

# TECHNICAL REPORT

# ISO/TR 10017

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## Guidance on statistical techniques for ISO 9001:1994

*Lignes directrices pour les techniques statistiques relatives à  
l'ISO 9001:1994*

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## Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

ISO/TR 10017 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

This Technical Report may be updated to reflect future revisions of ISO 9001. Comments on the contents of this Technical Report may be sent to ISO Central Secretariat for consideration in a future revision.

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## Introduction

The purpose of this Technical Report is to assist an organization in identifying statistical techniques that can be useful in developing, implementing or maintaining a quality system in compliance with ISO 9001:1994.

In this context, the usefulness of statistical techniques follows from the variability that may be observed in the behaviour and outcome of practically all processes, even under conditions of apparent stability. Such variability can be observed in the quantifiable characteristics of products and processes, and may be seen to exist at various stages over the total life cycle of products from market research to customer service and final disposal.

Statistical techniques can help measure, describe, analyse, interpret and model such variability, even with a relatively limited amount of data. Statistical analysis of such data can help provide a better understanding of the nature, extent and causes of variability. This could help to solve and even prevent problems that may result from such variability.

Statistical techniques can thus permit better use of available data to assist in decision making, and thereby help to improve to the quality of products and processes in the stages of design, development, production, installation and servicing.

This Technical Report is intended to guide and assist an organization in considering and selecting statistical techniques appropriate to the needs of the organization. The criteria for determining the need for statistical techniques, and the appropriateness of the technique(s) selected, remain the prerogative of the organization.

The statistical techniques described in this Technical Report are also relevant for use with other standards in the ISO 9000 family. In particular, annex D of ISO 9000-1:1994 is a cross-reference list of clause numbers for corresponding topics in ISO 9001, ISO 9002, ISO 9003 and ISO 9004-1 (1994 editions).

# Guidance on statistical techniques for ISO 9001:1994

## 1 Scope

This Technical Report provides guidance on the selection of appropriate statistical techniques that may be useful to an organization in developing, implementing or maintaining a quality system in compliance with ISO 9001. This is done by examining the requirements of ISO 9001 that involve the use of quantitative data, and then identifying and describing those statistical techniques that may be useful when applied to such data.

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

**This Technical Report is not intended for contractual, regulatory or certification purposes.** It is not intended to be used as a mandatory checklist for compliance with ISO 9001:1994 requirements. The justification for using statistical techniques is that their application would help to improve the effectiveness of the quality system.

## 2 Terms and definitions

For the purposes of this Technical Report, the terms and definitions given in ISO 8402, ISO 3534 (all parts) and IEC 60050 apply.

References in this Technical Report to "product" are applicable to the generic product categories of service, hardware, processed materials, software or a combination thereof, in accordance with Notes 1 and 2 accompanying the definition of "product" in ISO 8402.

## 3 Identification of potential needs for statistical techniques

The need for quantitative data that may reasonably be associated with the implementation of the clauses and sub-clauses of ISO 9001 is identified in Table 1. Listed against the need for quantitative data thus identified are one or more appropriate statistical techniques that potentially may be applied to such data, and whose application would benefit the organization.

Where no need for quantitative data could be readily associated with a clause or sub-clause of ISO 9001, no statistical technique is identified.

Discretion has been exercised in citing only those techniques that are well known and have been used in a wide range of applications, with recognized benefits to users.

Each of the statistical techniques noted below is described briefly in clause 4, to assist the organization to assess the relevance and value of the statistical techniques cited, and to help determine whether or not to use them in a specific context.

Table 1 — Needs involving quantitative data, and supporting statistical technique(s)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.1 Management responsibility 4.1.1 Quality policy	Need to assess the extent to which the quality policy is implemented in the organization	Sampling
4.1.2 Organization		
4.1.2.1 Responsibility and authority	None identified	
4.1.2.2 Resources	None identified	
4.1.2.3 Management representative	None identified	
4.1.3 Management review	Need for quantitative assessment of the organization's performance against its quality objectives	Descriptive statistics; Sampling; SPC charts; Time series analysis
4.2 Quality system		
4.2.1 General	None identified	
4.2.2 Quality system procedures	None identified	
4.2.3 Quality planning	None identified	
4.3 Contract review		
4.3.1 General	None identified	
4.3.2 Review		
4.3.2.a Review	None identified	
4.3.2.b Review	None identified	
4.3.2.c Review	Need to analyse tender, contract or order and to ensure that the supplier has the capability to meet requirements	Measurement analysis; Process capability analysis; Reliability analysis; Sampling
4.3.3 Amendment to a contract	None identified	
4.3.4 Records	None identified	
4.4 Design control		
4.4.1 General	None identified	
4.4.2 Design and development planning	None identified	
4.4.3 Organizational and technical interfaces	None identified	
4.4.4 Design input	Need to identify and review input requirements for adequacy, and resolve differences	Measurement analysis; Process capability analysis; Reliability analysis; Statistical tolerancing
4.4.5.a Design output	Need to assess that design outputs satisfy input requirements	Descriptive statistics; Hypothesis testing; Measurement analysis; Process capability analysis; Reliability analysis; Sampling; Statistical tolerancing
4.4.5.b Design output	None identified	
4.4.5.c Design output	Need to identify critical design characteristics	Regression analysis; Reliability analysis; Simulation
4.4.6 Design review	None identified	

