TECHNICAL REPORT

ISO/TR 10017

First edition
1999-09-01

Guidance on statistical techniques for ISO 9001:1994

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

Reference number
ISO/TR 10017:1999(E)

Contents

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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.

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 exercized 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 4.13.1General	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; Tme 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 meets 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[1]. 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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1) 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