standard 7870-4 for Graphics).	111
10.3.5.5 EWMA Control Chart.....	116
10.3.6 Attribute Control Chart for Discrete Characteristics .....	117
10.3.6.1 Introduction.....	117
10.3.6.2 Proportion of Nonconforming (p Chart).....	117
10.3.6.3 Number of Nonconforming (np Chart) .....	120
10.3.6.4 Number of Nonconformities per Unit (u Chart) .....	122
10.3.6.5 Number of Nonconformities (c Chart) .....	124
10.4 Reporting of Ongoing Performance and Capability .....	127
10.5 Special Cases .....	130
11 Application of Software.....	131
11.1 General Integration/Interfaces.....	131
11.2 Verification and Validation of Analysis Software .....	132
12 Documentation and Reporting .....	135
12.1 General Requirements .....	135
12.2 Example Reports.....	136
13 Traceability/Archiving.....	143
14 References and Bibliography.....	144

# 1 Foreword

This AIAG-VDA SPC Manual was jointly developed by the U.S. Automotive Industry Action Group (AIAG) and the German Association of the Automotive Industry (VDA) with the involvement of a global team of experts. The aim was to create a non-mandatory, common international standard, which can be of great benefit to international organizations. Therefore, this handbook harmonizes the latest statistical process control (SPC) practices and guidelines. However, this handbook is aimed at VDA members in terms of its recommendation character.

The global team of experts has looked at the latest techniques and methodologies to help organizations optimize their processes in the best possible way with SPC. Based on ISO and other international standards, the project group standardized the reference manuals, report templates and technical nomenclature, taking into account the changes made in the SPC techniques approach compared to previous versions.

This handbook covers most of the SPC use cases that typically occur. It is intended to restrict the application of SPC to specific processes or the development of SPC methods in general.

In addition to this AIAG-VDA SPC Manual, a Practical Application Guide (Practice Guide) is also available to provide practical examples and help users choose the best practices to achieve their goals.

The project team would like to thank all the people and companies involved in the creation and support of this handbook.

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## 2 Scope

This volume takes account of the whole supply chain in the automotive industry.

Several fundamental statistical methods are described that can be applied to continuously monitor and maintain the stability as well as the capability or performance of production processes, ensuring that the achieved quality is preserved and can serve as a basis for process improvement.

Statistical Process Control is a method that is meant to decrease variation, increase knowledge regarding the process and control the process in the desired manner (following ISO 3534). Ultimately, production processes are controlled in a cost-effective, timely and efficient manner. A pre-defined level of quality can thus be achieved. Improving the stability and performance/capability of production processes effectively reduces production rejects as well as machine downtime and therefore increases productivity. If defective production parts occur in a sample, they can be discarded, and further measures can be taken if required.

This volume constitutes an internationally harmonized recommendation that comprises commonly used methods for process qualification and process control in the automotive industry. It includes a description of the fundamental aspects of machine performance, process capability and application of control charts, the respective characteristics, the definition of the indices and a recommendation with regard to sample sizes. Capability or performance studies in relation to a characteristic provide information on the process location and process variation of the production process, thus making it possible to use quality control charts (QCCs). Statistical parameters (e.g., sample means) are graphically displayed on these control charts and are checked based on previously calculated control limits. This makes it possible to identify, analyze and eliminate suspected process disturbances in situ. Moreover, the definition and the handling of outliers are described to prevent misinterpretations of statistical parameters.

### **3 Standards and Guidelines**

- ISO 9000 Quality Management Systems
- ISO 9001 Quality Management Systems - Requirements
- ISO 3534 Statistics – Terms and Definitions
- IATF 16949 Automotive Quality Management System Requirements
- VDA 1 Documented Information and Retention
- VDA 6 Certification Requirements
- ISO 22514 Statistical methods in process management — Capability and performance
- AIAG CQI - 28
- AIAG Statistical Process Control
- ISO 7870 Control Charts
- ISO 11462 Guidelines for implementation of statistical process control (SPC)

## 4 Terms and Definitions

English term	Definition	German term	Definition	Source
<b>acceptance control chart</b>	A control chart is intended primarily to evaluate whether or not the plotted measure can be expected to satisfy specified tolerances (	<b>Annahme-Regelkarte</b>	Regelkarte, die dafür vorgesehen ist zu beurteilen, ob Toleranzen eingehalten werden	ISO 3534-2
<b>archival</b>	long-term, orderly, protected and change-proof storage of information	<b>Archivierung</b>	langfristige, geordnete, geschützte und veränderungssichere Speicherung von Informationen	
<b>attribute control chart</b>	Shewhart control chart in which the measure plotted represents countable or categorized data	<b>Attribut-Regelkarte</b>	Shewhart-Regelkarte mit Werten auf einer diskreten Skala	ISO 3534-2
<b>characteristic</b>	distinguishing feature	<b>Merkmal</b>	Kennzeichnende Eigenschaft	ISO 3534-2
<b>control chart</b>	chart on which some statistical measure of a series of samples is plotted in a particular order to steer the process with respect to that measure and to control and reduce variation	<b>Regelkarte</b>	grafische Darstellung, in der die Werte einer statistischen Kenngröße für eine Folge von Stichproben in einer bestimmten Ordnung eingetragen ist, um den Prozess in Bezug auf diese Kenngröße zu regeln, und um die Streuung zu vermindern	ISO 3534-2
<b>control limit</b>	line on a control chart used for judging the stability of a process, warning and action limits are special control limits	<b>Regelgrenze</b>	Linie in einer Regelkarte, mit der die Stabilität des Prozesses beurteilt wird. Warn- und Eingriffsgrenzen sind spezielle Regelgrenzen	ISO 3534-2
<b>control loop</b>	A control loop is a feedback system that continuously records and analyzes its output and initiates targeted corrective measures to counteract deviations from the target state and ensure that the actual state is as stable as possible.	<b>Regelkreis</b>	Ein Regelkreis stellt ein rückgekoppeltes System dar, das kontinuierlich seinen Output erfasst, analysiert und gezielt Korrekturmaßnahmen einleitet, um Abweichungen vom Sollzustand entgegenzuwirken und einen möglichst stabilen Istzustand zu gewährleisten.	Project team

<b>in control process</b>	Process that does not change or does only change within a known manner or within known limits	<b>Beherrschter Prozess</b>	Prozess, der sich nicht oder nur in bekannter Weise oder innerhalb bekannter Grenzen ändert	
<b>inherent process variation</b>	<i>variation</i> in a process, when the process is operating in a state of statistical control	<b>Prozess-eigenstreuung</b>	Streuung in einem beherrschten Prozess, d.h. Streuung, die nur zufälligen Ursachen unterliegt	ISO 3534-2
<b>minimum process capability index</b>	smaller of upper process capability index and lower process capability index	<b>Kleinster Prozess-fähigkeits-index</b>	der kleinere der Indizes oberer Prozessfähigkeitsindex und unterer Prozessfähigkeitsindex	ISO 3534-2
<b>minimum process performance index</b>	smaller of upper process performance index and lower process performance index	<b>Kleinster Prozess-leistungs-index</b>	der kleinere der Indizes oberer potenzieller Prozessleistungsindex und unterer potenzieller Prozessleistungsindex	ISO 3534-2
<b>operating characteristic curve</b>	a graph used in acceptance sampling. It describes how well an acceptance plan distinguishes between good and bad lots.	<b>Operations-Charakteristik</b>	Kurve für den Zusammenhang zwischen der Annahmewahrscheinlichkeit des Produkts und seiner Qualitätslage vor der Annahmestichprobenermittlung bei gegebener Annahmestichprobengröße	ISO 3534-2
<b>population</b>	totality of items under consideration	<b>Grundgesamtheit</b>	Gesamtheit der betrachteten Einheiten	ISO 3534-2
<b>population parameter</b>	a summary measure of the values of some characteristic of a population, e.g. population mean, population standard deviation	<b>Parameter der Grundgesamtheit</b>	Summarisches Maß der Werte eines Merkmals einer Grundgesamtheit. Beispiele. Mittelwert und Standardabweichung	ISO 3534-2
<b>process</b>	set of activities which transforms inputs into outputs	<b>Prozess</b>	Satz von Tätigkeiten, der Eingaben in Ergebnisse umwandelt	ISO 3534-2
<b>process capability</b>	<i>statistical</i> measure of the outcome of a characteristic from a process which has been demonstrated to be in control	<b>Prozess-fähigkeit</b>	Statistisches Maß für die Werteverteilung eines Merkmals aus einem beherrschten Prozess	ISO 3534-2
<b>process capability index</b>	<i>statistical</i> measurement that evaluates a process's ability to produce products that meet	<b>Prozess-fähigkeits-index</b>	Index, der die Prozessfähigkeit in Bezug auf eine festgelegte Toleranz	ISO 3534-2

	specified limits		angibt	
<b>process control</b>	<i>process management focused on fulfilling process requirements</i>	<b>Prozess-lenkung</b>	Prozessmanagement gerichtet auf das Erfüllen von Prozessanforderungen	ISO 3534-2
<b>process management</b>	coordinated activities to direct and control processes	<b>Prozess-management</b>	Koordinierte Maßnahmen, um Prozesse zu steuern und zu lenken	ISO 3534-2
<b>process performance</b>	a statistical measure of the outcome of a characteristic from a process which may not have been demonstrated to be in a state of statistical control	<b>Prozess-leistung</b>	Statistisches Maß für die Werteverteilung eines Merkmals aus einem nicht-beherrschten Prozess	ISO 3534-2
<b>process performance index</b>	<i>statistical metric that estimates how well a process meets its specifications and requirements</i>	<b>Prozess-leistungsindex</b>	<i>Pp Index, der die Prozessleistung im Verhältnis zur festgelegten Toleranz angibt</i>	ISO 3534-2
<b>quality characteristic</b>	inherent characteristic of a product, process or system related to a requirement	<b>Qualitäts-merkmal</b>	Inhärentes Merkmal eines Produktes, Prozesses oder Systems, auf das sich eine Anforderung bezieht	ISO 3534-2
<b>random cause</b>	source of process variation that is inherent in a process over time	<b>Zufällige Streuungs-ursache</b>	Ursache für die Prozesstreuung, die einem Prozess ständig innewohnt	ISO 3534-2
<b>report</b>	written or spoken account of an event or situation that is organized for a specific purpose and audience	<b>Bericht</b>	Ein Bericht ist eine strukturierte, sachliche Darstellung von Informationen, Ereignissen oder Ergebnissen, die in schriftlicher oder mündlicher Form erfolgt	
<b>sample</b>	subset of a population	<b>Stichprobe</b>	Teilmenge einer Grundgesamtheit	ISO 3534-2
<b>sample statistic</b>	summary measure of some observed value of a sample, e.g., arithmetic mean, empirical standard deviation	<b>Stichproben-kenngröße</b>	Zusammenfassendes Maß beobachteter Werte einer Stichprobe. Beispiele: arithmetischer Mittelwert und empirische Standardabweichung	ISO 3534-2
<b>scale</b>	system of reference values for a characteristic. A distinction is made between continuous scale, discrete scale,	<b>Skala</b>	System von Bezugswerten für ein Merkmal. Es werden kontinuierliche, diskrete, Nominal- und	ISO 3534-2

	nominal scale and ordinal scale.		Ordinalskalen unterschieden.	
<b>Shewhart control chart</b>	A control chart is intended primarily to distinguish between the variation due to random causes and that due to special causes.	<b>Shewhart-Regelkarte</b>	Regelkarte, die dafür vorgesehen ist zwischen systematischen und zufälligen Streuungsursachen zu unterscheiden	ISO 3534-2
<b>special cause</b>	source of process variation other than inherent process variation	<b>Systematische Streuungsursache</b>	Ursache für eine Prozessstreuung, die nicht die Prozesseigenstreuung ist	ISO 3534-2
<b>total process variation</b>	variation in a process due to both special causes and random causes	<b>Prozess-gesamtstreuung</b>	Streuung, die systematischen und zufälligen Ursachen unterliegt	ISO 3534-2
<b>traceability</b>	ability to track and document the history of a product or process	<b>Rückverfolgbarkeit</b>	Wiederauffinden von zugeordneten Informationen	
<b>validation</b>	confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled	<b>Validierung</b>	Bestätigung durch Vorlage objektiver Nachweise, dass die Anforderungen für eine bestimmte beabsichtigte Verwendung oder Anwendung erfüllt sind	ISO 9000
<b>variables control chart</b>	Shewhart control chart in which the measure plotted represents data on a continuous scale	<b>Variablen-Regelkarte</b>	Shewhart-Regelkarte mit Werten auf einer kontinuierlichen Skala	ISO 3534-2
<b>variation</b>	difference between values of a characteristic	<b>Streuung</b>	Unterschied zwischen Werten eines Merkmals	ISO 3534-2
<b>verification</b>	confirmation, through the provision of objective evidence, that specified requirements have been fulfilled	<b>Verifizierung</b>	Bestätigung durch Vorlage objektiver Nachweise, dass bestimmte Anforderungen erfüllt wurden	ISO 9000

## 5 Statistical Process Management/Control (SPC)

To gain a competitive advantage in today's market, manufacturers, suppliers, and service organizations must prioritize quality and commit to ongoing process improvement. Delivering high-value products and services to customers is essential, and organizations should focus on meeting the needs of both internal and external customers, making customer satisfaction a central business goal.

Achieving this requires a company-wide commitment to quality and the use of effective methods. This manual introduces fundamental statistical techniques that support quality improvement initiatives. It is designed for both practitioners and managers who are new to statistical methods, as well as those seeking a refresher on more advanced topics.

Before proceeding, these key points may be considered:

- Statistical Process Control (SPC) refers to the use of statistical methods to monitor and control processes. Traditionally, these methods have been applied to finished parts, but focusing on the processes themselves unlocks greater potential for quality improvement, productivity gains, and cost reduction.
- Collecting data and applying statistical analysis are not goals in themselves; the true objective is to deepen understanding of your processes. Expertise in techniques alone does not guarantee improvement – knowledge must lead to action.
- Suitable measurement processes are essential for reliable data analysis. It is assumed in this manual that the measurement process is capable, stable and does not significantly contribute to overall variation in the data.
- The principles of studying variation and using statistical signals to drive improvement can be applied in any setting, from the shop floor to the office. While this manual emphasizes shop floor applications, these methods can be applied to administrative or transactional processes providing services as well.
- While examples are provided throughout, real understanding comes from direct experience with process control situations. Hands-on practice is invaluable.
- This manual presents widely accepted statistical methods suitable for many scenarios. However, users should carefully assess their applicability and consult statistical experts as needed to ensure methods meet customer requirements.

## 5.1 Proactive Prevention over Reactive Detection

In the past, Manufacturing often depended on Production to make the product and on Quality to inspect the final product and screen out items not meeting specifications. This is wasteful because it allows time and materials to be invested in products that are not always usable. This “reactive detection” approach focuses on identifying and fixing defects after they have occurred.

With the development of the Zero Defects Strategy, it has been recognized that it is much more effective to minimize waste by shifting to an approach of “proactive prevention”.

This requires an understanding of the elements of SPC to actively monitor and identify issues early, allowing for timely corrective actions before defects occur.

A prevention strategy is directed at motivating organizations and people to “do it right the first time”.

While this serves as a motivational slogan, achieving this requires everyone in the organization to be dedicated to a Continual process improvement cycle.

A quality management system serves as the backbone of an organization’s quality efforts. ISO Standards, particularly ISO 9001, play a crucial role in driving Quality assurance. These internationally recognized standards provide a framework for implementing and maintaining effective quality management systems.

Quality assurance (QA) or quality management (QM) is a proactive process focused on preventing defects by monitoring and improving the overall production process, while quality control (QC) is a reactive process that involves inspecting finished products to identify and correct any defects that may exist, essentially checking if the product meets quality standards after it's been produced.

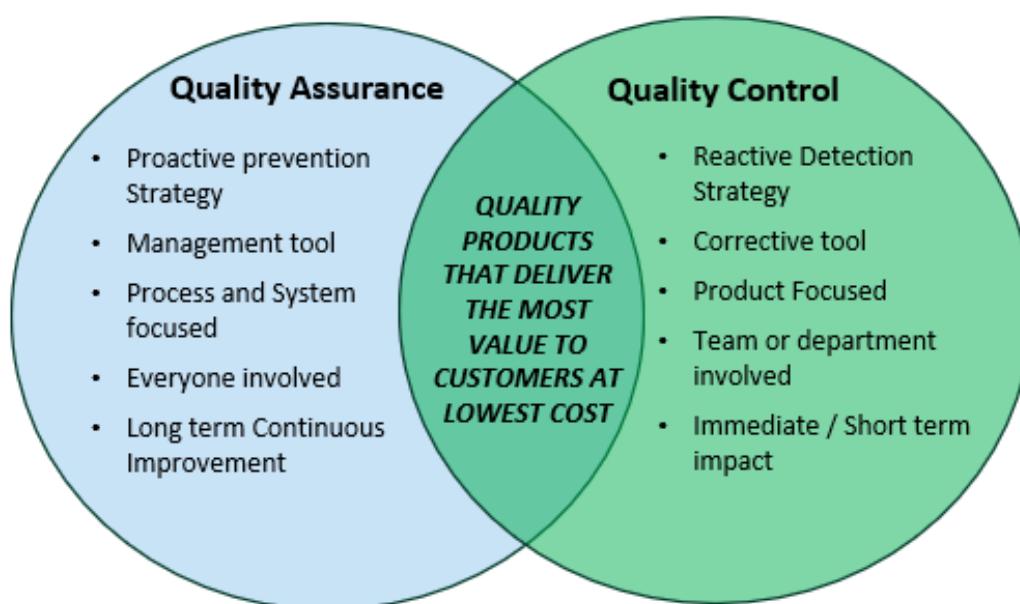


Figure 5-1: Comparison between Quality Assurance and Quality Control

## 5.2 Process Improvement Cycle and Process Control

A Process Improvement Cycle is a structured approach for identifying areas within a process that require improvement, analyzing root causes, implementing corrective actions, and monitoring outcomes to ensure sustained effectiveness. Conversely, Process Control focuses on continuously monitoring the process to maintain it within defined parameters, ensuring consistent results and minimizing deviations.

Continuous improvement is a fundamental principle of SPC and is driven by the PDCA (Plan-Do-Check-Act), also known as the Shewhart cycle or Deming cycle. The PDCA cycle should be repeated again and again to drive continuous improvement.

Here are the four core steps in the PDCA models:

- **Plan:** Recognize an opportunity, understand the problem, and set up quality control processes
- **Do:** Apply and test the change, carry out a small-scale study
- **Check:** Review the test, analyze/study the results, and identify what was learned
- **Act:** Take action based on what was learned, adjust and improve

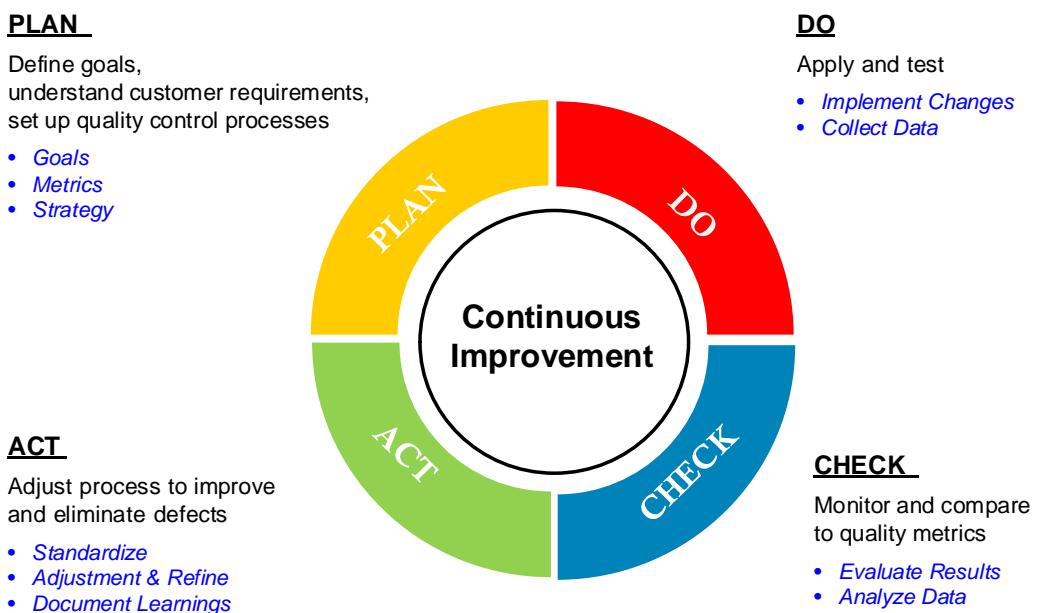


Figure 5-2: The Process Improvement Cycle

## 5.3 A Process Control System

A process control system can be described as a feedback system, with SPC being one type of such system. Other non-statistical feedback systems also exist.

The ISO 3534-2 standard, which defines terms related to applied statistics, describes:

- “Process control” as process management focused on fulfilling process requirements.
- “Statistical Process Control” as activities focused on the use of statistical techniques to reduce variation, increase knowledge about the processes and steer the process in the desired way.

Four key elements of this system are crucial for the discussions that follow:

### 1. The Process

This encompasses the entire combination of suppliers, producers, people, equipment, input materials, methods, and environment that work together to produce output, as well as the customers who use that output. The total performance of the process depends on communication between supplier and customer, the design and implementation of the process, and how it is operated and managed. The rest of the process control system is valuable only if it helps maintain a level of excellence or improves the overall performance of the process.

### 2. Information About Performance

Much can be learned about the actual performance of the process by studying its output. However, the most helpful information comes from understanding the process itself and its internal variability. Process characteristics (such as temperatures, cycle times, feed rates, absenteeism, turnover, tardiness, or number of interruptions) should be the primary focus. We need to determine the target values for these characteristics that result in the most productive operation and then monitor how close or far we are from those targets. If gathered and interpreted correctly, this information can indicate whether the process is behaving normally or unusually. Appropriate and timely actions can then be taken to correct the process or the just-produced output.

### 3. Action on the Process

It is often most economical to act on the process to prevent important characteristics (process or output) from deviating too far from their target values. This ensures stability and an acceptable variation of the process output. Such actions might include:

- Changes in operations, such as operator training or adjustments to incoming materials.
- Changes in the basic elements of the process itself, such as equipment, communication methods, and overall process design, which may be vulnerable to changes in shop temperature or humidity. The effects of these actions should

be monitored, with further analysis and action taken if necessary.

#### **4. Action on the Output**

It is often the least economical to restrict action to detecting and correcting out-of-specification products without addressing the underlying process problem. If the current output does not consistently meet customer requirements, it may be necessary to sort all products and scrap or rework any nonconforming items until the necessary corrective action on the process has been taken and verified. Inspection followed by action on only the output is a poor substitute for effective process management. Action on only the output should be used strictly as an interim measure for unstable or incapable processes. Therefore, the discussions that follow focus on gathering process information and analyzing it so that action can be taken to correct the inputs (set variables) of the process itself. Remember, the focus should be on prevention, not detection.

### **5.4 Quality Control Loops**

Defined quality control loops provide a detailed view of statistical process management. In addition to the interconnected methods of SPC, they also establish overarching objectives and identify the individuals responsible for implementation.

#### **Quality Control Loops**

1. Statistical Process Control (SPC)
2. Quality Conformance gates
3. Post-Process improvement cycle
4. Product Audits
5. Process Audits
6. System Audits

## ORGANIZATIONAL MANAGEMENT – CONTROL PHILOSOPHY

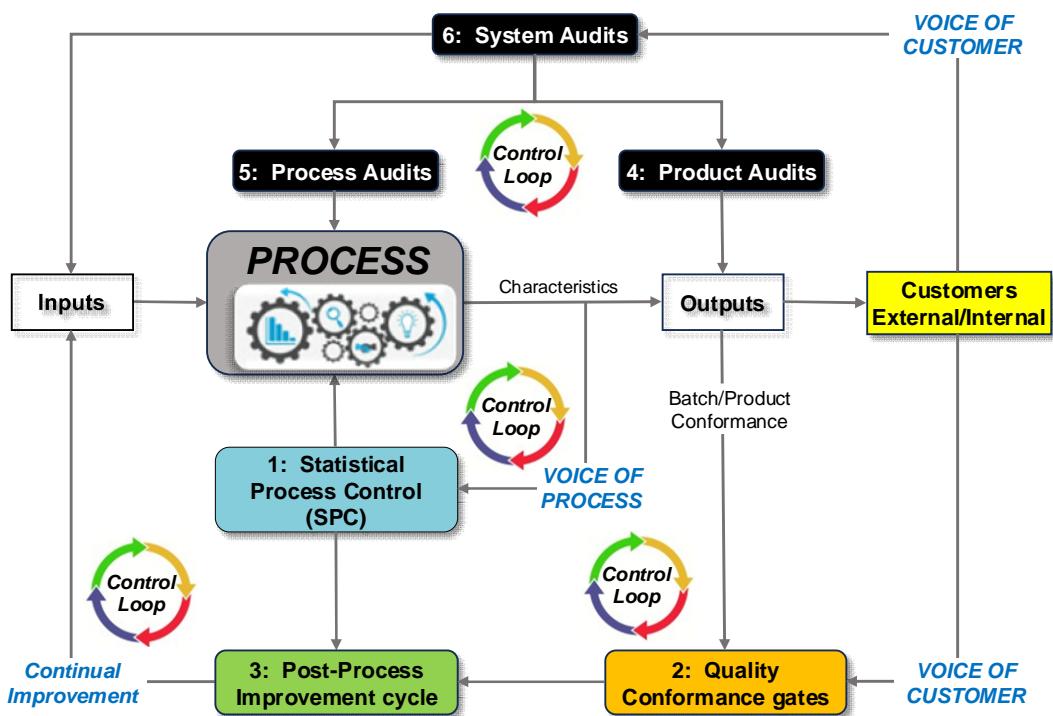


Figure 5-3: Process Control System with Control Loops

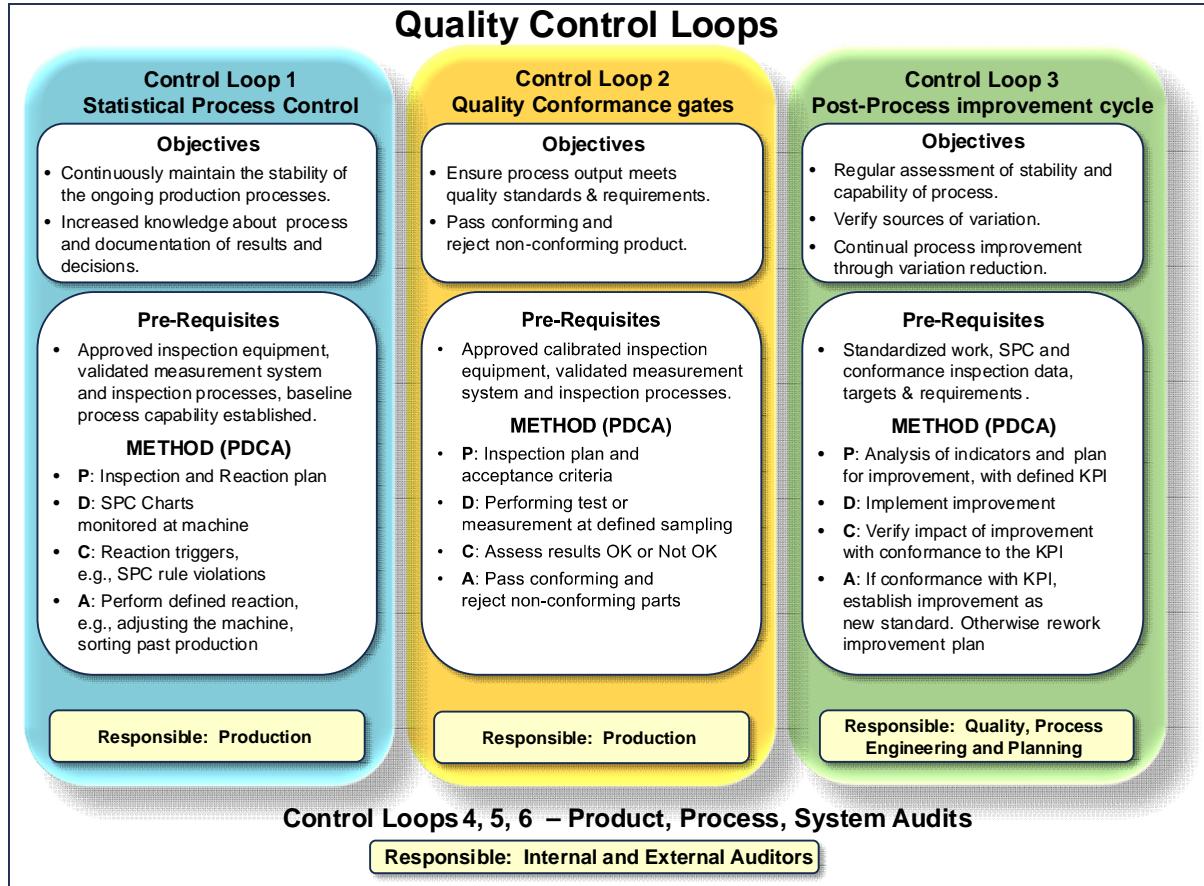


Figure 5-4: Statistical Process Management – Quality Control Loops

## 6 Requirements for SPC Applications

### 6.1 Introduction

The Statistical Process Control (SPC) applications presented in this volume can be used as stand-alone tools. However, this may not lead to the desired outcomes. Therefore, the SPC applications need to be integrated into the company-wide quality management system to ensure adequate and successful implementation. Above all, the tools must be used in a target-oriented manner. To identify the decisive quality characteristics and production processes and to apply the underlying control concepts, several requirements<sup>1</sup> must be met. These include:

- Clear product specifications
- Valid and capable inspection systems
- Process characterization
- Planning production and inspection planning
- Out-of-control action plan (OCAP)
- Sampling plan – Refer to Chapter 8 and 10
- Control chart selection – Refer to Chapter 10
- Control or process documentation and control plan
- Data collection, storage, and retrieval – Refer to Chapter 8
- Roles and competencies in SPC
- Periodic audits

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<sup>1</sup> Little, T. A., Ph. D. & Thomas A. Little Consulting. (2002). Ten Requirements for Effective Process Control. In ASQ Quality Progress.

[https://www.thomasalittleconsulting.com/publications/articles/Ten\\_Requirements\\_for\\_Effective\\_Process\\_Control.pdf](https://www.thomasalittleconsulting.com/publications/articles/Ten_Requirements_for_Effective_Process_Control.pdf)

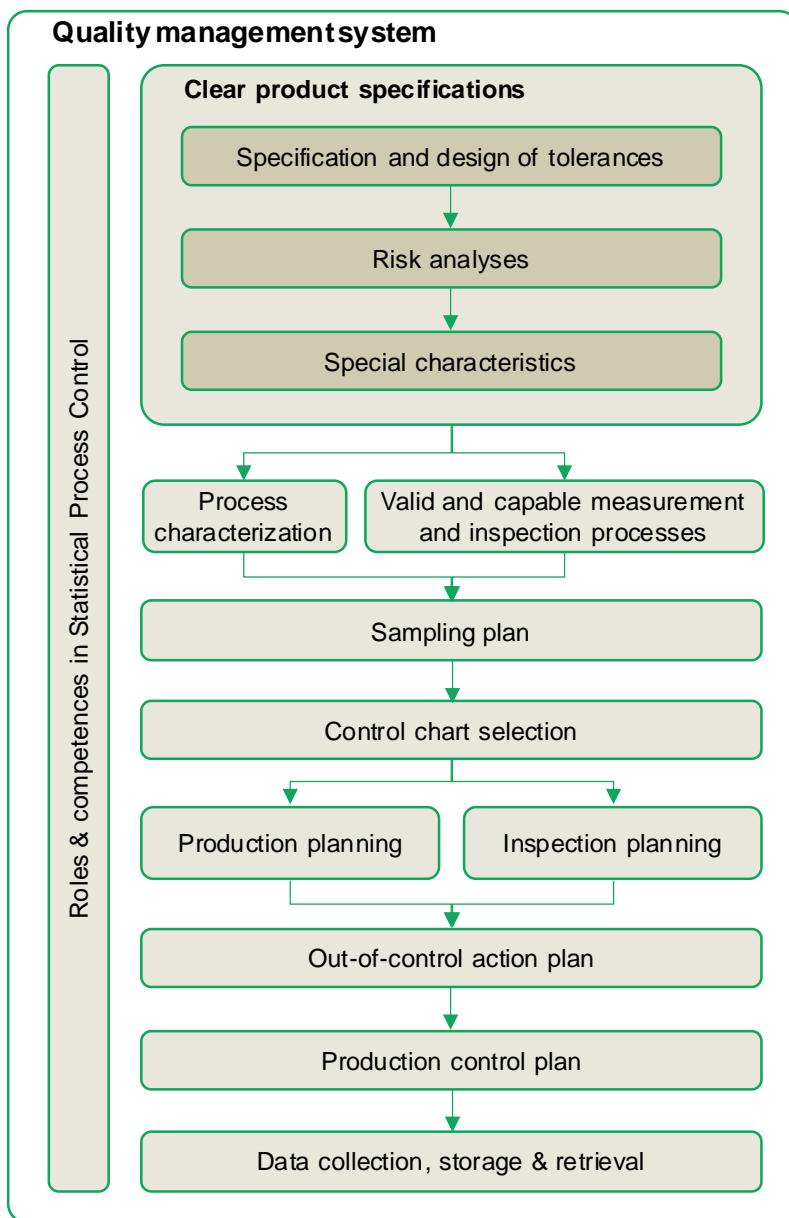


Figure 6-1: Schematic Sequence of the Preparatory Work for SPC

## 6.2 Clear Product Specifications

Clear product specifications provide precise characteristics specifications for the line operator in the acceptance, rejection or rework of the product during production. Considering a transparent and risk-based definition of these specifications allows for an effective and efficient control strategy for the product.

The following section on tolerancing is based on Geometrical Product Specification (GPS)/Geometric Dimensioning and Tolerancing (GD&T), which is used and known in the automotive business sector where dimensions, form/position and surface tolerances are widely relevant. For other tolerances that do not originate from the GPS or GD&T environment, other corresponding design rules and guidelines are applied.

### 6.2.1 Tolerancing and Responsibility Principles

Characteristic<sup>2</sup> tolerances must be clearly defined in terms of function, production and inspection.

Due to inevitable inaccuracies arising from production or the selection of materials, the desired ideal geometry is generally not feasible. The acceptability of production and material-related deviations primarily depends on the required functionality and the assembly capability. For each workpiece, it must be specified to what extent the actual geometry can deviate from the target geometry without significantly affecting functionality and assembly capability.

Unfortunately, those responsible for tolerancing often tend to choose unnecessarily small tolerances due to a lack of in-depth knowledge about tolerancing options and principles; these principles include:

- the envelope/independency principle
- the maximum/least material requirement
- the tolerance rule for general tolerances
- the simulation of tolerance chains or variation analysis studies

Geometric specifications provide a very precise language to communicate requirements in a standardized way of describing the shape, size and form of a component, making it easier to communicate design requirements across different stages of production and among various stakeholders. The prerequisites for adequate descriptions of geometries are:

- Functionality: the component must fulfil its defined function throughout the entire duration of use
- System-level compatibility: it must be possible to isolate and evaluate the fitting features of the component in a repeatable and reproducible manner, thus ensuring the fitting of the component at the superior system level
- Manufacturability: it must be possible to produce components using a capable production process
- Measurability/testability: it must be possible to inspect and measure the characteristics of the component in a simple and reliable way

The independency principle<sup>3</sup> states that each requirement regarding dimensional, form and positional tolerances must be able to be met irrespective of other requirements, as long as there is no special link or relationship, e.g., tolerance compensation via the maximum/least material requirement. Each specified tolerance

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<sup>2</sup> For reasons of simplicity, only geometric characteristics are referred to in the following. However, the principles naturally also apply to non-geometric characteristics.

<sup>3</sup> Described in International Organization for Standardization. (2011). Geometrical product specifications (GPS) – Fundamentals – Concepts, principles and rules (ISO 8015:2011). ISO. Chapter 5.5.

must then be observed and inspected separately.

In accordance with Taylor's principle (a.k.a. rule #1: the envelope principle<sup>4</sup>), inspections must be carried out in case of mating components to ensure that fitting conditions are met. In the case of a "GO / NO-GO" gauge, the "GO" gage forms the "envelope". For the "GO" inspection, the inspection condition must be fulfilled across the entire fit length, e.g., the envelope principle must be fulfilled. Regarding the "NO GO" inspection, it is sufficient if the "GO" condition is not met in one place. The maximum material size is thus observed under Taylor's principle, ensuring that the fitting conditions are met.

The envelope principle places restrictions on production, as all deviations of a form element must be within the envelope. If a significant portion of the tolerance is needed to form positional deviations, there is limited room for dimensional deviations. An envelope requirement is only necessary in cases where a fit function is required.

The responsibility principles<sup>5</sup> are meant to prevent situations where tolerance specifications already take into account uncertainties that do not fall within the design and development department's scope of responsibility. This can include specifications that restrict functional tolerances due to suspected measurement uncertainties or unstable, incapable production processes. However, rather than improving the initial situation, this generally makes it worse. In extreme cases, neither the measurement technology nor the production department can meet the requirements imposed on them, as the measurement uncertainty and the production variation – which fall within their scope of responsibility – are now factored in twice. This means that increased efforts are necessary in terms of measurement, the assurance of the production processes, and special releases due to non-fulfilment of requirements.

The development department is responsible for the specification operators that must correspond to the function operators, which means that the tolerance limits of a characteristic are identical to the functional limits.<sup>6</sup>.

The person responsible for measurement process is the person who provides proof of conformity or nonconformity with a specification. ISO 14253-1 and VDA Volume 5 (or AIAG MSA) must be observed in this regard.

<sup>4</sup> Described in American Society of Mechanical Engineers. (2018). Dimensioning and tolerancing (ASME Y14.5-2018). ASME. Chapter 5.8.1.

