INTERNATIONAL STANDARD

# ISO 10017

First edition
2021-07

# Quality management — Guidance on statistical techniques for ISO 9001:2015

*Management de la qualité — Recommandations relatives aux techniques statistiques pour l'ISO 9001:2015*

Reference number
ISO 10017:2021(E)

# Contents

Page

# Foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

This first edition of ISO 10017 cancels and replaces ISO/TR 10017:2003, which has been technically revised. The main changes compared with ISO/TR 10017:2003 are as follows:

— it has been revised as a full guidance document and aligned with ISO 9001:2015.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

Variability is inherent in the behaviour and outcome of practically all processes and activities, even under conditions of apparent stability. Such variability can be observed, over the total life cycle, in the quantifiable characteristics of processes and in the resulting products and services.

Statistical techniques can help to measure, describe, analyse, interpret and model variability (whether dealing with a relatively limited amount of data or with large data sets). Statistical analysis of data can provide a better understanding of the nature, extent and causes of variability. It can help to solve and even prevent problems and mitigate risks that can stem from such variability.

The analysis of data using statistical techniques can assist in decision-making and thereby help to improve the performance of processes and the resulting outputs. Statistical techniques are applicable to data in all sectors, with potentially beneficial outcomes.

The criteria for determining the need for statistical techniques, and the appropriateness of the technique(s) selected, remain the prerogative of the organization.

The purpose of this document is to assist an organization in identifying statistical techniques against the elements of a quality management system as defined by ISO 9001:2015. The application of such techniques can yield considerable benefits in quality, productivity and cost.

This document can be also used to support other management systems and supporting standards, e.g. an environmental management system, a health and safety management system.

# Quality management — Guidance on statistical techniques for ISO 9001:2015

## 1 Scope

This document gives guidelines for the selection of appropriate statistical techniques that can be useful to an organization, irrespective of size or complexity, in developing, implementing, maintaining and improving a quality management system in conformity with ISO 9001:2015.

This document does not provide guidance on how to use the statistical techniques.

## 2 Normative references

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

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

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

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

ISO 3534-4, *Statistics — Vocabulary and symbols — Part 4: Survey sampling*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1, ISO 3534-2, ISO 3534-3, ISO 3534-4, ISO 9000:2015 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

**3.1**
**statistical technique**
statistical method
methodology for the analysis of quantitative data associated with variation in products, processes, services and phenomena under study to provide information on the object of the study

Note 1 to entry: Statistical techniques are equally applicable to qualitative (non-numeric) data if such data can be converted to quantitative (numeric) data.

## 4 Statistical techniques in the implementation of ISO 9001

Statistical techniques can help to evaluate, control and improve processes and their resulting outputs, and help to assess and improve the effectiveness of a quality management system.

Statistical techniques, or families of techniques, that are widely used, and which find useful application in the implementation of ISO 9001 include:

— descriptive statistics (see 7.1);

— design of experiments (DOE) (see 7.2);

— hypothesis testing (see 7.3);

— measurement system analysis (MSA) (see 7.4);

— process capability analysis (see 7.5);

— regression analysis (see 7.6);

— reliability analysis (see 7.7);

— sampling (see 7.8);

— simulation (see 7.9);

— statistical process control (SPC) (see 7.10);

— statistical tolerance (see 7.11);

— time series analysis (see 7.12).

Many of these techniques are used in conjunction with other techniques or as sub-sets of other statistical techniques.

The list of statistical techniques cited in this document is neither complete nor exhaustive and does not preclude the use of any other techniques (statistical or otherwise) that are deemed to be beneficial to the organization. Furthermore, this document does not attempt to specify which statistical technique(s) should be used and it does not attempt to advise on how the technique(s) should be implemented.

## 5 Quantitative data and associated statistical techniques in ISO 9001

Quantitative data that can reasonably be encountered in activities associated with the clauses and subclauses of ISO 9001:2015 are noted in Table 1. Listed against the quantitative data identified are statistical techniques that can be of potential benefit to the organization when applied to such data.

No statistical techniques have been identified where quantitative data cannot be readily associated with a clause or sub-clause of ISO 9001.

The statistical techniques cited in this document are limited to those that are well known. A brief description of each of these statistical techniques is given in Clause 7.

The organization can assess the relevance and value of each statistical technique listed in Table 1 and determine whether it is useful in the context of that clause.

**Table 1 — Quantitative data and possible statistical technique(s)**

| Clause/subclause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| 1. Scope | Not applicable | — |
| 2. Normative references | Not applicable | — |
| 3. Terms and definitions | Not applicable | — |
| 4. Context of the organization | | |

**Table 1** *(continued)*

| Clause/subclause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| 4.1 Understanding the organization and its context | Data regarding internal and external issues, for example:<br>— financial<br>— employee surveys<br>— market research<br>— sales<br>— product and service performance<br>— competition/benchmarking<br>— customer surveys | Descriptive statistics<br>Statistical process control<br>Sampling<br>Time series analysis |
| 4.2 Understanding the needs and expectations of interested parties | Subjective and objective data regarding the expectations of interested parties (e.g. market research, customer surveys, employee surveys) | Descriptive statistics<br>Sampling<br>Time series analysis |
| 4.3 Determining the scope of the quality management system | None identified | — |
| 4.4 Quality management system and its processes | | |
| 4.4.1 | None identified | — |
| 4.4.2 | None identified | — |
| 5. Leadership | | |
| 5.1 Leadership and commitment | | |
| 5.1.1 General | None identified | — |
| 5.1.2 Customer focus | None identified | — |
| 5.2 Policy | | |
| 5.2.1 Establishing the quality policy | None identified | — |
| 5.2.2 Communicating the quality policy | Data to determine the extent to which the policy is understood | Descriptive statistics<br>Sampling |
| 5.3 Organizational roles, responsibilities and authorities | None identified | — |
| 6 Planning | | |
| 6.1 Actions to address risks and opportunities | | |
| 6.1.1 | Business data to assess risks | Descriptive statistics |
| 6.1.2 | Business data to assess the effectiveness of actions taken | Descriptive statistics |
| 6.2 Quality objectives and planning to achieve them | | |
| 6.2.1 | Historical performance data to assist establishing quality goals | — |
| 6.2.2 | Historical performance data to assist establishing quality goals | — |
| 6.3 Planning of changes | Historical performance data to assist establishing quality goals | — |
| 7 Support | | |
| 7.1 Resources | | |

**Table 1** *(continued)*

| Clause/subclause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| 7.1.1 General | Summary data on capability | Descriptive statistics |
| 7.1.2 People | None identified | — |
| 7.1.3 Infrastructure | Quantitative data related to the performance and reliability of equipment (hardware and software) and transportation | Descriptive statistics<br>Process capability analysis<br>Reliability analysis |
| 7.1.4 Environment for the operation of processes | Data on the environment, for example:<br>— contamination levels<br>— antistatic controls<br>— temperatures (e.g. bacteria control)<br>— morale (e.g. absenteeism) | Descriptive statistics<br>Measurement system analysis<br>Process capability analysis<br>Sampling<br>Statistical process control<br>Time series analysis |
| 7.1.5 Monitoring and measuring resources | | |
| 7.1.5.1 General | Data relating to measurement capability | Descriptive statistics<br>Measurement system analysis<br>Statistical tolerance |
| 7.1.5.2 Measurement traceability | Data relating to the stability of measurement systems | Descriptive statistics<br>Time series analysis |
| 7.1.6 Organizational knowledge | None identified | — |
| 7.2 Competence | Quantitative data on training and the effectiveness of training | Descriptive statistics<br>Hypothesis testing |
| 7.3 Awareness | Data regarding the level of awareness of quality policy and objectives | Descriptive statistics<br>Sampling |
| 7.4 Communication | None identified | — |
| 7.5 Documented information | | |
| 7.5.1 General | None identified | — |
| 7.5.2 Creating and updating | None identified | — |
| 7.5.3 Control of documented information | | |
| 7.5.3.1 | None identified | — |
| 7.5.3.2 | None identified | — |
| 8 Operation | | |
| 8.1 Operational planning and control | No specific data identified | — |
| 8.2 Requirements for products and services | | |
| 8.2.1 Customer communication | None identified | — |