Table 1 (continued)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.4.7 Design verification	Need to ensure that design meets stated requirements	Design of experiments; Hypothesis testing; Measurement analysis; Regression analysis; Reliability analysis; Sampling; Simulation
4.4.8 Design validation	Need to ensure that product conforms to defined user needs and/or requirements	Hypothesis testing; Regression analysis; Reliability analysis; Sampling; Simulation
4.4.9 Design changes	None identified	
4.5 Document and data control		
4.5.1 General	None identified	
4.5.2 Document and data approval and issue	None identified	
4.5.3 Document and data changes	None identified	
4.6 Purchasing		
4.6.1 General	None identified	
4.6.2.a Evaluation of subcontractors	Need to evaluate subcontractors on the basis of their ability to meet requirements	Descriptive statistics; Hypothesis testing; Process capability analysis; Sampling
4.6.2.b Evaluation of subcontractors	None identified	
4.6.2.c Evaluation of subcontractors	Need to describe and summarise performance of sub-contractors	Descriptive statistics
4.6.3 Purchasing data	None identified	
4.6.4 Verification of purchased product		
4.6.4.1 Supplier verification at subcontractor's premises	None identified	
4.6.4.2 Customer verification of subcontracted product	None identified	
4.7 Control of customer-supplied product	None identified	
4.8 Product identification and traceability	None identified	
4.9 Process control		
4.9.a Process control	None identified	
4.9.b Process control	Need to ensure the suitability of equipment	Descriptive statistics; Measurement analysis; Process capability analysis
4.9.c Process control	None identified	
4.9.d Process control	Need to monitor and control suitable process parameters and product characteristics	Descriptive statistics; Design of experiments; Regression analysis; Sampling; SPC charts; Time series analysis
4.9.e Process control	Need to approve processes and equipment	Descriptive statistics; Measurement analysis; Process capability analysis
4.9.f Process control	None identified	
4.9.g Process control	Need for suitable maintenance of equipment to ensure continuing process capability	Descriptive statistics; Process capability analysis; Reliability analysis; Simulation

Table 1 (continued)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.10 Inspection and testing 4.10.1 General	Need to specify inspection and test activities to verify that product requirements are met	Hypothesis testing; Reliability analysis; Sampling
4.10.2 Receiving inspection and testing 4.10.2.1 Receiving inspection and testing	Need to verify that incoming product conforms to specified requirements	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling
4.10.2.2 Receiving inspection and testing	None identified	
4.10.2.3 Receiving inspection and testing	None identified	
4.10.3.a In-process inspection and testing	Need to inspect and test product as required	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling
4.10.3.b In-process inspection and testing		
4.10.4 Final inspection and testing	Need to verify that finished product conforms to specified requirements	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling
4.10.5 Inspection and test records	None identified	
4.11 Control of inspection, measuring and test equipment 4.11.1 General	None identified	
4.11.2.a Control procedure	Need to assess the capability of inspection, measurement and test equipment	Descriptive statistics; Measurement analysis; Process capability analysis; SPC charts
4.11.2.b Control procedure	None identified	
4.11.2.c Control procedure	Need to define process for calibration of inspection, measurement and test equipment	Descriptive statistics; Measurement analysis; Process capability analysis; SPC charts
4.11.2.d Control procedure	None identified	
4.11.2.e Control procedure	None identified	
4.11.2.f Control procedure	Need to assess validity of previous inspection and test results.	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling; SPC charts
4.11.2.g Control procedure	None identified	
4.11.2.h Control procedure	None identified	
4.11.2.i Control procedure	None identified	
4.12 Inspection and test status	None identified	
4.13 Control of nonconforming product 4.13.1 General	None identified	
4.13.2.a Review and disposition of nonconforming product	None identified	
4.13.2.b Review and disposition of nonconforming product	None identified	