<sup>5</sup> Described in International Organization for Standardization. (2011). Geometrical product specifications (GPS) – Fundamentals – Concepts, principles and rules (ISO 8015:2011). ISO. Chapter 5.13.

<sup>6</sup> See International Organization for Standardization. (2011). Geometrical product specifications (GPS) – Fundamentals – Concepts, principles and rules (ISO 8015:2011). ISO. Chapter 4.3.

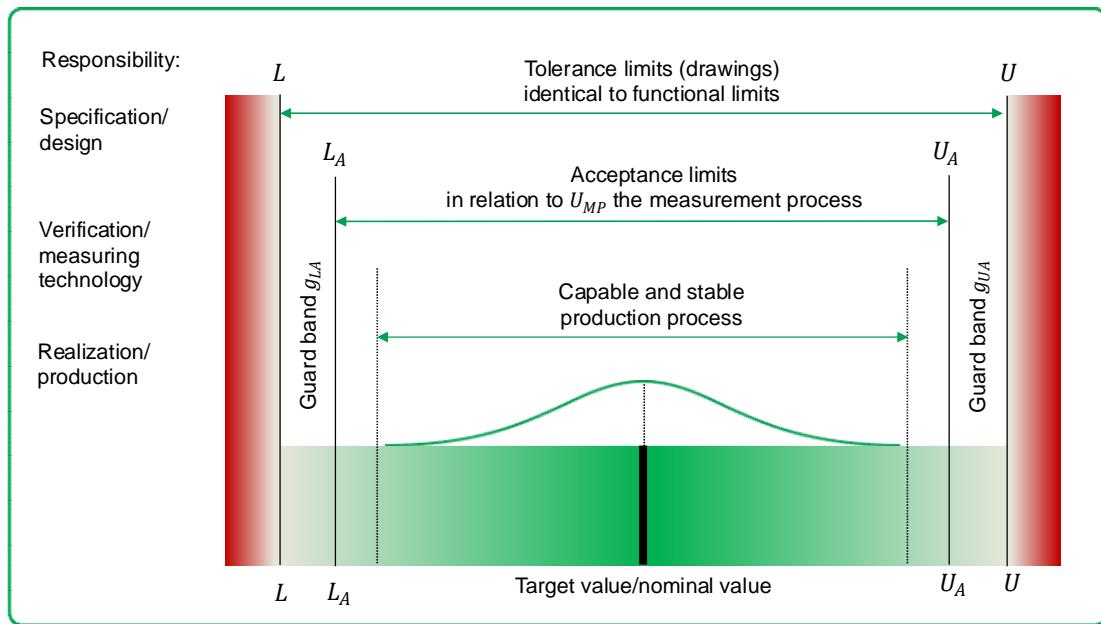


Figure 6-2: The Interaction of the Tolerance (Drawing), the Extended Measurement Uncertainty of the Measurement Process  $U_{MP}$ , and the Acceptance Limits, Capable and Stable Production Process

While this is not explicitly stated in ISO 8015, the logical consequence is that the production department is responsible for zero defect manufacturing. The production department must, therefore, minimize the probability of producing nonconforming product characteristics by ensuring that sufficiently capable and stable production processes are used.

SPC can only be adequately applied if these responsibility principles are observed.

## 6.2.2 Risk Analyses

A further important step towards implementing SPC is the risk assessment of the product characteristics and their tolerances. Companies often do not have the capacity to implement SPC monitoring of all characteristics, and from a business perspective, this also would not be reasonable. For that reason, monitoring should be limited in a reasonable way to the characteristics that are relevant at the respective validation levels. For initial acceptance procedures and releases of production equipment, this will naturally include more characteristics than will subsequently be monitored long-term using control charts.<sup>7</sup> One of the methods to be used for this purpose is “Failure Mode and Effects Analysis” (FMEA). Details on applying and conducting FMEAs at the various development levels, including the resulting task priorities and risk assessment, can be found in the AIAG and VDA FMEA handbook.

<sup>7</sup> See Automotive Industry Action Group. (2024). Advanced Product Quality Planning (APQP) reference manual (3rd ed.). AIAG. Chapter 0.8 and Automotive Industry Action Group. (2024). Control Plan reference manual (1st ed.). AIAG. Chapter 3.

### 6.2.3 Special Characteristics

Special characteristics are product characteristics or manufacturing process parameters that can affect safety or compliance with regulation, fit, form, function, performance, or the subsequent processing of the product.

In this regard, organizations can follow the IATF 16949 Chapter 8.3.3.3, AIAG "Control Plan" or VDA Volume "A Process Description Covering Special Characteristics". The method describes a multidisciplinary approach to identify, classify, document special characteristics and to establish safeguards (quality control loops) in the entire value stream, to ensure an efficient and effective production control.

Otherwise, organizations can define other categories to distinguish between different types of special characteristics and/or follow the customer-specified categories.

It must be ensured that these special characteristics meet the requirements by obtaining proofs of capability and conducting stability evaluations. If sufficient process capability cannot be proven, 100% inspections may have to be introduced.

## 6.3 Valid and Capable Measurement and Inspection Processes

Measurement systems are crucial for proper data analysis and must be well understood before collecting process data.<sup>8</sup>. If these systems lack statistical control or their variation accounts for a significant portion of the total variation in process data, inappropriate decisions may be made.

When it comes to the "resources for monitoring and measurement" according to ISO 9001,

- the capability of the provided resources for the respective type of monitoring/measurement, as well as
- their ongoing capability

must be ensured.

IATF 16949 makes the requirements more concrete by specifying that inspection process capability must be verified for all types of inspections and measurements specified in the control plan (includes both variable and attribute) and for all inspection and measuring systems listed in the plan.

It is thus ensured that the data required for SPC applications are generated by means of valid measurement and inspection processes. Without validated measurement systems and measurement as well as inspection processes, SPC

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<sup>8</sup> Measurement System Robustness is listed as pre-requisite (A) to SPC in the SPC Quick Start Guide, CQI-25, version 1. See Automotive Industry Action Group. (2015). SPC Quick Start Guide (CQI-25:2015). AIAG.

cannot be reliably applied; this manual assumes the measurement system is under control and not a significant contributor to total variation.

Further details can be found in the Measurement Systems Analysis (MSA) Manual from AIAG as well as in VDA Volume 5 (Measurement and Inspection Processes).

## 6.4 Process Characterization

Process characterization allows the engineer to determine precisely the relationship between process parameters and product characteristics. Generally, this is accomplished using the Design of Experiments (DoE) or regression analyses.

This characterization allows the identification of primary and secondary control factors, which will be used for process adjustments (see Chapter 6.6, OCAP).

## 6.5 Production and Inspection Planning

Production planning is the link between design and production/assembly. It is required for the future organization of production and comprises all one-off measures for ensuring cost-effective production. Production planning must consider the necessary workstations and work steps for SPC application, the spatial, logistical, and organizational requirements, as well as the requirements regarding equipment/operating material.

Inspection planning focuses on the actual measurement and inspection process and serves to ensure, by ISO 9001, that monitoring and measurement resources are traceable and suitable for the respective types of monitoring and measurement performed. The tasks include creating measurement and inspection concepts, specifying and procuring the measuring systems, and validating the measuring systems and measurement processes. Inspection planning can also be used to help ensure ongoing capability. Inspection planning thus ensures that valid data is available for the application of SPC.

## 6.6 Out-of-Control Action Plan (OCAP)

Quality planning focuses on control and inspection strategies. It must include guidelines for the operators for adjustment when a control rule is violated: out-of-control condition. Such an action plan is specific to the violated control rule and includes:

- Adjustment matrix for operator-based adjustment where appropriate,
- Responsible individuals for adjustment and escalations,
- Process log for adjustments and observations, and
- Assurance that production operators and supervisors understand the OCAP and can effectively apply it.

This is key to preventing situations where involved roles uncover process instability only to discover that nothing can be done about it.<sup>9/10</sup>.

## 6.7 Control Plan

The control plan is a central, multidisciplinary document and is part of advance quality planning. It comprises all production process steps, product characteristics and process parameters that affect product quality and must be controlled. In addition to the actual production, the control plan can include control strategies for initial acceptance procedures and releases of production equipment (e.g., pre-launch, safe launch).

Measuring systems, measurement and inspection processes as well as inspection methods are defined, sample frequencies and sample sizes are specified, and plans for reactions to violations of control or tolerance limits (out-of-control) are defined. The control plan can also provide the basis for preparing the inspection plans. It is thus the foundation for all SPC applications.

Further details can be found in AIAG Control Plan, IATF 16949, VDA Assessment of Quality Management Methods, and VDA Volume 6.3.

## 6.8 Roles and Competencies in SPC

### 6.8.1 Roles in SPC

#### Quality planning expert / Process owner

- Responsible for the SPC management process
- Defines and monitors the process performance
- Is responsible for ensuring that the process can be applied in practice
- Subject the process documentation for SPC to regular revision

#### Product developer/engineer

- Development and construction of the product
- Determination of the product characteristics, including specification limits (tolerance)
- Determines how relevant the characteristic is to product function (e.g., as part of a design FMEA)

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<sup>9</sup> Ability to React to Instability in Real Time is listed as pre-requisite (C) to SPC in the SPC Quick Start Guide, CQI-25, version 1. See Automotive Industry Action Group. (2015). *SPC Quick Start Guide* (CQI-25:2015). AIAG.

<sup>10</sup> The out-of-control action plan is also referred to as “OOC AP” or “out-of-control reaction plan (OOC RC)”

- Solving technical tasks

### **Manufacturing process planner / Process engineer / Industrialization engineer**

- Plans and implements production methods for manufacturing products based on the characteristics of product development
- Determines the probability of the occurrence of products bordering on the specification limits (e.g., as part of a process FMEA)

### **Inspection process planner**

- Carries out inspection process planning based on the characteristics of product development and the manufacturing process of planning

It is essential that the roles of product development, manufacturing process planning and inspection process planning are coordinated in order to attune tolerances, inherent manufacturing process variation and measurement uncertainty in the sense of a capable manufacturing process (see Chapter 5).

### **Manufacturing equipment procurer**

- Completes all purchasing tasks, e.g., ordering
- Transmitting the specifications as part of the contract documents

### **Line supervisor (manufacturing)**

- Ensures all operators are trained on the proper use of all line process controls
- Coordinates concerns on SPC with responsible engineers and managers
- Reviews SPC performance data with area personnel
- Audits operator performance to ensure operators are following correct SPC procedures

### **Line operator (manufacturing)**

- Disposition of the product in association with the product specifications
- Collects inspection data according to the control plan
- Charts the data and follows control rules for process adjustment
- Uses OCAP for any out-of-control condition

- Logs all process adjustments and any observation regarding machines, materials or process conditions

### 6.8.2 Competencies in SPC

All employees must be suitably qualified for the roles assigned to them. Table 6-1 below shows recommendations for role-specific competencies.

*Table 6-1: Recommendations for Role-Specific Competencies in SPC*

Competence	Role	Line Operator	Line Supervisor	Manufacturing Process Planner / Process Engineer / Industrialization Engineer	Procurement	Inspection Process Planner	Quality Planning Experts	Product Developer / Engineer
<b>Quality Management System</b> (understanding links between core tools, understanding pre-requisites)		1	1	1	1	1	2	1
<b>Technical Statistics</b>		1	-	1	1	1	2	1
<b>Machine Performance</b> (conditions and setup)		-	-	1	2	-	2	-
<b>Process Performance</b> (understanding capabilities, stability)		-	-	2	1	-	2	1
<b>Understanding Critical Parameters</b> (process knowledge, using, e.g., DoE, regression analysis)		-	-	2	2	1	1	-
<b>Process Control, defining Control Charts</b> (feedback loop 3)		-	-	2	-	2	2	-
<b>Process Control, using Control Charts</b> (feedback loop 1)		1	2	1	-	-	1	-

Key: 1 = basic level / 2 = expert level

The following list describes the minimum requirements for the corresponding competency from the point of view of the SPC book and does not claim to be exhaustive.

#### Quality management

- Placing products on the market (product liability)
- Monitoring and measurement resource requirements
- Control of documented information

- Specifying product characteristics
- Conformity, nonconformity and their consequences
- Release processes, response in case of nonconformity
- Opportunities and risks
- Continuous improvement

## **Technical statistics**

- Basic terms and definitions
- Continuous (variable) and discrete (attribute) characteristics
- Mathematics and numerical analysis
- Chance and probability
- Graphical display and numerical evaluation
- Significance of the standard normal distribution
- Distribution models for discrete characteristics
- Uncertainty of statistical elements

## **Machine performance**

- Inspection characteristics, constraints, and samples
- Evaluation and assessment of irregularities
- Stability study and limits of stability for mean values and standard deviations
- Calculating  $P_m$  and  $P_{mk}$

## **Process performance**

- Samples, calculating  $P_p$  and  $P_{pk}$
- Processes with systematics that cannot be eliminated
- Processes without trends
- Processes with trends that cannot be eliminated

## **Understanding critical parameters**

- The black box process model for statistical experimental design

- Experiment space conception and experimental design types
- Functional approach and error model – Approach for optimization with multiple variables
- Systems analysis for defining variables, factors and their set areas
- Experimental designs with constraints, special models, etc.
- Basics of evaluating experimental design data (regression)
- Steps for regression analyses – Reasons for the steps
- Limits for the evaluation of historic data
- Overview of special approaches (Robustness, Taguchi, Shainin)

### **Process control, defining control charts**

- Basics of SPC
- Determination and mode of operation of control limits
- Implementation of control charts for variable characteristics, mean values and variations, and for attributive characteristics

### **Process control, using control charts**

- Basics of SPC
- Basic knowledge of control limits & control charts
- Practical use of control charts, evaluation and taking action

## 7 Overview of Methods

### 7.1 Preliminary Remark

Chapter 7 introduces key topics & elements of a process control system that are explained in greater detail in Chapter 8, 9 and 10.

### 7.2 Difference between Performance and Capability

When evaluating a process, two related yet distinct terms must be explained.

- Process Performance – Calculated index  $P$
- Process Capability – Calculated index  $C$

These terms have developed historically and have not been uniformly defined in literature and therefore must be used with great care.

According to ISO 3534-1 and the ISO 22514 series, the following terms are used:

*Table 7-1: Terms and Indices on Process Evaluation*

Terms	Indices	Application Condition
Process Performance	$P$	<ul style="list-style-type: none"> <li>• Used when stability has not been investigated.</li> <li>• Used when data does not allow for stability assessment.</li> <li>• Used when stability requirements are not met (unstable: out of control).</li> </ul>
Process Capability	$C$	<ul style="list-style-type: none"> <li>• Used when stability requirements are met (stable: in statistical control or in control).</li> </ul>

Both indices (performance and capability) use the same formula utilizing the overall variation of a process (see Chapter 7.8).

In this manual, the term “capability” may be used as an overarching term when describing studies to demonstrate “proofs of capability”. A process capability study is used to assess a manufacturing process's ability to consistently produce outputs that meet specified quality requirements. Process stability is one of the critical factors in process capability, as an unstable process may produce products or services that are not consistent in quality.

If it is stated that “proofs or capability” are required, this generally refers to a capability index  $C$  or a performance index  $P$ . If performance indices are explicitly demanded, proofs of stability are implicitly not necessary or are not required.

## Process Indices

Calculated Process indices ( $P$  and  $C$ ) should be used to align the “Voice of the Process” to the “Voice of the Customer” (i.e., Specification limits).

Several different indices have been developed because:

- 1) No single index can be universally applied to all processes, and
- 2) No given process can be completely described by a single index.

All indices have weaknesses and can be misleading. Any inferences drawn from computed indices should be driven by appropriate interpretation of the data from which the indices were computed. It is the reader's responsibility to communicate with their customer to understand what is required and determine which indices to use.

The types of Capability studies performed across development phases vary based on the maturity of process, part availability and exposure to sources of variation over time. The sources of variation that typically influence a production process are defined as follows.

Common “5M” categories of variation

- Machine – Equipment, Tools, Machinery
- HuMan – People or Human resources.
- Method – Process
- Material – Materials used in the process.
- Milieu – Environment (Mother Nature), uncontrollable factors

*Note: A 6M model may be referred to, which adds the influence of measurement variation. A validated measurement system is a prerequisite when assessing process capability.*

Table 7-2: Capability Studies Over Time, Observable Variation Influences

Studies	Machine performance	Preliminary process performance	Process performance or capability
Indices	$P_m/P_{mk}$	$P_p / P_{pk}$	$P_p/P_{pk}$ or $C_p/C_{pk}$
Purpose	Release of production equipment/machines	Release of production processes	Monitoring of production processes
Process Variation due to	Machine (Machine variation only)	Machine, HuMan, Method, Material, and Milieu (Limited variation observed)	Machine, HuMan, Method, Material, and Milieu (Limited to full variation observed)

During process performance or capability studies, some product characteristics may not be in statistical control, but they could be "in control" under certain conditions. To be in control, the variation in the characteristic must be of no practical significance, or the range of values always falls within control limits, sufficiently within tolerance limits to make out-of-tolerance parts exceedingly unlikely. Such characteristics must rely on procedures followed by line operators and supervisors to monitor and adjust the process as required to maintain the characteristics in control over long time periods.

### 7.3 Machine Performance

The objective of machine performance studies is to assess influences on the production process that are exclusively due to the machine. Therefore, based on the familiar "5M" model, the other sources of variation that exist must be fixed, as shown in Table 7-3.

*Table 7-3: Assessing Influences on the Production Process (Example)*

5 M's →	Machine	HuMan	Method	Material	Milieu
Goal	Study Performance	Fix & Hold constant to isolate Machine influence			

The outcome of this study is to release production machines and equipment based on acceptable levels of performance, see Figure 7-1. According to ISO 22514-3, the indices  $P_m/P_{mk}$  are calculated to assess machine performance. In some cases, this may be referred to as a short-term study. However, this term can be misleading and can also comprise the short-term variation of further process influences. Therefore, the expression "short-term study" or "short-term capability" should not be considered a synonym for a machine performance study.

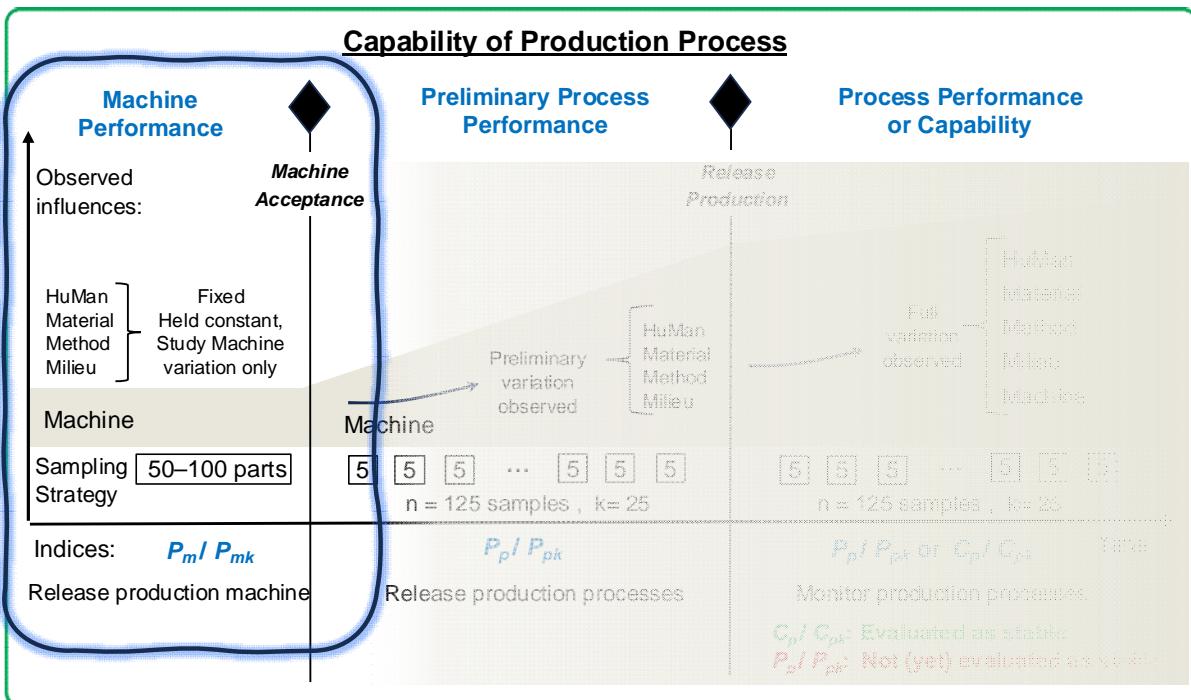


Figure 7-1: Capability of a Production Process Over Time – Machine Performance

A machine performance study requires thorough preparation with a well-laid out plan to fix and control influences of the other sources of variation. This means that, for example,

- the production equipment must be set to the nominal value
- tools that are used for processing must be run in (i.e., conduct pre-run)
- the production equipment must have reached operating temperature
- sufficiently homogeneous raw parts must be available for processing.

The high-level steps to conduct a machine performance study and calculate indices are as follows.

### Sample Parts

- A representative number of parts (according to DIN ISO 22514-3 n = 100, usually n = 50) must be produced in a continuous, uninterrupted production sequence.

*Note: In some cases, less than ideal sample sizes are available to perform an assessment. Indices can be calculated, but targets should be adjusted based on sample size to achieve performance with the desired level of confidence (see Chapter 8). A release can be authorized as long as it can be assumed that the machine influences are adequately reflected in the data. In some instances, taking multiple small samples, referred to as subgroups, may be helpful.*

## Document conditions

- The framework conditions and deviations from a continuous production flow must be documented.

Note: *The same applies in the case of changes to influencing or disturbance variables that are unrelated to the machine. This documentation can provide insights regarding possible causes of variation leading to optimization to improve future capability.*

## Record Measurements

- The characteristics of the parts must then be measured and documented according to the production sequence.

## Evaluate Trends

- Stability is not explicitly assessed, but a qualitative evaluation of trends is highly recommended.

## Calculate Machine performance indices

- See Chapter 8

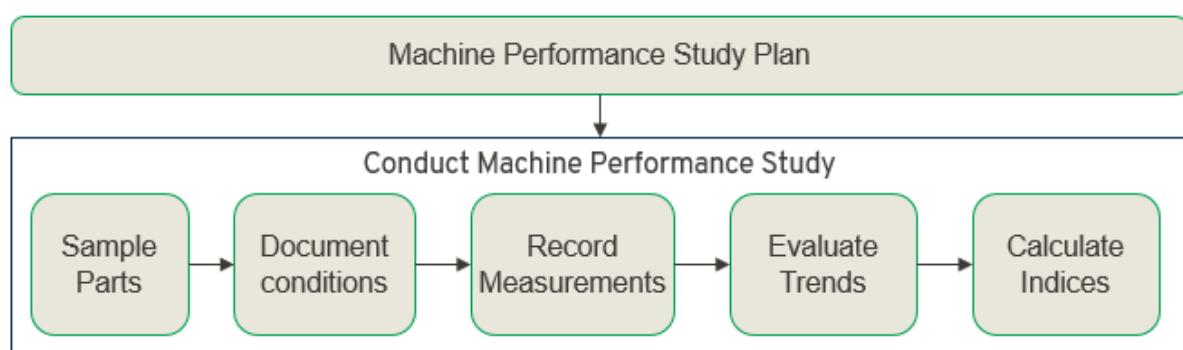


Figure 7-2: Machine Performance Study Plan

## 7.4 Process Capability and Performance Studies

The objective of a process capability/performance study is to capture and assess all influences on a production process that must be expected for series production. These influences can be put into categories according to the familiar “5M” model (machine, method, material, human, and milieu).

In many cases, this means that this is a long-term study. However, the expression “long-term study” can be misleading. It refers neither to the influences investigated nor to the actual objective explicitly. Consequently, the expressions “long-term study” / “long-term capability” and process capability study should not be used synonymously without providing further details.

According to ISO 22514-2, the capability indices  $C_p/C_{pk}$  or  $P_p/P_{pk}$  are used in order to evaluate process capability or performance. The designation of the indices depends on whether stability is explicitly evaluated. The indices  $C_p/C_{pk}$  must only be used if the process is stable (either statistically or controlled stable). If stability cannot or should not be evaluated, or if the process is explicitly unstable, the indices  $P_p/P_{pk}$  are used. Irrespective of the designation of the indices, the latter are calculated numerically in the same manner.

A process capability study requires measured product parts from a longer period that is representative of series production, such that all expected influences on the process have taken effect to the extent possible. It is, therefore, advisable to conduct a sample inspection, whereby small samples (usually 3 to 5 parts consecutively produced) are taken from the production process at adequate, defined intervals. The current process variation and process level of the production process can be determined based on the variation of the individual samples, and the resulting total variation and total process level can be determined on the basis of the entire data. The use of quality control charts (analysis charts) allows for a post-process stability evaluation. Based on the now known process behavior of a specified characteristic, an adequate on-site quality control chart (SPC chart) can be derived with which the process can be controlled in the future.

To evaluate the process capability and process performance indices, it is necessary to inspect a representative number of series parts (at least  $n = 125$  parts in at least  $k = 25$  individual samples) that have been taken over the course of a sufficiently long period of time, during which typical expected disturbances/influences have taken effect. The framework conditions and controls in the production process must be documented. This documentation can provide insights regarding possible optimization measures in case capability criteria are not met.

If it is not possible to produce the minimum number of parts, performance indices can still be calculated (taking account of the changed confidence interval of the parameters) and releases can be authorized, as long as it can be assumed that all expected process influences are adequately reflected in the data.

Especially at the start of series production, there are often not enough produced parts available, and they cannot be taken out of the manufacturing process over a sufficient period of time. It must thus be assumed that not all disturbances/influences have fully taken effect, as would have been expected in a series production process. However, a preliminary statement on the expected production process capability or performance can then still be made based on the data. This "preliminary process performance" according to VDA 4 or "initial process capability" according to AIAG PPAP should be labeled appropriately and should be determined under consideration of the changed confidence interval of the parameters (see Figure 7-3).

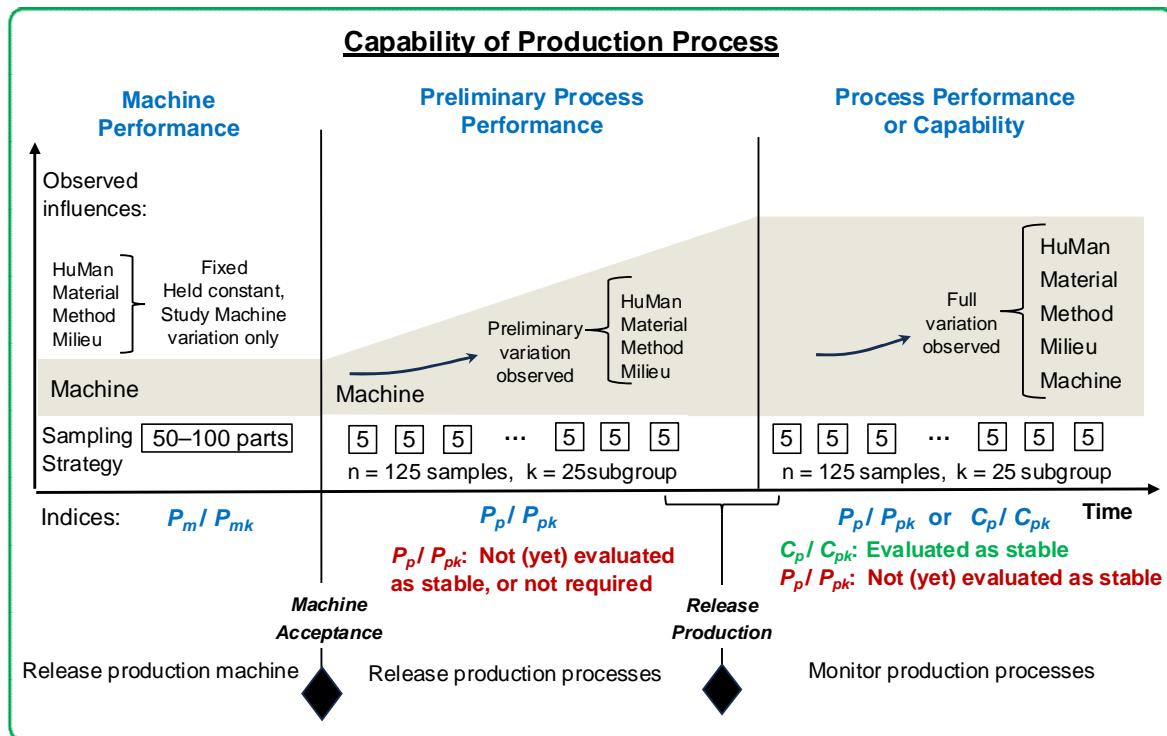


Figure 7-3: Capability of a Production Process Over Time

## 7.5 Quality Control Charts

The control chart technique was developed by Walter Andrew Shewhart in the 1920s and is described in detail in his publication "Economic Control of Quality of Manufactured Product". The technique has since been continuously refined and optimized. Thanks to the use of software, the effort required to determine and apply an appropriate quality control chart has been reduced to a minimum. This particularly applies to the calculation of control limits and the evaluation of stability.

Quality control charts are graphical aids for collecting and displaying measured values (or count results) and sample statistics (statistical parameters), as well as for comparing them against previously specified control limits. The control limits of a quality control chart must not be confused with the tolerance limits ("specification limits") specified on a drawing. Tolerance limits apply to the individual characteristic values and not to the sample parameters displayed on the control charts. By contrast, control limits are determined based on the random variation ranges of the statistical indices (e.g., mean values), which are monitored using the control chart. As a matter of principle, the tolerance limits are thus not included in quality control charts.

Typical quality control charts characterize process data as follows.

- Process Location (or center)
  - Individual value charts
  - Mean value charts
  - Median charts

- Process variation as
  - Range charts
  - Standard deviation charts

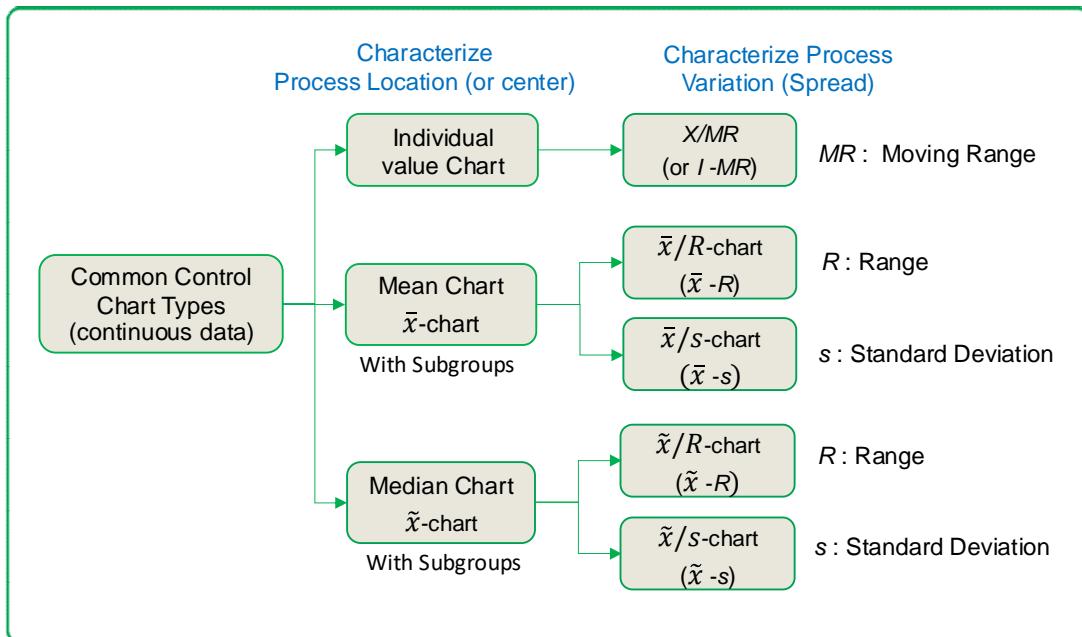


Figure 7-4: Common Control Charts Types to Characterize Data

Any desired combinations thereof can be used. For manual charts, median range charts ( $\tilde{x}/R$  charts) are often used, whereas mean value - standard deviation charts ( $\bar{x}/s$  charts) are favored if computers are used. Individual value charts can often be used without additional variation charts. However, they are suitable only to a limited extent given their weak “responsiveness”.

The control chart concept, according to Shewhart, presupposes that the control limits describe the inevitable random variation (random/chance causes) of a production process. In case of violations of the control limits, it is assumed that these violations are due to assignable causes, and measures are taken in order to eliminate the presumed process disturbance. The control limits depend on the distribution of the monitored statistical parameter as well as the chart type. Depending on the distribution of the characteristic and the size of the sample, Shewhart control charts, extended Shewhart charts, or Pearson charts are typically used.

A deviating concept is the so-called “acceptance control chart”, whose control limits are specified based on the tolerance limits. The objective of this chart is to identify whether specified “permissible” fractions nonconforming (parts that fall outside of the tolerance) are exceeded within the scope of a sample inspection. This concept is incompatible with the objective of continuous improvement and a modern zero-defect strategy. Nowadays, the acceptance control chart is therefore mostly used to control process parameters or non-critical characteristics that serve to monitor and optimize tool life.

Quality control charts can thus be put into two groups, depending on their control concepts:

- Process-related control charts are used to optimize the quality of a process and to ensure faultless production
- Tolerance-related control charts are used to optimize the “scope” of the production process and allow for specified fractions non-conforming

However, control charts can also be separated into two groups based on their objectives:

- Analysis charts are used to evaluate past processes on the basis of data collected over a longer period of time. Given that the random variation ranges under evaluation are calculated on the basis of specified error probabilities, analysis charts can take account of how many violations of control limits were to be expected due to the design rules of the charts (“false alarms”). These expected false alarms are taken into consideration in the post-process stability evaluation.
- SPC charts reflect the expectations regarding a process to be controlled based on a known process behavior. They are used on site, on the shop floor, for process control. Any violations of control limits or other instabilities must lead to immediate actions in order to control a process in a reliable and timely manner.

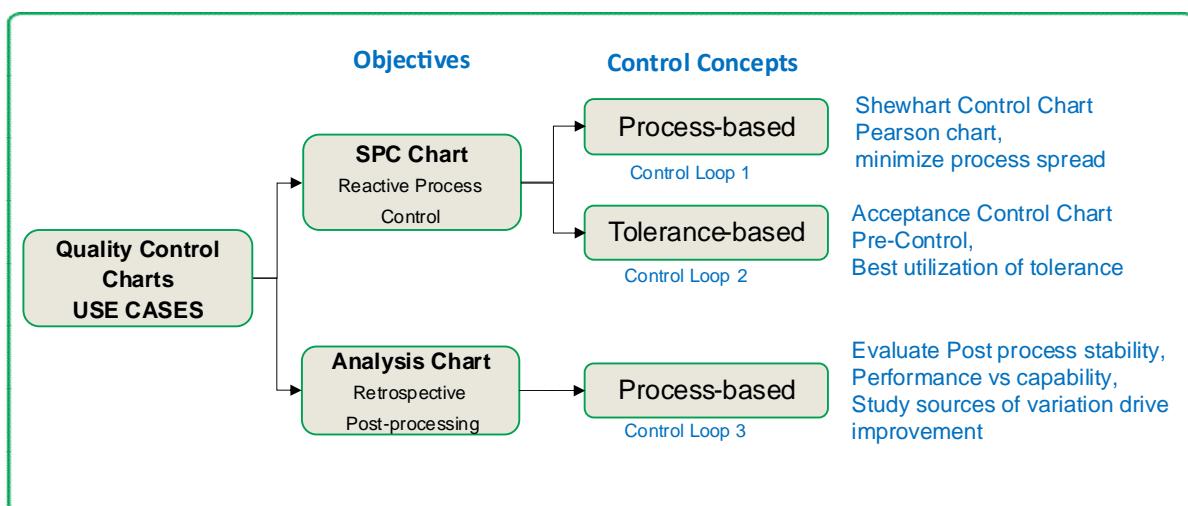


Figure 7-5: Control Chart Use Cases

Further criteria can be used when evaluating stability in process-related control charts. Essentially, each indication of non-random behavior can be interpreted as a violation of stability. Known stability criteria include

- The number of violations of control limits

- Runs, i.e., a certain number of consecutive values (usually  $n \geq 7$ ) that are above or below the center line
- Trends, i.e., a certain number of sequences (usually  $n \geq 7$ ) that are continuously rising or falling
- Middle third, i.e., an unexpectedly high or low number of values in the middle third of the control chart (e.g., less than 11 or more than 23 values at a run length of 25 values per control chart, for an error probability of 1%)

In addition, there are multiple sets of rules that are meant to simplify counting, such as the Western Electric Rules or Nelson Rules. However, these are often geared towards specific control chart variants and largely meet the above-mentioned stability criteria for these specific applications.

The quality of a control chart, i.e., the “sharpness” / “responsiveness” of a control chart, can be evaluated using two parameters that can be calculated based on the probability of control limits being violated in the specific setup of the control chart:

- The operating characteristic curve (OC) indicates the probability that a control limit is violated, if the process level changes by a specified value
- The average run length indicates after how many samples on average a violation of control limits (“alarm”) is to be expected if the process level changes by a specified value

## 7.6 Outliers: Definition and Handling

Within the scope of applying SPC, data quality is the most important factor for an appropriate application of the methods. This means that the data to be evaluated must be representative of the situation to be assessed and must not contain outliers.

Unfortunately, the term “outlier” is often used to refer to “values that fall substantially outside of the tolerance”, which is not the definition applied in this volume. How high a value is does not play a decisive role when it comes to identifying outliers. At most, this can raise suspicions that there may be an outlier. An outlier is defined as a value that does not belong to the population under investigation. Generally speaking, this means that the value cannot have arisen through the investigated process and thus also does not represent this process. Outliers can, for example, arise due to erroneous measurements, but also when inadvertently measuring parts multiple times even though these parts were only produced once. This is often due to input or transfer errors, mix-ups, operating errors, faulty measuring systems or unsuitable measurement processes. Based on the above-mentioned definition, calibration or setup measurements must also be considered outliers if the objective of the study is to determine machine or process capability; they do not represent the parts produced

in the series production process.