**Table 1** *(continued)*

| Clause/subclause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| 8.2.2 Determining the requirements for products and services | Data to demonstrate capability and organizational performance | Descriptive statistics<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Regression analysis<br>Reliability analysis<br>Sampling<br>Statistical process control |
| 8.2.3 Review of the requirements for products and services | | |
| 8.2.3.1 | Data to demonstrate capability and organizational performance | Descriptive statistics<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Reliability analysis<br>Statistical process control |
| 8.2.3.2 | None identified | — |
| 8.2.4 Changes to requirements for products and services | None identified | — |
| 8.3 Design and development of products and services | | |
| 8.3.1 General | None identified | — |
| 8.3.2 Design and development planning | None identified | — |
| 8.3.3 Design and development inputs | None identified | — |
| 8.3.4 Design and development controls | Verification and validation of design data | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Regression analysis<br>Sampling<br>Simulation<br>Statistical tolerance |
| 8.3.5 Design and development outputs | Verification of design output data | Descriptive statistics<br>Hypothesis testing<br>Process capability analysis<br>Simulation |
| 8.3.6 Design and development changes | Data related to-verification of the impact of changes | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Regression analysis<br>Sampling<br>Simulation |

**Table 1** *(continued)*

| Clause/subclause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| 8.4 Control of externally provided processes, products and services | | |
| 8.4.1 General | Data related to evaluation of externally provided processes, products and services, and their providers | Descriptive statistics<br>Sampling |
| 8.4.2 Type and extent of control | Incoming control data | Descriptive statistics<br>Measurement system analysis<br>Regression analysis<br>Sampling<br>Time series analysis |
| | External supplier process control data | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Reliability analysis<br>Sampling<br>Statistical process control<br>Statistical tolerances<br>Time series analysis |
| 8.4.3 Information for external providers | None identified | — |
| 8.5 Production and service provision | | |
| 8.5.1 Control of production and service provision | Production and service data | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Regression analysis<br>Sampling<br>Statistical process control<br>Time series analysis |
| 8.5.2 Identification and traceability | None identified | — |
| 8.5.3 Property belonging to customers or external providers | None identified | — |
| 8.5.4 Preservation | None identified | — |

**Table 1** *(continued)*

| Clause/subclause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| 8.5.5 Post-delivery activities | Data to determine requirements for post-delivery activities | Descriptive statistics<br>Hypothesis testing<br>Reliability analysis<br>Statistical process control<br>Sampling<br>Time series analysis |
| 8.5.6 Control of changes | Data related to verification of the effectiveness of changes | Descriptive statistics<br>DOE<br>Hypothesis testing<br>Process capability analysis<br>Reliability analysis<br>SPC |
| 8.6 Release of products and services | Data to demonstrate conformity to requirements | Descriptive statistics<br>Hypothesis testing<br>Reliability analysis<br>Sampling<br>Statistical process control |
| 8.7 Control of nonconforming outputs | | |
| 8.7.1 | None identified | — |
| 8.7.2 | None identified | — |
| 9 Performance evaluation | | |
| 9.1 Monitoring, measurement, analysis and evaluation | | |
| 9.1.1 General | None identified | — |
| 9.1.2 Customer satisfaction | Data on customer satisfaction | Descriptive statistics<br>Hypothesis testing<br>Sampling<br>Regression analysis |
| 9.1.3 Analysis and evaluation | Data on the performance of the quality management system | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Reliability analysis<br>Sampling<br>Statistical process control<br>Time series analysis |
| 9.2 Internal audit | | |
| 9.2.1 | None identified | — |

**Table 1** *(continued)*

| Clause/subclause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| 9.2.2 | Data serving as an input for audit planning | Descriptive statistics<br>Sampling<br>Time series analysis |
| 9.3 Management review | | |
| 9.3.1 General | None identified | — |
| 9.3.2 Management review inputs | Product, process and customer satisfaction data | Descriptive statistics<br>Time series analysis |
| 9.3.3 Management review outputs | None identified | — |
| 10 Improvement | | |
| 10.1 General | None identified | — |
| 10.2 Nonconformity and corrective action | | |
| 10.2.1 | Data pertaining to nonconformities | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Regression analysis<br>Reliability analysis<br>Sampling<br>Simulation<br>Statistical process control<br>Statistical tolerance<br>Time series analysis |
| 10.2.2 | None identified | — |
| 10.3 Continual improvement | Data pertaining to the state of the quality management system | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Regression analysis<br>Reliability analysis<br>Sampling<br>Simulation<br>Statistical process control<br>Statistical tolerance<br>Time series analysis |

# 6 Applicability of selected techniques

A brief description of each statistical technique, or family of techniques (cited in Table 1), is provided in 7.1 to 7.12. The descriptions are intended to assist a non-specialist to assess the potential applicability and benefit of using the statistical techniques in the context of a quality management system.

The choice of technique and the manner of its application will depend on the circumstances and purpose of the exercise, the size and complexity of the organization, and the potential benefit to the organization.

The actual application of statistical techniques will require more guidance and expertise than is provided by this guidance document. There is a large body of information on statistical techniques available in the public domain, such as textbooks, journals, reports, industry handbooks, International Standards and other sources of information, which can assist the organization in the use of statistical techniques.

In addition to the techniques cited in this document, the reader is encouraged to consider other statistical techniques that can meet the needs of the organization

NOTE 1 Listed in the Bibliography are ISO and IEC Standards and Technical Reports related to statistical techniques. They are cited for information. This document does not specify conformance with them.

NOTE 2 Many of the statistical techniques cited here have an application in product, service, process or system improvement initiatives such as "Six Sigma".

# 7 Description of statistical techniques

## 7.1 Descriptive statistics

### 7.1.1 General description

#### 7.1.1.1 Data characteristics

The term "descriptive statistics" refers to a broad range of techniques for summarizing and characterizing data. It is usually the initial step in the analysis of quantitative data, and often constitutes the first step towards the use of other statistical techniques. It should be regarded as a fundamental component of statistical analysis.

Whereas the role of descriptive statistics is to record and present data, the procedures for drawing an inference from the data constitute "inferential statistics", and such procedures are invoked in hypothesis testing (see 7.3).

The characteristics of data taken from a sample can serve as a basis for making inferences regarding the characteristics of populations from which the samples were drawn, with a prescribed margin of error and level of confidence.

The characteristics of the distribution of data can be presented numerically (see 7.1.2) or graphically (see 7.1.3), or both.

#### 7.1.1.2 Numerical

The characteristics of data that are typically of interest are their central value (most often described by the average or "mean"), and the spread or dispersion (usually measured by the range or "standard deviation"). Another characteristic of interest is the distribution of the data, for which there are quantitative measures that describe the shape of the distribution (such as the degree of "skewness").