Table 1 (continued)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.13.2.c Review and disposition of nonconforming product	None identified	
4.13.2.d Review and disposition of nonconforming product	None identified	
4.14 Corrective and preventive action 4.14.1 General	None identified	
4.14.2.a Corrective action	Need to assess effectiveness of process for handling customer complaints and reports of product nonconformities.	Descriptive statistics; Sampling
4.14.2.b Corrective action	Need to analyse the cause of non-conformities relating to product, process or quality system	Descriptive statistics; Design of experiments; Measurement analysis; Process capability analysis; Regression analysis; Reliability analysis; Sampling; Simulation; SPC charts; Statistical tolerancing; Time series analysis
4.14.2.c Corrective action	None identified	
4.14.2.d Corrective action	Need to evaluate the effectiveness of corrective action	Descriptive statistics; Hypothesis testing; Regression analysis; Sampling; SPC charts; Time series analysis
4.14.3.a Preventive action	Need to summarise and analyse product or process data related to actual or potential non-conformities	Descriptive statistics; Regression analysis; Time series analysis
4.14.3.b Preventive action	None identified	
4.14.3.c Preventive action	Need to ensure the effectiveness of preventive action	Descriptive statistics; Hypothesis testing; Regression analysis; Sampling; SPC charts; Time series analysis
4.14.3.d Preventive action	None identified	
4.15 Handling, storage, packaging, preservation and delivery 4.15.1 General	None identified	
4.15.2 Handling	None identified	
4.15.3 Storage	Need to assess deterioration of product in stock, and to determine appropriate interval between assessments	Descriptive statistics; Hypothesis testing; Reliability analysis; Sampling; Time series analysis
4.15.4 Packaging	Need to assess conformance of packing, packaging and marking processes to specified requirements	Descriptive statistics; Process capability analysis; Sampling; SPC charts;
4.15.5 Preservation	Need to assess the adequacy of preservation and segregation of product under supplier's control	Descriptive statistics; Hypothesis testing; Sampling; Time series analysis
4.15.6 Delivery	Need to assess adequacy of protection of product quality after final inspection and test	Descriptive statistics; Sampling
4.16 Control of quality records	None identified	

Table 1 (continued)

Clause/sub-clause of ISO 9001:1994	Needs involving the use of quantitative data	Statistical technique(s)
4.17 Internal quality audits	Potential need for sampling in planning and conducting internal audits; and need for summarising data from audits and verifying effectiveness	Descriptive statistics; Sampling
4.18 Training	None identified	
4.19 Servicing	Need to verify that servicing meets specified requirements	Descriptive statistics; Sampling
4.20 Statistical techniques 4.20.1 Identification of need	This clause calls for the identification of the need for statistical techniques.	Suitable statistical techniques identified for consideration.
4.20.2 Procedures	None identified	

The findings of Table 1 are summarized in annex A, which presents an overview of the range of statistical techniques and the extent to which they could be used to support the implementation of ISO 9001.

## 4 Descriptions of statistical techniques identified

### 4.1 General

The following statistical techniques, or families of techniques, that might help an organization to meet its needs, are identified in clause 3:

- descriptive statistics
- design of experiments
- hypothesis testing
- measurement analysis
- process capability analysis
- regression
- reliability analysis
- sampling
- simulation
- Statistical Process Control charts
- statistical tolerancing
- time series analysis

As stated earlier, the criteria used in selecting the techniques gathered above are that the techniques are well known and widely used, and their application has resulted in benefit to users.

The choice of technique and the manner of its application will depend on the circumstances and purpose of the exercise, which will differ from case to case.

A brief description of each statistical technique, or family of techniques, listed above is provided in 4.2 to 4.13. The descriptions are intended to assist a lay reader to assess the potential applicability and benefit of using the statistical techniques in implementing the requirements of a quality system. However, the actual application of statistical techniques cited here will require more guidance and expertise than is provided by this Technical Report.

There is a great body of information on statistical techniques available in the public domain, such as textbooks, journals, reports, industry handbooks and other sources of information, which may assist the organization in the effective use of statistical techniques<sup>1)</sup>. However it is beyond the scope of this Technical Report to cite these sources, and the search for such information is left to individual initiative.

## 4.2 Descriptive statistics

### 4.2.1 What it is

The term descriptive statistics refers to procedures for summarizing and presenting quantitative data in a manner that reveals the characteristics of the distribution of data.

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

The information provided by descriptive statistics can often be conveyed readily and effectively by a variety of graphical methods. These range from simple displays of data in the form of pie-charts, bar-charts, histograms, simple scatter plots and trend charts, to displays of a more complex nature involving specialised scaling such as probability plots, and graphics involving multiple dimensions and variables.

Graphical methods are useful in that they can often reveal unusual features of the data that may not be readily detected in quantitative analysis. They have extensive use in data analysis when exploring or verifying relationships between variables, and in estimating the parameters that describe such relationships. Also, they have an important application in summarising and presenting complex data or data relationships in an effective manner, especially for non-specialist audiences.

Graphical methods are implicitly invoked in many of the statistical techniques referred to in this Technical Report, and should be regarded as a vital component of statistical analysis.

### 4.2.2 What it is used for

Descriptive statistics is used for summarizing and characterising 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 procedures.