Outliers falsify:

- statistical indices (variation ranges, process locations)
- changes to processes over time
- frequency distributions and histograms
- assigned distributions and distribution time models
- performance and capability indices

Since outlier tests typically only determine whether measured values are in line with a presumed distribution model (generally normal distribution), these tests cannot be applied to identify measured values as outliers. At most, outlier tests can provide indications regarding measured values that could potentially be identified as outliers. Identifying a value as an outlier always requires clear justification as to why this measured value cannot have arisen from the underlying process. This means that outliers can only be identified if their occurrence is documented. Documentation should thus be ensured, and outliers should already be labeled as invalid when they arise.

Outliers are mistakes that can lead to losses and increased costs. Outliers should, therefore, not be deleted from the dataset. Rather, they should be disregarded in the evaluation, e.g., by marking them as invalid. The causes of outliers must be investigated and eliminated.

Measured values that have been identified as outliers must not be included in the calculation of parameters.

## 7.7 Overview Table

The methods described in this chapter are summarized in Table 7-4.

Table 7-4: Overview of Methods

Studies	Machine performance $P_m/P_{mk}$	Preliminary process performance $P_p/P_{pk}$	Process performance $P_p/P_{pk}$ or capability $C_p/C_{pk}$
Purpose	Release of production equipment	Release of production processes	Monitoring of production processes
Process Variation Influences (5M)	Machine only	<ul style="list-style-type: none"> <li>Machine, HuMan, method, material, and Milieu</li> <li>(Limited Exposure)</li> </ul>	<ul style="list-style-type: none"> <li>Machine, HuMan, method, material, and Milieu</li> <li>(Full exposure)</li> </ul>
Process Stability	<p>It cannot be proven.</p> <ul style="list-style-type: none"> <li>Limited exposure to process variation</li> </ul>	<p>It cannot be proven.</p> <ul style="list-style-type: none"> <li>Limited exposure to process variation</li> <li>Preliminary stability shall be assessed but not required.</li> </ul>	<p>Required assessment.</p> <ul style="list-style-type: none"> <li>Performance (process stability not proven: not in control): <math>P_p/P_{pk}</math></li> <li>Capability (process stability proven: in statistical control or in control): <math>C_p/C_{pk}</math></li> </ul>
Typical Sample Strategy (Example only)	<ul style="list-style-type: none"> <li><math>n = 50 - 100</math> parts</li> <li>Consecutively produced</li> </ul>	<ul style="list-style-type: none"> <li><math>n = 125</math> parts</li> <li>At least <math>k = 25</math> subgroups,</li> <li>subgroup size = 5</li> <li>Rational sampling method</li> </ul>	<ul style="list-style-type: none"> <li><math>n = 125</math> parts</li> <li>At least <math>k = 25</math> subgroups,</li> <li>subgroup size = 5</li> </ul> <p>Rational Sampling method</p>
Typical Targets for Safety critical characteristics (Example only)	<ul style="list-style-type: none"> <li><math>P_m \geq 2.00</math></li> <li><math>P_{mk} \geq 1.67</math></li> </ul>	<ul style="list-style-type: none"> <li><math>P_p \geq 1.67</math></li> <li><math>P_{pk} \geq 1.33</math></li> </ul>	<ul style="list-style-type: none"> <li><math>P_p/P_{pk} \geq 1.33</math></li> <li><math>C_p/C_{pk} \geq 1.33</math></li> </ul>
Note of Caution Naming conventions	"Machine performance" may be referred to as "Machine capability"	Preliminary process performance may be referred to as "Preliminary process capability"	"Process performance" for unstable process may be incorrectly referred to as "Process capability"

In some cases, less than ideal sample sizes are available to perform an assessment. Indices can be calculated but targets should be adjusted based on sample size to achieve performance with the desired level of confidence (e.g., 99.99%).

## 7.8 Calculating Capability Indices

### 7.8.1 Evaluation of the Statistical Distribution

Knowledge of the production process (e.g., grinding), the type of measured quantity (e.g., roundness), and the type of tolerancing (e.g., one-sided or two-sided specifications) often enables conclusions about the appropriate distribution model for describing the empirical distribution.

For example, a folded distribution is the theoretical distribution model for form tolerances in terms of straightness, flatness, roundness, cylindricity, line profile and surface profile, as well as the positional tolerances in terms of parallelism, perpendicularity, angularity, symmetry, roundness and axial run-out.

It is expressly pointed out that while particular distributions are to be expected, significant deviations are possible in individual cases. Consequently, a test must be carried out regarding the expected distribution. In case of significant deviations, a distribution that matches the measured values must be determined.

Regression analyses, distribution tests and graphical representations (e.g., probability plots) can be used to assess the quality of the distribution adjustment. Ultimately, it is up to the user to check and assess whether an adequate distribution model was assigned to the existing measured data, based on all statistical facts and taking account of the technical circumstances. This means the determination of the best fitting distribution should not be solely based on statistical tests, but also process knowledge taking into account the known physical/technical conditions or typical best known distribution.

Instead of describing measured values with suitable distribution models, the measured values can also be transformed to a normal distribution (e.g. using Box-Cox or Johnson transformations) to determine characteristic values (e.g. quantiles) in the mathematically transformed space. These characteristic values must then be retransformed and can subsequently be used in the same way as the quantiles of adapted parametric distributions.

### 7.8.2 Calculation of Capability and Performance Indices

There are two main methods for calculating performance and capability. They are described in the following. Depending on the method used, an additional index ( $G$  for general geometric and  $Z$  for z-Score) must be used. Where there is no  $G$  or  $Z$  index in this book, both methods can be meant.

#### 7.8.2.1 General Geometric Method

The method according to ISO series 22514 and 3534 to calculate capability and performance indices for machines and processes is the General Geometric Method (sometimes also referred to as “Quantile Method” and “Percentile Method”):

- It describes the location of the core of the distribution (99..73%) in relation to

the tolerance.

- It provides information on whether a reduction in variation or any shift in the location of the process would improve the capability.
- The necessary shift in the process to optimize the capability indices can be calculated directly from the indices
- It provides consistent interpretation of variation and location of the identified distribution and applies to all distribution models.

The calculation methods are identical for the indices  $P_{m.G}/P_{mk.G}$ ,  $P_{p.G}/P_{pk.G}$  and  $C_{p.G}/C_{pk.G}$  according to ISO series 22514 and 3534. The designation of the indices is used to indicate the boundary conditions under which the data was recorded and what the current control situation is. In summary, the following rules apply, which are explained in more detail in the following sections:

- $P_{m.G}/P_{mk.G}$  denotes an index based on data that only describes the influence of the production facility ("machine"). The other M (method, man, material, milieu) are kept constant during the study. Stability is not explicitly tested, but at most qualitatively assessed on the basis of time series charts without the application of control charts.
- $P_{p.G}/P_{pk.G}$  denotes an index that takes into account all process influences, but
  - either cannot reflect the stability of a process because the index is still based on a preliminary data set that does not capture full variation of all 5M.
  - or the in control situation of the process is not required and has therefore not been tested
  - or cannot be assessed as in control due to violations of in control criteria
- $C_{p.G}/C_{pk.G}$  denotes an index that takes into account all process influences and for which capability conditions are present, i.e. which can be considered as an in control process.

The ISO calculation method uses the formulas shown below. The following formulas are valid for both capability and performance indices.

$$\frac{P_{m.G}}{P_{p.G}} = \frac{\text{Tolerance}}{99.73\% \text{ process spread}} = \frac{U - L}{X_{99.865\%} - X_{0.135\%}}$$

$$\frac{P_{mU.G}}{P_{pU.G}} = \frac{U - X_{50\%}}{X_{99.865\%} - X_{50\%}}$$

$$\frac{P_{mL.G}}{P_{pL.G}} = \frac{X_{50\%} - L}{X_{50\%} - X_{0.135\%}}$$

$$\frac{P_{mk.G}}{C_{pk.G}} = \min \left( \frac{P_{mU.G}}{P_{pU.G}}, \frac{P_{mL.G}}{P_{pL.G}} \right) = \min \left( \frac{U - X_{50\%}}{X_{99.865\%} - X_{50\%}}, \frac{X_{50\%} - L}{X_{50\%} - X_{0.135\%}} \right)$$

where  $X_{0.135\%}$  and  $X_{99.865\%}$  are the 0.135 % and 99.865 % quantiles of the distribution used to fit the process data.

In the case of a normal distribution, these estimation functions correspond to the known formulas:

$$\frac{P_{m.G}}{P_{p.G}} = \frac{\text{Tolerance}}{99.73\% \text{ process spread}} = \frac{U - L}{6 \cdot s}$$

$$\frac{P_{mU.G}}{P_{pU.G}} = \frac{U - \bar{x}}{3 \cdot s}$$

$$\frac{P_{mL.G}}{P_{pL.G}} = \frac{\bar{x} - L}{3 \cdot s}$$

$$\frac{P_{mk.G}}{C_{pk.G}} = \min \left( \frac{P_{mU.G}}{P_{pU.G}}, \frac{P_{mL.G}}{P_{pL.G}} \right) = \min \left( \frac{U - \bar{x}}{3 \cdot s}, \frac{\bar{x} - L}{3 \cdot s} \right)$$

with

$$s = \sqrt{\frac{1}{n-1} \cdot \sum_{i=1}^n (x_i - \bar{x})^2}$$

Details on how to calculate the estimators for location and dispersion are lined out within ISO 22514-2. Besides the mentioned methods,  $X_{0.135\%}$  and  $X_{99.865\%}$  can be derived from the combined data set using the empirical quantiles when the sample size is large enough. As a general guideline, a minimum of 2000 observations is required. The organization estimating the distribution width by this approach has to ensure that the method is applied properly and that the boundary conditions are met for a sufficient confidence of the outcome.

### 7.8.2.2 One-Sided Tolerance Limits

In case of one-sided tolerances only one tolerance limit exists. Thus only  $P_{mk}/P_{pk}/C_{pk}$  referring to that one tolerance limit can be calculated.

For one-sided tolerances for which a second natural/physical/technical limit exists, the index  $P_{mk}/P_{pk}/C_{pk}$  is calculated referring to the given one-sided tolerance limit. In addition, the index  $P_m/P_p/C_p$  can also be calculated for information purposes because the situation is not clearly described by the indication of the  $P_{mk}/P_{pk}/C_{pk}$  index.

If the process is located very close to the natural/physical/technical limit, this is the only situation where  $P_{mk}/P_{pk}/C_{pk} > P_m/P_p/C_p$  can occur. In that case a process improvement cannot be achieved by shifting the process location, only by reducing variation.

If  $P_{mk}/P_{pk}/C_{pk} < P_m/P_p/C_p$  the process location is close to the specified limit and there is still a chance to improve the process by shifting towards natural/physical/technical limit.

Figure 7-6 shows the two situations:

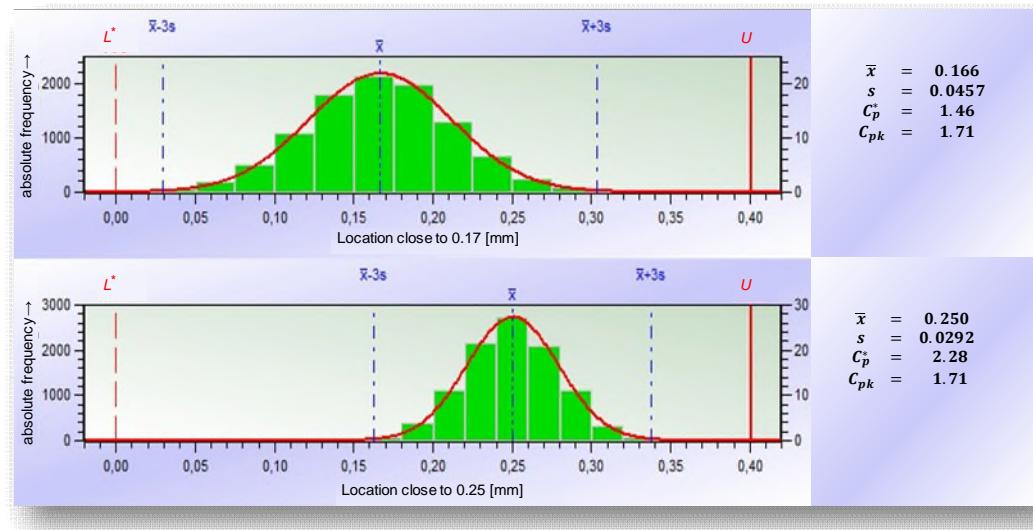


Figure 7-6: Capabilities for Naturally Limited One-Sided Characteristics

For characteristics that are naturally or physically limited to zero, the question arises whether the process capability index  $C_p$  should be calculated. One argument against calculating  $C_p$  is the risk of misinterpretation:  $C_p$  is often seen as the maximum possible value for  $C_{pk}$ , although in this context, it is possible for  $C_{pk}$  to exceed  $C_p$ . On the other hand, calculating  $C_p$  can be beneficial because  $C_{pk}$  only becomes clearly interpretable when considered alongside  $C_p$ .  $C_{pk}$  alone does not provide unique information about the position of the process, as illustrated by cases where

identical  $C_{pk}$  values can represent very different situations. Furthermore, graduated requirements — such as  $C_p \geq 2$  and  $C_{pk} \geq 1.67$  — can only be meaningfully implemented if both indices are considered. As a compromise, it is recommended to calculate  $C_p$  but refrain from assigning a specific target value to it.

### 7.8.2.3 Exceedance Proportion Method/z-Score/Bothe Method

The “Z-Score/Bothe-Method” is a widely used performance calculation that measures the proportion of out of specification (OOS) parts. It is a measure of a process’ ability to make parts within specified limits. The “z-Score/Bothe-Method” describes the estimated proportion OOS as capability index of a standardized normal distribution. This means that a capability index is always associated with a fixed proportion OOS independent of the observed distribution.

To calculate the non-normal equivalent to the  $P_{pk.Z}$  index, the non-normal form  $f(x)$  is used to determine the proportion nonconforming, i.e., the area of the non-normal distribution outside the upper and lower specification limits:

$$p_L = \int_{-\infty}^L f(x) dx$$

$$p_U = \int_U^{\infty} f(x) dx$$

These Values are converted to a  $z$  value using the inverse standard normal distribution. That is, the  $z_L$  and  $z_U$  values in the following equations are determined such that:

$$p_L = \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{z_L} e^{-\left(\frac{x}{2}\right)^2} dx$$

$$p_U = \frac{1}{\sqrt{2\pi}} \int_{z_U}^{\infty} e^{-\left(\frac{x}{2}\right)^2} dx$$

then

$$P_{pk.Z} = \frac{\min(z_L, z_U)}{3}$$

and

$$P_{p.Z} = \frac{z_L + z_U}{6}$$

In the case of normal distribution, both methods lead to the same result.

#### 7.8.2.4 Comparison of the Methods

The following table shows a brief comparison of the two calculation methods

Table 7-5: Comparison of General Geometric Method with z-Score Method

	<b>General Geometric Method</b>	<b>z-Score Method</b>
<b>Step 1</b>	Find a distribution model that adequately describes the data.	
<b>Step 2</b>	Calculate from the distribution model ... <ul style="list-style-type: none"> <li>• the proportion out of specifications</li> <li>• Quantiles:               <ul style="list-style-type: none"> <li>◦ Lower dispersion limit <math>X_{0,135\%}</math></li> <li>◦ Mid Value <math>X_{50\%}</math></li> <li>◦ Upper dispersion limit <math>X_{99,865\%}</math></li> </ul> </li> </ul>	
<b>Step 3</b>	Calculate the indices from ... <ul style="list-style-type: none"> <li>• Quantiles</li> <li>• z values</li> </ul>	
<b>Step 4</b>	Derive information from the indices on ... <ul style="list-style-type: none"> <li>• process variation/ dispersion of the process core (99.73%) related to tolerance (<math>P_{p.G}</math>, <math>C_{p.G}</math>)</li> <li>• process location related to tolerance center (<math>P_{pk.G}</math>, <math>C_{pk.G}</math>)</li> </ul>	
<b>Step 5</b>	Derive additional information from process analysis on ... <ul style="list-style-type: none"> <li>• proportions out of specifications (ppm)</li> <li>• proportions already calculated in step 2</li> </ul>	
<b>Summary</b>	Properties of the indices and distribution model <ul style="list-style-type: none"> <li>• provides a consistent interpretation of variation and location of the distribution for all distribution types</li> <li>• provides variation and location of the distribution core (99.73%) in relation to tolerance</li> <li>• refers to the spread of the distribution in the same way as a control chart</li> </ul>	
	<ul style="list-style-type: none"> <li>• provides a consistent interpretation of the proportions out of specifications for all distributions</li> <li>• z-Score method is a measure of a process's ability to make parts within specified limits</li> </ul>	

	<ul style="list-style-type: none"> <li>• provides information on the shift in location that is needed to fulfill capability requirements</li> <li>• deals with real variation and location of the process and avoids the use of corresponding but not actually present characteristic values of a standard normal distribution</li> </ul>	<ul style="list-style-type: none"> <li>• translates proportions out of specifications as capability of a standardized normal distribution</li> </ul>
<b>Comment</b>	<b>Comment</b>	
	<ul style="list-style-type: none"> <li>• comply with <ul style="list-style-type: none"> <li>◦ ISO series 22514</li> <li>◦ ISO series 3534</li> <li>◦ VDA books</li> <li>◦ AIAG SPC Manual</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• comply with <ul style="list-style-type: none"> <li>◦ AIAG SPC Manual</li> </ul> </li> </ul>

### 7.8.2.5 Within Capability

There is one process index that is calculated using within-subgroup estimates of variation instead of total overall variation. This index is called  $C_w$  and  $C_{wk}$ .<sup>11</sup>

The "within" in  $C_w$  and  $C_{wk}$  refers to the use of "within subgroup" standard deviation, which reflects the variation of the process over a short time period. This approach isolates the inherent variability that occurs when the process is operating under controlled conditions, excluding shifts or drifts over long periods of time.

To put this into perspective, process variation has various aspects:

- Inherent Process Variation — That portion of process variation due to common causes only
- Within-subgroup Variation  $\sigma_w$  — This is the variation due only to the variation within the subgroups. If the process is in statistical control this variation is a good estimate of the inherent process variation. It can be estimated from control charts by  $\frac{\bar{R}}{d_2}$  or  $\frac{\bar{s}}{c_4}$
- Between-subgroup Variation — This is the variation due to the variation between subgroups. If the process is in statistical control this variation should be (close to) zero
- Total Process Variation ( $\sigma_p$ ) — This is the variation due to both within-subgroup and between-subgroup variation. If the process is not in statistical control the total process variation will include the effect of the special cause(s) as well as the common causes. For normal distributions this variation may be

<sup>11</sup> In AIAG SPC 2<sup>nd</sup> edition the  $C_{wk}$  was referred to as  $C_{pk}$

estimated by  $s$ , the sample standard deviation, using all of the individual readings obtained from either a detailed control chart or a process study:

$\sigma_p = s = \sqrt{\sum_i^n \frac{(x_i - \bar{x})}{n-1}}$  where  $x_i$  is an individual reading,  $\bar{x}$  is the average of the individual readings, and  $n$  is the total number of individual readings

- Within Capability — The  $6\sigma_w$  range of inherent process variation, for statistically stable processes only, where  $\sigma_w$  is usually estimated by  $\frac{\bar{R}}{d_2}$  or  $\frac{\bar{s}}{c_4}$
- Process Performance and Capability — The 99.73% range of total process variation, where for normal distribution  $\hat{\sigma}$  is usually estimated by  $s$ , the total process standard deviation

A process that is in statistical control has a  $C_{wk}$  that is only slightly bigger than the  $C_{pk}$ . A large difference between  $C_{wk}$  and  $P_{pk}/C_{pk}$  indices, indicates the process is not “in a state of statistical control” as there is significant between subgroup variation. This may be true for processes that are “out of control” due to special causes or “in control” that have known, acceptable sources of variation between subgroups. For processes that are in control or even out of control, the  $C_{wk}$  is significantly bigger than the  $P_{pk}$ .

The  $C_{wk}$  can be used as an additional analysis tool to assess and improve manufacturing processes, as it helps identify areas where a process may require adjustment or improvement, but should not be used for reporting purposes.

Manufacturers can use  $C_{wk}$  to monitor and improve process capability and performance. By tracking  $C_{wk}$  over time, organizations can detect shifts in process location or increases in variation, supporting proactive quality control.

The formulas for  $C_w/C_{wk}$  calculations are shown in the following:

$$C_w = \frac{USL - LSL}{6\hat{\sigma}_w}$$

$$C_{wk} = \min \{CWU; CWL\}$$

$$CWU = \frac{USL - \bar{x}}{3\hat{\sigma}_w}$$

$$CWL = \frac{\bar{x} - LSL}{3\hat{\sigma}_w}$$

An example for the estimator  $\hat{\sigma}_w$  is  $\hat{\sigma}_w = \frac{\bar{R}}{d_2}$

## 8 Machine Performance for Releasing Production Facilities

### 8.1 Preliminary Remark

The objective of a machine performance study is to perform acceptance tests in case of procurement and release of manufacturing equipment, including machining and assembly equipment in production. This applies to both the preliminary tests at the supplier's facility and the final tests at the customer's facility.

Machine performance is an indirect evaluation of the production equipment for which the quality of the process output is assessed to evaluate the performance of the production equipment in relation to the process output requirements.

Such studies typically involve production parts processed sequentially under controlled repeatability conditions. Key characteristics of these parts are measured in accordance with the production sequence. The average process location and the dispersion of the measurement results are compared with the specifications of the characteristics. The approach of the study is to record exclusively and evaluate machine-related influences on the production process.

It is, therefore, important that all non-machine-related influencing and disturbance factors are kept constant. It can then be assumed that only machine-related influences and their changes affect the product and its properties.

Non-machine-related factors (4Ms) that can influence or disrupt the process must be controlled:

- HuMan (operator, technician, etc.)
- Material (raw material, semi-finished products, batches, manufacturer, pre-processing, etc.)
- Method (warm-up time of equipment, tool life, production flow, etc.)
- Milieu (vibrations, temperatures, humidity, air pressure, etc.)

Additionally, machine-specific parameters that are not already defined (e.g., cycle times, coolant flow, rotational speed, infeed, pressure) must be kept constant. Any fluctuations in these parameters, typically beyond the operator's control, are considered machine-related.

Changes to influencing or disturbance variables, even if occasional (e.g., operator change), should be documented. This documentation can help identify potential optimization opportunities if performance targets are not met.

Any deviations from the specified conditions must be agreed upon by both the customer and supplier and clearly outlined in the order.

## 8.2 Preparation

### 8.2.1 Sample Size

The number of parts used in the study is usually 50. If it can be proven that processing 50 parts is impossible for economic or technical reasons (e.g., availability of parts, processing time, duration of measurement), the sample size can be reduced to an agreed-upon minimum number once the customer has approved this. In this case, the target values for the performance indices are increased on the basis of the increased confidence interval in order to be able to accurately assess the actual performance (see Chapter 8.4).

In the case of a process with a high level of tool wear (e.g., grinding, honing), it is absolutely necessary to select a sample size that will include at least 1.5 dressing cycles. This concept can, in principle, be applied to all influencing factors that are susceptible to significant changes.

### 8.2.2 Material

All materials used in the study must meet the specifications and should be as far as possible homogeneous referring to the characteristics under investigation. For example:

- Machine tool for parts finishing: 50 Semi-finished parts tooled from the same batch of raw material on the same production line
- Manufacturing equipment for deburring die-cut parts: 50 die-cut parts from the same coil and the same punching tool
- Punching machine: 1 sheet metal coil, without start and end piece of the coil

### 8.2.3 Measuring System and Measurement Process

Proofs of measurement and inspection process capability, in accordance with AIAG MSA and VDA 5, are available for each measurement process employed, including the associated measuring systems.

### 8.2.4 Operating and Production Conditions

The production process must proceed without interruption under standard process conditions. Before initiating the study, the production equipment must have reached its operating temperature, and the tools should be properly conditioned - meaning they should have already processed several parts, ensuring that the study does not start with entirely new tools.

It is recommended to monitor and document the thermal characteristics of the machines until they stabilize at their operating temperature. Once this is achieved,

the production equipment should be adjusted so that the measured values fall as close as possible to the midpoint of the tolerance range. For characteristics with one-sided limits, settings should be optimized to achieve the best possible values relative to the specific characteristic being investigated.

If necessary, preliminary production runs, such as the "1 part/5 parts" method, can be conducted to adjust the process.

In cases where tools are non-adjustable or subject to rapid wear (e.g., grinding wheels with a tool life of  $\leq 5$  parts), the machine performance index  $P_{mk}$  may be excluded from evaluation, provided this has been agreed upon with the customer. The study must be repeated if the production sequence is interrupted.

### 8.2.5 Pre-Production Run (optional)

The following applies for each agreed-upon, acceptance-relevant characteristic in accordance with the inspection plan:

- Pre-production run, 1 part:
  - For characteristics with two-sided tolerances:
    - The characteristic value is within  $\pm 12.5\%$  of the tolerance center
  - For characteristics with one-sided tolerances and natural limits:
    - The characteristic is within 62.5% of the tolerance (see Figure 8-1)
- Pre-production run, 5 parts:
  - For characteristics with two-sided tolerances:
    - The mean value is within  $\pm 12.5\%$  of the tolerance center
    - The range is smaller than 25% of the tolerance
  - For characteristics with one-sided tolerances and natural limits:
    - The mean value is within 62.5% of the tolerance
    - The range is smaller than 25% of the tolerance

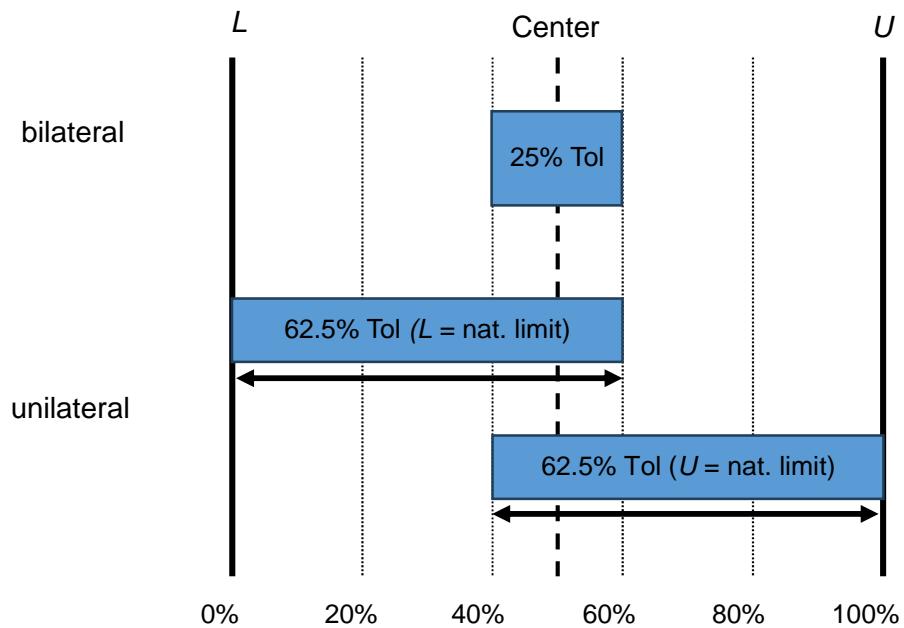


Figure 8-1: Pre-Run Percentage Areas

### 8.2.6 Special Circumstances

In the case of equipment with multiple clamping devices or cavities, each station, clamping device, or cavity should be treated as a separate machine when assessing machine performance, as repeatability conditions may not be consistent across all units.

For tools with multiple cavities, additional tests are generally recommended to evaluate the fluctuations both between and within the cavities.

In the case of systems with multiple stations, spindles, mold cavities, clamping fixtures, etc., multiple studies should be carried out accordingly while fulfilling repeatability conditions. For example, studies with or without repeated clamping/unclamping will result in different variation-related influences.

In special cases, a machine performance study may be substituted with an equivalent study, giving evidence on the machine's ability to consecutively produce parts corresponding to the required process output. Such studies can for example be based on process DoE (Design of Experiments). The alternative study must be appropriately documented and justified to ensure it meets the intent of machine performance verification.

## 8.3 Execution

### 8.3.1 Traceability of Data

Data must be traceable to be able to evaluate unexpected values. Both the

production and the collection sequence must be documented, such that it is possible to draw a data timeline that could provide indications of unexpected fluctuations. Reasons for suspicious deviations should be analyzed, and a decision should be made regarding the reliability of such data.

### 8.3.2 Storage and Blocking of Test Parts

For non-destructive testing, all test parts must be retained until machine acceptance to allow for additional testing if required. Furthermore, all test parts must remain blocked until final acceptance is completed.

### 8.3.3 Data Collection and Storage

Data should be recorded in numerical form with the respective number of significant digits.

### 8.3.4 Statistical Analysis of Data

#### 8.3.4.1 Qualitative Stability Study

Based on the value curve, it must be assessed whether the measured values that have been recorded are qualitatively stable.

Indications that the measured values might be unstable include:

- individual outliers for which no reasons can be found (see Chapter 7.5)
- patterns for which no reasons can be found (jumps, steps, trends, etc.)

If the value curve is not plausible, the causes for this behavior must be evaluated and eliminated. The performance study must then be repeated.

#### 8.3.4.2 Evaluation of the Statistical Distribution

The statistical distribution must be evaluated in accordance with Chapter 7.8.1.

## 8.4 Requirements Regarding the Performance Indices to be Achieved

The examples of target values for the potential/critical performance index  $P_m/P_{mk}$  shown in the table depend on the sample size and the classification of the characteristic (confidence interval of the capability estimation: 95%, confidence interval of the target value adjustment if number of parts < 50: 99.99%).

Table 8-1: Example Target Values with Adjustment for Sample Size

Machine performance	n ≥ 50		n = 45		n = 40		n = 35		n = 30	
	$P_m$	$P_{mk}$								
Critical	2.33	2.00	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Major	2.00	1.67	2.06	1.72	2.13	1.78	2.22	1.86	2.35	1.96
Minor	1.67	1.33	1.72	1.37	1.78	1.42	1.86	1.48	1.96	1.56
Others	1.00	1.00	1.03	1.03	1.07	1.07	1.11	1.11	1.18	1.18

The names of the characteristic classes may vary depending on the customer.

If the performance criteria are not met, a cause analysis must be carried out, and the study must be repeated if appropriate.

## 8.5 Special Cases

### 8.5.1 Multi-Stage Machining

#### 8.5.1.1 Approach

In production processes, machining centers with workpiece carriers or pallets are often used for the purpose of increasing flexibility. In some cases, complete acceptance can lead to an unmanageable number of parts to be produced. In these cases, an adequate procedure for machine approval should be defined in agreement between the supplier and customer.

#### 8.5.1.2 Application Example

For example, the following cases may occur:

- A machine uses one or two spindles. Each spindle processes one workpiece carrier. Each workpiece carrier can hold several workpieces. (example 1)
- Multiple machines process one workpiece each on a pallet. The pallets are randomly assigned to a machine, and this varies with each processing cycle (example 2)
- A machine processes a workpiece that is attached to a swivel table (workpiece carrier). Only one workpiece at a time is in the processing position, while the other is in the change position (example 3)

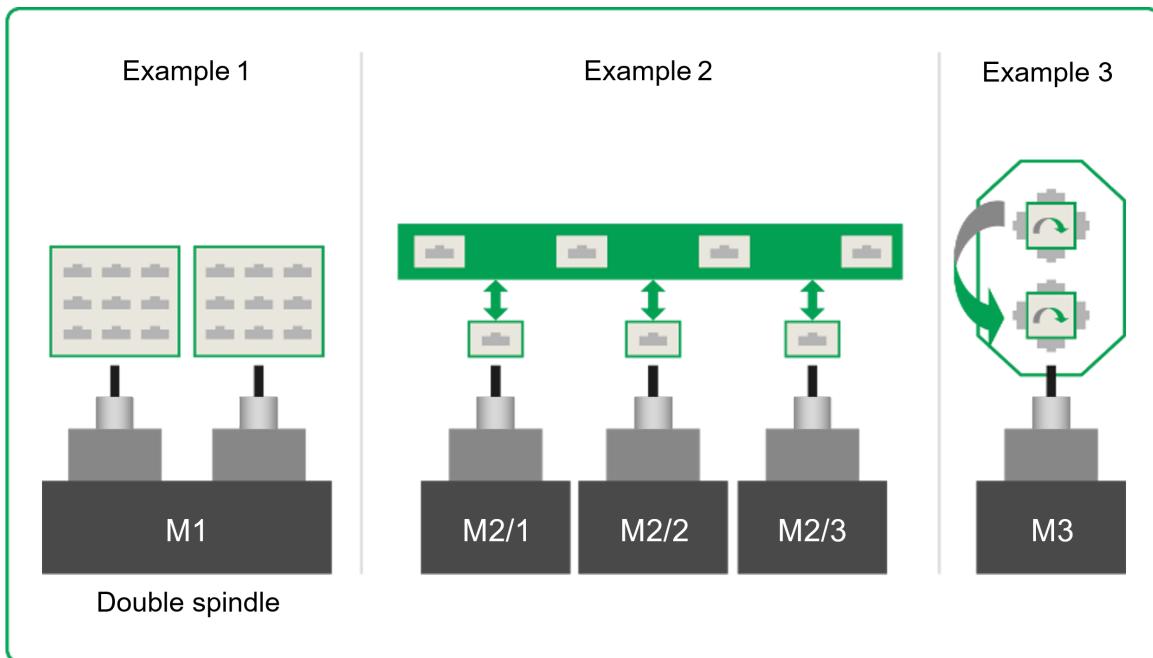


Figure 8-2: Example for Multi-Stage Machining

In a typical acceptance procedure, 50 parts per clamping position would have to be processed and evaluated in each case. If one considers the number of possible combinations, it becomes clear that an acceptance procedure cannot be carried out in this manner. In example 2 alone, production takes place on 3 identical machines and 7 pallets. Thus,  $3 * 7 * 50 = 1,050$  parts would have to be processed and evaluated for the purpose of acceptance. Therefore, a simplified acceptance procedure is suggested here.

### Prerequisite

For later operation, it must be ensured that all possible combinations of a workpiece on its way through a system are evaluated. In preparation for acceptance, the supplier must ensure that all combinations are statistically comparable.

This means that a component from pallet 1, produced on machine A, must be comparable to a component from pallet 2, produced on machine B. This is a fundamental prerequisite for simplified acceptance. Part of this comparison is done by the geometry inspection of the machine.

### Specifying the scope of inspection

To specify the scope of inspection, the number of possible combinations of a workpiece on its way through a system must first be determined. The number of combinations per operation is the product of the factors <number of components per pallet/workpiece carrier>, <number of pallets/workpiece carriers>, <spindles per machine>, and <number of machines in operation>.

For each combination, at least 5 components should be inspected in order to be able to make a sound statement. Furthermore, the scope of inspection should be specified

in such a way that at least 50 components per operation are inspected overall.

In agreement with all parties involved, the testing of individual combinations can be dispensed with if it is proven that they are “geometrically identical”.

### **Processing and inspection**

The workpieces should be labeled in such a way that the combination of

- Place on the pallet/workpiece carrier
- Identification number of the pallet/workpiece carrier
- Spindle of the machine
- Identification number of the machine

is clear.

When measuring the components, the measured values should be recorded in such a way that they are linked to the combination. For later evaluation, it is advisable to measure the components according to the combination in the processing sequences.

### **Analysis of the assessment**

The combinations should not play a role when it comes to the evaluation. All measurement results are evaluated together. If individual values deviate substantially from the overall values, the respective combination can be determined thanks to the allocation of the measurement results to the combinations.

To evaluate a combination, it is possible to select the values of a combination and evaluate the mean value and variation (process parameters) accordingly.

Alternatively, the methods used in process capability studies can also be used to identify errors. The sample size entered should then be the scope of inspection per combination. The mean and the variation are then calculated for each combination via the use of control charts.

Depending on how the system is designed, it can be sufficient to eliminate the deviation within the combination. In some cases, other combinations can also be affected by changes. It is, therefore, advisable to repeat the acceptance procedure completely after the correction.

#### **8.5.1.3      *Miscellaneous***

##### **Evaluation of form and position**

The descriptions provided relate to coordinates or positions. These are characteristics that depend on the geometry of the machine and the pallet/workpiece carrier. Characteristics such as roundness depend primarily on system rigidity, spindle run-out, and the machining process. A total of 50 components should be measured, distributed evenly across all spindles. This also applies similarly to surface parameters.

## Further potentials

Especially if pallets/workpiece carriers are used, it is often possible to measure the latter (e.g., clamping/fixing points). The pallets/workpiece carriers can then be selected representatively, distributed evenly across the tolerance. It is then conceivable to carry out the acceptance process with a lower number of pallets/workpiece carriers. As a result, the number of combinations can be further reduced. To inspect the pallets/workpiece carriers not used in the machine capability study, 5 components should be produced and measured for each pallet/workpiece carrier and clamping point. If processing takes place on several machines, it is advisable to distribute the processing evenly across the machines. In this case, the components should also be clearly labeled.

Further descriptions and examples in this regard can be found in ISO 22514-8.

### 8.5.2 Multidimensional/Multivariate Characteristics

The term “multivariate” can refer to both spatial dimensions in the context of coordinate measurement technology and measurement technology involving multiple measured quantities (e.g., unbalance).

For practical reasons, the multivariate normal distribution model was chosen to calculate the parameters discussed in the following sections.

However, this preselection does not rule out the possibility that, in certain cases, other distribution models may more accurately describe the actual conditions.

Additionally, for practical reasons, hyper-ellipsoid random variation ranges were chosen for this standard (referred to as elliptical in the case of two dimensions).

The most important theoretical principles and considerations about the multivariate normal distribution are described in ISO 22514-6.

#### 8.5.2.1 **Machine Performance Index $P_{mk}$ Related to Process Location and Variation**

The parameters of the probability density function are estimated based on the measured values of the sample.