#### 7.1.1.3 Graphical

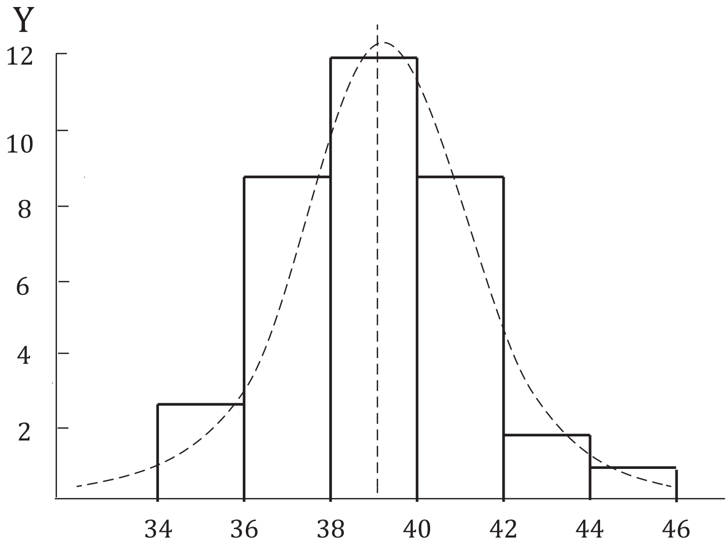
Information regarding the distribution of the data can often be conveyed readily and effectively by various graphical methods that include relatively simple displays of data such as:

— a histogram, which is a visual display of the distribution of values of a characteristic of interest (see Figure 1);

— a scatter plot, which displays values of two variables to assess their possible relationship (see Figure 2);

— a trend chart, also called a “run chart”, which is a plot of values of a characteristic of interest over time (see Figure 3).

| | | | |
|---|---|---|---|
| 40,3 | 40,6 | 37,9 | 44,0 |
| 39,8 | 42,2 | 38,9 | 41,1 |
| 39,6 | 38,1 | 39,2 | 40,7 |
| 38,7 | 40,4 | 39,4 | 40,1 |
| 41,3 | 38,7 | 37,2 | 38,4 |
| 37,1 | 39,2 | 34,1 | 35,6 |
| 42,5 | 40,4 | 36,0 | 35,9 |
| 39,3 | 36,1 | 37,7 | 37,2 |
| 39,4 | 37,2 | 40,3 | 36,5 |




**Key**

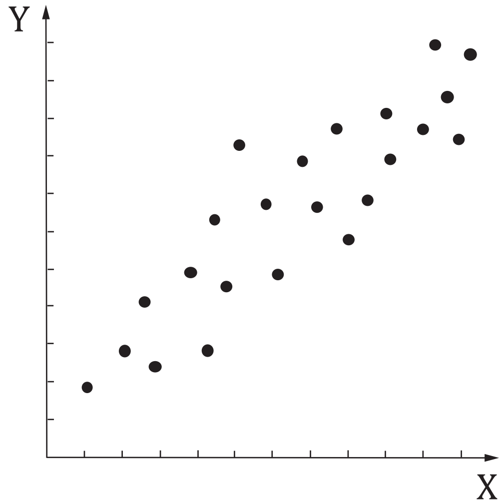
X numerical value

Y frequency

**Figure 1 — Graphical display of data via a histogram**

There is a wide array of graphical displays that can aid the interpretation and analysis of data. These range from the relatively simple tools cited above to techniques of a more complex nature.

Graphical methods can often reveal unusual features of the data that are not readily detected in numerical analysis. They can be very useful in summarizing and presenting complex data and revealing data relationships, and in communicating such information effectively to non-specialist audiences.

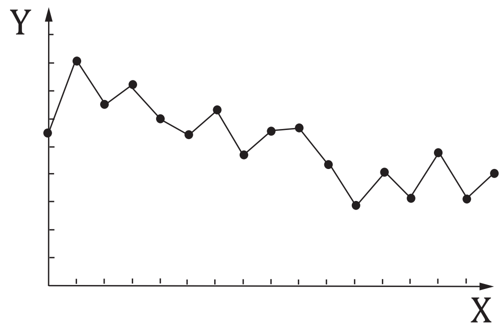



**Key**

X variable A

Y variable B

**Figure 2 — Scatter plot**




**Key**

X time

Y product/process/service data

**Figure 3 — Trend chart**

### 7.1.2 Benefits

Descriptive statistics offers an efficient and relatively simple way of summarizing and characterizing data.

Descriptive statistics is potentially applicable to all situations that involve the use of data. It can aid the analysis and interpretation of data and is a valuable aid in decision-making.

### 7.1.3 Limitations and cautions

Descriptive statistics provides quantitative measures of the characteristics (such as the average and spread) of sample data that are sometimes then used as estimates of the population. However, these measures are subject to the limitations of the sample size and sampling method employed. The conclusions are subject to meeting certain assumptions about the population.

### 7.1.4 Examples of applications

Descriptive statistics has a useful application in almost all areas where quantitative data are collected. It can provide information about the quality management system, its processes and its outputs and often has a useful role in management reviews. Examples of such applications include:

— summarizing key measures of product, service or process characteristics, such as the average value and spread;

— monitoring the performance of a product, service or process over time by means of a trend chart;

— characterizing and monitoring a process parameter, such as oven temperature;

— characterizing delivery time or response time in the service industry;

— summarizing data from customer surveys, such as customer satisfaction;

— illustrating measurement data, such as equipment calibration data;

— reporting financial performance data, such as stock price fluctuation over time;

— illustrating a possible relationship between variables such as, for example, employee satisfaction and quality of delivered service, by a scatter plot;

— reporting trends and economic indicators, such as GDP, consumer price index, cost of living, etc.;

— reporting and tracking human resource data, such as staff turnover, employee performance, etc.

## 7.2 Design of experiments

### 7.2.1 General description

Design of experiments (DOE) can be used for evaluating and/or improving one or more characteristics of a product, service, process or system such as defects, yield or variability.

DOE is particularly useful for investigating complex systems whose outcome can be influenced by a potentially large number of factors. DOE can help to identify the more influential factors, the magnitude of their effect and the relationships (if any) between the factors. The findings can be used to facilitate the design, development and improvement of a product, service or process, or to control or improve an existing system.

DOE can also be used to validate a characteristic of interest against a specified standard, or for the comparative assessment of several systems.

There are several techniques that can be used to analyse data from the experiment. These range from numerical techniques to those more graphical in nature.

DOE is the most efficient way of gaining insight into a process. The information from a designed experiment can be used to formulate a mathematical model that describes the characteristic of interest as a function of the influential factors. Such a model can be used for purposes of prediction of an outcome at a stated level of confidence.

### 7.2.2 Benefits

When estimating or validating a characteristic of interest, there is a need to ensure that the results obtained are not simply due to chance variation. This applies to assessments made against some prescribed standard, or when comparing two or more systems. DOE allows such assessments to be made with a prescribed level of confidence.

A major advantage of DOE is its relative efficiency and economy in investigating the effects of multiple factors in a process, as compared to investigating each factor individually. Also, its ability to identify the interactions between certain factors can lead to a deeper understanding of the process. Such benefits are especially pronounced when dealing with complex processes (i.e. processes that involve many potentially influential factors).

Finally, when investigating a system, there is the risk of incorrectly assuming causality where there can be only chance correlation between two or more variables. The risk of such error can be reduced using sound principles of experiment design.

#### 7.2.3 Limitations and cautions

Some level of inherent variation (often aptly called "noise") is present in all systems, and this can sometimes cloud the results of investigations and lead to incorrect conclusions. Other potential sources of error include the confounding effect of unknown (or simply unrecognized) factors that can be present, or the confounding effect of dependencies between the various factors in a system. The risk posed by such errors can be mitigated by, for example, the choice of sample size or by other considerations in the design of the experiment. However, such risks can never be eliminated and should therefore be borne in mind when forming conclusions.

Finally, the experiment findings are valid only for the factors and the range of values considered in the experiment. Therefore, caution should be exercised in extrapolating (or interpolating) much beyond the range of values considered in the experiment.

#### 7.2.4 Examples of applications

Typical examples of applications of designed experiments include:

— validating the effect of medical treatment, or assessing the relative effectiveness of several types of treatment;

— verifying the characteristics of a product, service or process against some specified performance standards;

— identifying the influential factors in complex processes to achieve desired outcomes, such as improvement in the mean value, or reduced variability of characteristics such as process yield, product strength, durability, noise level, etc.;

— solving problems in complex processes, by helping to identify the more significant process factors in complex processes as well as the relationships between the factors;

— ensuring that a newly designed product can accommodate variability in manufacturing and ultimately in usage;

— improving outcomes in agriculture by determining the effect of certain treatments in environments with non-controllable variables such as rain, sun, soil, etc.;

— determining the process settings and ingredients for optimum results in food production;

— assessing the effectiveness of in marketing trials of consumer products, using different promotions and advertising campaigns in different regions;

— examining the effect of changes in administrative and clerical procedures on process outcomes.