The characteristics of sample data may serve as a basis for making inferences regarding the characteristics of populations, with a prescribed margin of error and level of confidence, provided the underlying statistical assumptions are satisfied.

### 4.2.3 Benefits

Descriptive statistics offers an efficient and relatively simple way of summarizing and characterising data, and also offers a convenient way of presenting such information. It is easily understood and can be useful for analysis and decision making at all levels.

### 4.2.4 Limitations and cautions

Descriptive statistics provides quantitative measures of the characteristics (such as the mean and standard deviation) of sample data. However these measures are subject to the limitations of sample size and the sampling method employed. Also, these quantitative measures cannot be assumed to be valid estimates of characteristics of the population from which the sample was drawn, unless the statistical assumptions associated with sampling are satisfied.

### 4.2.5 Examples of applications

Descriptive statistics has useful application in almost all areas where quantitative data are collected. Some examples of such applications are:

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<sup>1)</sup> Listed in the bibliography are ISO and IEC standards and technical reports related to statistical techniques. They are cited here for information; this report does not specify compliance to them.

- summarizing key measures of product characteristics (such as the mean and spread);
- describing the performance of some process parameter, such as oven temperature;
- characterizing delivery time or response time in the service industry;
- summarizing data from customer surveys.

### 4.3 Design of experiments

#### 4.3.1 What it is

Design of experiments (abbreviated as "DOE", or sometimes abridged as "Designed Experiments") refers to investigations carried out in a planned manner, and which rely on a statistical assessment of results to reach conclusions at a stated level of confidence.

The specific arrangement and manner in which the experiments are to be carried out is called the "experiment design", and such design is governed by the objective of the exercise and the conditions under which the experiments are to be conducted.

DOE typically involves inducing change(s) to the system under investigation, and statistically assessing the effect of such change on the system. Its objective may be to *validate* some characteristic(s) of a system, or it may be to *investigate* the influence of one or more factors on some characteristic(s) of a system.

#### 4.3.2 What it is used for

DOE can be used for evaluating some characteristic of a product, process or system, with a stated level of confidence. This may be done for the purpose of validation against a specified standard, or for comparative assessment of several systems.

DOE is particularly useful for investigating complex systems whose outcome may be influenced by a potentially large number of factors. The objective of the experiment may be to maximize or optimize a characteristic of interest, or to reduce its variability. DOE can be used to identify the more influential factors in a system, the magnitude of their influence, and the relationships (i.e., "interactions") if any, between the factors. The findings may be used to facilitate the design and development of a product or process, or to control or improve an existing system.

The information from a designed experiment may be used to formulate a mathematical model that describes the system characteristic(s) of interest as a function of the influential factors; and with certain limitations (cited briefly below), such a model can be used for purposes of prediction.

#### 4.3.3 Benefits

When estimating or validating a characteristic of interest, there is a need to assure that the results obtained are not simply due to chance variation. This applies to assessments made against some prescribed standard, and to an even greater degree in comparing two or more systems. DOE allows one to make such assessments, 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 a large number of potentially influential factors.

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

#### 4.3.4 Limitations and cautions

Some level of inherent variation (often aptly described as "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 may 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 well

designed experiments through, for example, the choice of sample size or by other considerations in experiment design; but these risks can never be eliminated, and therefore must be borne in mind when forming conclusions.

Also, strictly speaking the experiment findings are valid for the factors and the range of values considered in the experiment. Therefore, one must exercise caution in extrapolating (or interpolating) much beyond the range of values considered in the experiment.

Finally, the theory of DOE makes certain fundamental assumptions, such as the existence of a canonical relationship between a mathematical model and the physical reality being studied, whose validity or adequacy are subject to debate.

#### 4.3.5 Examples of applications

A familiar application of DOE is in assessing products or processes as, for example, in validating the effect of medical treatment, or in assessing the relative effectiveness of several types of treatment. Industrial examples of such application include validation tests of products against some specified performance standards.

DOE is widely used to identify the influential factors in complex processes and thereby control or improve the mean value, or reduce the variability, of some characteristic of interest such as process yield, product strength, durability, noise level etc. Such experiments are frequently encountered in the production, for example, of electronic components, automobiles and chemicals. They are also widely used in areas as diverse as agriculture and medicine. The scope of applications remains potentially vast.

### 4.4 Hypothesis testing

#### 4.4.1 What it is

Hypothesis testing is a statistical procedure to determine, with a prescribed level of risk, if a set of data (typically from a sample) is compatible with a given hypothesis. The hypothesis may pertain to an assumption of a particular statistical distribution or model, or it may pertain to the value of some parameter of a distribution (such as its mean value).

The procedure for hypothesis testing involves assessing the evidence (in the form of data) to decide whether a given hypothesis regarding a statistical model or parameter, should or should not be rejected.