The hyper ellipsoid random variation range whose border touches that of the tolerance hyper ellipsoid, and is otherwise entirely inside the tolerance hyper ellipsoid, is determined.

Based on the values of the parameters of this random variation range, the probability  $p$  that represents this hyper ellipsoid is now calculated.

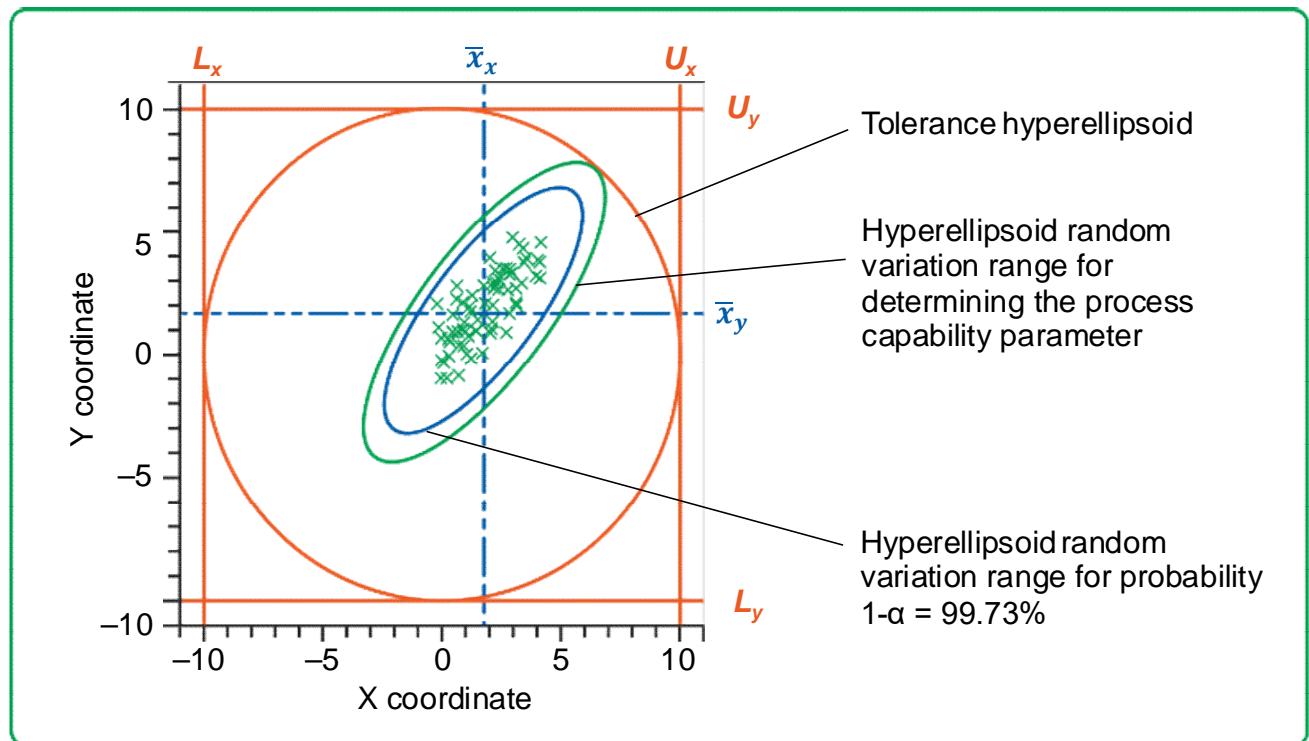


Figure 8-3: Two-Dimensional Example for  $P_m$  Calculation

Case 1: The center of the random variation range lies within the tolerance hyper ellipsoid or on its border

$$P_{mk} = \frac{p\text{-Quantile of the standardised univariate normal distribution}}{99.865\%\text{-Quantile of the standardised normal distribution}} = \frac{u_p}{3}$$

Case 2: The center of the random variation range is outside of the tolerance hyper ellipsoid

$$-1 \cdot \frac{u_p}{3}$$

The 99.865% quantile of the standardized normal distribution represents the two-sided, symmetrical boundary between the random variation range and the probability of 99.73%.

### 8.5.2.2 Machine Performance Index $P_m$ Related to Variation Only

The parameters of the probability density function are estimated based on the measured values of the sample.

The hyper ellipsoid random variation range whose border touches that of the tolerance hyper ellipsoid, and is otherwise entirely inside the tolerance hyper ellipsoid, is determined.

The center of one hyper ellipsoid must have moved in such a way that it coincides

with the center of the other hyper ellipsoid.

Based on the values of the parameters of this random variation range, the probability  $p$  that represents this hyper ellipsoid is now calculated.

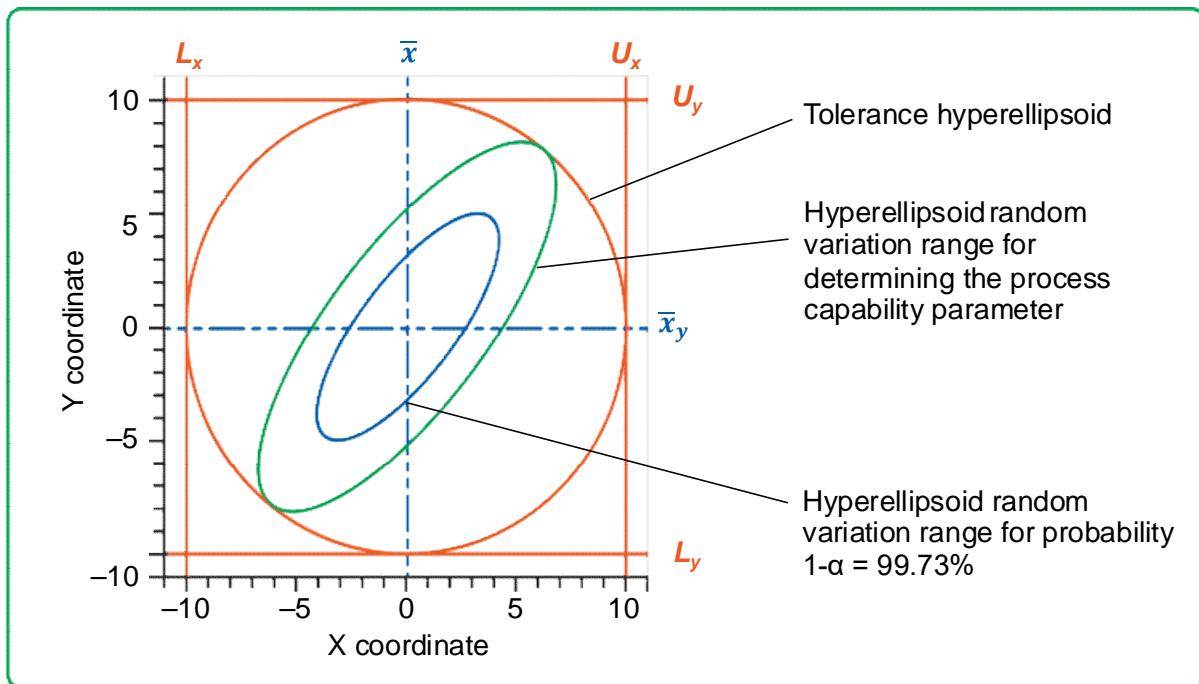


Figure 8-4: Two-Dimensional Example for  $P_{mk}$  Calculation

The quality capability statistic is calculated as follows:

$$\frac{\text{p-Quantile of the standardised univariate normal distribution}}{99.865\%-\text{Quantile of the standardised normal distribution}} = \frac{u_p}{3}$$

The 99.865% quantile of the standardized normal distribution represents the two-sided, symmetrical boundary between the random variation range and the probability 99.730%

Relevant examples can be found in ISO 22514-6.

### 8.5.3 Geometric Dimensioning and Tolerancing (GD&T) and Maximum/Least Material Condition (MMC/LMC)

Over the past couple of years, it has become more and more common in the design and development departments to not only use linear tolerances but also modifiers, as well as geometrical tolerances with or without maximum material requirements.

This is facilitated by measuring devices whose results are given in the form of multi-

dimensional coordinates instead of an individual scalar value.

Calculating capability and performance is challenging in such cases.

In general, it must be determined how capability and performance can be calculated if there are functional requirements in relation to the parts.

For example, the “maximum material condition” (MMC) relates to the “assembly capability”, whereas the “least material requirement” (LMR) relates to the “minimum wall thickness” of a part. Each requirement (MMR and LMR) combines two independent requirements into an overall requirement that simulates the intended function of the workpiece. In some cases, the “reciprocity requirement” can be added to both MMR and LMR.

### Example

A bracket with a hole and a retaining plate with a bolt should be fitted.

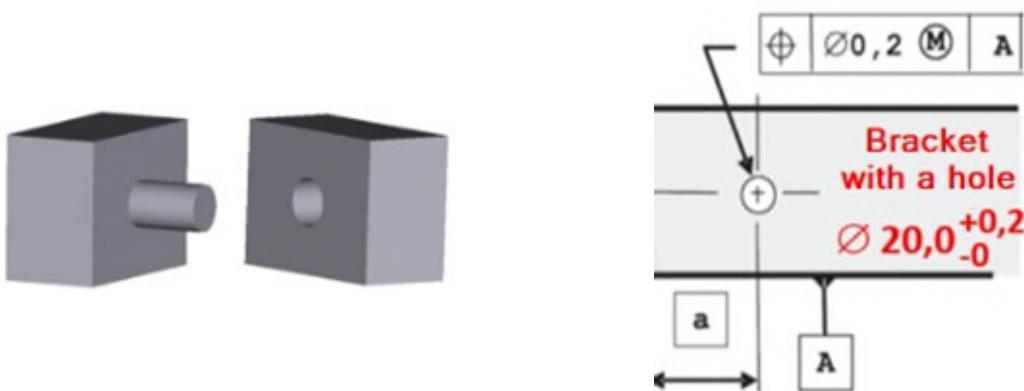


Figure 8-5: Drawing Example Dimensioning

#### Bore diameter requirements

- Nominal size  $D = 20.0 \text{ mm}$
- Tolerance  $T_D = 0.2 \text{ mm}$
- Lower specification limit  $L_D = 20.0 \text{ mm}$
- Upper specification limit  $U_D = 20.2 \text{ mm}$

#### Maximum material size

- Minimum bore size  $MMS = L_D = 20.0 \text{ mm}$

#### Requirement for the maximum position deviation of the hole

- Tolerance  $T_P = 0.2 \text{ mm}$
- Lower specification limit  $L_P = 0.0 \text{ mm}$
- Upper specification limit  $U_P = 0.2 \text{ mm}$

The absolute value of the position deviation  $x_p$  corresponds to the circle diameter

$$d = 2\sqrt{\Delta x^2 + \Delta y^2}$$

so that a direct comparison with the permissible tolerance circle is possible.

Effective maximum material virtual size (limiting pairing size)  $MMVS$  for the bore diameter

$$MMVS = MMS - T = L_D - T_P = 19.8 \text{ mm}$$

The requirement for a part is now the actual assembly clearance,  $C$  of the parts is greater than zero

- $C = +x_D + x_P - MMVS \geq 0$
- $x_D$ : Measured diameter of the bore on the part
- $x_P$ : Measured position deviation of the hole on the part

For assembly clearance  $C$ , the distribution of the measurement results from a sufficiently large sample can now be used to calculate a

- Location value  $C_{50\%}$
- as well as
- Quantiles of the 99.73% spread  $C_{0.135\%}$  and  $C_{99.865\%}$

This information can be used to calculate a performance or capability index in relation to the one-sided lower specification limit

$$L_C = 0$$

Further descriptions and examples can be found in ISO 22514-6 and ISO 22514-9.

## 9 Process Performance and Capability for Releasing Manufacturing Processes

### 9.1 Preliminary Remark

The purpose of a process is to produce a product or provide a service that meets a set of predetermined specifications. The specifications for a process to be evaluated are contractually agreed with the customer for one or more characteristics of the product or service. For process performance and capability, however, only one measurable characteristic is evaluated at a time.

The concept of process capability was developed in the early 1950s, when a pragmatic method was sought to describe the level of fulfillment of specified requirements. The assessment of capabilities is, therefore, a relatively young method of applied statistics in quality management. The designation of the index  $C_{pk}$  is made up of  $C$  = Capability,  $p$  = Process,  $k$  = Katayori = Bias.

The terms capability and performance have now been fundamentally revised. The term capability is now only used if the stability of a process has been proven. This volume applies this definition to the extent that a distinction is made between preliminary performance,  $P_{pk}$  and final capability  $C_{pk}$ . However, final capabilities  $C_{pk}$  naturally require ongoing stability monitoring through the use of appropriate control charts.

The performance and capability studies outlined in Figure 7-3 vary in terms of their timing and the sampling strategies used. However, they follow the same estimation and calculation methods.

Process performances and capabilities are used to determine the ability of a process to meet the specification. The assigned distribution models are also used to assess the proportion of products that fall outside of the specification.

Preliminary performance studies describe the maturity level of a production process and provide the basis for its continuous improvement. Preliminary performance studies are followed by final capabilities.

### 9.2 Data Collection and Sampling Strategies

The characteristics are typically assessed using a random sample, such as 25 subgroups of 5 parts each, collected at the middle of a shift. The overall sample must comprehensively represent the process, accounting for variations in tools, material batches, and shifts. Process stability is monitored through control charts.

### 9.3 Execution

Before starting a process performance or process capability analysis, the capability of the measurement and inspection process must be proven, and machine performance must be analyzed.

Process performance and process capability analyses must always be carried out over a longer period of time that is representative of series production. To the extent possible, all expected influences (5M) must take effect.

As part of a process performance or process capability analysis, the process must be set up according to control plan and monitored by means of control charts. The production of parts must not be interrupted. All changes must be documented.

Characteristics can be described by means of location, variation, skewness and a time-dependent distribution model [ISO 22514-2].

The instantaneous distribution of a characteristic describes the short-term properties of the characteristic, for example, for one of the 25 subgroups taken.

The resulting distribution and the “dynamic long-term behavior” of a characteristic are described using the resulting overall sample ( $125 = 25 \times 5$ ) and the time-dependent distribution model derived therefrom.

### 9.4 Time-Dependent Distribution Models (according to ISO 22514-2)

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

A time-dependent distribution model describes the actual behavior of a process by using an instantaneous distribution, where parameters can either remain constant or change over time. For the model to be accurate, the theoretical distribution density function should match the observed frequency and density of measured data. This alignment can be visually examined using a probability plot or a histogram and numerically evaluated using net correlation. To ensure a reliable fit, it is recommended to first assess the entire dataset and then focus on the 25% of the data closest to the specification limit to which  $Pmk$ ,  $Ppk$  or  $Cpk$  is calculated.

Based on the instantaneous distribution and how it evolves over time, eight different time-dependent distribution models can be identified, as outlined in DIN ISO 22514-2 (labeled A to D in the figures on the following pages)

The instantaneous distribution characterizes the behavior of the characteristic under investigation during a short interval. Usually, it is the time interval during which the

sample (e.g. the subgroup) can be taken from the process. Observing the process continuously in time for a longer time interval the output from the process is called the resulting process distribution and it is described by a corresponding time-dependent distribution model that reflects

- the subgroup distribution of the characteristic under consideration, and
- the changes of its location, variation and shape parameters during the time interval of process observation.

In practice, the resulting distribution can be represented by the whole data set, e.g. when SPC is applied, by all subgroups gained during the interval of the process observation. Time-dependent distribution models can be classified into four groups according to whether the location and variation moments are constant or changing (see Table 9-1).

- a) A process whose location and variation are constant is in time-dependent distribution model A. In this case only, all the means and variances of the instantaneous distributions are equal to each other and they are equal to the resulting distribution.
- b) If the variation of a process is changing with time, but the location stays constant, the process is said to be in time-dependent distribution model B.
- c) If the variation is constant, but the location is changing, we have time-dependent distribution model C.
- d) Otherwise, we have time-dependent distribution model D

Table 9-1 Time-Dependent Distribution Model Referring to ISO 22514-2

		process location							
		<i>constant</i>				<i>not constant</i>			
process variation	<i>constant</i>		A		location	C			
			A1	A2		C1	C2	C3	C4
		instantaneous and resulting distribution	normal distributed	not normally distributed – unimodal	instantaneous distribution	random	random	systematically (e.g., trend)	systematically and random (e.g., lot to lot)
					resulting distribution	normal distributed	normal distributed	unimodal	any shape
						not normally distributed unimodal	any shape	any shape e.g. multimodal	
	<i>not constant</i>		B			D			
		resulting distribution	any shape – unimodal		resulting distribution	any shape – multimodal			

For changing moments, the models can be classified according to whether the changes are random, systematic or both

There are subclasses of time-dependent distribution models A and C which are introduced due to their practical importance. They differ in the shape of the resulting distribution and in the cause of the process being in an out-of-statistical-control state.

It is often possible to deduce the resulting time-dependent distribution model based on the nature of the process and the tolerance specification, e.g., naturally limited characteristic (see also Chapter 8.3.4). Practically unavoidable influences are, for example

- Systematic wear of a tool during machining
- Use of a new tool
- Batch change

*Note: The assignment of a time-dependent distribution model to an analyzed process is not related to the capability or performance of this process because no reference is made to the tolerance.*

The figures on the following pages show some examples of the processes mentioned above and the associated time-dependent distribution models, with the following diagrams being shown

- Schematic representation of the time-dependent distribution model
- Time series of the individual values (single value diagram)
- Histogram
- Representation of the individual values in the probability plot of a normal distribution
- $\bar{x}/s$  control chart

These distributions are not drawn to scale. The choice of models and their verification requires extensive data analysis.

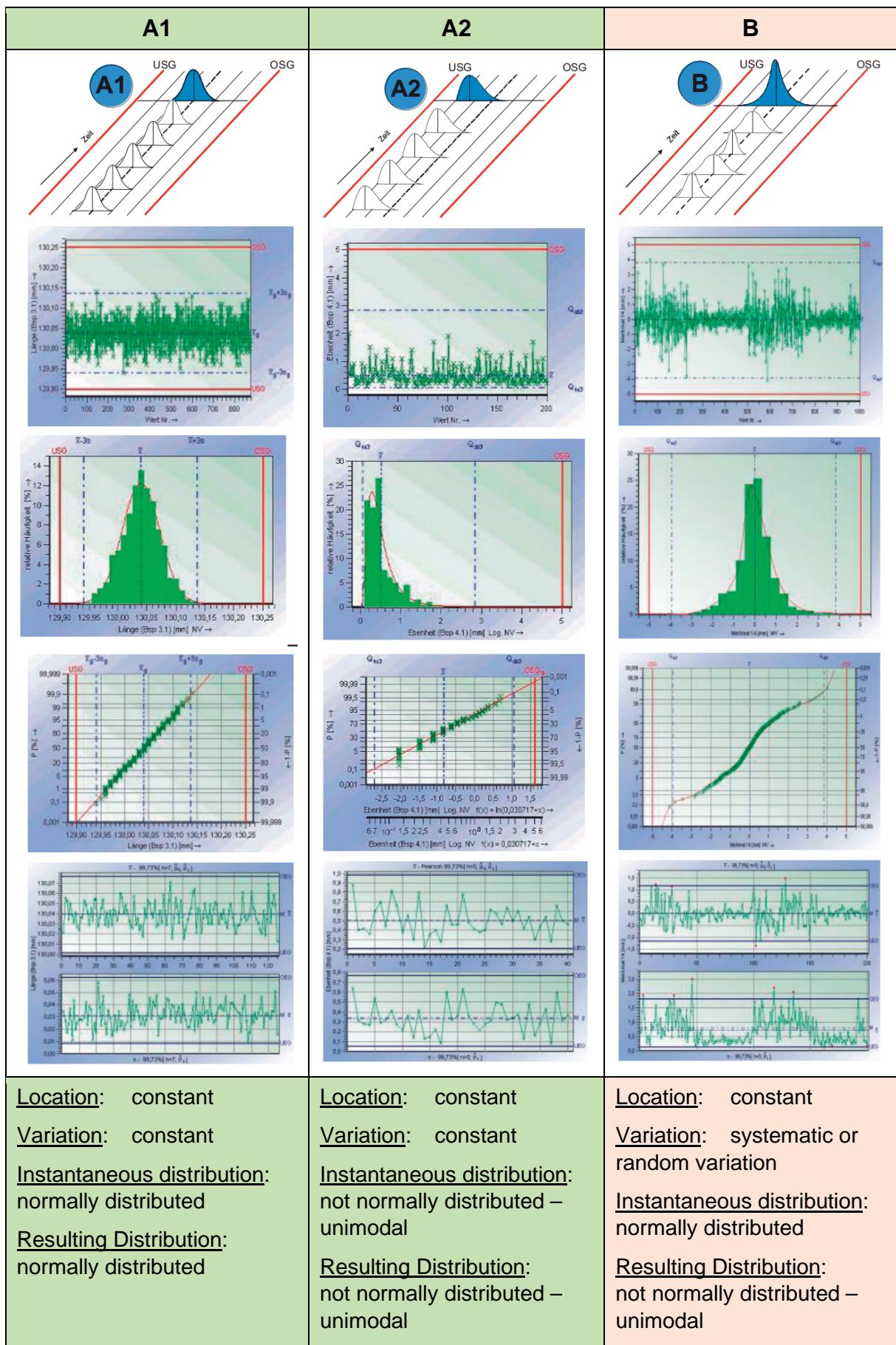


Figure 9-1: Exemplary Representation of Time-Dependent Distribution Models (Part 1)

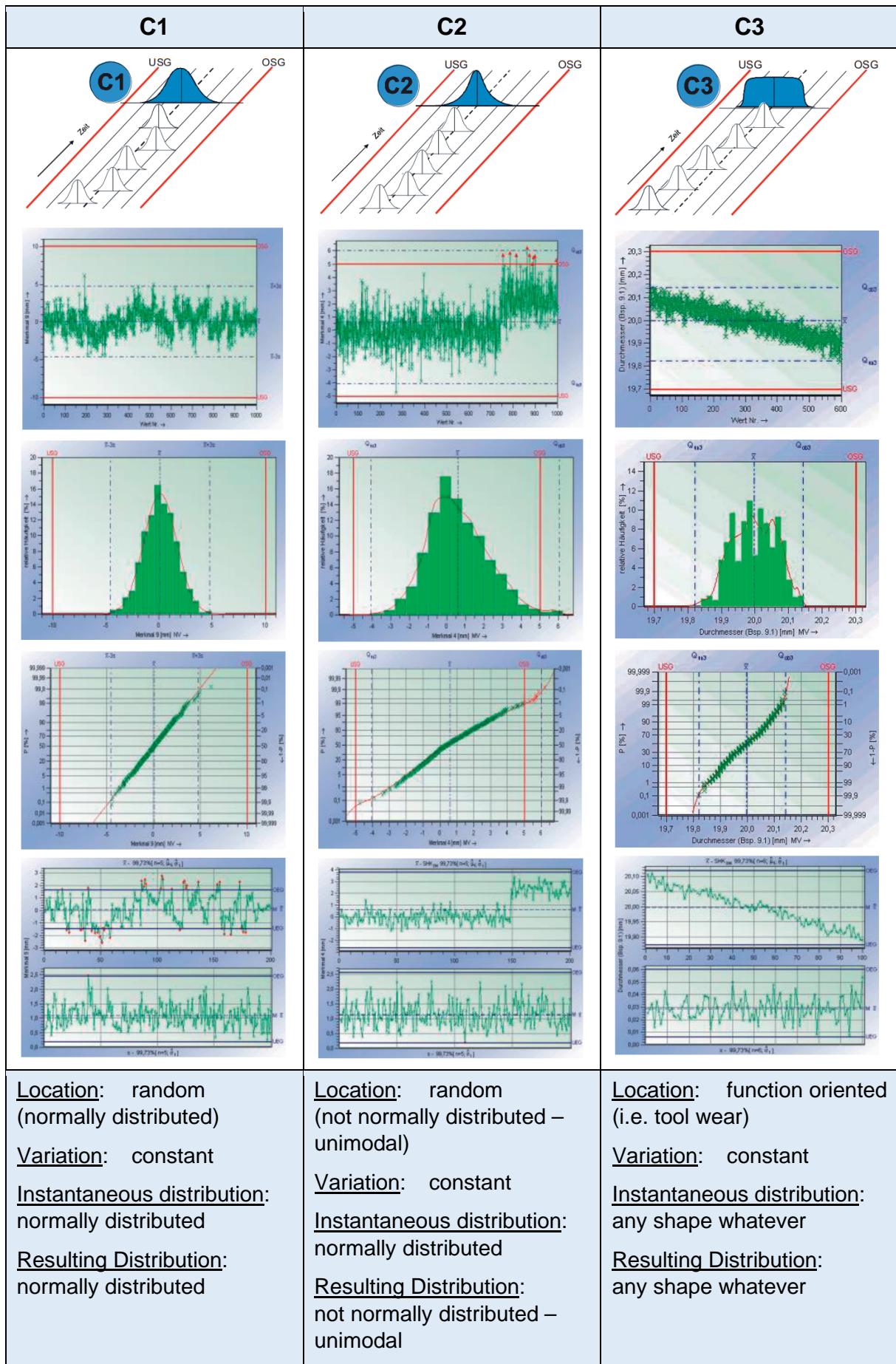


Figure 9-2: Exemplary Representation of Time-Dependent Distribution Models (Part 2)

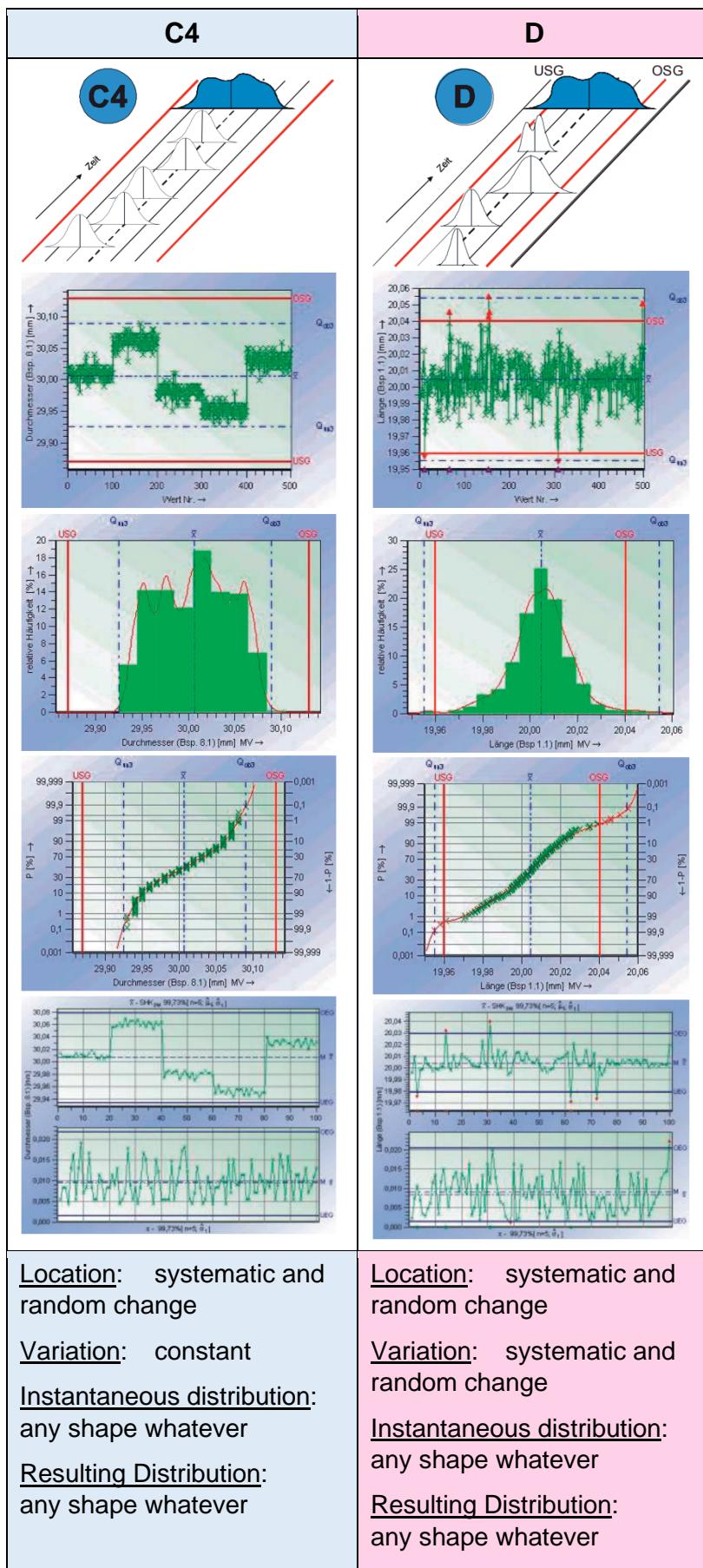


Figure 9-3: Exemplary Representation of Time-Dependent Distribution Models (Part 3)

The following table summarizes the characteristics of each time dependent distribution model:

*Table 9-2: Characteristics of Each Time-Dependent Distribution Model*

Time dependent distribution model	A		B	C				D
	A1	A2	B	C1	C2	C3	C4	D
<b>Example</b>	the measured length of an item from a process in a state of statistical control	the surface roughness of an item as an example for a physically limited characteristic	different wear of the spindles on a multiple-spindle automatic machine with equal centring	different centring of workholding fixtures	fixed tools	trend, caused by wear, and cycle	tool changes or change of batches	multi-stream processes
<b>Location</b>	constant	constant	constant	random (normally distributed)	random (not normally distributed, unimodal)	function oriented (see examples)	systematic and random change	systematic and random change
<b>Variation</b>	constant	constant	systematic or random variation	constant	constant	constant	constant	systematic and random change
<b>Instantaneous distribution</b>	normally distributed	not normally distributed - unimodal	normally distributed	normally distributed	normally distributed	any shape whatever	any shape whatever	any shape whatever
<b>Resulting distribution</b>	normally distributed	not normally distributed - unimodal	not normally distributed, unimodal	normally distributed	not normally distributed, unimodal	any shape whatever	any shape whatever	any shape whatever
<b>In statistical control?</b>	yes	yes	no	no	no	no	no	no

Only cases A1 and A2 represent processes in a state of statistical control (statistically stable). However, there are cases when characteristics following other time dependent behavior might be in control (controlled stable) but not in statistical control. To be in control, a process performance or capability study must show that all values stay within control limits, sufficiently within tolerance limits to make out-of-tolerance values exceedingly unlikely. Further, line operators and supervisors must follow procedures to monitor the characteristic regularly and to take action to maintain its values within control limits. In these situations,  $C_p$  and  $C_{pk}$  may be used to measure capability, to indicate the characteristics are determined to be in control.

From a quality and voice of customer viewpoint, it is preferable to have a statistically stable process than one that is “only” controlled stable. However, in many real situations, a controlled stable process is less costly to operate than a statistically stable, self-controlled process. Therefore, not in statistical control but in control processes offer a compromise for difficult situations.

## 9.5 Requirements

The examples of target values for potential/critical performance and capability indices shown in Table 9-3 ( $P_p / P_{pk}$  and  $C_p / C_{pk}$ ) depend on the sample size and the classification of the characteristic (confidence interval of the capability estimation: 95%, confidence interval of the target value adjustment if number of parts < 125: 99.99%).

*Table 9-3: Examples of Target Values for Preliminary and Final Process Performance and Capability Depending on the Sample Size n*

Preliminary process performance $P_p/P_{pk}$	$n \geq 125$		$n = 100$		$n = 75$	
	$P_p$	$P_{pk}$	$P_p$	$P_{pk}$	$P_p$	$P_{pk}$
Critical	2.00	1.67	2.07	1.73	2.18	1.82
Major	1.67	1.33	1.73	1.38	1.82	1.45
Minor	1.33	1.00	1.38	1.04	1.45	1.09
Others	1.33	1.00	1.38	1.04	1.45	1.09

Process performance or capability $P_p/P_{pk}$ or $C_p/C_{pk}$	$n \geq 125$	
	$P_p/C_p$	$P_{pk}/C_{pk}$
Critical	1.67	1.67
Major	1.33	1.33
Minor	1.00	1.00
Others	1.00	1.00

The designations of characteristic classes are typically company specific. The target capability and performance values to be achieved are based on an agreement between the organization and the customer (internal or external).

If the performance and capability criteria are not met, a root cause analysis must be carried out, and the study must be repeated (if necessary)

## 10 Control Charts for Statistical Process Control and Ongoing Capability

SPC involves the study of variation which can be referred to as either common cause – often think of inherent variation or noise – or special cause, meaning there is an assignable reason for its occurrence. Special cause variation results from circumstances that are not always acting on the process, but when they are, instability will affect the output until they are identified and addressed.<sup>12</sup>

The purpose of SPC is to cost effectively ensure that products produced meet the customer's expectations. From a "system" standpoint, it defines the extent of common cause variation and also signals when a special cause has acted on it so that its source can be identified and reacted to before problems arise. This is why SPC is considered a prevention activity. Of course, every part could be inspected prior to shipment (100% inspection), but that is not as cost effective and has been proven to be much less than a guarantee of quality. Implemented correctly, SPC will give you confidence that the customer requirements are met regularly and with only a small percentage of the products being checked.

When 100% inspection is uneconomical or impossible (or not desired), conclusions can be drawn regarding the population by using statistical procedures based on samples, also known as SPC. Besides verifying that specifications are met, the objective of drawing such a conclusion is also to improve the process.

It reflects the quality level of the process. SPC comprises all activities that reduce the variation, shift the process level to the desired degree and improve process knowledge based on the insights gained.

The sample results are entered into so-called control charts. By using an appropriate control chart, the stability of a process can be continuously monitored. Based on the initially determined process capability and the stability evaluation, it is possible to forecast ongoing process capability. Control charts are graphical tools that show characteristic values or statistical parameters to allow for a comparison with previously specified control limits. Control limits can be warning as well as control limits.

Different types of control charts are used depending on the underlying type of data (e.g., continuous or attribute). Control charts for continuous characteristics used for monitoring the stability of the process location and the process variation typically have two separate charts, one for the process level and one for the variation, on which the respective parameters are shown. These parameters depend on the type of control chart (see Chapter 10.3). Typically, the arithmetic means of the individual

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<sup>12</sup> An example illustrating the distinction between the two types of variation is the daily commute to work. Even when the same route is taken, arrival times can vary from day to day. Factors such as traffic volume or the number of red lights encountered fluctuate slightly and represent common-cause variation, which is considered part of the system. In contrast, an unexpected snowfall that significantly increases travel time constitutes special-cause variation.

samples are shown on the location chart, and the empirical standard deviations of the individual samples are shown on the variation chart. These individual samples typically have a constant sample size.

Statements regarding stability are made based on stability criteria (see Chapter 10.2.2).

## 10.1 Different Control Concepts (Process- vs. Tolerance-Related)

As mentioned in Chapter 7, both process-related and tolerance-related control concepts can be used. The main difference between process-related and tolerance-related control charts is that process-related control charts are used to improve a process, while tolerance-related control charts are used to ensure compliance with a tolerance.

Process-related control charts are used to monitor a process over time to optimize the quality of a process and to achieve zero defect production. The use of control charts ensures that an achieved quality level is maintained and follows Shewhart's fundamental principle.<sup>13</sup> Control limits are calculated based on the process parameters (level/variation) without taking specification limits into account. The control limits must be reassessed once process improvements have been made. The distances between the control limits will become smaller based on recalculated control limits to maintain the new quality level.

Tolerance-related control charts are used to ensure a process meets a tolerance instead of improving process. They allow for a specified nonconforming fraction. The control limits are calculated based on the specification limits and the process variation. The distance between the control limits will increase after process improvements have been made and the control limits have been reassessed to take the benefits of reduced process variations while maintaining the same permissible nonconforming fraction.

Which control concept is used depends on the application and the control objective. The process-related control charts are based on prevention strategy, while tolerance-related control charts are more for detection purposes.

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<sup>13</sup> See Shewhart's principle is to distinguish between common cause and special cause variation, to eliminate the latter to have a stable process.

## 10.2 Out of Control Conditions and Quality Criteria of Control Charts

When implementing control charts, there are two different assessment methods: analysis and SPC control charts. Using an analysis control chart, the previous process behavior is analyzed retrospectively (post process). With an SPC control chart, however, the knowledge about the previous process behavior is used as a basis for future control.

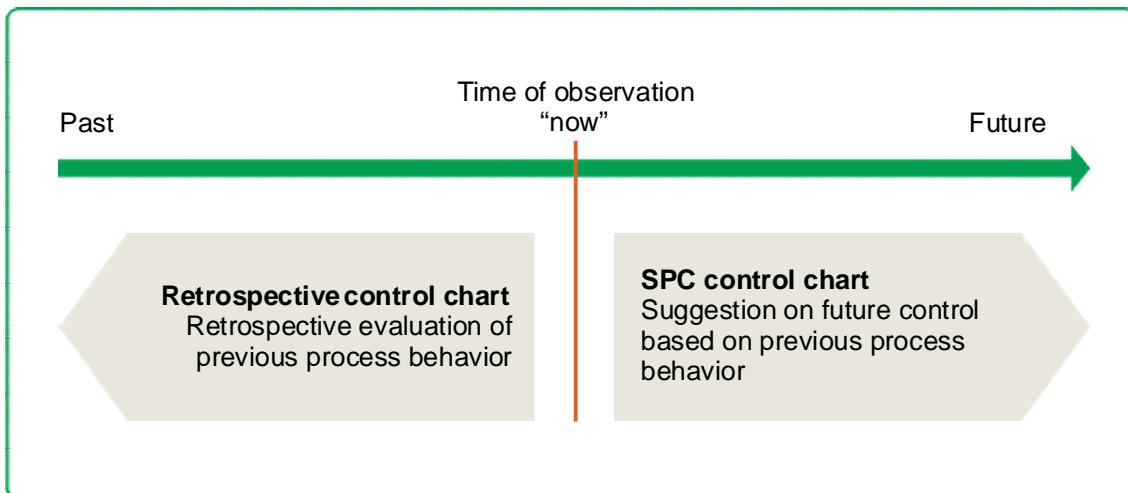


Figure 10-1: Two Different Assessment Methods: Retrospective Control Chart or SPC Control Chart

### 10.2.1 Retrospective (Analysis) Control Chart vs. SPC Control Chart

The analysis control chart is used to analyze past process behavior (control loop 3, see Chapter 5.1). The results from a defined period are assessed retrospectively. The stability assessment of the analysis control chart provides a basis for differentiating between process capability and process performance.