### 7.3 Hypothesis testing

#### 7.3.1 General description

Hypothesis testing is used to determine (at a stated level of significance) whether or not a hypothesis regarding a parameter of a population is true. The procedure can therefore be applied to test whether or not a population parameter meets a particular standard, or it can be used to test for differences in two or more populations. It is thus useful in decision-making.

Hypothesis testing is also used for testing model assumptions, such as whether or not the distribution of a population is normal or whether sample data are random.

The hypothesis test is explicitly or implicitly invoked in many of the statistical techniques cited in this document, such as DOE, sampling, SPC, regression analysis and MSA.

#### 7.3.2 Benefits

Hypothesis testing allows an assertion to be made about some parameter of a population at a defined level of significance. As such, it can be of assistance in making decisions that depend on the parameter.

Hypothesis testing can similarly allow assertions to be made regarding the nature of the distribution of a population.

#### 7.3.3 Limitations and cautions

The conclusions reached through hypothesis testing are based on several statistical assumptions, notably that the samples are independently and randomly drawn, and that underlying distribution is normal. Also, the significance level of the conclusion is governed by the sample size.

#### 7.3.4 Examples of applications

Hypothesis testing has general application when an assertion needs to be made about a parameter or the distribution of one or more populations (as estimated by a sample) or in assessing the sample data itself. For example, the procedure can be used in the following ways:

— to test whether the average value (mean) or the spread (standard deviation) of a population meets a given value, such as a target or a standard;

— to test whether the means of two (or more) populations are different, as when comparing different batches of components;

— to test that the proportion of a population with defects does not exceed a given value;

— to test for differences in the proportion of defective units in the outputs of two processes;

— to test whether the sample data have been randomly drawn from a single population;

— to test if the distribution of a population is normal;

— to test whether an observation in a sample is an “outlier”, i.e. an extreme value of questionable validity;

— to test if there has been an improvement in some product, service or process characteristic;

— to determine the sample size required to reject (or not) a hypothesis, at a stated level of significance;

— to test whether changes in clerical, administrative, transportation and delivery processes have a statistically significant effect on outcomes, such as completion times, error rates, employee satisfaction, customer satisfaction, etc.

### 7.4 Measurement system analysis

#### 7.4.1 General description

Measurement system analysis (MSA), also referred to as “measurement uncertainty analysis”, is a set of procedures to evaluate the uncertainty of measurement systems under the range of conditions in which the system operates. Measurement uncertainty should be considered wherever data are collected.

MSA is used for assessing, at a prescribed level of confidence, whether the measurement system is suitable for its intended purpose. It involves quantifying variation from a variety of sources, such as variation due to the appraiser (i.e. the person taking the measurement), or variation from the measurement process or from the measurement instrument itself. It can also be used to measure the variation due to the measurement system as a proportion of the total process variation or the total allowable variation.

#### 7.4.2 Benefits

MSA, through the quantification of measurement uncertainties, offers various benefits. It can for example:

a) reveal variability in areas that are critical to product quality, and thereby guide an organization in allocating resources in those areas to improve or maintain quality;

b) help to determine whether an instrument is capable of satisfactorily measuring a product or process parameter of interest, and provide a quantitative and cost-effective basis for selecting a new measurement instrument;

c) be used to assure customers (internal or external) that the measurement equipment, methods and processes are capable of adequately measuring the quality level to be achieved;

d) assist in the selection of the most appropriate and cost-effective measurement method(s) (in terms of trueness, repeatability, etc.) to be used in support of assuring product quality;

e) help in assessing and quantifying an organization's measurement system by comparing its measurement results with those obtained from other measurement systems ("proficiency testing").

In summary, MSA can enable or assist an organization to evaluate and improve its measurement equipment, methods and processes; and thereby help to maintain or improve product and process quality and provide assurance to the organization's customers.

#### 7.4.3 Limitations and cautions

In all but the simplest cases, MSA calls for expertise in application, as the results can encourage false and potentially costly over-optimism, both in the measurement results and in the acceptability of the item being measured. Conversely, over-pessimism can result in the unnecessary replacement of adequate measurement systems.

#### 7.4.4 Examples of applications

MSA has a useful application in industrial, medical, pharmaceutical, service and other sectors which call for especially high levels of measurement consistency and accuracy in products and services. The utility of MSA is illustrated in the examples listed below:

a) an assessment of the consistency of inspection within a group of operators revealed an uneven understanding of acceptance criteria, and the need for better training procedures;

b) an instrument for measuring gold plating thickness was found to have insufficient measurement discrimination for adequately assessing the parameter of interest;

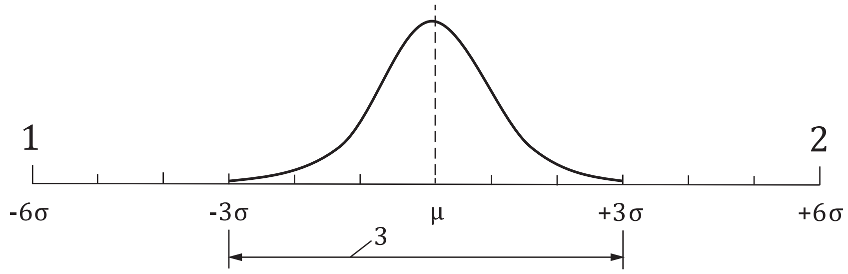
c) a comparative analysis of products tested using different test equipment revealed an issue with the test hardware.

### 7.5 Process capability analysis

#### 7.5.1 General description

Process capability analysis (see Figure 4) involves the measurement of the dispersion (or spread) of a product parameter against the range of variation permitted by specifications, to assess the ability of the process to meet those specifications.




**Key**

1 lower specification limit

2 upper specification limit

3 process spread

**Figure 4 — Process capability**

A typical measure of process dispersion is the standard deviation ($\sigma$, "sigma") of the process data. If the distribution of process data is "normal" (i.e. bell shaped) and its mean value written as "$\mu$", then the output of the process is typically defined as $\mu \pm 3\sigma$. This range of values, termed "process spread", will (in theory) encompass 99,73 % of the output of the process when it is stable.

A convenient measure of process capability is $C_p$, a capability index, which is the ratio of process spread ($\mu \pm 3\sigma$) against allowable specifications, when the process mean is centred between the specifications. Where the process mean is not centred between the specifications, a corresponding measure of process capability is $C_{pk}$. These concepts underlie the business improvement programme called "Six Sigma".

When the process data involve "attributes" (e.g. per cent nonconforming or the number of nonconformities), process capability is stated as the average proportion of nonconforming units or the average rate of nonconformities.

This concept can be applied to assessing the capability of an entire system or process, or any sub-set of a process such as a specific machine (in which case, the assessment is called "machine performance analysis").

### 7.5.2 Benefits

Process capability analysis enables the organization to estimate the level of nonconformity and the associated costs, and can help guide decisions regarding correction, process improvement and resource allocation.

Setting minimum standards for process capability can guide the organization in selecting processes and equipment that reduce the risk of producing unacceptable products and services.

Machine performance analysis is used to assess the ability of a machine to produce or perform to stated requirements. This is helpful in making purchase or repair decisions.

Automotive, aerospace, electronics, food, pharmaceutical, medical and other sectors routinely use process capability as a major criterion to assess suppliers and products. This allows a customer to minimize the direct inspection of purchased products and materials.

### 7.5.3 Limitations and cautions

Process capability analysis assumes that the process is demonstrably stable. Therefore, process capability analysis should be performed in conjunction with control methods to ensure ongoing verification of control.

Estimates of the percentage of nonconforming products are subject to assumptions of a normal distribution. When this is not realized in practice, such estimates should be treated with caution.

Likewise, in the case of processes that are subject to systematic assignable causes of variation, such as tool wear, specialized approaches should be used to calculate and interpret capability.