#### 4.4.2 What it is used for

Hypothesis testing is widely used to enable one to conclude, at a stated level of confidence, whether or not a hypothesis regarding a parameter of a population (as estimated from a sample) is valid. The procedure can therefore be applied to test whether or not a population parameter meets a particular standard; or it may be used to test for differences in two or more populations.

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

The hypothesis test is explicitly or implicitly invoked in many of the statistical techniques cited in this Technical Report such as sampling, SPC charts, design of experiments, regression analysis, measurement analysis, etc.

In addition to a hypothesis test, a range of values in which the parameter in question may plausibly lie (described as a "confidence interval") may be constructed to provide useful supplementary information.

#### 4.4.3 Benefits

Hypothesis testing allows an assertion to be made about some parameter of a population, with a stated level of confidence. As such, it may be of assistance in making decisions that may depend on the parameter.

Hypothesis testing can similarly allow assertions to be made regarding the nature of the distribution of a population, as well as properties of the sample data itself.

#### 4.4.4 Limitations and cautions

To ensure the validity of conclusions reached from hypothesis testing, it is essential that the underlying statistical assumptions are adequately satisfied, notably that the samples are independently and randomly drawn. At a theoretical level, there is some debate regarding how a hypothesis test can be used to make valid inferences.

#### 4.4.5 Examples of applications

Hypothesis testing has general application when an assertion must 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 may be used:

- to test whether the mean (or standard deviation) of a population meets a given value, such as a target or a standard;
- to test whether the means of two 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 has 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.

### 4.5 Measurement analysis

#### 4.5.1 What it is

Measurement analysis (also referred to as "measurement system analysis") is a set of procedures to evaluate the uncertainty of measurement systems under the range of conditions in which the system operates. Measurement errors can be analysed using the same methods as those used to analyse product characteristics.

#### 4.5.2 What it is used for

Measurement uncertainty should be taken into account whenever data are collected. Measurement analysis is used for assessing, at a prescribed level of confidence, whether the measurement system is suitable for its intended purpose. It is used for quantifying variation from various sources such as variation due to the appraiser (i.e. the person taking the measurement), or variation from the measurement instrument itself. It is also used to describe the variation due to the measurement system as a proportion of the total process variation, or the total allowable variation.

#### 4.5.3 Benefits

Measurement analysis provides a quantitative and cost-effective way of selecting a measurement instrument, or for deciding whether the instrument is capable of assessing the product or process parameter being examined.

Measurement analysis provides a basis for comparing and reconciling differences in measurement, by quantifying variation from various sources in measurement systems themselves.

#### 4.5.4 Limitations and cautions

In all but the simplest cases, measurement analysis needs to be conducted by trained specialists. Unless care and expertise is used in its application, the results of measurement analysis may encourage false and potentially costly over-optimism, both in the measurement results and in the acceptability of the product. Conversely, over-pessimism can result in the unnecessary replacement of adequate measurement systems.

### 4.5.5 Examples of applications

- a) Measurement uncertainty determination: The quantification of measurement uncertainties can serve to support an organization's assurance to its customers (internal or external) that its measurement processes are capable of adequately measuring the quality level to be achieved. Measurement uncertainty analysis can often highlight variability in areas that are critical to product quality, and hence guide an organization in allocating resources in such areas to improve or maintain quality.
- b) Selection of new instruments: Measurement analysis can help guide the choice of a new instrument by examining the proportion of variation that is associated with the instrument.
- c) Determination of the characteristics of a particular method (trueness, precision, repeatability, reproducibility, etc.): This allows the selection of the most appropriate measurement method(s) to be used in support of assuring product quality. It may also allow an organization to balance the cost and effectiveness of various measurement methods against their effect on product quality.
- d) Proficiency testing: An organization's measurement system can be assessed and quantified by comparing its measurement results with those obtained from other measurement systems. Also, in addition to providing assurance to customers, this may help an organization to improve its methods or the training of its staff with regard to measurement analysis.

## 4.6 Process capability analysis

### 4.6.1 What it is

Process capability analysis is the examination of the inherent variability and distribution of a process, in order to estimate its ability to produce output that conforms to the range of variation permitted by specifications.

When the data are measurable variables (of the product or process), the inherent variability of the process is stated in terms of the "spread" of the process when it is in a state of statistical control (see 4.11), and is usually measured as six standard deviations ( $6\sigma$ ) of the process distribution. If the process data is a normally distributed ("bell shaped") variable, this spread will (in theory) encompass 99,73 % of the population.

Process capability may be conveniently expressed as an index, which relates the actual process variability to the tolerance permitted by specifications. A widely used capability index for variable data is " $C_p$ ", a ratio of the total tolerance divided by  $6\sigma$ , which is a measure of the theoretical capability of a process that is perfectly centred between the specification limits. Another widely used index is " $C_{pk}$ ", which describes the actual capability of a process which may or not be centred. Other capability indices have been devised to better account for long- and short-term variability and for variation around the intended process target value.