The SPC control chart is used for direct process control (control loop 1, see Chapter 5.1). In this case, the control chart is used to control the process directly, in which violation of control limits are not acceptable. Each violation of control limit or stability criteria must be followed by a corrective action plan (see Chapter 10.2.2).

Table 10-1: Comparison between Retrospective Control Chart and SPC Control Chart

Aspect	Retrospective Control Chart	SPC Control Chart
<b>Time Focus</b>	Looks backward – uses historical data already collected.	Looks forward/in real time – monitors the current process as data are produced.
<b>Purpose</b>	To analyze past performance and check if the process was in control.	To control and maintain stability by detecting <i>special causes</i> as they happen.
<b>Nature</b>	Diagnostic / Corrective – learns from history, identifies what went wrong.	Preventive / Real-time SPC – prevents defects by acting when variation starts to increase.
<b>Data Source</b>	Past production or testing records.	Ongoing measurements from operators or systems.
<b>Typical Questions Answered</b>	<ul style="list-style-type: none"> <li>• Was the process stable in the past?</li> <li>• Can I trust my capability analysis?</li> <li>• Were there any special causes before?</li> </ul>	<ul style="list-style-type: none"> <li>• Is the process currently in control?</li> <li>• Do I need to stop or adjust the process?</li> <li>• Are special causes occurring now?</li> </ul>
<b>Reaction Type</b>	Investigate past deviations (corrective action).	Immediate response to prevent out-of-control conditions (preventive action).
<b>Control Loop</b>	3	1

### 10.2.2 Stability Criteria

The stability of a process is analyzed by using stability criteria, also known as “out-of-control criteria”. Violations of the control limits are the first, simple criteria to determine stability of a process.

Moreover, additional limits can be used in addition to the control limits to better control the process (e.g., warning limits).

The entries in the control charts can be checked for instabilities based on the following statistical criteria, e.g.

- Runs, i.e., a certain number of consecutive points that are above or below the center line
- Trends — a defined number of sequences that are continuously rising or falling
- Middle third – fewer or more points within the middle third of the region between the control limits

For normally distributed processes, the stability criteria known as "Western Electric Rules" or "Nelson Rules" that are based on the standard deviation can be followed. Based on these rules, a process is deemed unstable as soon as one of the following criteria is met.

- one point outside of the control limits ( $\pm 3s$ )
- 2 out of 3 consecutive points are on the same side of the center line and farther than  $\pm 2s$  from it
- 4 out of 5 consecutive points are on the same side of the center line and farther than  $\pm 1s$  from it
- A run of nine in a row is on the same side of the center line
- 15 consecutive points are within  $\pm 1s$  of the center line

#### **10.2.2.1      Process Control with SPC Charts**

The decision as to which criteria to use for process control depends on the process being studied.

Generally, care should be given not to apply multiple criteria except in those cases where it makes sense. The application of each additional criterion increases the sensitivity of finding a special cause but also increases the chance of a type I error.<sup>14</sup>

If at least one of the so-defined stability criteria is not met, it must be assumed that the process is no longer stable.

#### **10.2.2.2      Post-Process Stability Evaluation with Analysis Control Charts**

If the process data on an analysis control chart indicates violations of control limits relative to the previously defined levels, then the process should be considered unstable.

The reactions that follow depend on the type of process.

### **10.2.3 Corrective Action Plan in Case of Instabilities**

If instability arises, the sample measurement shall be repeated, or a second sample will be taken to ensure that the sample is valid.

In case the sample is valid, the process parameters shall be verified and readjusted as needed (e.g., adjustment of pressure, temperature, rotational speed).

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<sup>14</sup> Type I error: false rejection of a true null hypothesis "false negative",  
type II error: false acceptance of a wrong null hypothesis "false positive"

If the above actions do not yield the intended results, a second step shall be followed by adjusting the process elements (e.g., mounts, guides, tools, machine parts).

To verify the effectiveness of the actions taken, a new sample shall be analyzed for process validation. If this sample meets all stability criteria and shows no violation of the control limits, stability monitoring shall be continued. The corrective action implemented shall be documented in a reaction plan.

If the stability cannot be re-established with the above corrective actions, a more detailed root-cause analysis and a more structured problem-solving approach shall be taken (e.g., 8D process, Ishikawa, 5-Why). In line with a risk-based approach, product conformance should be ensured using appropriate measures (i.e., sorting). The analysis must be continued until effectiveness has been validated.

If the process location (mean, median, etc.) or the variation changes as a result of process control or optimization, the control limits must be re-evaluated.

Setting up SPC control charts makes sense only where you have process ownership and where you have the ability to adjust the process whenever instability (i.e., out-of-control conditions) due to special cause variation is encountered. Nothing is more frustrating for the members involved than uncovering process instability only to discover that nothing can be done about it. So, having an effective out of control action plan (OCAP) that includes sequence of activities that should be followed upon detection of OOC (out of control) / OOS (out of specification) conditions in the process is essential.



Figure 10-2: Elements of OCAP

#### 10.2.4 Measures for Evaluating the Effectiveness of Control Charts

Conventional Shewhart charts detect shifts in the mean of more than three sigma quite quickly and the use of additional rules help detect smaller shifts with a higher false alarm rate. Other processes need different control schemes such as the need to detect small shift in the mean rather than bigger shifts, other processes may need to detect linear drift in the mean rather than a shift.

To evaluate chart performance, we can compare the chart using the false alarm rate,

however, it's sometimes hard to compare in small numbers, so instead, we look at the average time for the chart to signal. This measure is known as the average run length or ARL.

#### 10.2.4.1 Operating Characteristic

The operating characteristic of a control chart defines the probability of intervention or probability of alarms. Thus, the proportion of false alarms, i.e., the type I error, can be estimated.

For instance, the operating characteristic of a process location chart shows the probability of violations of the control limits if the process location changes. With this information, suitable control charts and their parameter settings can be chosen. An example of an operating characteristic of a control chart is shown in Figure 10-3:

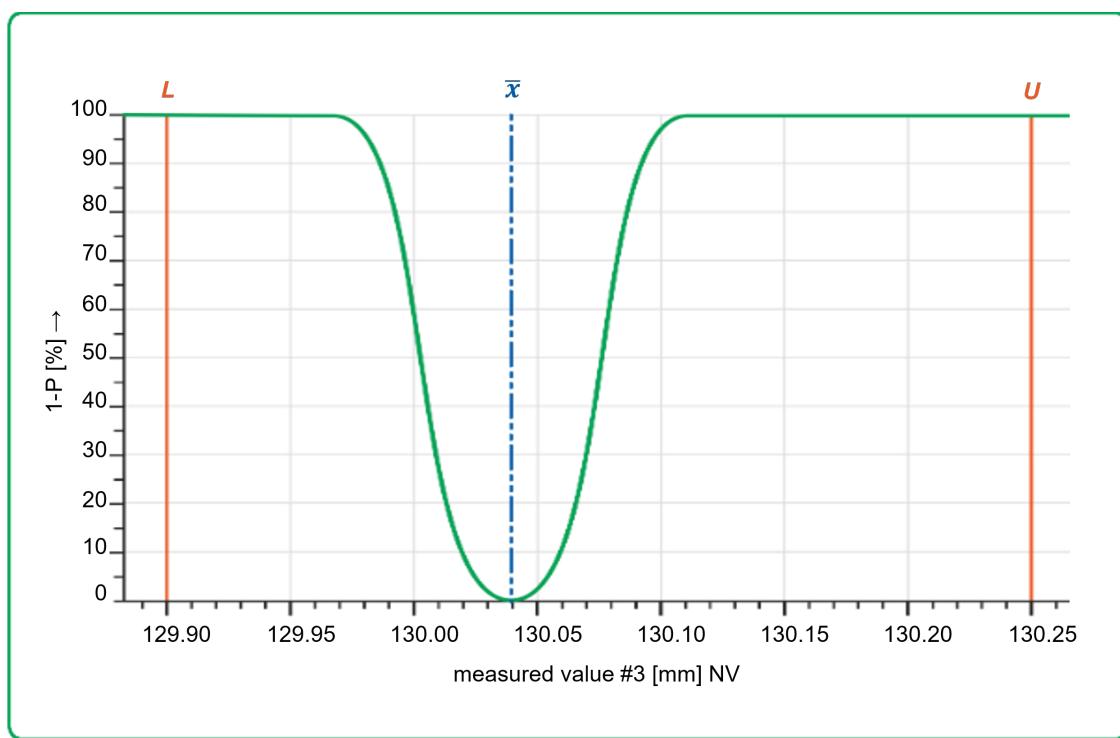


Figure 10-3: Operating Characteristic

#### 10.2.4.2 Average Run Length

The average run length (ARL) is the expected average number of samples taken at a predefined process location or process variation until there is a violation of control limits causing an out-of-control condition. It is important to ensure that the average run length is small enough for the process to be controlled effectively.

The Figure 10-4 below shows the average run length of a mean value chart as a function of a change of the process location at a probability level of non-intervention

at 99%. The green line shows the ARL for individual sample sizes of  $n = 2$ , and the blue line for  $n = 10$ . Increasing the sample size means that changes to the process location are identified much faster.

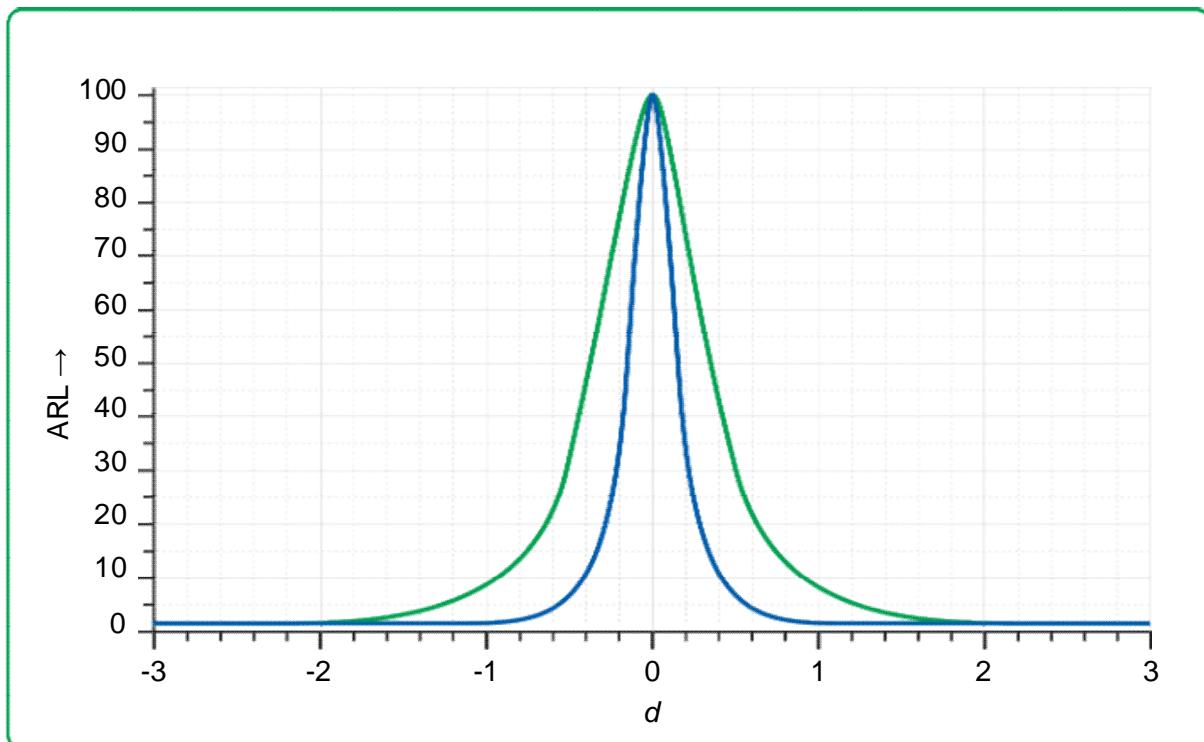


Figure 10-4: Average Run Length as a Function of a Change  $d$  of the Process Location ( $d$  is a Multiple of the Standard Deviation)

## 10.3 Types of Control Charts

### 10.3.1 General Information

As described in Chapter 7, control charts are graphical aids for collecting and displaying measured values, counting results, or sample characteristics (statistical parameters) of the location and variation of a process, as well as their comparison to either calculated or predetermined limits.

The visualization of the data facilitates the evaluation of changes to an ongoing process. For evaluation purposes, the process location and/or variation are displayed over time and compared with limits (control and/or warning limits). If required, further stability criteria may be applied. This allows us to assess the stability of the process.

The following aspects should be taken into account when creating control charts:

- Header data to identify the process and the controlled characteristic
- Unambiguous, easily recognizable graphical display of the
  - Center line or position of central tendency

- Control limits (typically calculated control limits)
- Warning limits, if applicable
- Entry of the measured values and/or the statistical parameters
- In general, specification limits are not typically displayed for users on the shopfloor (on site, control loop 1). In order to reach decisions in higher control loops, there are some chart types that do display the specification limits.
- Displaying the sample number and further information such as date/time/line/user, as applicable
- Appropriate axis scaling to enable visual discrimination of changes to the process
- Marking/labeling of violations of stability criteria
- Documentation of incidents (causes) and/or countermeasures taken to recover process control if and/or when such events occur

The primary aim of using a control chart is to maintain the previously verified performance or capability or to further improve upon the previously verified process performance or capability. Gaining further process knowledge can provide the basis for process improvements. However, in some cases, seemingly random process improvements are simply because the process is controlled effectively. There are also further techniques for targeted process optimization, e.g., DoE, the Shainin method, and root cause analysis. If process optimization has indeed taken place, the process capability and possibly the control chart and its limits should be reevaluated.

Appropriate visualization must be ensured, such that the respective limits can be clearly distinguished. For example, control limits and warning limits should be a different color from the specification limits typically used in value charts to avoid mistakes. However, the specification limits for control charts on site/on the line (control loop 1, see Chapter 5.4) should never be entered for the user to ensure that the process control focuses on the control limits. A link to the specification limits should only be made for the purpose of decisions regarding safeguarding measures in case of instabilities (control loops 2 and 3, see Chapter 5.4). It is then advisable to use individual value charts and other statistical representations of individual values (individuals/measured values).

A recommendation for standardization of display, colors, and formula symbols can be found in ISO 7870-1.

## 10.3.2 Which Control Chart is Recommended for which Application?

### 10.3.2.1 *Introduction*

Several criteria must be taken into account when selecting control charts:

- The type of characteristic (attributive/discrete/counted or continuous/measured)
- The direction of observation (post-process/analytical or continuous SPC control on site/on the line)
- The type and objective of control (process-related or tolerance-related)
- Control chart for the current process condition or control charts “with memory”
- Control charts for characteristics that are non-normally distributed
- Control charts for preliminary control without knowledge of the process or for targeted control based on a known process (after process analysis)
- Control charts for individual characteristics or multivariate control charts for controlling several interacting characteristics.

This Roadmap for Control Chart Selection is provided to assist in ensuring the control chart best suited for the data to be collected is chosen. Pay particular attention to data type and sample sizes in the decision making.

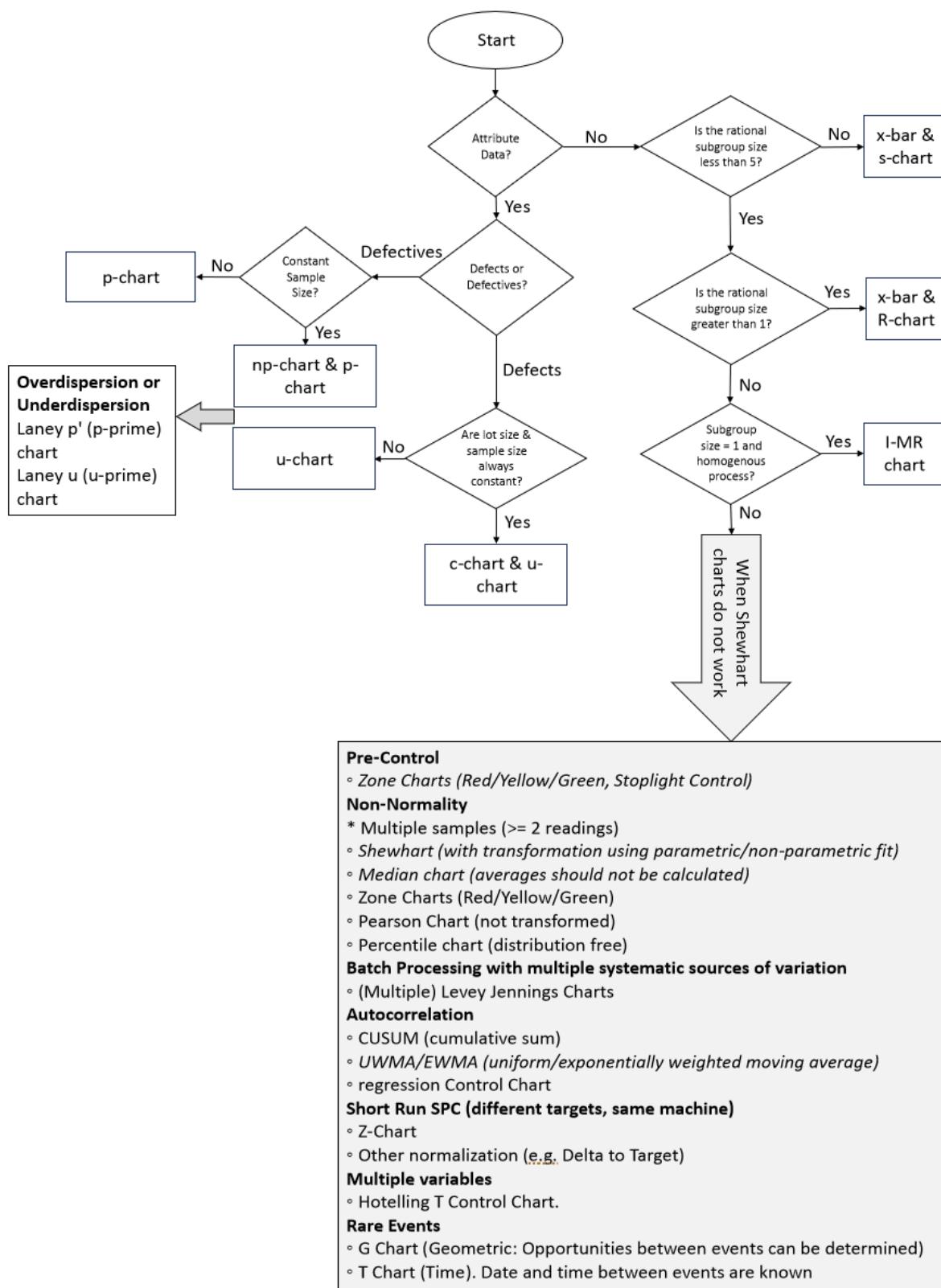


Figure 10-5: Control Chart Selection Guide

The highlighted/recommended control charts are described in greater detail in the following chapters.

A short description for non-Shewhart-charts is given here:

- Pre-control: For purpose of nonconformance control instead of process control, which means tolerance related limits are used
- Short Runs Or high mix/low volume: processes that only produce a small number of products during a single run (e.g., job shops)
- Detecting Small Changes: small changes in the process mean can cause problems. Shewhart control charts may not be sensitive enough to efficiently detect these changes, e.g. less than 1.5 standard deviations.
- Non-Normal subgrouped data: Sufficiently large subgroup size based on central limit theorem (CLT) not being able to mitigate the effect of non-normality of the underlying distribution.
- Multivariate: simultaneously control two or more related characteristics that influence the performance of a process or product.
- Autocorrelated Data: High-speed, automated processes are often found to exhibit autocorrelation on some characteristics.
- Multiple Stream or Multiple heads Process: Sources of Variation (SoV) study can be conducted for decisions to be made on how to collect and monitor the data e.g. batch process with nested data structure

#### **10.3.2.2      *Characteristic Type***

For attribute characteristics that are evaluated based on discrete values for the number of nonconformities, discrete control charts must be used. These control charts have the disadvantage that they count nonconformities, and control is thus only possible as long as a sufficient number of nonconformities can be found. They are, therefore, not suitable for a zero-error strategy. While reactive, if the rules of control are followed, they can be preventive by warning of worsening conditions. They can also be used to help indicate that the process has been improved.

A multitude of control charts can be used for continuous characteristics. They can be based on the principle of a Shewhart control chart (process-related) and thus a zero-error strategy. Alternatively, they can also be tolerance-related. In the following these include all control charts that are not explicitly labeled as discrete control charts.

#### **10.3.2.3      *Type of Observation Approach***

Post-process analysis charts are used to evaluate a process at a specified time about its past behavior. They monitor stability concerning a past period and must take possible false alarms into account due to the parameterized probability of non-

intervention. This means that the process is only evaluated as unstable once the number of alarms exceeds the number of expected false alarms. Given that the number of samples  $k$  to be evaluated is usually small, the random variation range of the expected false alarms must be taken into account. If the random variation range is very small (based on experience,  $k \geq 300$ ), it can be neglected. Process-related control charts are used as analysis charts. The analysis chart determines whether the performance index or the capability index of the process is used.

SPC control charts are used for continuous process control. Immediate action must be taken if the selected stability criteria are violated. In the advent of digitized and automated data collection systems, automatic alerts can be sent to personnel for intervention. Some types of manufacturing equipment now can automatically compensate and adjust based on programmed shifts or trends (“auto-compensation” or “autocomp”). Process-related or tolerance-related control charts are used as SPC control charts.

#### **10.3.2.4     *Process or Tolerance-Related Control Charts***

In process-related control charts, the expected “natural” variation limits of a process provide the basis for the control limits. If these limits are exceeded, this is taken to mean that the process is not behaving as expected based on the determined statistical criteria. This means that the process has changed, which potentially also results in worsening performance or capability indexes. In addition, further statistical criteria can be used for process control. In particular cases, process improvements can also be identified (e.g., reducing the variation, with a lower control limit on the variation chart being undershot accordingly, inner middle third). However, it must then be ensured that an apparent improvement is not accompanied by errors in the measurement process. Using process-related control charts, zero-error strategies can be implemented.

Tolerance-related control charts use the known (estimated) variation of a production process to add a type of “safety margin” to the tolerance limits. However, the parameterization involves specified acceptable fractions nonconforming, and violations of these acceptable fractions are only detected with a specified probability of intervention. Therefore tolerance-related control charts can not be used to implement a zero-defect strategy. Only violations of warning and control limits can be used as stability criteria. A prerequisite for using tolerance-related control charts is that the current process variation is substantially lower than the resulting overall variation.

#### **10.3.2.5     *Control Charts for the Instantaneous Process State or Control Charts with Memory***

Control charts that only calculate characteristic values based on a recently drawn sample or only analyze stability based on the current measured values only evaluate

the current condition of the process compared to the past condition of the process. Small, successive changes are therefore recognized very late.

So-called “control-charts with memory” continuously evaluate current changes, taking previous process behavior into account. They can detect small changes in the production process more easily. This group includes charts with infinite memory (CUSUM) as well as control charts with exponentially decreasing memory (EWMA). The advent of digitization with automated detection of these small changes can make this process much less cumbersome for users.

#### **10.3.2.6 Control Charts for Non-Normal Distributed Characteristics**

The control charts developed by Shewhart require normally distributed data. In the case of an undisturbed process with variation only due to statistically random influencing quantities, the assumptions are justified.

In practice, there are other factors that influence an ongoing process. In the case of processes with natural zero limits (example: form and true position), significant deviations from the normal distribution may occur. Tool wear or the use of different tools or tool clusters (clamping devices) can lead to deviations from normal distributions. Insofar as these deviations are unavoidable and/or acceptable, they can be included in the control chart calculation. Known variants include so-called Pearson charts for skewed distributions or extended Shewhart charts for multimodal distributions.

Although many control charts for variable data are formally based on the assumption of normality, you can also achieve good results with non-normal data if you record the data in sufficiently large subgroups and monitor parameters such as the mean or median of the subgroups. The relationship between robustness to non-normality and sample size is based on the central limit theorem. As long as your subgroups are independent, larger subgroup sizes tend to produce subgroup means that are more normally distributed.

Unimodal skewed distributions can be converted into normally distributed data using transformations (Box-Cox, Johnson, etc.). To monitor data showing autocorrelation, e.g. the autoregressive model can be used for transformation. By this, it is then possible to use conventional, normally based control charts. However, the correction values derived from the control charts must be retransformed using the inverse transformation to know which corrections need to be applied. This means that these control charts can only be used as SPC control charts on site to a limited extent.

#### **10.3.2.7 Control Charts for Preliminary Control without Process Knowledge or for Targeted Control Based on a Known Process (After Process Analysis)**

When a new process is initiated, there is no prior process information that can be

used to control the process. However, the aim should still be to detect unexpected deviations as early as possible. This led to the development of control charts that provide suitable control limits for preliminary control based on expectations of a future process.

For process-related charts, it is possible to use maximum variation or expected process level parameters, which are derived from the required performance and capability indexes. If necessary, characteristic values from known, comparable processes can also be used for the preliminary parameterization of control charts.

For tolerance-related charts, maximum expected variation values from specifications can equally be used (preliminary acceptance chart). In some cases, a simple division of the tolerance, usually into three zones, can be used (pre-control chart).

These preliminary charts are only suitable for monitoring a process. Clear signs of instability may also be detected. Preliminary charts should not be used to control a process.

#### ***10.3.2.8 Control Charts for Individual Characteristics or Multivariate Control Charts for Controlling Several Interacting Characteristics***

When using control charts that are designed for an individual characteristic, it is assumed that this characteristic influences the quality of the product independently of the condition of other characteristics. If the process is sufficiently well known, instabilities can then directly be assigned to particular measures, e.g., replacing a tool if a control limit is undershot.

Multivariate control charts are used if the quality is determined based on the interaction between several characteristics. In such cases, multivariate control charts can be applied, e.g. the Hotelling's T<sup>2</sup> chart, the Multivariate Exponentially Weighted Moving Average Chart (MEWMA) or the Multivariate Cumulative Sum Chart (MCUSUM). In contrast to univariate charts, it is not easy to identify which characteristic is causing instability. In many cases, it is not possible to determine this, and the measure to be taken relates to the interaction between several characteristics.

#### ***10.3.2.9 Short-Run Control Charts***

Short run SPC is a technique used to analyze processes with an insufficient amount of data available to adequately define the characteristics of the process. Short-run SPC is used in high-mix, low-volume manufacturing environments where traditional SPC methods are impractical. It combines data from multiple short production runs to create a single analysis. Techniques like Z-MR charts standardize data by subtracting the mean and dividing by the standard deviation, allowing for control charts that are independent of measurement units. This approach helps monitor and control processes with limited data, ensuring stability and quality across different

products and runs.

Short-run SPC also involves stabilizing attribute control charts to handle varying sample sizes and subgroup numbers. These charts eliminate issues with different control limits and central lines, making it easier to interpret data visually. By combining data from several runs, short-run SPC ensures that even with limited data, processes can be monitored for stability and quality.

This approach is particularly useful in industries where production runs are tailored to individual customer needs, minimizing inventory and improving responsiveness while maintaining high-quality standards.

More details can be found in ISO 7870-8 Control charts - Part 8: Charting techniques for short runs and small mixed batches.

### 10.3.3 Variable Control Charts (Shewhart Control Charts for Continuous Characteristics)

#### 10.3.3.1 *Introduction*

The Shewhart control chart is used for controlled processes where continuous (variable) characteristics are monitored.

Changes to the process are evaluated based on the process location and variation. The individual values or the median or mean value of a sample (subgroup) is shown on the process location chart. The standard deviation or the range of a sample (subgroup) is shown on the variation chart.

#### 10.3.3.2 *Average and Standard Deviation*

Mean value ( $\bar{x}$ ) and standard deviation ( $s$ ) ("x-bar-s Chart")

Description of the control chart

Used for continuous data. It displays and controls the mean value ( $\bar{x}$ ) for process location (center of tolerance) and standard deviation ( $s$ ) for process variation over time. Based on individual values, the control limits are typically  $\pm 2.58$  or  $3\sigma$  around the nominal value with an "a-risk" for overcontrol by false alarm of  $\leq 1\%$  or  $\leq 0.27\%$ . The actual control limits for the  $\bar{x}$  – average chart needs to be calculated based on the subgroup size and are smaller, as mean values are narrowing down the process compared to individual values (e.g.,  $\pm 2.58\sigma$  control limit for individual values will turn to  $\pm 1.15\sigma$  with a sample size of 5).

Relation between the variance (standard deviation  $\sigma_x$ ) of the single values and the variance (standard deviation  $\sigma_{\bar{x}}$ ) of the mean values:

$$\sigma_{\bar{x}} = \frac{\sigma_x}{\sqrt{n}}$$

Computer assisted calculation of control limits is recommended.

### Application examples for this control chart

This chart should be used as the standard chart for continuous two-sided limited characteristics *with a normally distributed process behavior*, without trends. It requires sufficient samples of a minimum 3-5 parts to calculate a standard deviation of the sub-groups instead of using just the range to display the variance of the process like in the  $\bar{x}$  R-chart. It requires a consistent sample size and frequency for equally valid control limits and consistent control on special causes changing the process on the respective SPC-controlled characteristic. As the control limit for process location is dependent on  $\sigma$ , first, the  $s$  - chart needs to be checked and if out of control, be corrected, before the evaluation of  $\bar{x}$  – chart.

### Visualization of the control chart, including description

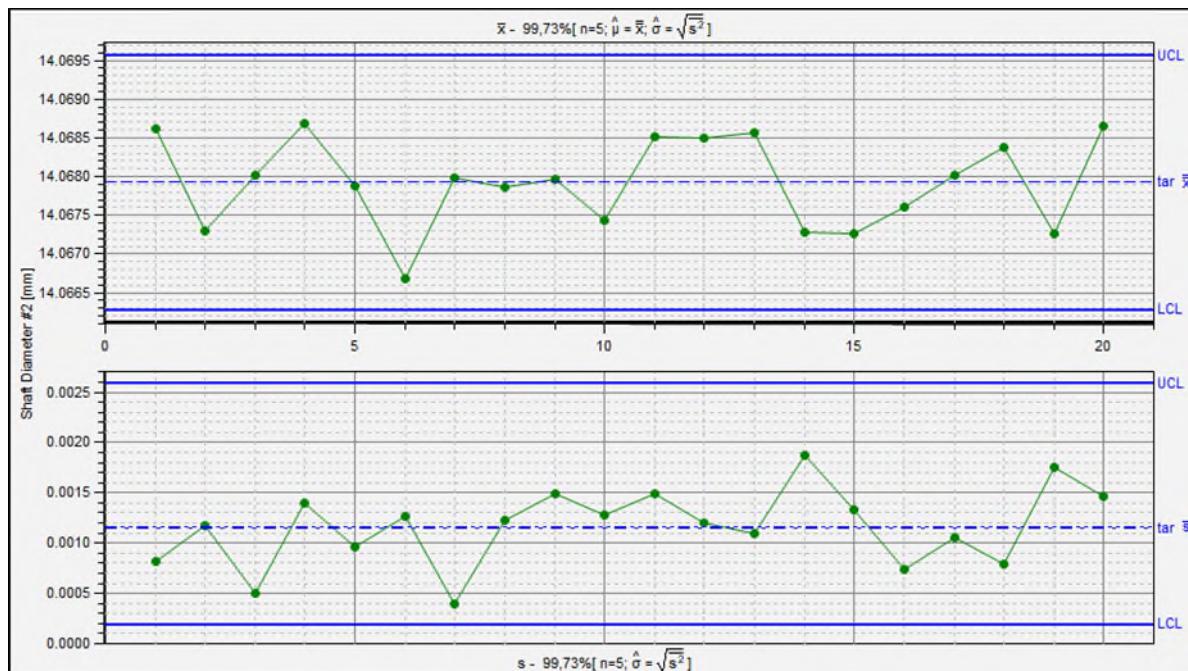


Figure 10-6:  $\bar{x}/s$ -Chart for Subgroup Size  $n = 5$  and Estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \sqrt{s^2}$ . Variation Chart Calculated on Exact Formula for  $\chi^2$  Distribution.

UCL — Upper control limit

LCL — Lower control limit

tar — Center Line CL (target)

Selection of formulas

Process location chart

<p>Overall formula (control limits)</p> $UCL_{\mu} = \hat{\mu} + u_{1-\alpha/2} \cdot \frac{1}{\sqrt{n}} \cdot \hat{\sigma}$ $LCL_{\mu} = \hat{\mu} - u_{1-\alpha/2} \cdot \frac{1}{\sqrt{n}} \cdot \hat{\sigma}$ <p>Example: If using estimators</p> $\hat{\mu} = \bar{x}$ $\hat{\sigma} = \sqrt{\bar{s}^2}$ <p>the formulas are</p> $UCL_{\mu} = \bar{x} + u_{1-\alpha/2} \cdot \frac{1}{\sqrt{n}} \cdot \sqrt{\bar{s}^2}$ $LCL_{\mu} = \bar{x} - u_{1-\alpha/2} \cdot \frac{1}{\sqrt{n}} \cdot \sqrt{\bar{s}^2}$	<p>Explanation of the formulas (including estimators)</p> <p><b>UCL</b> – upper control limit</p> <p><b>LCL</b> – lower control limit</p> <p><math>\hat{\mu}</math> – estimator for process location</p> <p><math>\hat{\sigma}</math> – estimator for process standard variation</p> <p><math>n</math> – subgroup size</p> <p><math>\alpha</math> – Probability of false alarm (non-interference probability <math>1 - \alpha</math>)</p> <p><math>u_{1-\alpha/2}</math> – quantile of the standardized normal distribution (depending on defined <math>\alpha</math> – risk)</p> <p><math>\bar{x}</math> – mean of mean values (total mean; grand mean)</p> <p><math>s</math> – subgroup standard deviation</p> <p><math>\sqrt{\bar{s}^2}</math> – Standard deviation calculated from square root of the average variance of the subgroups as estimator <math>\hat{\sigma}</math></p>
<p>Variation chart</p> <p>Overall formula (control limits)</p> $UCL_s = \frac{\sqrt{\chi^2_{f;1-\frac{\alpha}{2}}}}{f} \cdot \hat{\sigma}$ $LCL_s = \frac{\sqrt{\chi^2_{f;\frac{\alpha}{2}}}}{f} \cdot \hat{\sigma}$ <p>If using estimator</p> $\hat{\sigma} = \sqrt{\bar{s}^2}$ <p>the formulas are</p> $UCL_s = \frac{\sqrt{\chi^2_{f;1-\frac{\alpha}{2}}}}{f} \cdot \sqrt{\bar{s}^2}$ $LCL_s = \frac{\sqrt{\chi^2_{f;\frac{\alpha}{2}}}}{f} \cdot \sqrt{\bar{s}^2}$	<p>Explanation of the formulas (including estimators)</p> <p>if required, reference to other charts that could be used</p> <p><math>f = n - 1</math> – degrees of freedom</p> <p><math>n</math> – subgroup size</p> <p><math>\alpha</math> – Probability [%] for false alarm (non-interference probability <math>1 - \alpha</math>)</p> <p><math>\hat{\sigma}</math> – estimator for process standard variation</p> <p><math>\chi^2</math> – chi square distribution</p> <p><math>s</math> – subgroup standard deviation</p> <p><math>\sqrt{\bar{s}^2}</math> – Standard deviation calculated from square root of the average variance of the subgroups as estimator <math>\hat{\sigma}</math></p>

### 10.3.3.3 Average and Range

Mean value ( $\bar{x}$ ) and range ( $R$ ) ("x-bar-R Chart")

Used for continuous data. It displays and controls the mean value ( $\bar{x}$ ) for process location (center of tolerance) and range of the measured samples ( $R$ ) for process variation over time. Mean value ( $\bar{x}$ ) and range ( $R$ ) charts can be used if the sample size is small (usually smaller than 10). The reason for this is that as the sample size increases, the range becomes less meaningful when it comes to estimating the standard deviation. In the past, manual  $\bar{x}$  and  $R$ -charts provided the advantage that they were easier to use, as they required fewer calculations. With computer calculation the  $\bar{x}$ -  $s$ -chart is recommended in most scenarios.

Application examples for this control chart

See  $\bar{x}$  and  $s$ -chart. Apply if the range is to be monitored instead of the standard deviation.