#### 7.5.4 Examples of applications

The utility of process capability analysis is illustrated by the following examples.

a) Process capability is used to establish rational engineering specifications for manufactured products by ensuring that component variations are consistent with allowable tolerance build-ups in the assembled product. When tight tolerances are necessary, component manufacturers are required to achieve specified levels of process capability to ensure high yields and minimum waste.

b) High process capability index goals (e.g. $C_p > 2$) are sometimes used at the component and subsystem level to achieve desired cumulative quality and reliability of complex systems.

c) Process capability analysis is widely used in high volume, steady-state production processes where, for example, a target, a maximum or a minimum value of a certain characteristic is specified.

d) Companies in manufacturing and service industries track process capability indices to identify the need for process improvements or to verify the effectiveness of such improvements.

e) Process capability analysis can reveal whether the system is capable of meeting stated goals or customer commitments regarding, for example, service delivery.

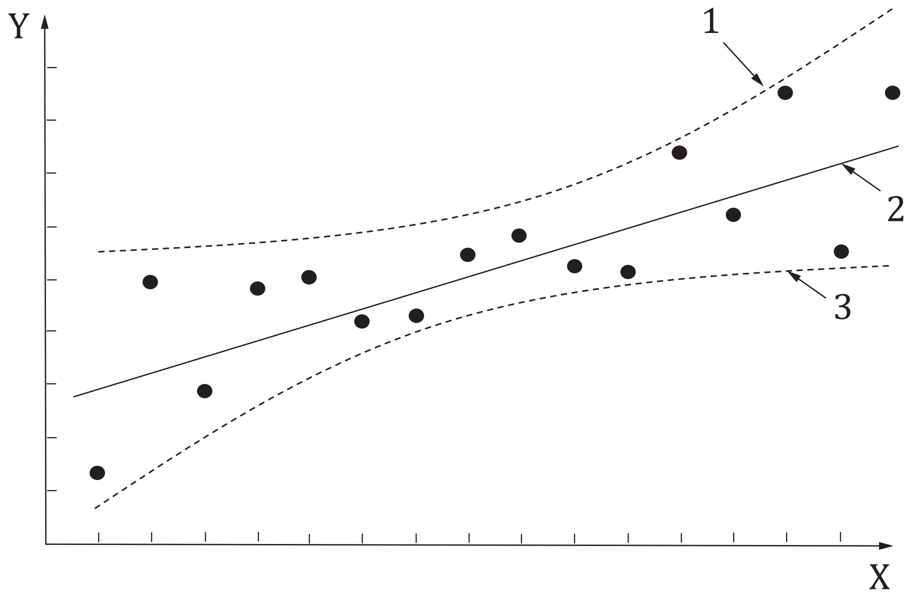
f) Process capability analysis can help determine the level of demand that an IT service centre can accommodate, and thereby assist in determining resources to address demand.

### 7.6 Regression analysis

#### 7.6.1 General description

Regression analysis (see Figure 5) helps to determine the effect of various factors (usually called “explanatory” or “independent” variables) on a characteristic of interest (usually called the “response” or “dependent” variable).

Regression analysis allows a model to be developed empirically. It can also be used to test a model that comes from science, economics, engineering, etc.




**Key**

X explanatory variable

Y response variable

1 95 % confidence band

2 “best fit” regression line

3 95 % confidence band

**Figure 5 — Regression plot**

Regression analysis allows the user to, for example:

— predict the value of the response variable, for specific values of the explanatory variables;

— predict (at a stated level of confidence) the range of values within which the response is expected to lie, given specific values for the explanatory variables;

— test hypotheses about the influence of potential explanatory variables on the response.

NOTE A related methodology is “correlation analysis”, which is used to estimate the nature and degree of association between two variables. Such association does not imply causation.

### 7.6.2 Benefits

Regression analysis can provide insight into the relationship between various process factors and the response of interest; and such insight can help guide decisions regarding the process and ultimately improve the process.

It allows one to explore or compare different but related subsets of data to analyse potential cause-and-effect relationships. This information is potentially useful in controlling or improving process outcomes.

### 7.6.3 Limitations and cautions

When modelling a process, skill is required in specifying a suitable regression model (e.g. linear, exponential, multivariate) and in using diagnostics to improve the model. The presence of omitted variables, measurement error(s) and other sources of unexplained variation in the response can lead to incorrect conclusions. Other risks lie in the assumptions that are made, the characteristics of the available data, and in the estimation technique.

A problem sometimes encountered in developing a regression model is the presence of data whose validity is questionable. Such data should be investigated where possible, since the inclusion or omission of the data from the analysis can influence the estimates of the model parameters, and thereby the response.

Simplifying the model, by minimizing the number of explanatory variables, is important in modelling. The inclusion of unnecessary variables can cloud the influence of explanatory variables and reduce the precision of model predictions.

#### 7.6.4 Examples of applications

Regression analysis can be used, for example:

a) to model production characteristics such as yield, throughput, quality of performance, cycle time, probability of failing a test or inspection, and various patterns of deficiencies in processes;

b) to identify the most important factors in a process, and the magnitude and nature of their contribution to variation in the characteristic of interest;

c) to predict the outcomes from an experiment or from a retrospective study of existing data;

d) to verify the substitution of one measurement method by another (e.g. replacing a destructive or time-consuming method by a non-destructive or time-saving one);

e) to model drug concentrations as functions of time and weight of respondents or to model chemical reactions as a function of time, temperature and pressure;

f) to better understand which design elements drive desired emotional quality aesthetics of a product;

g) to identify the effect (if any) of employee training on process outcomes.

### 7.7 Reliability analysis

#### 7.7.1 General description

Reliability analysis is the application of engineering and analytical methods to the assessment, prediction and assurance of problem-free performance over time of a product or system under study.

The methods used in reliability analysis often require the use of statistical techniques to deal with uncertainties, random characteristics or the probabilities of occurrence (of failures, etc.) over time. Such analyses generally involve the use of appropriate statistical models to characterize variables of interest, such as the time-to-failure or mean-time-between-failures. The parameters of these statistical models are estimated from empirical data obtained through laboratory or factory testing or from field operation.

Reliability analysis employs a wide range of tools and techniques, such as failure mode and effect analysis (FMEA), which examines the physical nature and causes of failure, and the prevention or reduction of future failures. Such techniques, quantitative and qualitative, are used in concert with statistical techniques.

Reliability analysis can, for example, be used:

— to verify that specified reliability targets are met, on the basis of data from a test of limited duration and involving a specific number of test units;

— to predict the probability of problem-free operation, or other measures of reliability such as the failure rate or the mean-time-between-failures of components or systems;

— to model failure patterns and operating scenarios of product or service performance;

— to provide data on design parameters, such as stress and strength, which are useful for probabilistic design;

— to identify critical or high-risk components and the probable failure modes and mechanisms, and to support the search for causes and preventive measures.

The statistical techniques employed in reliability analysis allow a statistical significance level to be attached to the estimates of the parameters of reliability models that are developed, and to predictions made using such models.

NOTE Reliability analysis is closely related to the wider field of “dependability”, which also includes maintainability and availability. These and other related techniques and approaches are defined and discussed in the IEC publications cited in the Bibliography.

### 7.7.2 Benefits

Reliability analysis provides a quantitative measure of product and service performance without failures or service interruptions. Reliability analysis is an aid in the containment of risk in system operation. Reliability is an influential factor in the perception of product or service quality, as well as in customer satisfaction.

The benefits of using statistical techniques in reliability analysis include:

— predicting and quantifying the likelihood of failure and other reliability measures at stated significance levels, and these can help guide future improvement initiatives;

— establishing objective acceptance or rejection criteria for performing compliance tests to demonstrate that reliability requirements are met;

— providing estimates of system/product/service reliability that can guide customer commitments and warranties.