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

### 4.6.2 What it is used for

Process capability analysis is used to assess the ability of a process to produce outputs that consistently conform to specifications, and to estimate the amount of nonconforming product that can be expected.

This concept can be applied to assessing the capability of any sub-set of a process, such as a specific machine. The analysis of "machine capability" can be used, for example, to evaluate specific equipment or to assess its contribution to overall process capability.

### 4.6.3 Benefits

Process capability analysis provides an assessment of the inherent variability of a process and an estimate of the percentage of nonconforming items that can be expected. This enables the organization to estimate the costs of nonconformance, and can help guide decisions regarding process improvement.

Setting minimum standards for process capability can guide the organization in selecting processes and equipment that can produce acceptable product.

#### 4.6.4 Limitations and cautions

The concept of capability strictly applies to a process in a state of statistical control. Therefore, process capability analysis should be performed in conjunction with control methods to provide ongoing verification of control.

Estimates of the percentage of nonconforming product are subject to assumptions of normality. When strict normality is not realized in practice, such estimates should be treated with caution, especially in the case of processes with high capability ratios.

Capability indices can be misleading when the process distribution is substantially non-normal.

Estimates of the percentage of nonconforming units should be based on methods of analysis developed for such distributions. Likewise, in the case of processes that are subject to systematic assignable causes of variation, such as tool wear, specialised approaches must be used to calculate and interpret capability.

#### 4.6.5 Examples of applications:

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. Conversely, when tight tolerances are necessary, component manufacturers are required to achieve specified levels of process capability to ensure high yields and minimum waste.

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

Machine capability 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 and medical device manufacturers routinely use process capability as a major criterion to assess sub-contractors and products. This allows the manufacturer to minimise direct inspection of purchased products and materials.

Some 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.

### 4.7 Regression analysis

#### 4.7.1 What it is

Regression analysis relates the behaviour of a characteristic of interest (usually called the "response variable") with potentially causal factors (usually called "explanatory variables"). Such a relationship is specified by a model that may come from science, economics, engineering, etc. The objective is to help understand the potential cause of variation in the response, and to explain how much each factor contributes to that variation. This is achieved by statistically relating variation in the response variable with variation in the explanatory variables, and obtaining the best fit by minimizing the deviations between the predicted and the actual response.

#### 4.7.2 What it is used for

Regression analysis allows the user to do the following:

- to test hypotheses about the influence of potential explanatory variables on the response, and use this information to describe the estimated change in the response for a given change in an explanatory variable;
- to predict the value of the response variable, for specific values of the explanatory variables;
- to 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;
- to estimate the direction and degree of association between the response variable and an explanatory variable (although such an association does not imply causation). Such information might be used, for example, to determine the effect of changing a factor such as temperature on process yield, while other factors are held constant.

### 4.7.3 Benefits

Regression analysis can provide insight into the relationship between various factors and the response of interest, and such insight can help guide decisions related to the process under study and ultimately improve the process.

The insight yielded by regression analysis follows from its ability to describe patterns in response data concisely, compare different but related subsets of data, and analyse potential cause-and-effect relationships. When the relationships are modelled well, regression analysis can provide an estimate of the relative magnitudes of the effect of explanatory variables, as well as the relative strengths of those variables. This information is potentially valuable in controlling or improving process outcomes.

Regression analysis can also provide estimates of the magnitude and source of influences on the response that come from factors that are either unmeasured or omitted in the analysis. This information can be used to improve the measuring system or to control the process.

Regression analysis can be used to predict the value of the response variable for given values of one or more explanatory variables; likewise it may be used to forecast the effect of changes in explanatory variables on an existing or predicted response. It may be useful to conduct such analyses before investing time or money in a problem when the effectiveness of the action is not known.

### 4.7.4 Limitations and cautions

When modelling a process, skill is required in defining the best specification of the regression model, 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 complicate modelling. Specific assumptions behind the regression model in question, and characteristics of the available data, determine what estimation technique is appropriate in a regression analysis problem.

Whether included or omitted from the analysis, a single observation or a small set of observations may influence estimates of the response. Therefore influential observations must be understood and distinguished from "outliers" in the data; i.e. extreme values whose validity must be investigated where possible.

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. However, omitting an important explanatory variable may seriously limit the model and the usefulness of the results.

### 4.7.5 Examples of applications

Regression analysis is used 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. Regression analysis is used to identify the most important factors in those processes, and the magnitude and nature of their contribution to variation in the characteristic of interest.

Regression analysis is used to predict the outcomes from an experiment, or from controlled prospective or retrospective study of variation in materials or production conditions.

Regression analysis is also used 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.

Examples of applications of non-linear regression include modelling drug concentrations as functions of time and mass of respondents; modelling chemical reactions as a function of time, temperature and pressure, etc.