Visualization of the control chart, including description

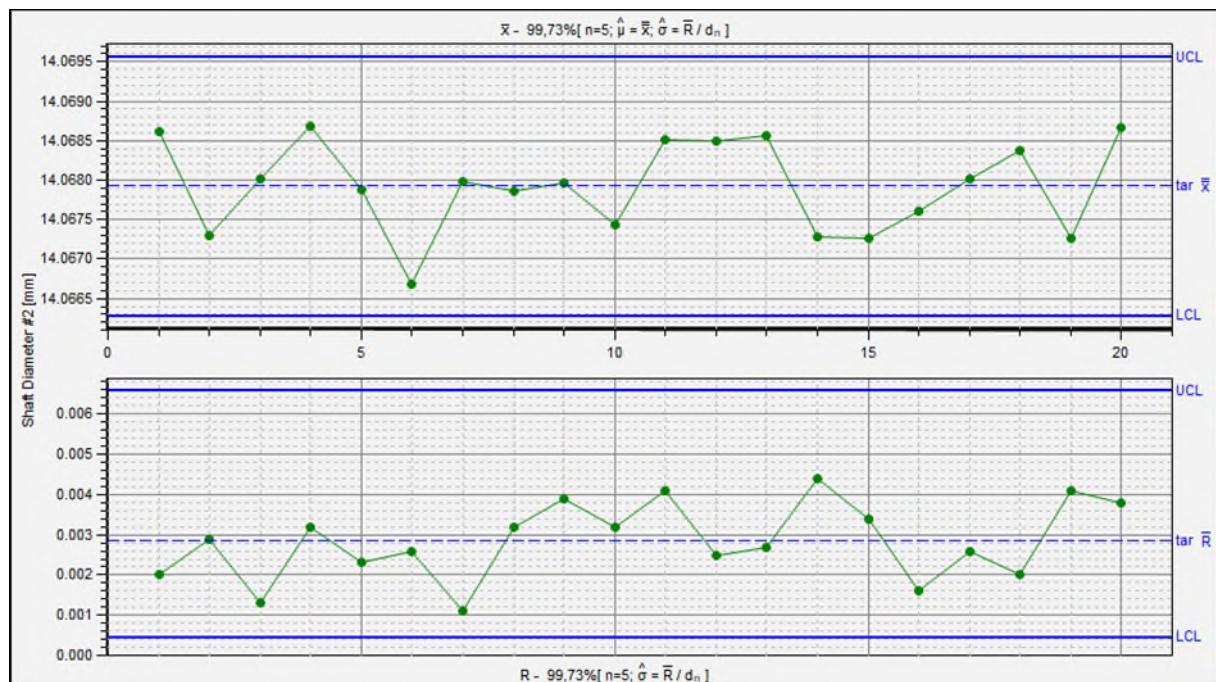


Figure 10-7:  $\bar{x}/R$ -Chart for Subgroup Size  $n = 5$  and Estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \frac{\bar{R}}{d_n}$

UCL – Upper control limit

LCL – Lower control limit

tar – Center Line CL (target)

$\bar{x}/R$ -chart for subgroup size  $n = 5$  and estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \frac{\bar{R}}{d_n}$ .

Variation chart calculated on exact formula for  $\chi^2$ - or  $w$ -distribution.

Based on same raw data as Figure 10-6.

Collection of Formulas																																																										
Process location chart																																																										
Overall formula (control limits) See 10.3.3.2 Average and standard deviation			Explanation of the formulas (including estimators) See 10.3.3.2 Average and standard deviation																																																							
Variation chart																																																										
Overall formula (control limits) Calculation based on $w$ -distribution of standardized range $R/\sigma$ (exact calculation) $UCL_R = w_{n;1-\frac{\alpha}{2}} \cdot \hat{\sigma}$ $CL_R = \bar{R}$ $LCL_R = w_{n;\frac{\alpha}{2}} \cdot \hat{\sigma}$ <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th rowspan="2">Sub-group Size (<math>n</math>)</th> <th colspan="2"><math>\alpha = 99\%</math></th> <th colspan="2"><math>\alpha = 99.73\%</math></th> </tr> <tr> <th><math>w_{n;\frac{\alpha}{2}}</math></th> <th><math>w_{n;1-\frac{\alpha}{2}}</math></th> <th><math>w_{n;\frac{\alpha}{2}}</math></th> <th><math>w_{n;1-\frac{\alpha}{2}}</math></th> </tr> </thead> <tbody> <tr><td>2</td><td>0.009</td><td>3.97</td><td>0.002</td><td>4.533</td></tr> <tr><td>3</td><td>0.135</td><td>4.424</td><td>0.070</td><td>4.950</td></tr> <tr><td>4</td><td>0.343</td><td>4.694</td><td>0.221</td><td>5.200</td></tr> <tr><td>5</td><td>0.555</td><td>4.886</td><td>0.397</td><td>5.378</td></tr> <tr><td>6</td><td>0.749</td><td>5.033</td><td>0.569</td><td>5.515</td></tr> <tr><td>7</td><td>0.922</td><td>5.154</td><td>0.729</td><td>5.627</td></tr> <tr><td>8</td><td>1.075</td><td>5.255</td><td>0.874</td><td>5.722</td></tr> <tr><td>9</td><td>1.212</td><td>5.341</td><td>1.006</td><td>5.803</td></tr> <tr><td>10</td><td>1.335</td><td>5.418</td><td>1.126</td><td>5.875</td></tr> </tbody> </table> Calculation based on quantiles of the normal distribution (approximated calculation) $UCL_R = \bar{R} + u_{1-\frac{\alpha}{2}} \cdot d_3 \cdot \hat{\sigma}$					Sub-group Size ( $n$ )	$\alpha = 99\%$		$\alpha = 99.73\%$		$w_{n;\frac{\alpha}{2}}$	$w_{n;1-\frac{\alpha}{2}}$	$w_{n;\frac{\alpha}{2}}$	$w_{n;1-\frac{\alpha}{2}}$	2	0.009	3.97	0.002	4.533	3	0.135	4.424	0.070	4.950	4	0.343	4.694	0.221	5.200	5	0.555	4.886	0.397	5.378	6	0.749	5.033	0.569	5.515	7	0.922	5.154	0.729	5.627	8	1.075	5.255	0.874	5.722	9	1.212	5.341	1.006	5.803	10	1.335	5.418	1.126	5.875
Sub-group Size ( $n$ )	$\alpha = 99\%$		$\alpha = 99.73\%$																																																							
	$w_{n;\frac{\alpha}{2}}$	$w_{n;1-\frac{\alpha}{2}}$	$w_{n;\frac{\alpha}{2}}$	$w_{n;1-\frac{\alpha}{2}}$																																																						
2	0.009	3.97	0.002	4.533																																																						
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$CL_R = \bar{R}$ $LCL_R = \bar{R} - u_{1-\frac{\alpha}{2}} \cdot d_3 \cdot \hat{\sigma}$ $\bar{R} = \frac{\sum R_i}{k}$ <p><b>Example:</b> If using estimator</p> $\hat{\sigma} = \frac{\bar{R}}{d_2}$ <p>the formulas for control limits are</p> <ul style="list-style-type: none"> <li>- based on standardized Range (exact calculation)</li> </ul> $UCL_R = w_{n;1-\frac{\alpha}{2}} \cdot \frac{\bar{R}}{d_2}$ $LCL_R = w_{n;\frac{\alpha}{2}} \cdot \frac{\bar{R}}{d_2}$ <ul style="list-style-type: none"> <li>- based on quantiles of normal distribution (approximate calculation)</li> </ul> $UCL_R = \bar{R} + u_{1-\frac{\alpha}{2}} \cdot d_3 \cdot \frac{\bar{R}}{d_2}$ $= \left(1 + u_{1-\frac{\alpha}{2}} \cdot \frac{d_3}{d_2}\right) \cdot \bar{R}$ $LCL_R = \bar{R} - u_{1-\frac{\alpha}{2}} \cdot d_3 \cdot \frac{\bar{R}}{d_2}$ $= \left(1 - u_{1-\frac{\alpha}{2}} \cdot \frac{d_3}{d_2}\right) \cdot \bar{R}$	<p><b>Note 1:</b> if <math>1 \pm u_{1-\alpha/2} \cdot \frac{d_3}{d_2} \leq 0</math>, then <math>LCL_R = 0</math></p> <p><b>Note 2:</b> In literature, the parameters</p> $1 \pm u_{1-\alpha/2} \cdot \frac{d_3}{d_2}$ <p>are often summarized in tables with different designations (e.g., <math>D_3, D_4</math>). When using these tables, it must be ensured that the tables consider the desired non-interference probability.</p>
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Subgroup Size ( $n$ )	$d_2$	$d_3$
2	1.128	0.8525
3	1.693	0.8884
4	2.059	0.8798
5	2.326	0.8641

6	2.534	0.8480	
7	2.704	0.8332	
8	2.847	0.8198	
9	2.970	0.8078	
10	3.078	0.7971	

#### 10.3.3.4 Median and Range

Median ( $\tilde{x}$ ) and range ( $R$ )
Description of the control chart
Median ( $\tilde{x}$ ) charts are an alternative to mean value ( $\bar{x}$ ) charts when it comes to controlling the process location, especially if the aim is to reduce the influence of extreme values within the sample. This alternative is especially useful in case of samples from automated measurements with a high degree of variability, such as when measuring tensile strength. It must be noted that $\tilde{x}$ -charts react more slowly to unstable conditions compared to $\bar{x}$ -charts. The control limits for $\tilde{x}$ -charts can either be calculated based on the mean value of the sample medians and the ranges or the median of the sample medians and the median of the ranges. In ISO 7870-2, the mean value of the medians is preferred.
In the past, manual $\tilde{x}$ -charts provided the advantage that they were easier to use, as they required fewer calculations than $\bar{x}$ -charts, especially in case of smaller sample sizes with an uneven number of observations. This increased its acceptance in production, especially if individual values and their median were shown on the same chart.
Application examples for this control chart
See $\bar{x}$ and $s$ -chart. Apply if the median and range is to be monitored instead of the mean value and standard deviation.
Visualization of the control chart, including description

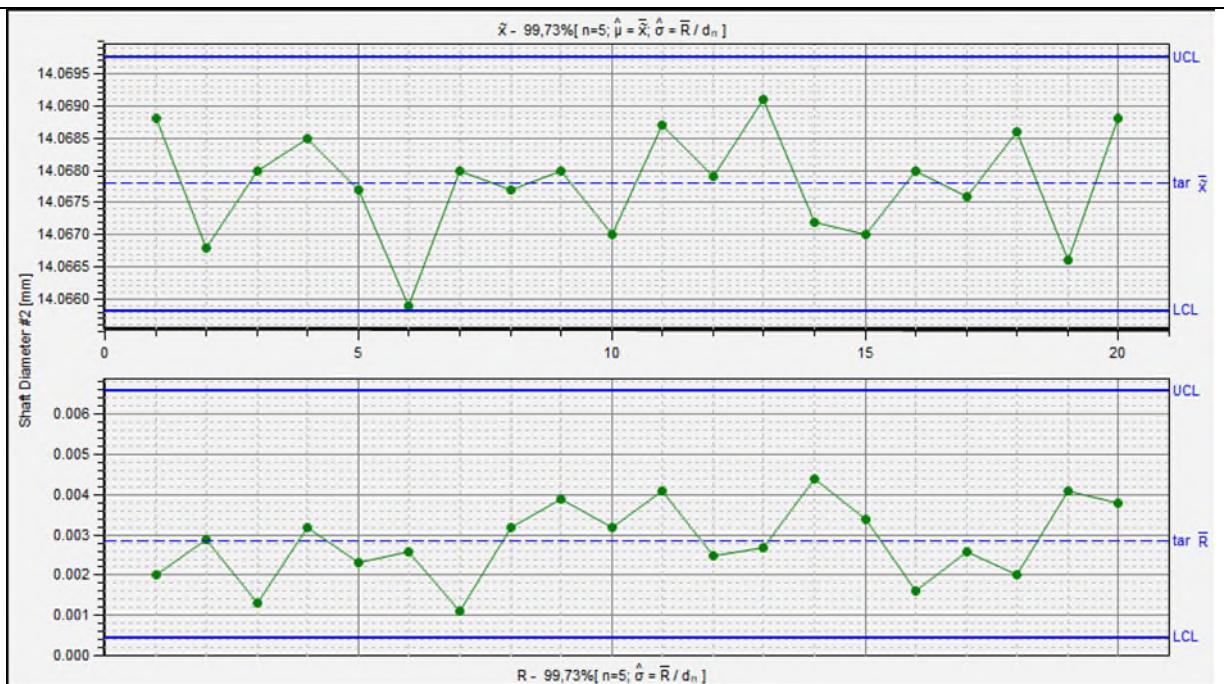


Figure 10-8:  $\bar{x}/R$ -Chart for Subgroup Size  $n = 5$  and Estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \frac{\bar{R}}{d_n}$

UCL — Upper control limit

LCL — Lower control limit

tar — Center Line CL (target)

$\bar{x}/R$ -chart for subgroup size  $n = 5$  and estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \frac{\bar{R}}{d_n}$ .

Variation chart calculated on exact formula for  $\chi^2$ -distribution.

Based on the same raw data as Figure 10-6.

#### Selection of formulas

#### Process location chart

##### Overall formula (control limits)

$$UCL_{\mu} = \hat{\mu} + u_{1-\alpha/2} \cdot \frac{1}{\sqrt{n}} \cdot c_n \cdot \hat{\sigma}$$

$$LCL_{\mu} = \hat{\mu} - u_{1-\alpha/2} \cdot \frac{1}{\sqrt{n}} \cdot c_n \cdot \hat{\sigma}$$

Example:

If using estimators

$$\hat{\mu} = \bar{x}$$

Explanation of the formulas (including estimators)

UCL — upper control limit

LCL — lower control limit

$\bar{x}$  — the overall average of all subgroup averages

$\bar{R}$  — the average range of the subgroups

$\hat{\mu}$  — estimator for process location

$\hat{\sigma}$  — estimator for process standard variation

<b>Subgroup Size (<math>n</math>)</b>	$c_n$ $= \sigma_{\bar{x}}/\sigma_x$	$d_2$
---	--	-------

<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>2</td><td>1.000</td><td>1.128</td></tr> <tr><td>3</td><td>1.160</td><td>1.693</td></tr> <tr><td>4</td><td>1.092</td><td>2.059</td></tr> <tr><td>5</td><td>1.198</td><td>2.326</td></tr> <tr><td>6</td><td>1.136</td><td>2.534</td></tr> <tr><td>7</td><td>1.214</td><td>2.704</td></tr> <tr><td>8</td><td>1.159</td><td>2.847</td></tr> <tr><td>9</td><td>1.223</td><td>2.970</td></tr> <tr><td>10</td><td>1.175</td><td>3.078</td></tr> </table> $\hat{\sigma} = \frac{\bar{R}}{d_2}$ <p>the formulas are</p> $UCL_{\mu} = \bar{x} + u_{1-\alpha/2} \cdot \frac{c_n}{\sqrt{n}} \cdot \frac{\bar{R}}{d_2}$ $LCL_{\mu} = \bar{x} - u_{1-\alpha/2} \cdot \frac{c_n}{\sqrt{n}} \cdot \frac{\bar{R}}{d_2}$	2	1.000	1.128	3	1.160	1.693	4	1.092	2.059	5	1.198	2.326	6	1.136	2.534	7	1.214	2.704	8	1.159	2.847	9	1.223	2.970	10	1.175	3.078	<p><math>n</math> – subgroup size</p> <p><math>\alpha</math> – probability [%] for false alarm – part of distribution outside control limits</p> <p><math>u_{1-\alpha/2}</math> – one sided sigma range for upper and lower control limits depending on defined <math>\alpha</math> – risk</p> <p><math>c_n</math> – ratio of standard deviations of median and average <math>c_n = \sigma_{\bar{x}}/\sigma_x</math></p> <p>Example</p> <p><math>\bar{x}</math> – average of sample averages</p> <p><math>\bar{R}</math> – Average subgroup range</p> <p><math>d_2 (= d_n)</math> – expected value of the standardized distribution of range <math>E\left(\frac{R}{\sigma}\right)</math>, depending on <math>n</math>.</p> <p>Note:</p> <p>In literature, the parameters</p> $u_{1-\alpha/2} \cdot c_n \cdot \frac{1}{\sqrt{n}} \cdot \frac{1}{d_2}$ <p>are often summarized in tables with different designations (e.g., <math>A_2</math>). When using these tables, it must be ensured that the tables consider the desired non-interference probability.</p>
2	1.000	1.128																										
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10	1.175	3.078																										
<p>Variation chart</p>	<p>Overall formula (control limits) See 10.3.3.3 Average and range</p> <p>Explanation of the formulas (including estimators) See 10.3.3.3 Average and range</p>																											
<p>Overall formula (control limits) See 10.3.3.3 Average and range</p>	<p>Explanation of the formulas (including estimators) See 10.3.3.3 Average and range</p>																											

### **10.3.3.5     *Individuals and Moving Range***

Individual value ( $x$ ) and moving range ( $R_m$ ) (also known as I-MR Chart)

Description of the control chart

If it is not possible or not practical to take samples for process control, it is advisable to use moving sample characteristics to monitor the momentary variation. This moving variation chart is often combined with a single value chart for the process location, whereby moving location parameters are also possible.

The moving characteristic value is calculated over at least two consecutive observations. Larger moving samples are possible, which reduces the randomness of the scattering characteristics but also increases the averaging period.

Individual value ( $x$ ) charts react less sensitively to process changes than mean ( $\bar{x}$ ) and median ( $\tilde{x}$ ) charts. The average run length is greater for the same non-intervention probabilities (see Chapter 10.2.4.1 Operation characteristics) and therefore changes are recognized later on average.

After a violation of a control limit or a planned intervention in the production process (e.g., tool change), a moving control chart shows further control limit violations despite the process having already been corrected, as the causal observation is still used to calculate the moving sample characteristics. To avoid triggering another action limit violation, the calculation of the moving sample characteristics must be restarted.

As with the first start, this results in a “blindspot” of timing with the moving control chart of  $n - 1$  samples with a moving sample size of  $n$ . This can be prevented by incrementally adjusting the sample size  $n$  from  $n = 2$  to the desired sample size each time the control chart is restarted. The control limit is recalculated for each incrementally new sample size. Due to the computational effort involved, the use of software to calculate the control limits is recommended. Details on moving control charts can be found in ISO 7870-5 Control charts - Part 5: Specialized control charts.

Application examples for this control chart

- Destructive, time-consuming and/or expensive testing
- Sampling large, highly homogenized batches (Chemical industry, fluids, powder) 100% testing, where rational subgroups are not possible
- Processes known as highly stable and capable

### Visualization of the control chart, including description

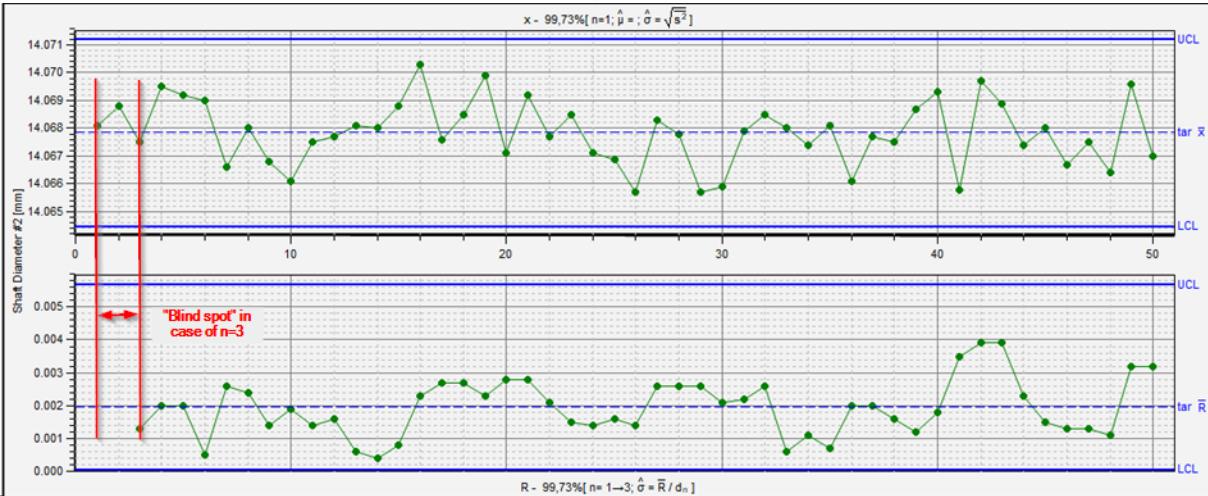


Figure 10-9:  $x/R$ -Chart for Subgroup Size  $n = 1 \rightarrow 3$  and Estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \frac{\bar{R}}{d_n}$

Individuals and moving range charts can be presented in different ways. On the one hand the  $x/R$ -chart for subgroup size  $n = 1 \rightarrow 3$  and estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \frac{\bar{R}}{d_n}$ . Variation chart calculated on exact formula for  $\chi^2$ -distribution. Based on the same raw data as Figure 10-6.

In case of 100% inspection and process control with control charts, it may also make sense to use a moving average as a location chart. This evaluates the change in position more sensitive, as the random variation of the individual values is reduced by averaging.

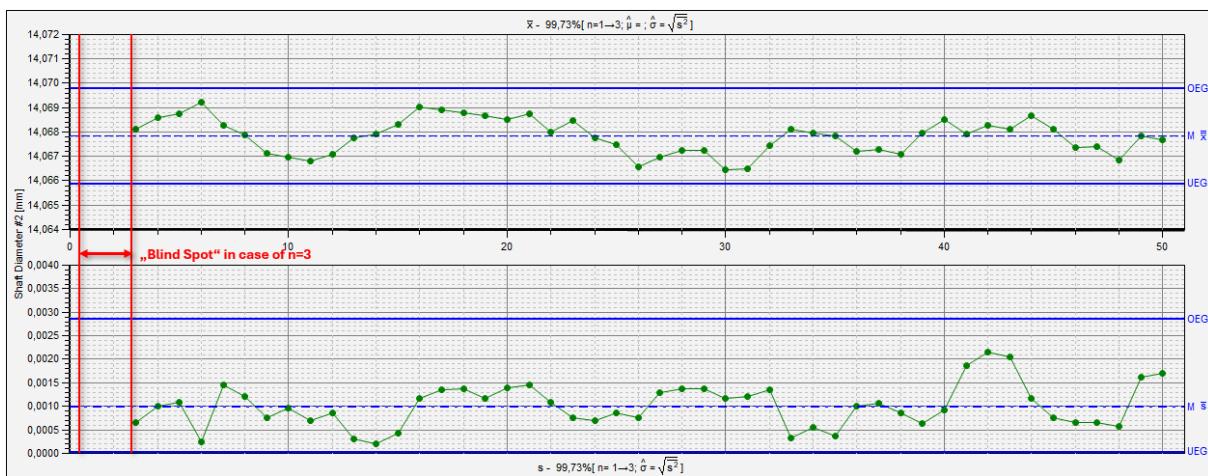


Figure 10-10:  $x /R$ -Chart for Subgroup Size  $n = 1 \rightarrow 3$  and Estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \sqrt{s^2}$

In the following example, the control limits are calculated from start with incrementing sample size from  $n = 1$  to the defined moving sample size of  $n = 3$ .

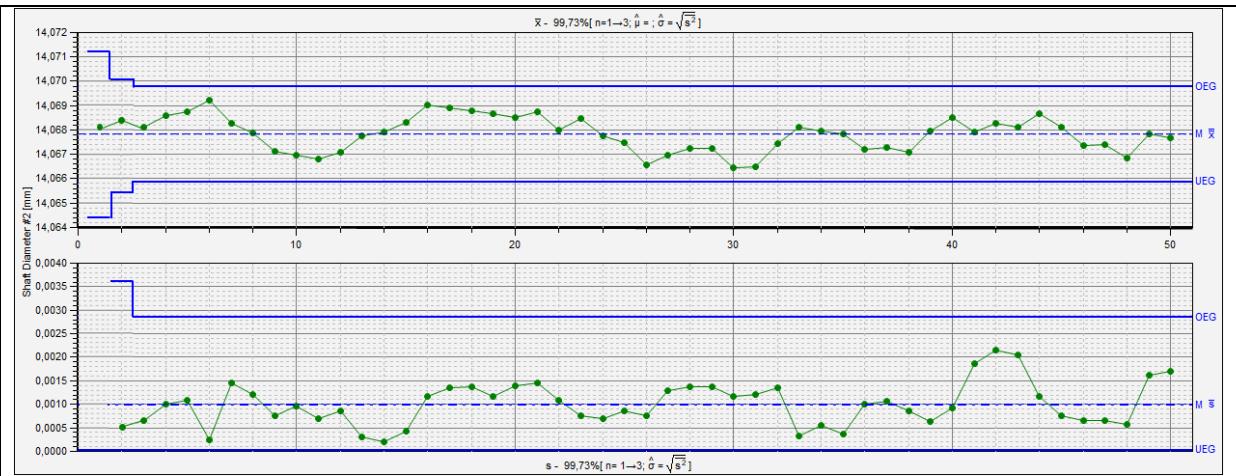


Figure 10-11:  $\bar{x}$  /  $R$ -Chart for Subgroup Size  $n = 1 \rightarrow 3$  and Estimators  $\hat{\mu} = \bar{x}$  and  $\hat{\sigma} = \sqrt{\bar{s}^2}$   
Adjusted Control Limits for the First Samples

UCL – Upper control limit

LCL – Lower control limit

tar – Center Line CL (target)

#### Process location chart

Overall formula (control limits)

$$UCL = \hat{\mu} + u_{\frac{(1-\sqrt{1-\alpha})}{2}} \cdot \hat{\sigma}$$

$$CL = \hat{\mu}$$

$$LCL = \hat{\mu} - u_{\frac{(1-\sqrt{1-\alpha})}{2}} \cdot \hat{\sigma}$$

Example:

If using estimators

$$\hat{\mu} = \bar{x}$$

$$\hat{\sigma} = \sqrt{\bar{s}^2}$$

the formulas are

$$UCL = \bar{x} + u_{\frac{(1-\sqrt{1-\alpha})}{2}} \cdot \sqrt{\bar{s}^2}$$

$$CL = \bar{x}$$

$$LCL = \bar{x} - u_{\frac{(1-\sqrt{1-\alpha})}{2}} \cdot \sqrt{\bar{s}^2}$$

Explanation of the formulas (including estimators)

$UCL$  – upper control limit

$LCL$  – lower control limit

$\hat{\mu}$  – estimator for process location

$\hat{\sigma}$  – estimator for process standard variation

$n$  – subgroup size

$\alpha$  – Probability of false alarm (non-interference probability  $1 - \alpha$ )

$u_{1-\alpha/2}$  – quantile of the standardized normal distribution (depending on defined  $\alpha$  – risk)

$\bar{x}$  – average of subgroup averages

$s$  – standard deviation of a subgroup

$\sqrt{\bar{s}^2}$  – Standard deviation calculated from square root of the average variance of the subgroups as estimator  $\hat{\sigma}$

## Variation chart

Overall formula (control limits)

See Chapter 10.3.3.3 Average and range using the moving range between current subgroup value and previous subgroup value

Explanation of the formulas (including estimators)

See Chapter 10.3.3.3 Average and range

## 10.3.4 Tolerance-Related Control Charts

As is explained in greater detail in Chapter 10.1, acceptance control charts are the only tolerance-related control charts covered in this volume.

### Acceptance control chart

For processes with system-related and accepted changes to the process location, the control limits can be defined about the tolerance in special cases. The prerequisite for this is a sufficiently small instantaneous within subgroup variation about the tolerance. It is usually expected that the within variation is less than 1/10 of the tolerance, i.e.,  $\hat{\sigma} \leq \frac{T}{10}$

When tolerance-related control limits are used, the process is generally less well controlled than when process-related control limits are used, as the aim is to comply with the tolerance specification and not to optimize the process (stabilization, centering).

A so-called delimitation factor  $k_A$  is used to calculate the control limits. The delimitation factor is defined in such a way that an exceedance percentage  $p = 1\%$  is detected with a probability of  $P_A = 99\%$ . That means, acceptance control charts are based on a defined maximum permissible fraction nonconforming  $p_0$ , which is not compatible with a zero defect strategy.

Application examples for this control chart

- Trend processes, e.g. tool wear (stamping process)
- Mechanical machining with step drill, boring tool, forming disk

Image of control chart including description

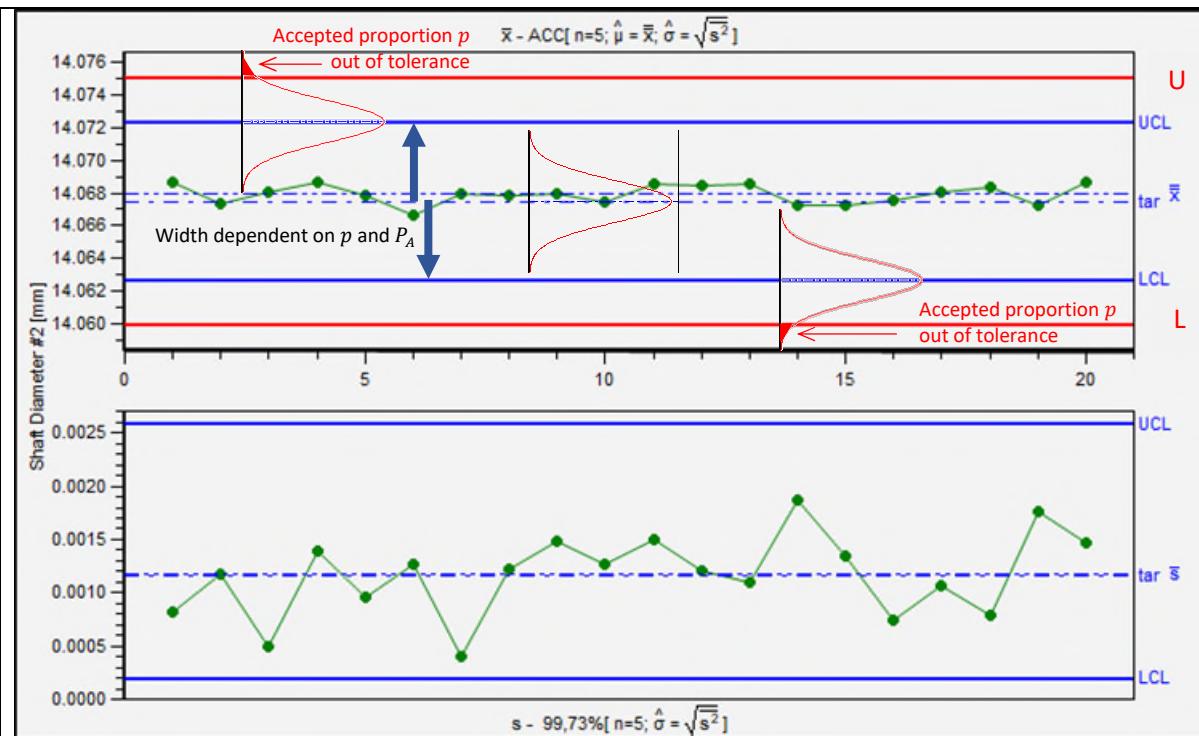


Figure 10-12: Acceptance Chart

UCL — Upper control limit

LCL — Lower control limit

tar — Center Line CL (target)

Based on same raw data as Figure 10-6.

### Formula symbol

#### Process location chart

##### Control limits

for  $\bar{x}$  chart

$$UCL = U - k_A \cdot \hat{\sigma}$$

$$LCL = L + k_A \cdot \hat{\sigma}$$

where

$$k_A = u_{1-p} + \frac{1}{\sqrt{n}} \cdot u_{P_A}$$

for  $\tilde{x}$  chart

$$UCL = U - k_C \cdot \hat{\sigma}$$

$$LCL = L + k_C \cdot \hat{\sigma}$$

where

$$k_C = u_{1-p} + c_n \frac{1}{\sqrt{n}} \cdot u_{P_A}$$

Explanation of the formulas (including estimators)

$p$ : Accepted proportion out of tolerance

$P_A$ : Probability of intervention (if accepted proportion out of tolerance is exceeded)

$n$ : Supgroup size

$\hat{\sigma}$ : Estimator for within subgroup variation

$$\hat{\sigma}_1 = \sqrt{\bar{s}^2} \text{ (preferred)}$$

$$\hat{\sigma}_2 = \frac{\bar{s}}{a_n}$$

$$\hat{\sigma}_3 = \frac{\bar{R}}{d_n}$$

<p>for <math>x</math> charts</p> $UCL = U - k_E \hat{\sigma}$ $LCL = L + k_E \hat{\sigma}$ <p>where</p> $k_E = u_{1-p} + u_{(n\sqrt{P_A})}$	<p><math>u</math>: Quantiles of the standard normal distribution</p>
<b>Variation chart</b>	
<p>The acceptance control chart is based on a process with stable variation. It is therefore advisable to monitor the variation in a suitable way.</p>	

### 10.3.5 Special Control Chart

#### 10.3.5.1 *Introduction*

There are several types of control charts that were not covered in the previous chapters. Most of these charts were developed for specific process situations or conditions which could compromise the optimum use of the standard control charts. A few of these special control charts are described below. The control charts are defined and explained, and it is specified when they should be used. The formulas associated with the control charts are also listed.

#### 10.3.5.2 *Pearson Control Chart*

##### **Pearson control chart**

Pearson control charts are process-related control charts for skewed process distribution (See Chapter 9.4-time dependent process model A2).

Even if it is possible to control a process with an  $\bar{x}/s$  chart for sufficiently large subgroups, a Pearson control chart can represent the skewness of a process and the resulting asymmetry more accurately. If individual/moving range charts are used instead of  $\bar{x}/s$  charts or if sample sizes  $n$  are smaller than 9, Pearson charts should always be preferred.

Pearson charts are calculated in the same way as Shewhart charts, whereby the percentiles calculated by Shewhart using the standardized normal distribution are replaced by the quantiles of appropriate skewed distributions. Originally, Pearson charts were calculated using standardized Pearson curves, which require an estimate of skewness and kurtosis in addition to the mean and standard deviation

of the data. The use of computer-aided techniques simplifies the determination of quantiles and allows the use of other unimodal distribution models.

### Application examples for this control chart

- Processes close to natural limits (e.g., Runout, flatness, straightness, ...)
- Processes that show asymmetry due to special control techniques (e.g., tolerance limits with different criticality, ...)