### 7.7.3 Limitations and cautions

A basic assumption of reliability analysis is that the performance of a system under study can be reasonably characterized by a statistical distribution. The accuracy of reliability estimates will therefore depend on the validity of this assumption.

The complexity of reliability analysis is compounded when multiple failure modes are present, and when it is not certain whether they conform to the same statistical distribution. Also, when the number of failures observed in a reliability stress test is small, this can dramatically affect the statistical confidence and precision attached to estimates of reliability.

The conditions under which the reliability test is conducted are critically important, particularly when the test involves some form of “elevated” stress (i.e. stress that is significantly greater than that which the product will experience in normal usage) to accelerate failure. It can be difficult to determine the relationship between the failures observed under stress test and product performance under normal operating conditions, and this will add to the uncertainty of reliability predictions.

### 7.7.4 Examples of applications

Typical examples of applications of reliability analysis include:

— verification that components or products can meet stated reliability requirements;

— projection of product life cycle cost based on a reliability analysis of data from tests at new product introduction;

— guidance on decisions to make or buy off-the-shelf products, based on the analysis of their reliability, and the estimated effect on delivery targets and downstream costs related to projected failures;

— projection of software product maturity based on test results, quality improvement and reliability growth, and establishing software release targets compatible with market requirements;

— determination of the dominant product wear-out characteristics to help improve product design or to plan the appropriate service maintenance schedule and effort required;

— analysis or verification of the shelf life of food products in stores;

— determining and optimizing maintenance and replacement strategies and resources for tools, repairs, customer support, services, etc;

— tracking response times for service issues, or time to close issues, in order to allocate resources for optimum outcomes.

## 7.8 Sampling

### 7.8.1 General description

Sampling is a statistical methodology for estimating information about some characteristic of a population by studying a representative fraction (i.e. sample) of the population. There are various sampling techniques that can be employed, such as simple random sampling, stratified sampling, systematic sampling, sequential sampling and skip-lot sampling. The choice of technique is determined by the purpose of the sampling and the conditions under which it should be conducted.

Sampling can be loosely divided into two broad non-exclusive areas: “acceptance sampling” and “survey sampling”.

Acceptance sampling is concerned with making a decision with regard to accepting or not accepting a “lot” (i.e. a group of items) based on the result of a sample(s) selected from that lot. A wide range of acceptance sampling plans are available to satisfy specific requirements and applications.

Survey sampling is used in enumerative or analytical studies for estimating the values of one or more characteristics in a population, or for estimating how those characteristics are distributed across the population. Survey sampling is often associated with polls where information is gathered on people’s opinions on a subject, as in customer surveys. It can equally be applied to data-gathering for other purposes, such as audits.

Specialized applications of survey sampling include, for example:

a) exploratory sampling, to gain information about one or more characteristics of a population or a subset of the population;

b) production sampling, which can be carried out to conduct an assessment of a process capability;

c) bulk sampling of materials (e.g. minerals, liquids, gases) to assess the properties of a shipped batch.

### 7.8.2 Benefits

A properly constructed sampling plan offers savings in time, cost and labour when compared with, for example, a census of the total population or 100 % inspection of a lot. Where product inspection involves destructive testing, sampling is the only practical way of obtaining pertinent information.

Sampling offers a cost-effective and timely way of obtaining information regarding the value or distribution of a characteristic of interest in a population.

### 7.8.3 Limitations and cautions

When constructing a sampling plan, close attention should be paid to decisions regarding sample size, sampling frequency, sample selection, the basis of sub-grouping and other aspects of sampling methodology.

Sampling requires that the sample be chosen in an unbiased fashion, i.e. the sample is representative of the population from which it is drawn. If this is not done, it will result in poor estimates of the population characteristics. In the case of acceptance sampling, non-representative samples can result in either the unnecessary rejection of acceptable quality lots or the unwanted acceptance of unacceptable quality lots.

Even with unbiased samples, information derived from samples is subject to a degree of error. The magnitude of this error can be reduced by taking a larger sample size, but it cannot be eliminated. Depending on the specific question and context of sampling, the sample size required to achieve the desired level of confidence and precision can sometimes be too large to be of practical value.

#### 7.8.4 Examples of applications

Examples of applications of sampling include the following.

a) A frequent application of survey sampling is in market research, to estimate, for example, the proportion of a population that might buy a particular product/service.

b) Another application of survey sampling is in audits of inventory to estimate the percentage of items that meet specified criteria.

c) Sampling is used to conduct process checks of machines, products or services in order to monitor variation, and to define corrective and preventive actions.

d) Acceptance sampling is extensively used in industry to provide a level of assurance that incoming material satisfies pre-specified requirements.

e) By means of bulk sampling, the amount or the properties of constituents in bulk material (e.g. minerals, liquids, gases) can be estimated.

f) Sampling can be a more cost-effective alternative to mass surveys, and has extensive application in almost every sector in estimating characteristics of interest, such as product preference, customer satisfaction, employee satisfaction, etc.

### 7.9 Simulation

#### 7.9.1 General description

Simulation is a collective term for procedures by which a (theoretical or empirical) system is represented mathematically by a computer program for the definition (and eventual solution) of a problem. If the representation involves concepts of probability theory, in particular random variables, simulation can be called the “Monte Carlo method”.

In the context of theoretical science, simulation is used if no comprehensive theory for the solution of a problem is known (or, if known, is impossible or difficult to solve), and where the solution can be obtained through brute computer force. In the empirical context, simulation is used if the system can be adequately described by a computer program. Simulation is also a helpful tool in the teaching of statistics.

The evolution of relatively inexpensive computing capability is resulting in the increasing application of simulation to problems that hitherto have not been addressed.

#### 7.9.2 Benefits

Within theoretical sciences, simulation (in particular, the Monte Carlo method) is used if explicit calculations of solutions to problems are impossible or too cumbersome to carry out directly. Similarly, in the empirical context, simulation is used when empirical investigations are too costly or impossible. The benefit of simulation is that it allows a solution with a saving of time and money, or that it allows a solution at all.

#### 7.9.3 Limitations and cautions

Within theoretical science, proofs based on conceptual reasoning should be preferred over simulation, since simulation often provides no understanding of the reasons for the result.

Computer simulation of empirical models is subject to the limitation that the model is not necessarily adequate (i.e. it is possible that it does not represent the problem sufficiently). Therefore, it cannot be considered a substitute for actual empirical investigations and experimentation.

#### 7.9.4 Examples of applications

Large-scale projects (such as the space programme) routinely use the Monte Carlo method. Applications are not limited to any specific type of industry. Typical areas of applications include statistical tolerance, process evaluation, system optimization, reliability theory and prediction. Examples of applications are:

— modelling variation in mechanical sub-assemblies;

— modelling vibration profiles in complex assemblies;

— determining optimal preventive maintenance schedules;

— conducting cost and other analyses in design and production processes to optimize the allocation of resources;

— studying a complex delivery process as a cost-effective alternative to field trials.

### 7.10 Statistical process control

#### 7.10.1 General description

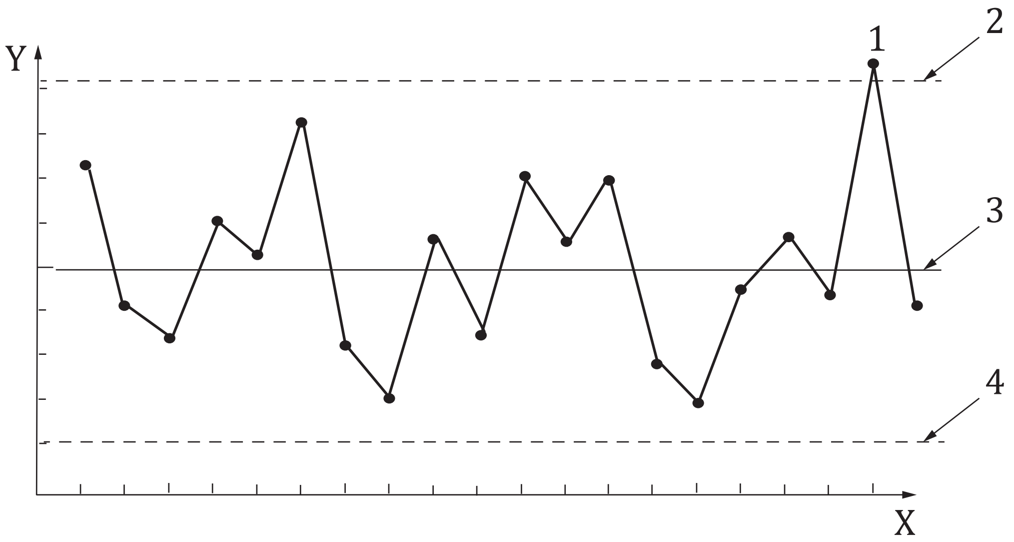
Statistical process control (SPC) refers to the use of process data to monitor, control, evaluate and improve a process, and the resulting product/service.