## 4.8 Reliability analysis

### 4.8.1 What it is

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<sup>2)</sup>.

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

Reliability analysis encompasses other techniques (such as fault mode and effect analysis) which focus on the physical nature and causes of failure, and the prevention or reduction of failures.

### 4.8.2 What it is used for

Reliability analysis is used for the following purposes:

- to verify that specified reliability measures are met, on the basis of data from a test of limited duration and involving a specified 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 statistical data on design parameters, such as stress and strength, 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 statistical confidence levels to be attached to the estimates of the parameters of reliability models that are developed, and to predictions made using such models.

### 4.8.3 Benefits

Reliability analysis provides a quantitative measure of product and service performance against failures or service interruptions. Reliability activities are closely associated with the containment of risk in system operation. Reliability is often an influencing factor in the perception of product or service quality, and in customer satisfaction.

The benefits of using statistical techniques in reliability analysis include:

- the ability to predict and quantify the likelihood of failure and other reliability measures within stated confidence limits;
- insights to guide decisions regarding different design alternatives using different redundancy and mitigation strategies;
- the development of objective acceptance or rejection criteria for performing compliance tests to demonstrate that reliability requirements are met;
- the capability to plan optimal preventive maintenance and replacement schedules based on the reliability analysis of product performance, service and wearout data.

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<sup>2)</sup> Reliability analysis is closely related to the wider field of “dependability” which includes maintainability and availability. These, and other related techniques and approaches, are defined and discussed in the IEC publications cited in the bibliography.

#### 4.8.4 Limitations and cautions

A basic assumption of reliability analysis is that the performance of a system under study can be reasonably characterised 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, which may or may not conform to the same statistical distribution. Also, when the number of failures observed in a reliability test is small, it may severely affect the statistical confidence and precision attached to estimates of reliability.

Another concern relates to the conditions under which the reliability test is conducted, and this is particularly pronounced when the test involves some form of "accelerated stress", i.e. stress that is significantly greater than what the product will experience in normal usage. It may be difficult to determine the relationship between the failures observed under test and product performance under normal operating conditions, and this will add to the uncertainty of reliability predictions.

#### 4.8.5 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 costs based on 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 wearout characteristics to help improve product design, or to plan the appropriate service maintenance schedule and effort required.

### 4.9 Sampling

#### 4.9.1 What it is

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

#### 4.9.2 What it is used for

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 grouping 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 analytic studies for estimating the values of one or more characteristics in a population, or for estimating how those characteristics are distributed across the population. While survey sampling is often associated with polls where information is gathered on people's opinion on a subject, it can be applied equally to data gathering for other purposes, such as audits.

Exploratory sampling used in enumerative studies to gain information about a characteristic(s) of a population or a subset of the population is a specialised form of survey sampling. So is production sampling, which may be carried out to conduct say, a process capability analysis.

### 4.9.3 Benefits

A properly constructed sampling plan offers savings in time, cost and labour when compared with either 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 preliminary information regarding the value or distribution of a characteristic of interest in a population.

### 4.9.4 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 various 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 may 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 may be too large to be of practical value.

### 4.9.5 Examples of applications

A frequent application of survey sampling is in market research, to estimate (say) the proportion of a population that may buy a particular product. Another application is in audits of inventory to estimate the percentage of items that meet specified criteria.

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

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

## 4.10 Simulation

### 4.10.1 What it is

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

### 4.10.2 What it is used for

In the context of theoretical science, simulation is used if no comprehensive theory for the solution of a problem is known (or, if known, 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.

### 4.10.3 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 (e.g. n-dimensional integration). Similarly, in the empirical context, simulation is used when empirical investigations are impossible or too costly. The benefit of simulation is that it allows a solution with saving of time and money, or that it allows a solution at all.

The benefit of using simulation in the teaching of statistics is obvious, since it can effectively illustrate random variation.

#### 4.10.4 Limitations and cautions

Within theoretical science, proofs based on conceptual reasoning are to 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 may not be adequate, i.e. it may not represent the problem sufficiently. Therefore, it cannot be considered a substitute for actual empirical investigations and experimentation.

#### 4.10.5 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 tolerancing, process simulation, system optimization, reliability theory and prediction. Some specific 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 allocation of resources.

### 4.11 SPC charts (Statistical Process Control charts)

#### 4.11.1 What it is

An SPC chart or "control chart" is a graph of data derived from samples that are periodically drawn from a process, and plotted in sequence. Also noted on the SPC chart are "control limits" that 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.

Any variable (measurement data) or attribute (count data) representing a characteristic of interest of a product or process may be plotted. In the case of variable data, a control chart is usually used for monitoring changes in the process centre, and a separate control chart for monitoring changes in process variability.