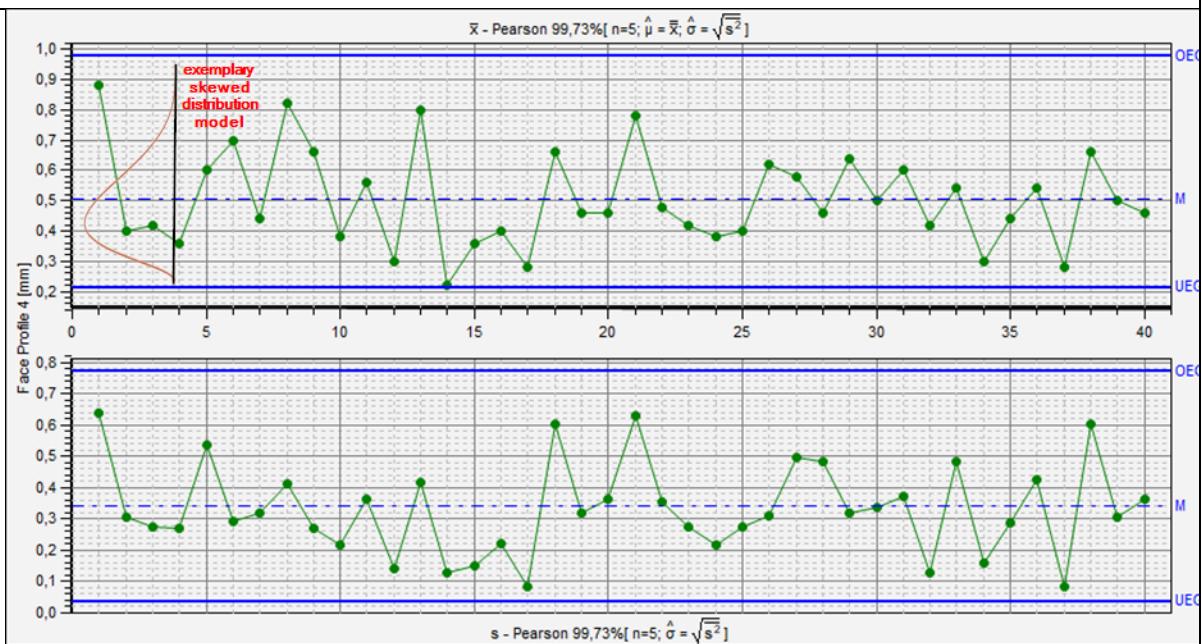


Figure 10-13: Pearson Chart

UCL – Upper control limit (same notation for mean and variation chart)

LCL – Lower control limit (same notation for mean and variation charts)

tar – Center Line CL (target)

### Collection of formulas

#### Process location chart

When the average (or individual) values do not follow a normal distribution and a suitable, continuous distribution is fitted to the data:

$$C_L = \bar{x}$$

$$UCL = X_{99.865\%}$$

$$LCL = X_{0.135\%}$$

When one of the distributions of the

$C_L$  – Center Line

$\bar{x}$  – arithmetic mean of subgroup averages (for  $n = 1$  average of individual values)

$UCL$  – Upper control limit

$X_{99.865\%}$  – 99.865%-quantile of distribution used to fit the data

$X_{0.135\%}$  – 0.135%-quantile of distribution used to fit the data

<p>Pearson family is chosen, the limits can be estimated by the approximation which goes back to Clements<sup>15</sup> and is lined out in ISO 7870-5 and ISO 22514-4:</p> $C_L = \bar{x}$ $UCL = \bar{x} + \hat{s}_{\bar{x}} \cdot P_{99.865\%}(\hat{\gamma}_1, \hat{\beta}_2)$ $LCL = \bar{x} - \hat{s}_{\bar{x}} \cdot P_{0.135\%}(\hat{\gamma}_1, \hat{\beta}_2)$	<p><math>LCL</math> — Lower control limit</p> <p><math>\hat{s}_{\bar{x}}</math> — Estimator of standard deviation of subgroup averages (for <math>n = 1</math> standard deviation of individual values)</p> <p><math>P_{x\%}(\hat{\gamma}_1, \hat{\beta}_2)</math> — <math>x</math> % quantile of the standardized Pearson distribution defined by the skewness and kurtosis estimators <math>\hat{\gamma}_1</math> and <math>\hat{\beta}_2</math> (see ISO 22514-4)</p>
<b>Variation chart</b>	
see Shewhart control chart or ISO 7870-2 and ISO 7870-5 for $n > 1$	

### 10.3.5.3 *Shewhart Control Chart with Extended Limits*

<b>Shewhart control chart with extended limits</b>
<p>Shewhart control charts with extended limits belong to the category of process-related control charts.</p> <p>Control via known control limits based on the Shewhart control chart becomes uneconomical in case of expected process-inherent changes of the mean value. In this case, the control limits are extended. For the calculation of the process level control limits, the fluctuation of the mean value is taken into account with another term. It follows that this control chart can be used for processes with distribution time models C1, C2, C3, B and D. For distribution time model C3, an acceptance control chart can also be used as an alternative.</p>
<p>Application examples for this control chart</p> <ul style="list-style-type: none"> <li>• Processes susceptible to trends (e.g., tool wear, environmental influences, ...)</li> <li>• Process levels are not constant (e.g., different production equipment, ...)</li> </ul>

<sup>15</sup> Clements J.A. Process capability calculations for non-normal distributions. Quality Process. 1989, 22 pp. 95–100

### Image of control chart including description

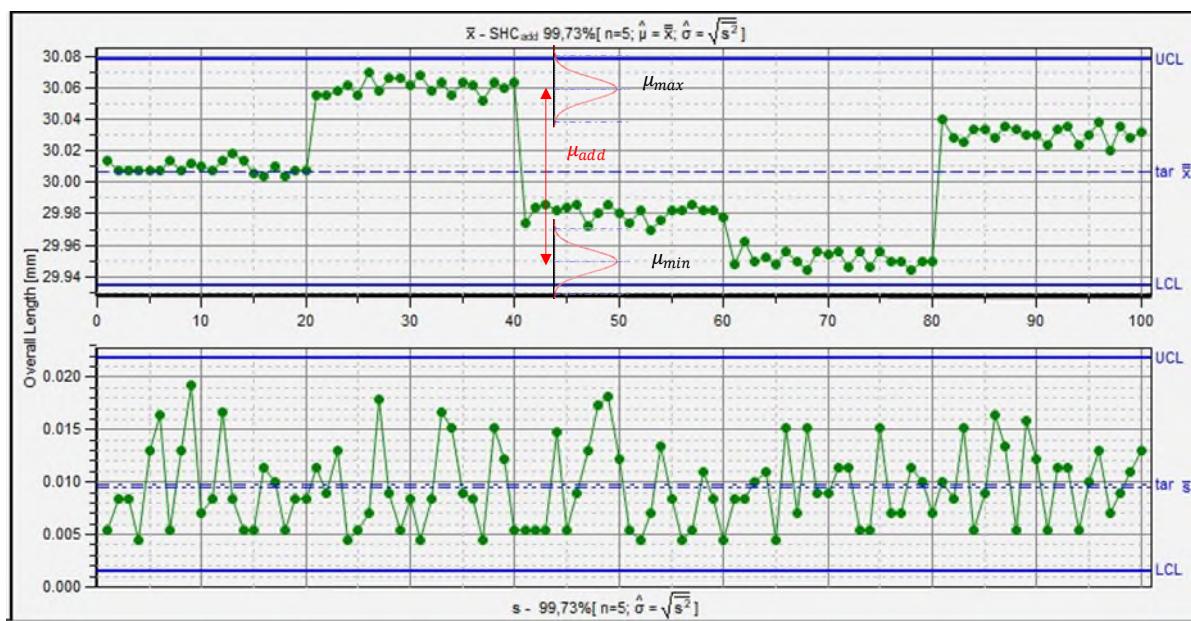


Figure 10-14: Extended Shewhart Chart

UCL — Upper control limit

LCL — Lower control limit

tar — Center Line CL (target)

$\mu_{add}$  — Additional shift or drift of the average

SHC\_add — Extended Shewhart chart

### Collection of formulas

#### Process location chart (central tendency, mean, median, mode, etc.)

Overall formula (control limits)  
based on  
estimated  $\hat{\mu}_{max}$  and  $\hat{\mu}_{min}$

$$UCL = \hat{\mu}_{max} + u_{in} \cdot \frac{1}{\sqrt{n}} \hat{\sigma}_{in}$$

$$LCL = \hat{\mu}_{min} - u_{in} \cdot \frac{1}{\sqrt{n}} \hat{\sigma}_{in}$$

based on  
estimated  $\hat{\sigma}_{out}$  using ANOVA

$$C_L = \hat{\mu}$$

Explanation of the formulas (including estimators)

UCL — upper control limit

LCL — lower control limit

$\hat{\mu}$  — estimator for process location

$\hat{\mu}_{max}$  — estimator for maximum process location

$\hat{\mu}_{min}$  — estimator for minimum process location

$\hat{\sigma}$  — estimator for process standard variation

$\hat{\sigma}_{in}$  — estimator for within standard variation (within subgroups)

$U_{CL} = \hat{\mu} + u_{in} \cdot \frac{1}{\sqrt{n}} \cdot \hat{\sigma}_{in} + u_{out} \cdot \hat{\sigma}_{out}$ $L_{CL} = \hat{\mu} - u_{in} \cdot \frac{1}{\sqrt{n}} \cdot \hat{\sigma}_{in} - u_{out} \cdot \hat{\sigma}_{out}$ <p>with</p> $u_{in} = u_{(1-\frac{\alpha_{in}}{2})}$ $u_{out} = u_{(1-\frac{\alpha_{out}}{2})}$ <p>Example based on estimated <math>\mu_{max}</math> and <math>\mu_{min}</math>:</p> <p>If using estimators</p> $\hat{\mu}_{max} = \bar{\bar{x}}_{max (3)}$ <p>(average of 3 largest <math>\bar{x}_i</math>)</p> $\hat{\mu}_{min} = \bar{\bar{x}}_{min (3)}$ <p>(average of 3 smallest <math>\bar{x}_i</math>)</p> $\hat{\sigma}_{in} = \sqrt{\bar{s}^2}$ <p>the formulas are</p> $UCL = \bar{\bar{x}}_{max (3)} + u_{in} \cdot \frac{1}{\sqrt{n}} \sqrt{\bar{s}^2}$ $LCL = \bar{\bar{x}}_{min (3)} - u_{in} \cdot \frac{1}{\sqrt{n}} \sqrt{\bar{s}^2}$ <p>Example based on estimated <math>\sigma_{out}</math> using ANOVA</p> <p>If using estimators</p> $\hat{\mu} = \bar{\bar{x}}$ $\hat{\sigma}_{in} = \sqrt{\bar{s}^2}$ $\hat{\sigma}_{out} = \sqrt{s_A^2} = s_A$ <p>the formulas are</p>	<p><math>\hat{\sigma}_{out}</math> — estimator for outer standard variation (between subgroups)</p> <p><math>n</math> — subgroup size</p> <p><math>u_{1-\alpha/2}</math> — quantile of the standardized normal distribution (depending on defined <math>\alpha</math> – risk)</p> <p><math>u_{in}</math> — quantile of the standardized normal distribution referring to within standard variation</p> <p><math>u_{out}</math> — quantile of the standardized normal distribution referring to outer standard variation</p> <p><math>\alpha_{in}</math> — alpha error probability referring to within standard variation</p> <p><math>\alpha_{out}</math> — alpha error probability referring to between standard variation</p> <p><math>\bar{\bar{x}}</math> — average of subgroup averages</p> <p><math>s</math> — standard deviation of a subgroup</p> <p><math>\sqrt{\bar{s}^2}</math> — Standard deviation calculated from square root of the average variance of the subgroups as estimator <math>\hat{\sigma}</math></p> <p><math>s_A^2</math> — variance between subgroups from analysis of variance (ANOVA)</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>• <math>u_{out} = 1.5</math> is a frequently used empirical value for application of extended Shewhart charts.</li> <li>• <math>u_{in}</math> is usually equated with the non-intervention probability that the company typically uses for Shewhart charts.</li> </ul>
---	--

$C_L = \bar{\bar{x}}$ $U_{CL} = \bar{\bar{x}} + u_{in} \cdot \frac{1}{\sqrt{n}} \cdot \sqrt{s^2} + u_{out} \cdot s_A$ $L_{CL} = \bar{\bar{x}} - u_{in} \cdot \frac{1}{\sqrt{n}} \cdot \sqrt{s^2} - u_{out} \cdot s_A$	
<b>Variation chart</b>	
see Shewhart control chart	

#### 10.3.5.4 CUSUM Control Chart (Refer to ISO Standard 7870-4 for Graphics)

<p>CUSUM cumulative sum chart</p> <p>Description of the control chart</p> <p>CUSUM charts display the cumulative sum of the difference between the sample values and the target value. CUSUM charts are sensitive to small changes in the mean value. The values should show random variation around zero. A falling straight line signals a decreasing mean value, while a rising straight line shows an increasing mean value. If the points are outside of the control limits, the process is considered unstable.</p> <p>The times of process changes, potential trends or process patterns can be read quickly and precisely from the CUSUM chart. A key prerequisite for the use of CUSUM charts is a generally stable process variation, i.e., the process variation must be in a statistically stable condition.</p> <p>Evaluation of the intervention decisions:</p> <p>The main evaluation of the decision aids is done by means of the ARL. The ARL is the number of samples taken before an actual process change is detected. The ARL is shown in the form of a table as a function of the shift in the process mean as follows:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">Shift in process mean from target value (in units of <math>\sigma_e</math>)</th><th style="text-align: center;">CUSUM</th></tr> </thead> <tbody> <tr> <td style="text-align: center;">0.0</td><td style="text-align: center;">370.4</td></tr> <tr> <td style="text-align: center;">0.2</td><td style="text-align: center;">163.6</td></tr> <tr> <td style="text-align: center;">0.4</td><td style="text-align: center;">54.5</td></tr> <tr> <td style="text-align: center;">0.6</td><td style="text-align: center;">24.6</td></tr> </tbody> </table>	Shift in process mean from target value (in units of $\sigma_e$ )	CUSUM	0.0	370.4	0.2	163.6	0.4	54.5	0.6	24.6	
Shift in process mean from target value (in units of $\sigma_e$ )	CUSUM										
0.0	370.4										
0.2	163.6										
0.4	54.5										
0.6	24.6										

0.8	14.4
1.0	9.9
1.2	7.5
1.4	6.1
1.6	5.1
1.8	4.4
2.0	3.9
2.2	3.5
2.4	3.1
2.6	2.9
2.8	2.7
3.0	2.5

Intervention decisions:

### CUSUM table

This is not a classic visualization by means of a control chart but a mathematical evaluation. Instead of a visual representation of the CUSUM values (current measured value - target value), the values are calculated:

current measured value - (*target value*  $\pm$   $f\sigma$ ).

This results in horizontal decision lines:  $\pm h\sigma$

CUSUM tables are also explained in ISO 7870-4.

Application:

1) Definition of the CUSUM parameters

Determination of a decision interval  $h$ , an intervention line  $f$ , definition of the target value and the determination of the process variation

2) Calculation of the CUSUM criteria:  $(T \pm f\sigma)$

3) CUSUM table:

Sample number

Measured value

Measured value -  $(T \pm f\sigma)$

CUSUM (upper/lower) [*measured value* -  $(T \pm f\sigma)$ ]

## V-mask CUSUM

These charts use a V-mask instead of control limits to determine whether a situation has arisen that is out of control. For further details regarding the V-mask chart, please refer to ISO 7870-4.

V-mask: Detects changes to the predicted curve profile

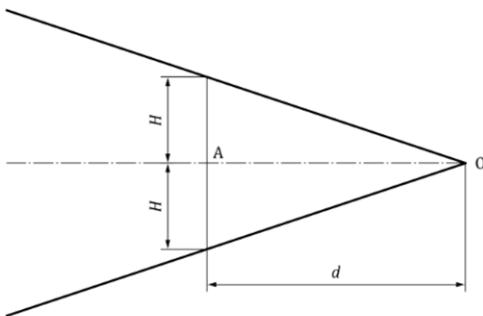


Figure 10-15: V-mask for CUSUM chart

A: Current CUSUM value

H: Decision interval: e.g.  $3\sigma$

d: Distance to vertex

O: Vertex

Examples of application for this control chart:

Chemical processes in which even small fluctuations in concentrations can have significant effects

Visualization of the control chart, including description

Comparison between Shewhart and CUSUM chart

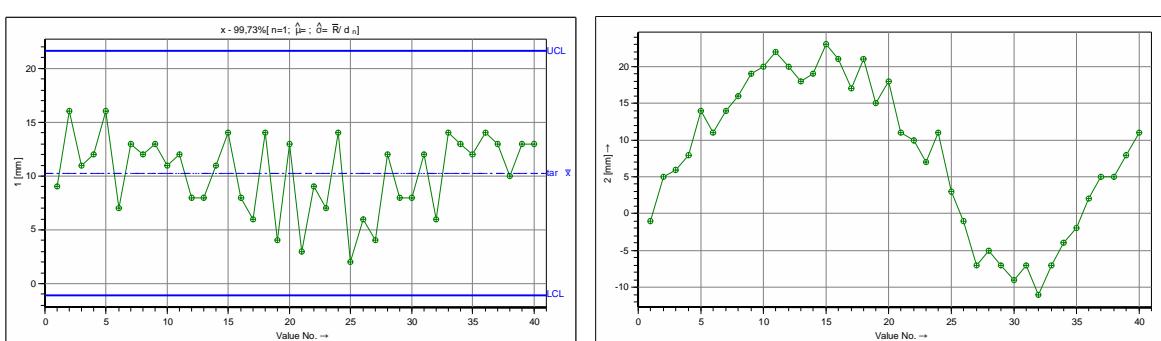


Figure 10-16: Comparison between Shewhart and CUSUM Chart

Example of a V-mask:

- a) No significant change in process mean with respect to CUSUM target value

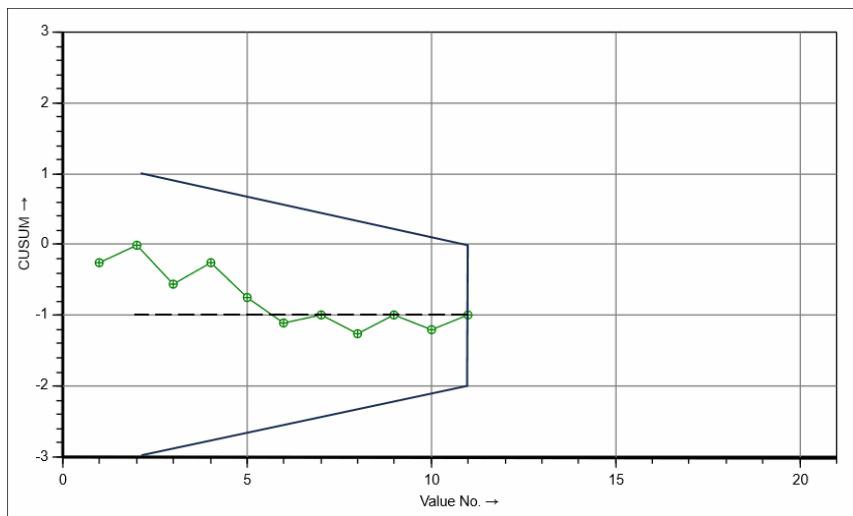


Figure 10-17: V-Mask Example a) No Significant Change in Process Mean

- b) significant increase in process mean with respect to CUSUM target value

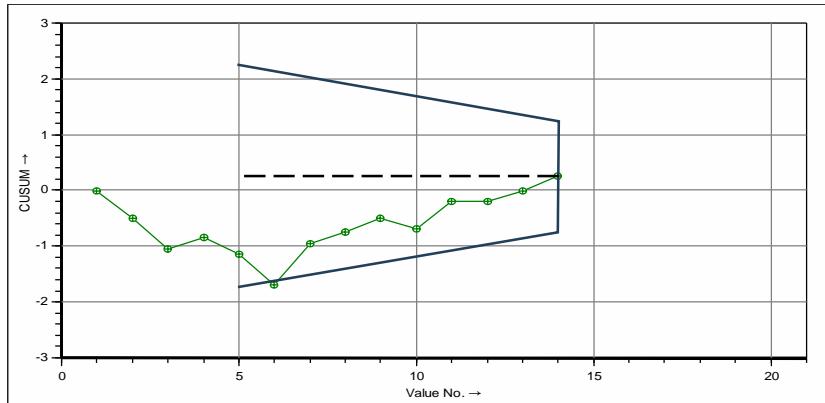


Figure 10-18: V-Mask Example b) Significant Increase in Process Mean

Legend (formula symbols)

*target value T*

value for which a departure from an average level is required to be detected

*representative out of control value*

(tabulated CUSUM) value which controls the sensitivity of the procedure

Note: The upper out of control value is  $T + f\sigma_e$  for monitoring an upward shift.

The lower control value is  $T - f\sigma_e$  for monitoring a downward shift.

<p><b>CUSUM:</b> cumulated sums (measured value - target value) <math>F, f</math></p> <p>(tabulated CUSUM) difference between the <i>target value</i> and the <i>representative out of control value</i></p> <p><i>decision interval</i> <math>H, h</math></p> <p>(tabulated CUSUM) cumulative sum of deviations from a <i>representative out of control value</i> required to yield a signal</p> <p><math>H = X * \sigma</math></p> <p><i>average run length ARL</i></p> <p>average number of samples taken up to the point at which a signal occurs</p>	
<p>Process location chart (central tendency, mean, median, mode, etc)</p>	
<p>Center line</p> <p>For the standard CUSUM-chart the center line is 0</p> $CL = 0$ $LCL = -h \frac{\sigma}{\sqrt{m}}$ $UCL = h \frac{\sigma}{\sqrt{m}}$ <p>Presented points</p> <p>The data entered in a CUSUM chart are <math>CU_i, CO_i</math></p> <p>Value of a lower tabular CUSUM at time <math>i</math></p> $CU_i = \min \{0, CU_{i-1} + \bar{x}_i \left( T - k \frac{\sigma}{\sqrt{m}} \right)\}$	<p>Explanation of the formulas (including estimators)</p> <p><math>\bar{x}_i</math> mean value of the subgroup</p> <p><math>T</math> target value</p> <p><math>k</math> size of the shift to be detected</p> <p><math>\sigma</math> standard deviation of the process</p> <p><math>m</math> subgroup size</p> <p><math>f</math> FIR</p> <p><math>h</math> decision interval</p>
Variation chart	
not applicable	not applicable

### 10.3.5.5 EWMA Control Chart

#### Exponentially Weighted Moving Average (EWMA) chart

This chart is used to calculate and visualize the exponentially weighted moving average of all prior sample means. EWMA weights samples in exponentially decreasing order, meaning that the most recent samples are weighted most highly while the most distant samples are weighted the least. How much they are weighted is determined by the parameter  $\lambda$ .

In general, EWMA charts are used to detect small shifts in the process mean. However, they are slower when it comes to detecting large shifts. When using EWMA charts, it is therefore recommended to use a Shewhart chart at the same time in order to detect both small and large shifts in the mean.

For more detailed information, please refer to ISO 7870-6 or specialist literature.

#### Examples of application for this control chart

Products are deliberately produced close to the specification limit so that very small changes are detected.

#### Visualization of the control chart, including description

(Figure including legend)

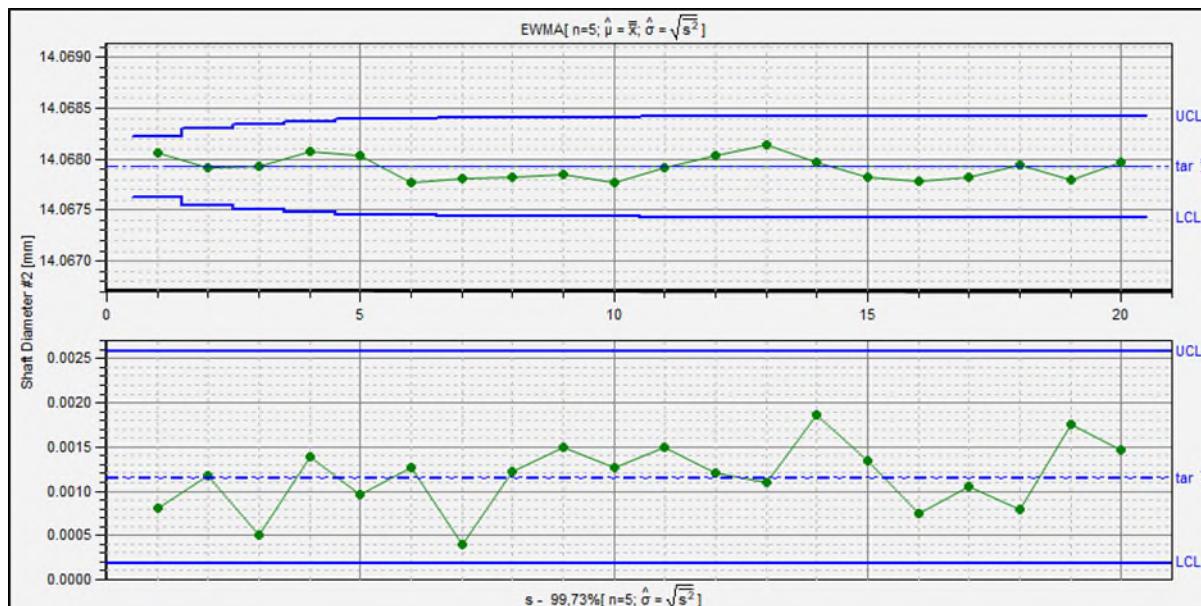


Figure 10-19: EWMA-Chart

#### Selection of formulas

UCL — Upper control limit value for the EWMA control chart

LCL — Lower control limit value for the EWMA control chart. If LCL is negative, then it is taken as zero

tar – Center Line CL of the control chart	
Process location chart (central tendency, mean, median, mode, etc)	
see ISO 7870-6	see ISO 7870-6
Variation chart	
Not applicable.	Not applicable.

### 10.3.6 Attribute Control Chart for Discrete Characteristics

#### 10.3.6.1 *Introduction*

Shewhart charts belong to the category of process-related charts. There are two different subtypes: variable control charts and attribute control charts for discrete characteristics.

The charts for discrete characteristics are based on the existence and detection of “nonconforming units” / “proportions of nonconforming units” (np / p-charts) or the “number of nonconformities per unit” / “proportion of nonconformities per unit” (u / c-chart). Therefore, a certain number of nonconformities must be allowed from the start. In contrast to the charts for continuous characteristics, they do not warn against negative process changes if a certain number of nonconformities has not already occurred. In practice, attribute control charts can not be used within the scope of a zero-defect strategy.

The binomial distribution is suitable for determining the control limits for “nonconforming units”, while the Poisson distribution is used for the “number of nonconformities per unit”. Under certain conditions ( $n * \hat{p} * (1 - \hat{p}) \geq 9$ ), both can be approximated using a normal distribution. However, direct calculation is preferable, given today's typical use of software.

#### 10.3.6.2 *Proportion of Nonconforming (p Chart)*

Number of nonconforming units p
Description  The “p”-chart is used if the number of nonconforming units is monitored in the form of a proportion of nonconformities (number of nonconformities/sample size). Multiple types of nonconformities are also counted as one nonconformity of a unit. The sample size should be above 50 to detect even small changes in process

quality. Fluctuations of the sample size should be avoided as they can make it necessary to recalculate the control limits. In case of fluctuations below 25%, no recalculation is necessary.

The control limits are determined based on the random variation range of the binomial distribution. The approximation of the control limits using the normal distribution is only valid under certain conditions and should be avoided, given today's typical use of software. If the lower control limit is very small or negative due to inaccuracies in the calculations, it can be neglected. If the control limits are rounded, the change to the probability of non-intervention must be taken into account.

#### Application examples for this control chart

- Incoming goods are evaluated using a gage (e.g., size of a drilled hole go/no go gage)
- Visual comparison with boundary samples (e.g. gloss level of an individual part)

#### Visualization of the control chart

##### p-chart with constant sample size

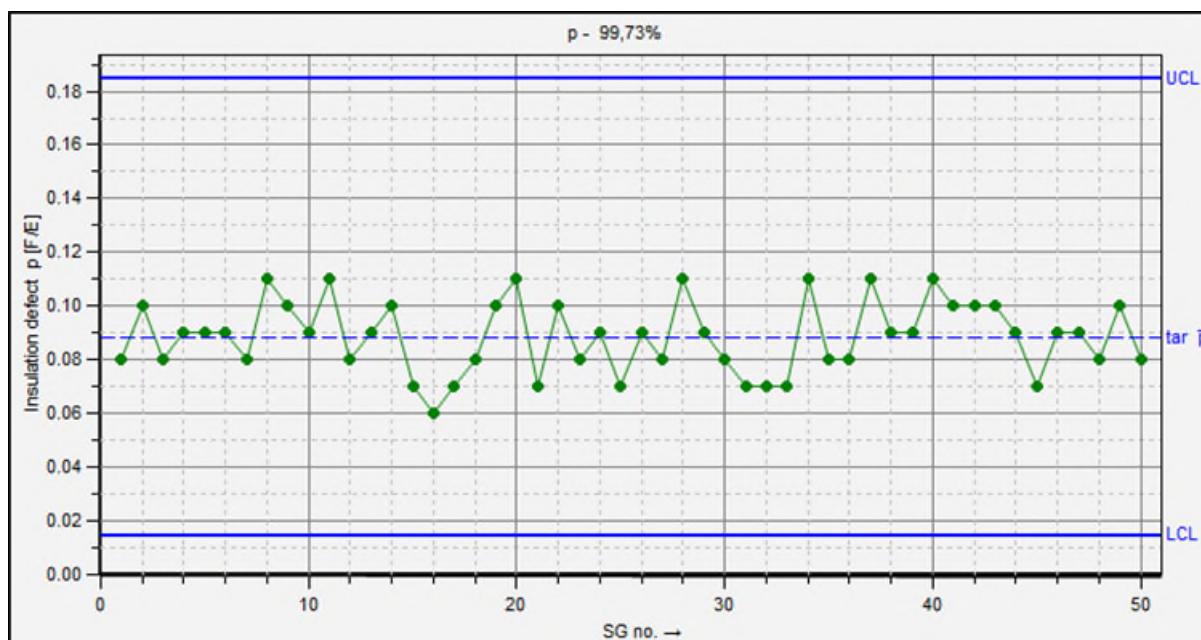


Figure 10-20: p-Chart for the Proportion of Nonconforming Units, Sample Size Constant

Sample size constant  $n = 100$  (e.g. fixed sample size drawn from production)

##### p-chart with non-constant sample size

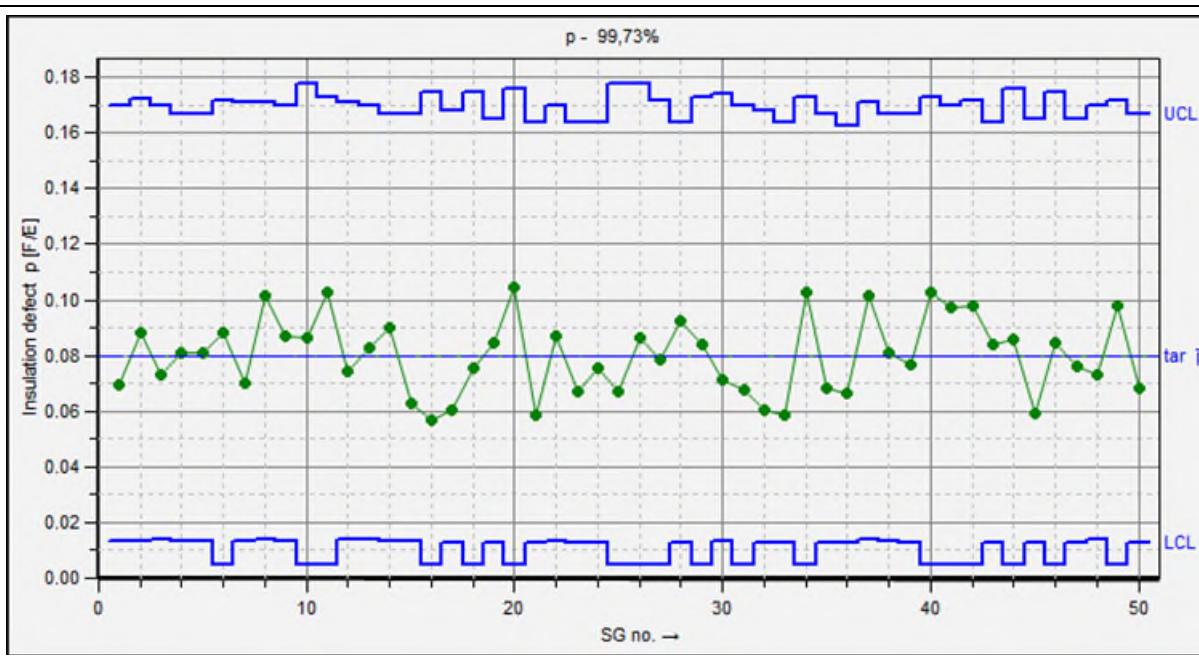


Figure 10-21: *p*-Chart for the Proportion of Nonconforming Units, Sample Size Not Constant

Sample size not constant  $102 \leq n \leq 120$  (e.g. daily output)

Note: Same amount of detected errors (raw data) as above (Figure 10-20)

Legend:

UCL — Upper control limit

LCL — Lower control limit

tar — Center line (target)

SG no. — Number of sample group

#### Process level chart

Proportion of nonconformities in a sample

$$p_i = \frac{x_i}{n_i}$$

with

$x_i$  = Number of nonconforming parts in the ith sample (sample number i)

$n_i$  = sample size of the ith sample (sample number i)

Average proportion of nonconforming units

$$\bar{p} = \frac{x_1 + x_2 + \dots + x_k}{n_1 + n_2 + \dots + n_k}$$

with

$x_i$  = Number of nonconforming parts in the ith sample (sample number i)

$n_i$  = sample size of the ith sample (sample number i)

	$k$ = Number of samples
Control limits $G(x_{un}; n, p) \leq \alpha/2$ $G(x_{ob}; n, p) \leq 1 - \alpha/2$	Random variation range of the binomial distribution with $P = 95\%$ or $99\%$ , with software, tables or nomogram
Variation chart	
Not applicable	

#### 10.3.6.3 **Number of Nonconforming (*np* Chart)**

Number of nonconforming units <i>np</i>
Description The “np”-chart is used if the nonconforming units are counted directly. Multiple types of nonconformities are also counted as one nonconformity of a unit. The sample size should be above 50 to detect even small changes in process quality. Fluctuations of the sample size should be avoided as they can make it necessary to recalculate the control limits. In case of fluctuations below 25%, no recalculation is necessary. The control limits are determined based on the random variation range of the binomial distribution. The approximation of the control limits using the normal distribution is only valid under certain conditions and should be avoided, given today's typical use of software. If the lower control limit is very small or negative due to inaccuracies in the calculations, it can be neglected. If the control limits are rounded, the change to the probability of non-intervention must be taken into account.
Application examples for this control chart <ul style="list-style-type: none"><li>• Incoming goods are evaluated using a gage (e.g., size of a drilled hole go/no go gage)</li><li>• Visual comparison with boundary samples (e.g. gloss level of an individual part)</li></ul>
Visualization of the control chart

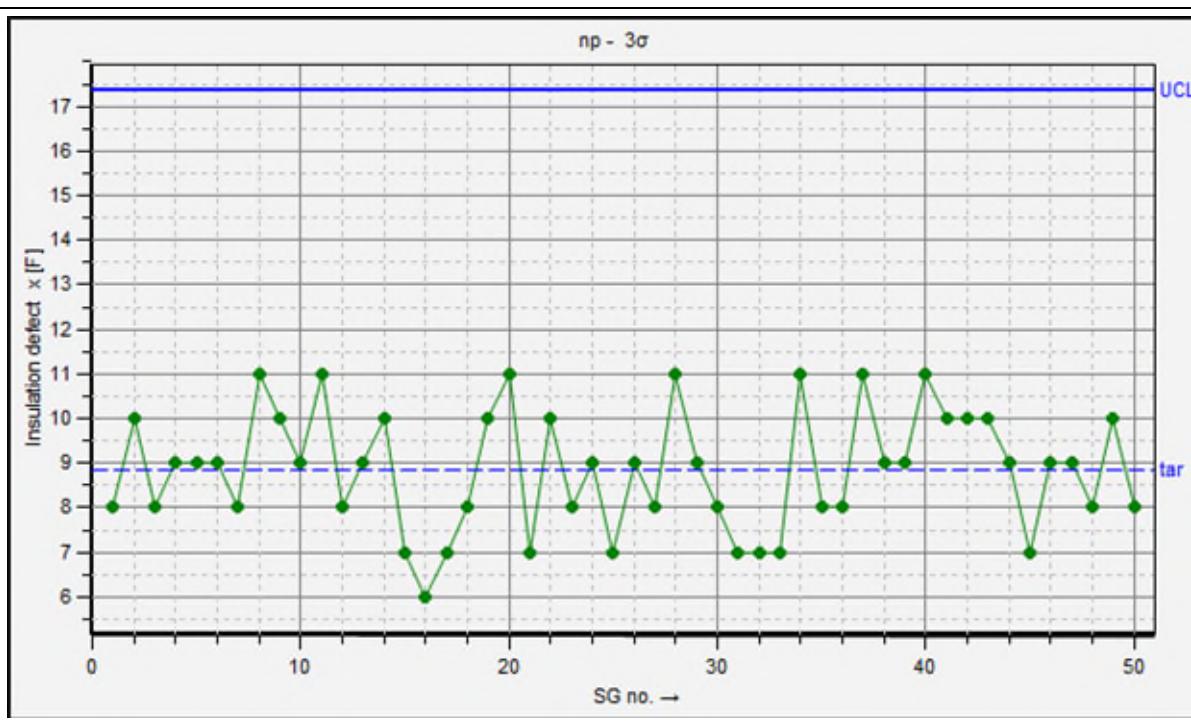


Figure 10-22: np-Chart for Number of Nonconforming Units

Same raw data as in . Due to the approximation of a normal distribution, LCL  $\leq 0$  and improvements cannot be detected by LCL.

Legend:

UCL — Upper control limit

LCL — Lower control limit

tar — Center line (target)

SG no. — Number of sample group

#### Process level chart

Number of nonconforming units $x_i$	with $x_i$ = Number of nonconforming parts in the ith sample
Average proportion of nonconforming units $\hat{p} = \frac{\sum_{i=1}^k x_i}{\sum_{i=1}^k n_i}$	with $x_i$ = Number of nonconforming parts in the ith sample $n_i$ = sample size of the ith sample $k$ = Number of samples

Process mean	with $M = \bar{n} * \hat{p}$ $n_i$ = mean sample size
Control limits	with $UCL = n * \hat{p} + u_{1-\frac{\alpha}{2}} * \sqrt{n\hat{p} * (1 - \hat{p})}$ $LCL = n * \hat{p} - u_{1-\frac{\alpha}{2}} * \sqrt{n\hat{p} * (1 - \hat{p})}$ $n$ = sample size $\alpha$ = probability of type 1 error (probability of error) $u$ = standardized variable for normal distribution
Variation chart	
Not applicable	

#### 10.3.6.4 Number of Nonconformities per Unit (*u* Chart)

<b>Number of nonconformities per unit <i>u</i></b>
Description of control chart The <i>u</i> -chart is used if the number of nonconformities per unit is monitored by means of the proportion of nonconformities (number of nonconformities/unit). The unit can be a component, a fixed number of components or a constant quantity of material. Multiple types of nonconformities are also counted as one nonconformity of a unit. The sample size should be above 50 to detect even small changes in process quality. Fluctuations of the sample size should be avoided as they can make it necessary to recalculate the control limits. In case of fluctuations below 25%, no recalculation is necessary. The control limits are determined based on the random variation range of the Poisson distribution. The approximation of the control limits using the normal distribution is only valid under certain conditions and should be avoided, given today's typical use of software. If the lower control limit is very small or negative due to inaccuracies in the calculations, it can be neglected. If the control limits are rounded, the change to the probability of non-intervention must be taken into account.
Application examples for this control chart

- Nonconformities distributed across a more or less continuous production flow (e.g., bubbles in glass)
- Nonconformities of many different types => inspection chart (e.g., one or more nonconformities at a repair station)

### Visualization of the control chart

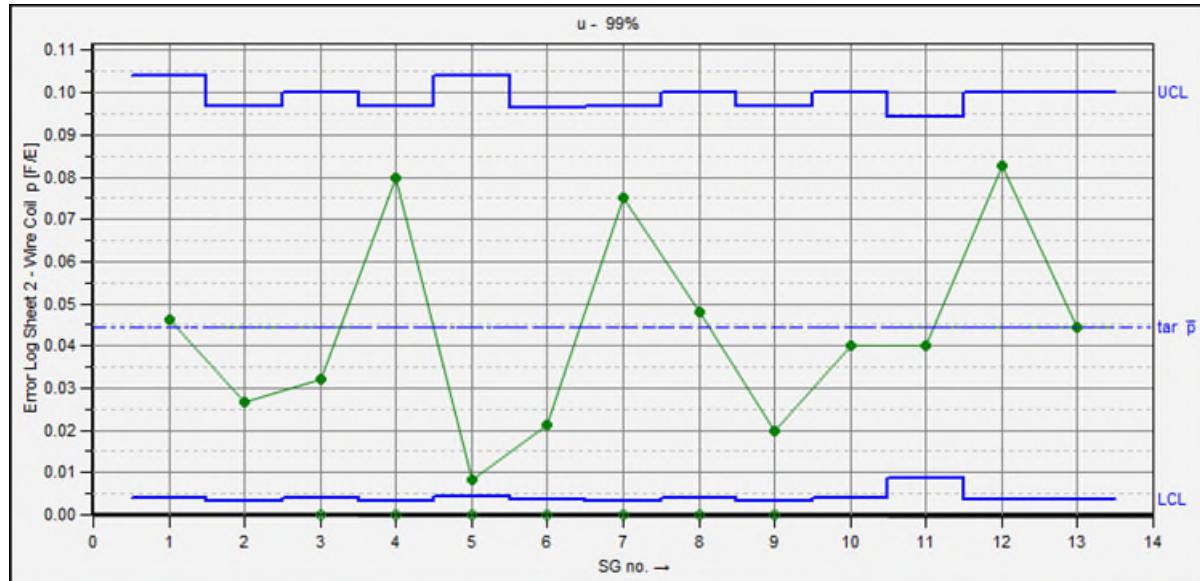


Figure 10-23: u-Chart for the Proportion of Nonconformities per Unit Based on Poisson Distribution

Error Log Sheet for non-constant number of units and 6 different error types in sum calculated based on Poisson distribution

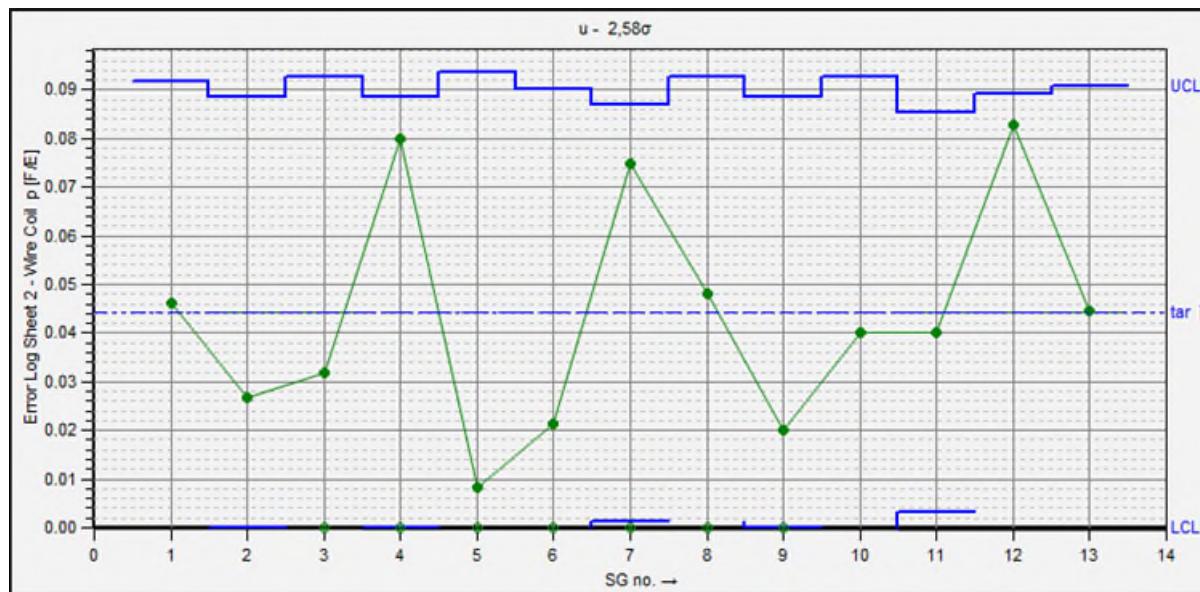


Figure 10-24: u-Chart for the Proportion of Nonconformities per Unit Based on Normal Distribution

Error Log Sheet for non-constant number of units and 6 different error types in sum

calculated based on approximated normal distribution. Same raw data as in Figure 10-18	
<b>Legend:</b> UCL – Upper control limit LCL – Lower control limit tar – Center line (target) SG no. – Number of sample group	
<b>Process level chart</b>	
Average proportion of nonconforming units $\bar{x}(F) = \frac{x_1+x_2 + \dots + x_k}{n_1+n_2 + \dots + n_k}$	with $x_i$ = Number of nonconforming parts per unit in the $i$ th sample $n_i$ = sample size of the $i$ th sample $k$ = Number of samples
mean sample size $\bar{n} = \frac{1}{k} * \sum_{i=1}^k n_i$	with $n_i$ = sample size of the $i$ th sample $k$ = Number of samples
Control limits $UCL = \bar{x}(F) \pm u_{1-\frac{\alpha}{2}} * \sqrt{\frac{\bar{x}(F)}{\bar{n}}}$ $LCL = \bar{x}(F) - u_{\frac{\alpha}{2}} * \sqrt{\frac{\bar{x}(F)}{\bar{n}}}$	with $\alpha$ = probability of type 1 error ( $\alpha$ = probability of error) $u$ = standardized variable for normal distribution
<b>Variation chart</b>	
Not applicable	

### 10.3.6.5 Number of Nonconformities (c Chart)

<b>Number of nonconformities c</b>
Description of control chart

The “c”-chart is used if the number of nonconformities per unit is monitored directly. The unit can be a component, a fixed number of components or a constant quantity of material. Multiple types of nonconformities are also counted as one nonconformity of a unit.