A statistical process control chart (sometimes abbreviated as "control chart") is a plot of data derived from samples that are periodically drawn from a process and plotted in time sequence (see Figure 6). Also plotted on the SPC chart are lines described as "control limits", and these describe the inherent variability of the process when it is stable. The function of the control chart is to help assess the stability of the process, and this is done by examining the plotted data in relation to the control limits.

At the simplest level, a plotted point that falls outside the control limits signals a possible change in the process, possibly due to some "assignable cause". This points to the need to investigate the cause of the "out-of-control" point and make process adjustments where necessary. This helps to maintain process stability and improve processes in the long run.

Any variable (measurement data) representing a characteristic of interest of a product, service or process can be plotted.

In the case of attribute data, control charts are commonly maintained of the number or proportion of nonconforming units, or the number or proportion of nonconformities, found in samples drawn from the process.




**Key**

X time

Y data

1 time

2 upper control limit

3 average

4 lower control limit

**Figure 6 — Statistical process control chart**

The conventional form of a control chart for variable data are termed the "Shewhart" chart. The use of such control charts can be refined to yield a more rapid indication of process changes, or increased sensitivity to small changes, by using additional criteria in interpreting the trends and patterns in the plotted data.

There are other forms of control charts, each with properties that are suited for applications in special circumstances. Examples of these include "cusum charts" that allow for increased sensitivity to small shifts in the process, and "moving average charts" (uniform or weighted) that serve to smooth out short-term variations to reveal persistent trends.

### 7.10.2 Benefits

In addition to presenting the data in a visible form to the user, control charts facilitate the appropriate response to process variation. They help the user to distinguish the random variation that is inherent in a stable process, from variation that can be due to "assignable causes" (i.e. one to which a specific cause can be assigned) and whose timely detection and correction can help to improve the process.

The value of control charts in various contexts is illustrated in the following examples:

— Process control: Variable control charts can be used to detect changes in the process centre or process variability and to trigger corrective action, thus maintaining or restoring process stability. Control charts also help to avoid ad-hoc or unnecessary process intervention by enabling users to distinguish between variation that is inherent to the process and variation that can be attributed to an "assignable cause".

— Process capability analysis: If the process is in a stable state, the data from the control chart can be used subsequently to estimate process capability (see 7.5).

— Cause and effect analysis: A correlation between process events and control chart patterns can help to infer underlying assignable causes and to plan effective corrective action.

— Continuous improvement: Control charts are used to monitor process variation, and they can help to identify and address the cause(s) of variation. They are found to be effective when they are used as part of a programme of continual improvement within an organization.

#### 7.10.3 Limitations and cautions

It is important to draw process samples in a way that best reveals the variation of interest, and such a sample is termed a “rational subgroup”. This is central to the effective use and interpretation of SPC charts, and to understanding the sources of process variation.

Short run processes present special difficulties as there is sometimes insufficient data to establish appropriate control limits. In such cases, there are various practical approaches for addressing this limitation.

There is a risk of “false alarms” when interpreting control charts (i.e. the risk of concluding that a change has occurred when this is not the case). There is also the risk of failing to detect a change that has occurred. These risks can be mitigated but never eliminated.

#### 7.10.4 Examples of applications

Listed below are examples of applications of SPC.

a) Companies in automotive, electronics, defence and other sectors often use control charts (for critical characteristics) to achieve and demonstrate continuing process stability and capability. If nonconforming products/services are received, the charts are used to help establish the risk and determine the scope of corrective action.

b) Control charts are used in problem solving in the workplace. They have been applied at all levels of organizations to support problem recognition and root cause analysis.

c) Control charts of sample characteristics, such as average response time, error rate and complaint frequency, are used to measure, diagnose and improve performance in service industries (such as, for example, ambulance response time, merchandise delivery time, shipping errors).

d) Control charts are used in measurement system analysis to determine whether the measurement system is sufficiently capable of detecting the variability of the process or product/service of interest. Control charts are also be used to monitor the measurement process itself (see 7.4).

### 7.11 Statistical tolerance

#### 7.11.1 General description

Statistical tolerance refers to a procedure based on statistical principles, used for establishing tolerances. It makes use of the statistical distributions of relevant dimensions of individual components to determine the overall tolerance for the assembled unit.

When assembling multiple individual components into a module, the critical factor or requirement (in terms of assembly and interchangeability) of such modules is often not the dimensions of the individual components but instead the total dimension achieved as a result of assembly.

For a statistical determination of overall tolerances, it is assumed that, in assemblies involving a large number of individual components, dimensions from one end of the range of individual tolerances will be balanced by dimensions from the other end of the tolerance ranges. For example, an individual dimension lying at the lower end of the tolerance range can be matched with another dimension (or combination of dimensions) at the high end of the tolerance range.

On statistical grounds, the total dimension will have an approximately normal distribution under certain circumstances. This fact is independent of the distribution of the individual dimensions and can therefore be used to estimate the tolerance range of the total dimension of the assembled module.

Alternatively, given the overall dimension tolerance, it can be used to determine the permissible tolerance range of the individual components.

#### 7.11.2 Benefits

Given a set of tolerances (which need not be the same) for individual components, the calculation of the statistical overall tolerance will yield an overall dimensional tolerance that will usually be significantly smaller than the overall dimensional tolerance calculated arithmetically.

This means that, given an overall dimensional tolerance, statistical tolerance will permit the use of individual components with wider tolerances, than those determined by arithmetical calculation. In practical terms, this can be a significant benefit since wider tolerances are associated with lower cost methods of production.

#### 7.11.3 Limitations and cautions

The first step in statistical tolerancing is to determine the proportion of assembled modules that can acceptably lie outside the tolerance range of the total dimension. Statistical tolerancing, to be practicable without necessitating advanced methods, is subject to the following conditions:

— the individual actual dimensions can be considered as uncorrelated random variables;

— the dimensional chain is linear;

— the dimensional chain has at least four units;

— the individual tolerances are of the same order of magnitude;

— the distributions of the individual dimensions of the dimensional chain are known.

It is obvious that some of these requirements can only be met if the manufacture of the individual components in question can be controlled and continuously monitored. In the case of a product still under development, experience and engineering knowledge should guide the application of statistical tolerance.

#### 7.11.4 Examples of applications

The theory of statistical tolerance is routinely applied in the assembly of parts that involve additive relations or cases involving simple subtraction (e.g. shaft and hole). Industrial sectors that use statistical tolerance include mechanical, electronic and chemical industries. The theory is also applied in computer simulation to determine optimum tolerances.

### 7.12 Time series analysis

#### 7.12.1 General description

A time series is a sequence of observations ordered in time, and the analysis of such data is called “time series analysis”. It is used to describe patterns in time series data, for identifying “outliers” (i.e. extreme values whose validity should be investigated) to help understand the patterns or to make process adjustments, and for detecting turning points in a trend. Another use is to explain patterns in one time series with those of another time series, with all the objectives inherent in regression analysis (see 7.6).