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

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

#### 4.11.2 What it is used for

An SPC chart is used for detecting changes in a process. The plotted data, which may be an individual reading or some statistic such as the sample average, is compared with 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 identifies the need to investigate the cause of the "out-of-control" reading, and make process adjustments where necessary. This helps to maintain process stability and improve processes in the long run.

The use of control charts can be refined to yield a more rapid indication of process changes, or increased sensitivity to small changes, through the use of additional criteria in interpreting the trends and patterns in the plotted data.

#### 4.11.3 Benefits

In addition to making data visible to the user, control charts facilitate the appropriate response to process variation by distinguishing the random variation that is inherent in a stable process from variation that is probably due to "assignable causes". The role and value of control charts in some process-related activities are noted below.

- a) Process control: variable control charts are used to detect changes in the process centre or process variability and to trigger corrective action, thus maintaining or restoring process stability.
- b) Process capability analysis: if the process is in a stable state, the data from the control chart may be used subsequently to estimate process capability.

- c) Measurement system analysis: by incorporating control limits that reflect the inherent variability of the measurement system, a control chart can show whether the measurement system is capable of detecting the variability of the process or product of interest. Control charts may also be used to monitor the measurement process itself.
- d) Cause and effect analysis: correlation between process events and control chart patterns can help to infer the underlying assignable causes and plan effective action.
- e) Continuous improvement: control charts are used to monitor and help identify causes of process variation, and to help reduce causes of variation.

#### 4.11.4 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 the "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 sufficient data is seldom present to establish the appropriate control limits.

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.

#### 4.11.5 Examples of applications

Companies in automotive, electronics, defence and other sectors often require their suppliers to maintain control charts for critical characteristics to demonstrate continuing process stability and capability. If nonconforming products are received, the charts are used to help establish the risk and determine the scope of corrective action.

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

Control charts are used in machining industries to reduce unnecessary process intervention (over-adjustment) by enabling employees to distinguish between variation that is inherent to the process, and variation that may be attributed to an "assignable cause".

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.

### 4.12 Statistical tolerancing

#### 4.12.1 What it is

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

#### 4.12.2 What it is used for

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

Extreme values for the total dimension, i.e. very large or small values, only occur if the dimensions of *all* individual components lie either at the lower or upper end of their relevant individual ranges of tolerances. Within the framework of a chain of tolerances, if the individual tolerances are added up into a total dimension tolerance, then one refers to this as the arithmetical overall tolerance.

For statistical determination of overall tolerances, one assumes 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 may 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 quite independent of the distribution of the individual dimensions, and may therefore be used to estimate the tolerance range of the total dimension of the assembled module. Alternatively given the overall dimension tolerance, it may be used to determine the permissible tolerance range of the individual components.

#### 4.12.3 Benefits

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

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

#### 4.12.4 Limitations and cautions

Statistical tolerancing requires one to first establish what proportion of assembled modules could acceptably lie outside the tolerance range of the total dimension. The following prerequisites should then be met for statistical tolerancing to be practicable (without necessitating advanced methods):

- 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 tolerancing.

#### 4.12.5 Examples of applications

The theory of statistical tolerancing 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 tolerancing include mechanical, electronic and chemical industry. The theory is also applied in computer simulation to determine optimum tolerances.

### 4.13 Time series analysis

#### 4.13.1 What it is

Time series analysis (sometimes called trend analysis) is a family of methods for studying a collection of observations made sequentially in time. The methods include:

- plotting a time series, often called trend chart, of some characteristic of interest on the (vertical)  $y$ -axis and the time period on the (horizontal)  $x$ -axis;
- 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 that are cyclical or seasonal, to understand how causal factors in the past may 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.

#### 4.13.2 What it is used for

Time series analysis is used for describing patterns in time series data, for identifying “outliers” (i.e. extreme values whose validity must be investigated) either to help understand the patterns or to make adjustments, and for detecting turning points in a trend. Another use is for explaining patterns in one time series with those of another time series, with all the objectives inherent in regression analysis.

Time series analysis is used for predicting future values of time series, typically with some upper and lower limits known as the forecast interval. It has extensive use in the area of control and is often applied to automated processes. In that case, a probability model is fitted to the historical time series, future values are predicted, and then specific process parameters are adjusted to keep the process on target, with as little variation as possible.

#### 4.13.3 Benefits

Time series analysis methods are useful in planning, in control engineering, in identifying a change in a process, in generating forecasts, and in 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 may 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 and trend components.

Time series analysis is often useful for understanding how a process will behave under specified conditions, and what adjustments (if any) may influence the process in the direction of some target value, or what adjustments may reduce process variability.

#### 4.13.4 Limitations and cautions

The limitations and cautions cited for regression analysis also apply to time series analysis. When modelling a process 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 may 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 may 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 time 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.

#### 4.13.5 Examples of applications

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

Forecasting applications include predicting spare parts, absenteeism, customer orders, materials needs, electric power consumption, etc.

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 equipment outages.