The sample size should be above 50 to detect even small changes in process quality. Fluctuations of the sample size should be avoided, as they can make it necessary to recalculate the control limits. In case of fluctuations below 25%, no recalculation is necessary.

The control limits are determined based on the random variation range of the Poisson distribution. The approximation of the control limits using the normal distribution is only valid under certain conditions and should be avoided, given today's typical use of software. If the lower control limit is very small or negative due to inaccuracies in the calculations, it can be neglected. If the control limits are rounded, the change to the probability of non-intervention must be taken into account.

#### Application examples for this control chart

- Nonconformities distributed across a more or less continuous production flow (e.g., bubbles in glass)
- Nonconformities of many different types => inspection chart (e.g., one or more nonconformities at a repair station)

#### Visualization of the control chart

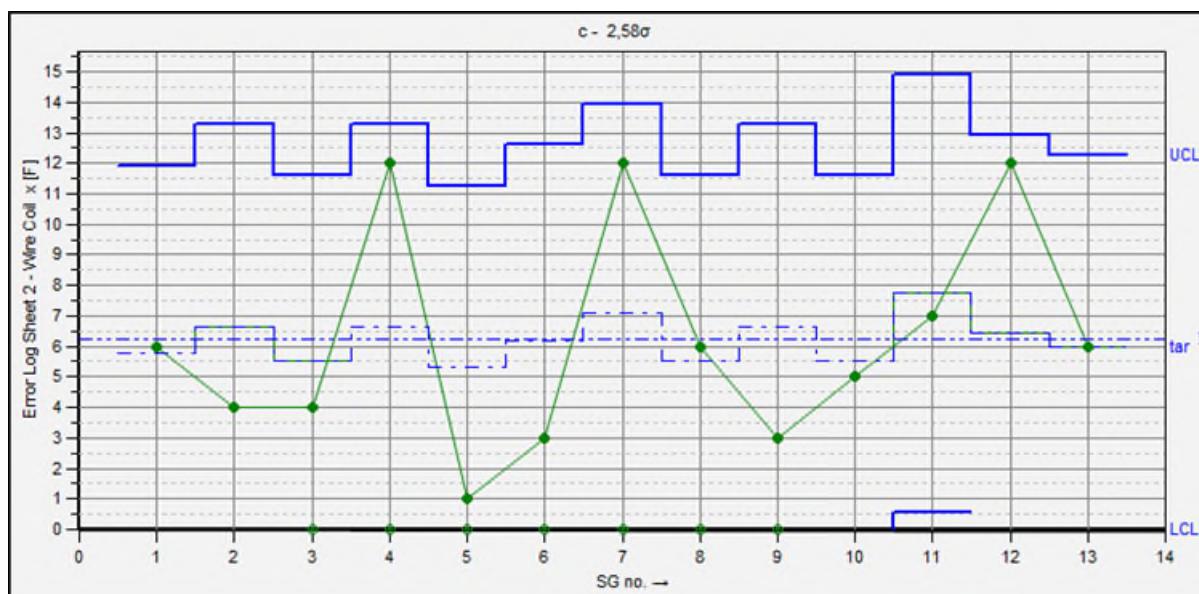


Figure 10-25: c-Chart for Number (Counts) of Nonconformities per Unit

c-chart for Error Log Sheet for non-constant number of units and 6 different error types in sum calculated based on approximated normal distribution (same raw data

as in the u-chart).

Legend:

UCL – Upper control limit

LCL – Lower control limit

tar – Center line (target)

SG no. – Number of sample group

#### Process location chart

Number of nonconformities

$x_i$

with

$x_i$  = Number of nonconformities in the ith sample

Average proportion of nonconforming

$$\mu = \frac{\sum_{i=1}^k x_i}{k}$$

with

$x_i$  = Number of nonconforming parts in the ith sample

$k$  = Number of samples

Control limits

$$UCL = \mu \pm u_{1-\frac{\alpha}{2}} * \sqrt{\mu}$$

with

$\alpha$  = probability of type 1 error  
(probability of error)

$u$  = standardized variable for normal distribution

#### Variation chart

Not applicable

## 10.4 Reporting of Ongoing Performance and Capability

In the previous chapters, the concepts of machine performance, preliminary process performance, process capability and stability were introduced, and it was explained how the relevant studies are carried out.

The following logic was first described in Chapter 7:

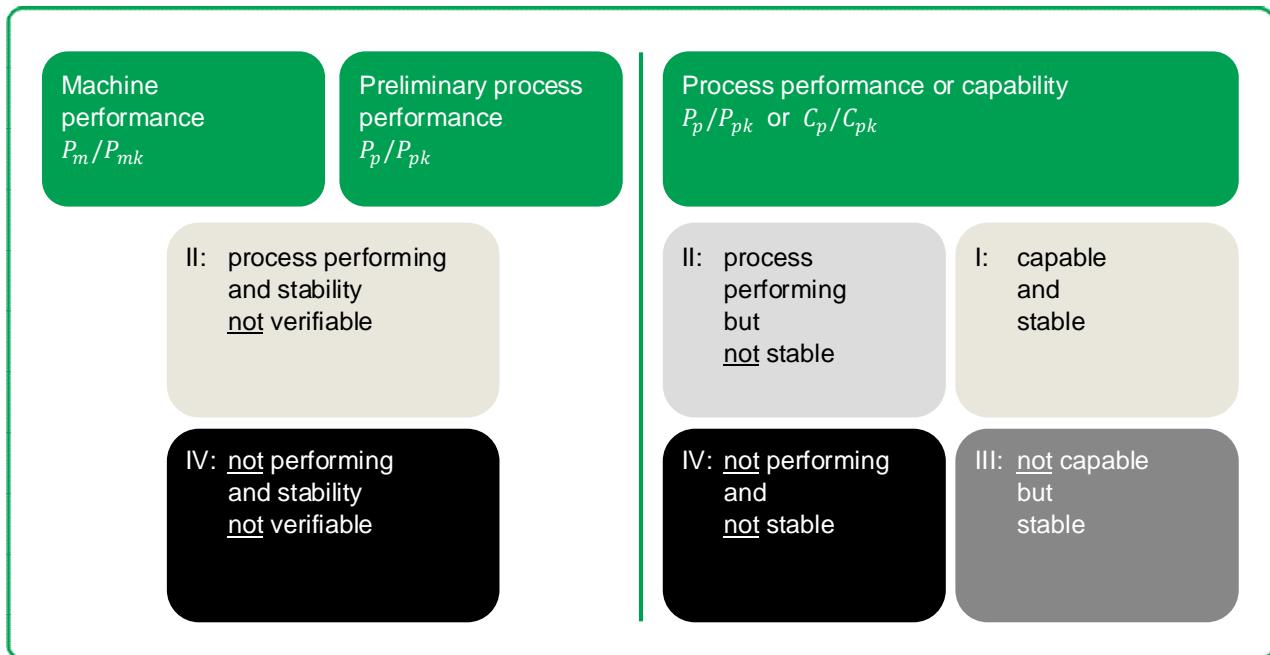


Figure 10-26: 4-Quadrant Matrix

Figure 10-26 illustrates the difference between process performance and process capability. Stability (as per the criteria outlined in Chapter 10.2.2) determines whether the indices shown are called “performance”  $P_p/P_{pk}$  oder “capability”  $C_p/C_{pk}$  indices. Stability can only be assessed after enough observations have been gathered (see right column in Figure 10-26). This means stability cannot be judged by machine performance or preliminary process performance (see left and middle column in Figure 10-26).

In the right column (process performance or capability), processes are assessed using the indices and categorized into quadrants accordingly. Processes found in quadrants II and IV are deemed unstable, as they fail to meet the designated stability criteria. Additionally, processes in the quadrants IV and III (lower quadrants) do not achieve the necessary process capability index. Only those in quadrant I (top right) fulfill both stability and capability requirements. The processes located in the other three quadrants demand additional measures based on their specific properties.

For better comprehension of the process and to initiate process optimizations, it is important to not only assess the process once but to continuously evaluate the process performance and capability. Even processes that are continuously monitored can be assigned to one of the four quadrants in order to derive measures more effectively. This evaluation and assignment forms the basis of regular reporting. The contractual partners are responsible for the definition of the form and scope of

reporting, and the control loops provide orientation in this regard.

The first reporting level can for example be on the shopfloor. Within the planning process, the sample frequency is defined based on the risk, the process itself and the quality criteria of the control chart. The index with the data from the samples can be recalculated using the analysis control chart. The calculation is typically done for a rolling time period.

For continuous process monitoring, the control limits, the sample frequency and the sample size (among other things) must be verified on the basis of the increasing amount of data.

The correctness of the defined control limits is determined by evaluating how the variation has changed over time. If the limits are too narrow, over-regulation can increase process variation. If the limits are too far apart, the probability of intervention decreases, and thus the potential for process improvements decreases as well. Centerline and control limits should be recalculated when special causes for instability cannot be identified (i.e., actual additional common cause variation), or if the process changes expectedly.

In developing a Control Chart, the design should align with the specific needs and flow of the process it supports, rather than forcing the process to adapt to the chart. Detection mechanisms on the chart must include monitoring for occurrences of violations in control limits, whether more or fewer than statistically expected (see Chapter 7.4). It is important to select adequate sample frequencies and samples sizes according to current process knowledge in order to control the process effectively. There is no universally valid formula in order to determine the optimum sample frequency and sample size, as this depends on various factors such as the type of process, the size of the sample, the available experience, process maturity and the desired accuracy.

Two important considerations to determine sampling frequency and sample size are rational sampling and rational subgrouping. Rational sampling considers how the process distribution can change so data is taken in an appropriate rate to find signal changes in a timely manner. Sampling frequency is related to the rate at which the process can change. Samples taken too far apart will miss signals while samples taken too close can lead to autocorrelation in the data and false signals. Rational subgrouping means that subgroups are chosen so that special causes happen between the subgroup and not within.

A higher sample frequency can contribute to detecting smaller deviations in the process but can also lead to higher costs. A lower sample frequency can mean that larger deviations in the process remain undetected. The effectiveness of the sampling strategy can be determined with the help of the ARL and/or OC Curve. (see Chapter 10.2.4 Quality criteria).

If frequent location changes (this can include both gradual or rapid shifts) are to be expected in a process (in case of low variation), a lower sample size and high frequency are advisable. If non-frequent variation changes are to be expected (in

case of constant location), a higher sample size and lower frequency are advisable.

Depending on the changes to these factors (sample size and frequency, control limits), it can make sense to select another type of control chart.

The database grows with each sample. Older values only play a minor role when it comes to monitoring a process. The length of the rolling time period for calculating the process performance/capability indexes and the control limits should be adjusted appropriately. The number of parts produced, the changes to environmental influences, set-up times etc. must be taken into account. In case of continuous production, for example, the calculation should not be based on samples that are older than a few months. In case of sporadic production, an appropriate number of samples may only be reached after a period of several months. These considerations are part of the evaluation with the analysis chart (see Chapter 10.2.1).

Within the scope of reporting, new insights can be gained regarding the quality assurance concept over a longer period of time. These insights provide the basis for continuous improvement at the organizational level. For example, they may result in changes to control loops, responsibilities or the control and assurance concept itself. Besides the implementation of SPC for further characteristics or a revision of the SPC approach (i.e. implementation of 100% inspection if capability is not given), this can also mean that SPC is reduced to minimum effort for individual characteristics (i.e., minimal sample size, frequency, ...).

To determine the right SPC approach, the process behavior over time should be considered. The different time-dependent distribution models can be used for guidance. Following ISO 22514-2 processes can be classified into 4 main groups of 8 different time-dependent distribution models (see Chapter 9.4). These four groups can be considered as different risk levels.

1. Model A is an almost stable process. A1 is normally distributed, A2 non-normal distributed. A small sample size and, depending on the temporal behaviour of the influencing factors, a low sampling frequency is sufficient.
2. Model B is a process in which the location is constant, but the variation is not. This time-dependent process model is difficult to control, as the variation cannot be easily readjusted. To control a variating variation usually a higher sample size is recommended. Depending on the temporal behaviour of the influencing factors, a low sampling frequency is sufficient
3. Model C shows a constant variation over time, but a variable location. ISO 22514-2 shows 4 different ways how location may vary. If the parts come from a machine tool, for example, this process can be easily adapted. In the case of mould nests, for example, adaptation is only possible by reworking the moulds. Since the variation is assumed to be constant, a small sample size is sufficient. Depending on the temporal behaviour of the influencing factors, a higher sampling frequency is recommended.
4. Model D shows non-constant location and variation. In this case, both a larger sample size and a higher sampling frequency are recommended.

The following table shows an example of control chart selection and sample size/frequency:

*Table 10-2: Example of Control Chart Selection and Sample Size/Frequency*

Model	A1	A2	B	C	D
Analysis chart	Shewhart	Pearson	Pearson	Extended Shewhart	Extended Shewhart
SPC chart	Shewhart	Pearson	Shewhart	Acceptance	Acceptance
Sample size*	smaller	smaller	bigger	smaller	bigger
Sample frequency*	lower	lower	lower	higher	higher

\* Explicit numbers can be calculated according to the methods mentioned above

Aside from these examples, also other control charts may be used. For example, it may be possible to identify and isolate sources of variation that may result in multimodal distributions or autocorrelated data behavior. A deeper process understanding can lead to other control methods based on the observed data.

## 10.5 Special Cases

Besides the already listed control charts, there are further approaches to process control. For example, this includes the “Part Average Analysis” (PAA) as well as AI applications. PAA is mainly used in the area of semiconductor production. Using artificial intelligence, it is possible to apply models to detect anomalies or patterns in large amounts of data.

For internal use, control concepts can be applied as desired beyond the agreed standards. If the concepts are used as an alternative to the standards agreed upon between the customer and the supplier, they must be coordinated between the respective contracting parties and released.

# 11 Application of Software

Quality control analysis software plays a critical role in managing and controlling processes to ensure that requirements are consistently met. To achieve this, several key practices apply:

- Suppliers must use validated analysis software for agreed-upon characteristics between customer and supplier.
- Validation means confirming, with objective evidence, that software meets requirements for its intended use; verification confirms specified requirements are fulfilled.
- Both verification and validation are required for analysis software in quality management.
- Exceptions are only possible if the customer has authorized it.

## 11.1 General Integration/Interfaces

To maximize effectiveness, analysis software should provide timely feedback to ensure that all relevant personnel are promptly informed of any deviations within the quality process. This proactive approach helps reduce waste and the shipment of defective products.

The main goal of the software is to continuously and automatically monitor processes, generating and distributing notifications whenever deviations occur.

Regular review and analysis of collected data is essential. When process requirements are not fulfilled, standardized notifications or reports should be generated and shared promptly to enable swift corrective actions.

Ideally, measurement and inspection results should be transferred automatically from the equipment to a database through an interface, rather than being entered manually. This automation greatly reduces the likelihood of data errors.

The ability to instantly visualize collected data — alongside historical data — enables early detection of trends and supports direct process control.

By setting custom alarm conditions (such as alerts when control limits are exceeded), data is monitored statistically in real time as it is captured. Incidents, actions and (if known) causes shall be documented, making it easier to analyze and understand deviations to drive continuous improvement

For instance, the OPC Unified Architecture (OPC UA) standard is known as a platform-independent, service-oriented architecture (SOA) for the networking of

machines.

Ideally, interfaces between data collection systems (measuring systems) and evaluation systems are standardized and validated. One example for a standardized interface format is provided by ISO/TR 11462-5.

Ideally, the SPC-related software and its interfaces are integrated in a Computer Aided Quality (CAQ) system.

In general, processes at the various process management levels outlined in this volume are supported by software solutions. It must be ensured that the connections between software components are thoroughly validated and, where feasible, automated, to mitigate the risk of errors arising from manual intervention.

## 11.2 Verification and Validation of Analysis Software

Section 7.1.5.2.1 of IATF 16949:2016, the automotive industry's quality management system standard, stipulates that all production-related software utilized for product and process control must undergo verification. This requirement, as further articulated in DIN EN ISO 9000:2015, is broadly applicable across industry and is considered essential for compliance.

To ensure conformity, it is imperative to ascertain the rationale for validating analysis software within the scope of quality management, to precisely define the term "validation" in this context, to distinguish it from "verification," and to identify the specific types of analysis software to which these requirements pertain.

To clarify the distinction between "validation" and "verification" as outlined in DIN EN ISO 9000:2015 and IATF 16949:2016:

### Validation (DIN EN ISO 9000:2015, section 3.8.13):

- Confirmation, through objective evidence, that requirements for a specific intended use or application have been fulfilled.
- Objective evidence for validation is typically obtained through testing.

### Verification (DIN EN ISO 9000:2015, section 3.8.12):

- Confirmation, through objective evidence, that specified requirements have been fulfilled.
- Objective evidence for verification is typically obtained through inspection.

Both verification and validation are mandatory for analysis software. Within the customer–supplier relationship, verification is regarded as a necessary condition,

while validation is considered sufficient to demonstrate the software's suitability for its intended purpose.

A comprehensive understanding of the parameters employed in analysis is indispensable. For instance, it is critical to discern whether a reported value is based on the arithmetic mean or the median, as misinterpretations may arise in the absence of such clarity.

The same principles apply to the validation of analysis software. When measured values are analyzed and results—such as process capability—are produced, it is essential to know the parameter settings used in the analysis. These parameters may include minimum sample size, methods for detecting and handling outliers, confidence intervals for estimates, estimator design, and calculations for one-sided tolerances. Without transparency regarding these parameters, the analysis software functions as a “black box,” making proper validation impossible. This requirement applies equally to both commercial and open-source software products.

In some cases, customers may have different agreed upon requirements for estimation of analysis results, therefore it is critical that the software selected can be easily configured to meet all customer specific requirements (i.e. by storing customer-specific sets of parameters).

SPC methods—such as estimating process capability indices or generating quality control charts for operator inspection—are generally based on specified product and process characteristics. These characteristic values are derived from measurement and inspection processes, as well as the systems and tasks defined for those processes.

To avoid misinterpretation, recorded characteristic values must accurately reflect reality; thus, measurement and inspection processes must be appropriate for their intended application. The analysis software used to demonstrate measurement and inspection process capability must also be verified, validated, and deemed “capable” (see Chapter 6.6).

To validate and verify analysis software, the software should be checked against predefined requirements. In practice, this involves evaluating the software with suitable test examples and confirming its accuracy by comparing the calculated results with documented reference results. It is critical that the individual responsible for validation is familiar with the organization’s methods and estimation procedures.

A range of test scenarios can be employed to demonstrate the effectiveness of analysis software. ISO/TR 11462-3 is commonly cited, as it specifies eleven distinct examples designed for software validation, incorporating criteria from the ISO 7870 series (control charts) and the ISO 22514 series (capability and performance). These examples were created to help software developers assess their systems. Each example includes relevant datasets, supporting information, and expected outcomes. The examples cover a range of scenarios including amongst others:

- Different sample and subgroup sizes, as well as the precision of calculations for both large and small numbers

- Visualization of data through histograms and probability plots
- Computation of sample statistics for both central tendency and variability
- Evaluation for a range of distribution models
- Determination of control limits for location and variation
- Identification of out-of-control situations

## 12 Documentation and Reporting

### 12.1 General Requirements

The ISO 22514 standard series requires that studies are well-documented, data is traceable, and results are presented in a clear, standardized format to support decision-making. The table below summarizes the core reporting requirements found throughout the series. While the specific standard must be consulted for a definitive list, typical reporting requirements for a process study generally include:

- **Process Identification:** Name of the process, machine, part, or characteristic being studied.
- **Specification Limits:** The upper (U) and lower (L) specification limits, target values, and specified tolerance.
- **Data Collection Conditions:** Detailed information on the conditions under which data were collected, including location, duration, frequency, input batches, operators, tools, environmental factors and non-standard conditions.
- **Measurement Process:** A description of the measurement process used, including its resolution, accuracy, repeatability, and reproducibility or measurement uncertainty (often supported by a separate capability of measurement process study/measurement system analysis (MSA) as referenced in ISO 22514-3 and ISO 22514-7).
- **Sample Information:** The total sample size (N) and, subgroup size (n) and number of subgroups (k).
- **Graphical Analysis:** Run/value chart of the data, histogram and probability plot.
- **Distribution Model:** The distribution used to model the data and the methods used to determine or verify it.
- **Stability Evaluation:** Documentation or demonstration that the process was in a state of statistical control or in-control (for capability indices) or an acknowledgment that it was not (for performance indices) represented on a (retrospective) control chart.
- **Sample Statistics:** Quantiles:  $X_{0,135\%}$ ,  $X_{50\%}$ ,  $X_{99,865\%}$ , confidence intervals (for normal distribution: mean and standard deviation).
- **Calculated Indices:** The actual calculated values of relevant indices (including calculation method), such as  $P_m/P_{mk}$ ,  $P_p/P_{pk}$ ,  $C_p/C_{pk}$  including G or Z extension.
- **Interpretation:** An assessment of the results in relation to the specified requirements, often including the expected proportion of nonconforming parts (parts per million or percentage, based on the selected distribution model).

## 12.2 Example Reports

To ensure clarity and consistency in reporting, it is recommended to establish a standardized format that aligns to ISO and specific customer requirements. The following key elements are expected to be included in a process capability report. This section provides examples of reporting formats for both normal and non-normal distribution process capability studies:

- **Figure 12-1:** Example Report for Process Capability (Normal Distribution)
- **Figure 12-2:** Example Report for Process Capability (Non-normal Distribution)
- **Figure 12-3:** Example Report for Process Capability (Non-normal Distribution)

Note: The reporting format and content included must be mutually agreed upon by both the customer and the supplier.

### List of possible reporting elements

1. Name of Process, Machine and location study was performed
2. Reference numbers associated with Process and Machine
3. People who performed the study and took the measurements
4. Time and duration of the data collection
5. Name and reference number for the part
6. Identified part characteristic & Specification Limits (units of measure)
7. Technical conditions under which the study was run (batches, operation, tools)
8. Deviations from defined stable operating conditions (environment, process settings, cycle time)
9. Number of values used for calculation
10. Frequency of sampling & subgroup size
11. Histogram of the data
12. A Run chart for qualitative assessment of data over time
13. Probability plot of the data
14. Control Chart for stability assessment
15. Estimated parameter for process location with calculation method
16. Estimated parameter for process variation with calculation method
17. Selected distribution model used for estimates
18. Performance / capability requirements / Calculation method
19. Calculated performance / capability indices, estimated % out of specification (with confidence intervals as required)

20. Conclusions & Recommendation, Corrective actions

**Other elements that may be included:**

21. Time dependent distribution model

22. Measurement uncertainty and guard bands for 100% inspections or conformity testing in case of out-of-control or out-of-specification situations.

**Title: SPC & Process Capability Study Report**  
**AIAG / VDA SPC harmonized standard**

1	Process Name: Process X	Machine Name: Tool A	Study Location: Company / Site A	
2	Process ID: Mfg. Process XYZ	Machine ID: Machine ABC	3 Operator Name: Quality Joe Smith	
4	Study Date: YEAR-MM-DD	Data collection time duration (Start / End): <i>Start: YEAR-MM-DD, 07.35.08, End: YEAR-MM-DD, 14.21.02</i>		
5	Part Name & ID: Widget A, ID: 123456	6 Characteristic Name & ID: Distance, ID=3	Characteristic Specification Limits LSL: 129.90 mm, USL: 130.25 mm	
7	Study Remarks: Process Capability Study, $\bar{x}$ /s chart, normal distribution			
8				
9	Sample Size = 875, Subgroup Size = 7, Sampling Strategy = Fixed			
11	Histogram	12	Raw Value Chart	
13	Probability Plot	14	$\bar{x}/s$ – Shewhart Chart: 99,73%, n = 7, $\hat{\mu} = \bar{x}$ , $\hat{\sigma} = \sqrt{s^2}$	
15	Process Location estimate $X_{50\%} = 130.0392$	16	Process variation estimate $X_{99,865\%} - X_{0,135\%} = 0.1956$	
17	Distribution Model <i>Normal Distribution</i>			
18	Performance / Capability Requirement: $C_{p,G} = 1.67$ , $C_{pk,G} = 1.33$ Calculation Method: Geometric Method			
19	Calculated Performance / Capability indices: $C_{p,G} = 1.79$ (95% CI: 1.71 to 1.87) $C_{pk,G} = 1.42$ (95% CI: 1.35 to 1.49)		Estimated percentage out of specification: $P > USL = 0.00000\%$ (0.0 PPM) $P < LSL = 0.00098\%$ (9.8 PPM)	
20	Conclusions / Recommendations / Corrective Actions: The $C_{p,G}$ , $C_{pk,G}$ requirements are met, process is demonstrated to be stable over time, no actions required, continue to monitor per plan			

Figure 12-1: Example Report with Fictional Data for Process Capability (Normal Distribution)

## **Summary of Key Report Observations, as illustrated in Figure 12-1**

- **Element 11:** Histogram indicates the data appears to be normally distributed but not centered within specification limits
- **Element 12:** Process location and variation appear to be consistent over time, no outliers, shifts or drifts observed
- **Element 13, 17:** Probability plot confirms the distribution selection, “Normal distribution” to be used for performance/capability estimates
- **Element 14:** Process is in a state of statistical control, stable over time (no points outside of control limits)
- **Element 18,19:** Performance/capability indices are calculated by the Geometric method, estimates are  $C_{p.G} = 1.79$ ,  $C_{pk.G} = 1.42$
- **Element 20:** Both  $C_{p.G}$  &  $C_{pk.G}$  indices meet the targets requirements, even at the lower bound of 95% confidence interval. Capability indices labeled “C” are used because the process study was sufficient to confirm stability over time, capturing the full scope of process variation across all 5M factors.

**Title: SPC & Process Capability Study Report**  
**AIAG / VDA SPC harmonized standard**

1	Process Name: Process X	Machine Name: Tool A	Study Location: Company / Site A	
2	Process ID: Mfg. Process XYZ	Machine ID: Machine ABC	3 Operator Name: Quality Joe Smith	
4	Study Date: YEAR-MM-DD	Data collection time duration (Start / End): <i>Start: YYYY-MM-DD, hh:mm:ss, End: YYYY-MM-DD, hh:mm:ss</i>		
5	Part Name & ID: Widget A, ID: 123456	6 Characteristic Name & ID: Distance, ID=3	Characteristic Specification Limits LSL: 29.860 mm, USL: 0.280 mm	
7	8 Study Remarks: Process Capability Study with fixed tooling change			
9	10 Sample Size = 500, Subgroup Size = 5, Sampling Strategy = Fixed			
11	Histogram	12 Raw Value Chart		
13	Probability Plot	14 $\bar{x}/s$ - Extended Shewhart Chart: 99% [ $n = 5, \bar{x} = \bar{x}, \hat{\sigma} = \sqrt{s^2}$ ]	 	
15	Process Location estimate $X_{50\%} = 30.0092$	16 Process variation estimate $X_{99.865\%} - X_{0.135\%} = 0.16188$	17 Distribution Model <i>Mixed Distribution</i>	
18	Performance / Capability Requirement: $C_{p,G} = 1.67, C_{pk,G} = 1.33$ Calculation Method: Geometric Method			
21	Time Dependent Distribution Model: C4	22 Exp. Measurement Uncertainty: 0.0211 Guard Band (95%): 0.0174		
19	Calculated Performance / Capability indices: $C_{p,G} = 1.73$ (95% CI: 1.62 to 1.84) $C_{pk,G} = 1.67$ (95% CI: 1.57 to 1.78)	Estimated percentage out of specification: P%> USL = 0.00000% (0.0 PPM) P%< LSL = 0.00000% (0.0 PPM)		
20	Conclusions / Recommendations / Corrective Actions: The $C_{p,G}, C_{pk,G}$ requirements are met, process is demonstrated to be in control, no actions required, continue to monitor per plan			

Figure 12-2: Example Report with Fictional Data for Process Capability (Non-Normal Distribution)

## Interpretation of the Report Elements

What can be identified in the sample report? :

1. The process location is not constant over time (12) due to fixed tooling and tool change (7)(8).
2. Variation seems to be constant over time (14).
3. There seem to be no outliers (12).
4. The process is not normally distributed (11).
5. A multimode distribution is appropriate (13), and a mixed distribution based on the EM-Method (Expectation-Maximization-Method) with up to 5 kernel is used (11)(17).
6. The assumed distribution is confirmed in the probability plot (13).
7. Therefore, we assume distribution time model C4 (21).
8. The calculated performance/capability is  $C_{p,G} = 1.73$  and  $C_{pk,G} = 1.67$  (19), calculated with general geometric (quantile) method (18).
9. Both indices exceed the target indices (18),  $C_{pk,G}$  even with a lower confidence limit (19) based on a 95% confidence interval.
10. The process shows no out-of-control situations in the control chart (14). The control chart is in this case an Extended Shewhart Chart.
11. Since the process is in control (14), the resulting indices are named  $C$  instead of  $P$  (19).
12. In case of an unexpected future out-of-control situation, the expanded uncertainty of the measurement system is 0.0211 mm, and the guard band is 0.0175 mm for 5% error probability (22).

Another example of a report of the same dataset as example 2 with additional information is shown in Figure 12-3. The table allows a direct comparison of the drawing data with the measured values and statistical results.:.

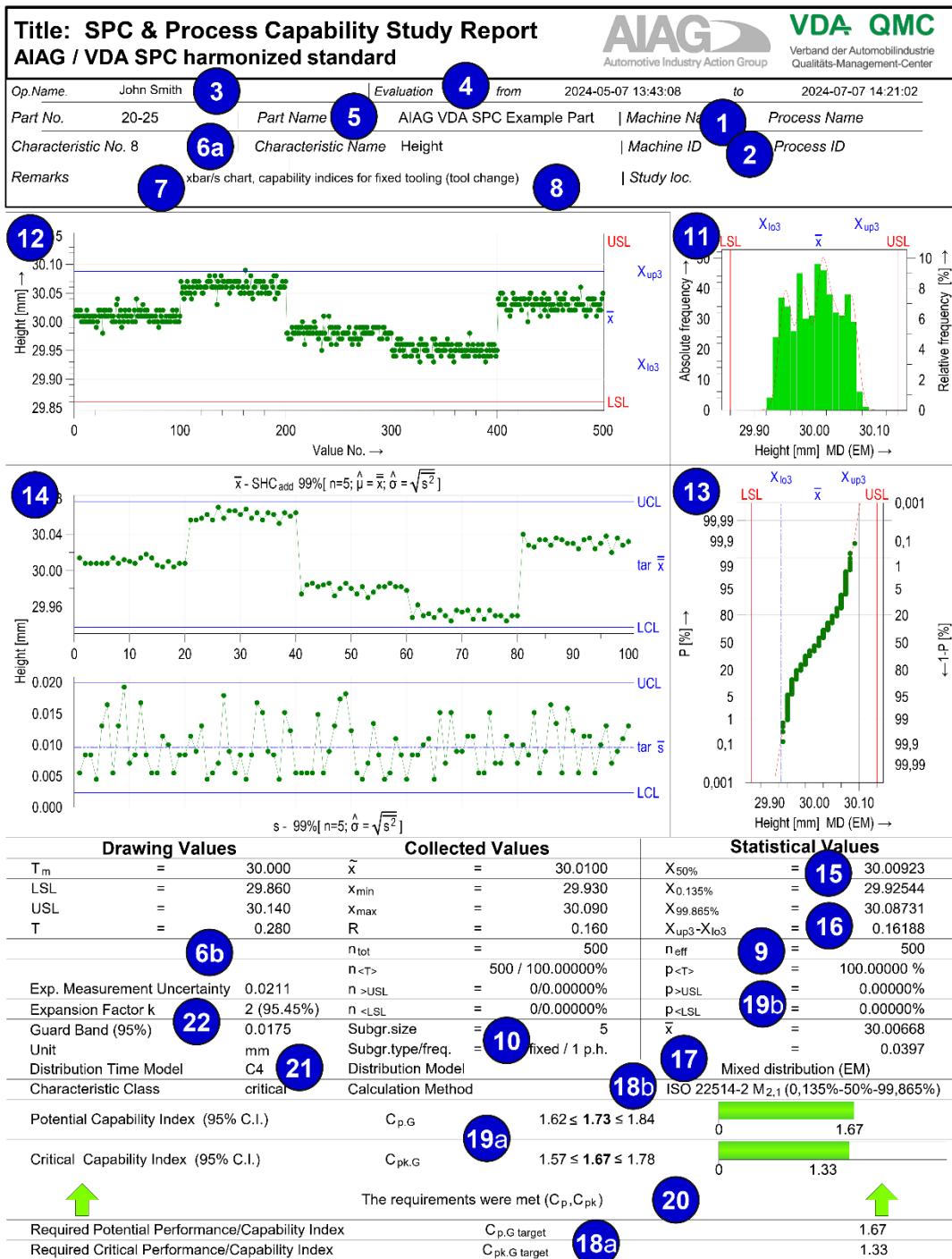


Figure 12-3 Example Report with Fictional Data for Process Capability (Non-Normal Distribution)

## 13 Traceability/Archiving

Archiving and traceability requirements are based on the fundamental documentation requirements, which are, for example, described in VDA Volume 1 “Documented Information and Retention”, IATF 16949 clause 7.5.3.2.1 “Record Retention“ or the AIAG “Traceability Guideline” CQI28.

In light of legal/statutory requirements and the prevailing risks, each company must make decisions with regard to retention periods, storage media and storage locations for its documented information. Globally operating companies potentially have to meet locally varying statutory and regulatory requirements. In addition, further requirements can arise from customer contracts.

In order to assess the risks, it is advisable to introduce a classification system for the documents. According to the system of VDA Volume 1, SPC involves both specification documentation and reports. They can be assigned to the “documentation of the quality assurance for production planning” and “documentation of the ongoing production process”.

The relevant documents include, e.g. relevant contents of the quality management system, such as process standards for implementing the methods named in control loop 1 “direct process control” (Chapter 5). Furthermore, the underlying inspection orders as well as the measurement and inspection methods must be documented, versioned and archived. When it comes to archiving, traceability to the causative incidents and processes must be ensured, and the documents must be change-proof, protected, available and readable. In the case of processed data, such as in control loop 3 “retrospective process control”, this applies to the evaluation as well as to the respective parameterization used for the statistical calculations.

## **14 References and Bibliography**