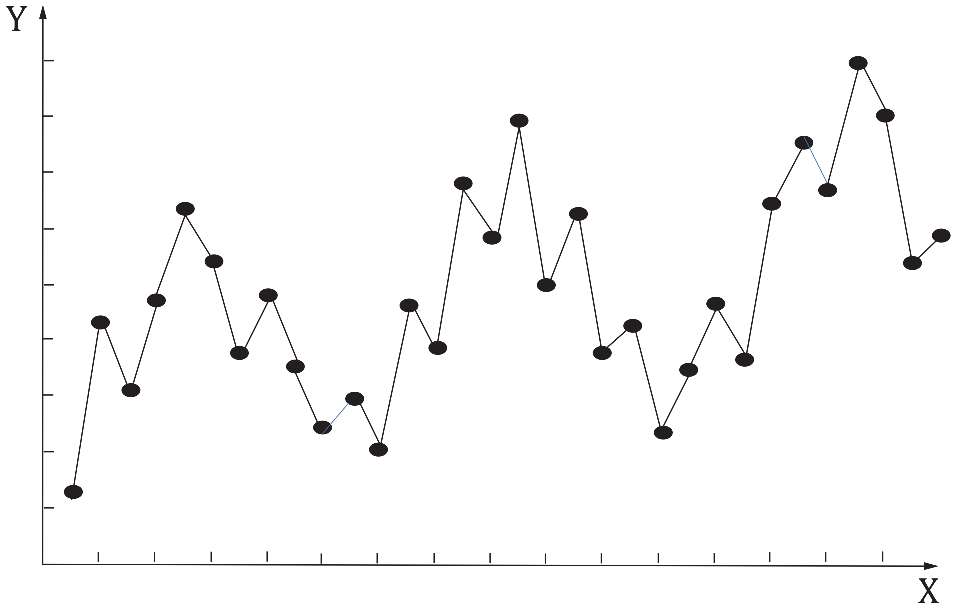
Time series analysis (see Figure 7) refers to analytical techniques in applications such as:

— finding “lag” patterns by statistically looking at how each observation is correlated with the observation immediately before it, and repeating this for each successive lagged period;

— finding patterns (in, for example, sales) that are cyclical or seasonal, to understand how causal factors in the past can have repeated influences in the future;

— using statistical tools to predict future observations or to understand which causal factors have contributed most to variations in the time series.




**Key**

X time

Y characteristic

**Figure 7 — Time series plot**

While the techniques employed in time series analysis can include simple “trend charts”, such elementary plots are listed among the simple graphical methods cited in 7.1.

Time series analysis can be used to predict future values, typically bounded by upper and lower values known as the “forecast interval”. It has extensive application in the area of control and is often a feature of automated processes. In those cases, a probability model is fitted to the historical time series to predict future values. Then specific process parameters are adjusted to keep the process on target, with as little variation as possible.

### 7.12.2 Benefits

Time series analysis methods are useful in planning, control engineering, identifying a change in a process, generating forecasts and measuring the effect of some outside intervention or action.

Time series analysis is also useful for comparing the projected performance of a process with predicted values in the time series if a specific change were to be made.

Time series methods can provide insights into possible cause-and-effect patterns. Methods exist for separating systematic (or assignable) causes from chance causes, and for breaking down patterns in a time series into cyclical, seasonal, trend and level components.

Time series analysis can be used to determine how a process will behave under specified conditions and what adjustments (if any) can influence the process in relation to some target value or what adjustments can reduce process variability.

### 7.12.3 Limitations and cautions

The limitations and cautions cited for regression analysis also apply to time series analysis. When modelling a process in order to understand causes and effects, a significant level of skill is required to select the most appropriate model and to use diagnostic tools to improve the model.

Whether included or omitted from the analysis, a single observation or a small set of observations can have a significant influence on the model. Therefore, influential observations should be understood and distinguished from “outliers” in the data.

Different time-series estimation techniques can have varying degrees of success, depending on the patterns in the time series and on the number of periods for which predictions are desired, relative to the number of periods for which time-series data are available. The choice of a model should consider the objective of the analysis, the nature of the data, the relative cost, and the analytical and predictive properties of the various models.

### 7.12.4 Examples of applications

Listed below are examples of applications of time series analysis.

a) Time series analysis is applied to study patterns of performance over time, for example, process measurements, customer complaints, nonconformance, productivity and test results.

b) Forecasting applications include predicting spare parts, absenteeism, customer orders, material needs and electric power consumption.

c) Causal time-series analysis is used to develop predictive models of demand. For example, in the context of reliability, it is used to predict the number of events in a given time period and the distribution of time intervals between events such as, for example, equipment outages.

d) Time series analysis can be used to differentiate variation from assignable causes from variation due to random occurrences.

e) Time series analysis can be used to monitor seasonal variation in sales processes by tracking missed and moved order dates.

# Bibliography


[1] ISO 9001:2015, *Quality management systems — Requirements*

[2] ISO 2602, *Statistical interpretation of test results — Estimation of the mean — Confidence interval*

[3] ISO 2854, *Statistical interpretation of data — Techniques of estimation and tests relating to means and variances*

[4] ISO 2859 (all parts), *Sampling procedures for inspection by attributes*

[5] ISO 3301, *Statistical interpretation of data — Comparison of two means in the case of paired observations*

[6] ISO 3494, *Statistical interpretation of data — Power of tests relating to means and variances*

[7] ISO 3951 (all parts), *Sampling procedures for inspection by variables*

[8] ISO 5479, *Statistical interpretation of data — Tests for departure from the normal distribution*

[9] ISO 5725 (all parts), *Accuracy (trueness and precision) of measurement methods and results*

[10] ISO 7870 (all parts), *Control charts*

[11] ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

[12] ISO 10725, *Acceptance sampling plans and procedures for the inspection of bulk materials*

[13] ISO 11095, *Linear calibration using reference materials*

[14] ISO 11453, *Statistical interpretation of data — Tests and confidence intervals relating to proportions*

[15] ISO 11462 (all parts), *Guidelines for implementation of statistical process control (SPC)*

[16] ISO 11648-2, *Statistical aspects of sampling from bulk materials — Part 2: Sampling of particulate materials*

[17] ISO 11843 (all parts), *Capability of detection*

[18] ISO/TR 12845, *Selected illustrations of fractional factorial screening experiments*

[19] ISO/TR 12888, *Selected illustrations of gauge repeatability and reproducibility studies*

[20] ISO 13053 (all parts), *Quantitative methods in process improvement — Six Sigma*

[21] ISO/TR 13195, *Selected illustrations of response surface method — Central composite design*

[22] ISO 16269 (all parts), *Statistical interpretation of data*

[23] ISO 16336, *Applications of statistical and related methods to new technology and product development process — Robust parameter design (RPD)*

[24] ISO 16355 (all parts), *Applications of statistical and related methods to new technology and product development process*

[25] ISO 18404, *Quantitative methods in process improvement — Six Sigma — Competencies for key personnel and their organizations in relation to Six Sigma and Lean implementation*

[26] ISO/TS 21749, *Measurement uncertainty for metrological applications — Repeated measurements and nested experiments*

[27] ISO 22514 (all parts), *Statistical methods in process management — Capability and performance*

[28] ISO 28590, *Sampling procedures for inspection by attributes — Introduction to the ISO 2859 series of standards for sampling for inspection by attributes*

[29] ISO/TR 29901, *Selected illustrations of full factorial experiments with four factors*

[30] ISO/IEC Guide 98-1, *Uncertainty of measurement — Part 1: Introduction to the expression of uncertainty in measurement*

[31] IEC 31010, *Risk management — Risk assessment techniques*

[32] IEC 60050-192, *International Electrotechnical Vocabulary — Part 192: Dependability*

[33] IEC 61070, *Compliance test procedures for steady-state availability*

[34] IEC 61123, *Reliability testing — Compliance test plans for success ratio*

[35] IEC 61649, *Weibull analysis*

**ICS 03.120.30; 03.120.10**
Price based on 30 pages