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Napotki za statistiļne metode v zvezi z ISO 9001:2000

Guidance on statistical techniques for ISO 9001:2000

Lignes directrices pour les techniques statistiques relatives à l'ISO 9001:2000

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TECHNICAL REPORT

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Guidance on statistical techniques for ISO 9001:2000

Lignes directrices pour les techniques statistiques relatives à l'ISO 9001:2000

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Contents

Page

Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO/TR 10017:1999) and is now based on ISO 9001:2000.

This Technical Report might 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, maintaining and improving a quality management system in compliance with the requirements of ISO 9001:2000.

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

Statistical techniques can thus allow better use of available data to assist in decision making, and thereby help to continually improve the quality of products and processes to achieve customer satisfaction. These techniques are applicable to a wide spectrum of activities, such as market research, design, development, production, verification, 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 applicable to other standards in the ISO 9000 family, in particular ISO 9004:2000.

Guidance on statistical techniques for ISO 9001:2000

1 Scope

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

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

This Technical Report is not intended for contractual, regulatory or certification/registration purposes. It is not intended to be used as a mandatory checklist for compliance with ISO 9001:2000 requirements. The justification for using statistical techniques is that their application would help to improve the effectiveness of the quality management system.

NOTE 1 The terms “statistical techniques” and “statistical methods” are often used interchangeably.

NOTE 2 References in this Technical Report to “product” are applicable to the generic product categories of service, software, hardware and processed materials, or a combination thereof, in accordance with the definition of “product” in ISO 9000:2000.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9001:2000, *Quality management systems — Requirements*

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 statistical techniques that could be of potential benefit to the organization, when appropriately applied to such data.

NOTE Statistical techniques can be usefully applied to qualitative data, if such data can be converted into quantitative data.

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

The statistical techniques cited in this Technical Report are limited to those that are well known. Likewise, only relatively straightforward applications of statistical techniques are identified here.

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 the organization should use them in a specific context.

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

Clause/subclause of ISO 9001:2000	Needs involving the use of quantitative data	Statistical technique(s)
4 Quality management system		
4.1 General requirements	See Introduction to this Technical Report	
4.2 Documentation requirements		
4.2.1 General	None identified	
4.2.2 Quality manual	None identified	
4.2.3 Control of documents	None identified	
4.2.4 Control of records	None identified	
5 Management responsibility		
5.1 Management commitment	None identified	
5.2 Customer focus	Need to determine customer requirements	See 7.2.2 in this table
	Need to assess customer satisfaction	See 8.2.1 in this table
5.3 Quality policy	None identified	
5.4 Planning		
5.4.1 Quality objectives	None identified	
5.4.2 Quality management system planning	None identified	
5.5 Responsibility, authority and communication	None identified	
5.5.1 Responsibility and authority	None identified	
5.5.2 Management representative	None identified	
5.5.3 Internal communication	None identified	
5.6 Management review		
5.6.1 General	None identified	
5.6.2 Review input		
a) results of audits	Need to obtain and evaluate audit data	Descriptive statistics; sampling
b) customer feedback	Need to obtain and assess customer feedback	Descriptive statistics; sampling
c) process performance and product conformity	Need to assess process performance and product conformity	Descriptive statistics; process capability analysis; sampling; SPC charts
d) status of preventive and corrective actions	Need to obtain and evaluate data from preventive and corrective actions	Descriptive statistics
5.6.3 Review output	None identified	

Clause/subclause of ISO 9001:2000	Needs involving the use of quantitative data	Statistical technique(s)
6 Resource management 6.1 Provision of resources	None identified	
6.2 Human resources 6.2.1 General	None identified	
6.2.2 Competence, awareness and training 6.2.2 a)	None identified	
6.2.2 b)	None identified	
6.2.2 c) evaluate the effectiveness of the actions taken	Need to assess competence, and effectiveness of training	Descriptive statistics; sampling
6.2.2 d)	None identified	
6.2.2 e)	None identified	
6.3 Infrastructure	None identified	
6.4 Work environment	Need to monitor the work environment	Descriptive statistics; SPC charts
7 Product realization 7.1 Planning of product realization	None identified	
7.2 Customer-related processes 7.2.1 Determination of requirements related to the product	None identified	
7.2.2 Review of requirements related to the product	Need to assess the organization's ability to meet defined requirements	Descriptive statistics; measurement analysis; process capability analysis; sampling; statistical tolerancing
7.2.3 Customer communication	None identified	
7.3 Design and development 7.3.1 Design and development planning	None identified	
7.3.2 Design and development inputs	None identified	
7.3.3 Design and development outputs	Need to verify that design outputs satisfy input requirements	Descriptive statistics; design of experiments; hypothesis testing; measurement analysis; regression analysis; reliability analysis; sampling; simulation; time series analysis
7.3.4 Design and development review	None identified	
7.3.5 Design and development verification	Need to verify that design outputs satisfy input requirements	Descriptive statistics; design of experiments; hypothesis testing; measurement analysis; process capability analysis; regression analysis; reliability analysis; sampling; simulation; time series analysis
7.3.6 Design and development validation	Need to validate that product meets stated use and needs	Descriptive statistics; design of experiments; hypothesis testing; measurement analysis; process capability analysis; regression analysis; reliability analysis; sampling; simulation

Clause/subclause of ISO 9001:2000	Needs involving the use of quantitative data	Statistical technique(s)
7.3.7 Control of design and development changes	Need to evaluate, verify and validate effect of design changes	Descriptive statistics; design of experiments; hypothesis testing; measurement analysis; process capability analysis; regression analysis; reliability analysis; sampling; simulation
7.4 Purchasing		
7.4.1 Purchasing process	Need to ensure that purchased product conforms to specified purchase requirements	Descriptive statistics; hypothesis testing; measurement analysis; process capability analysis; regression analysis; reliability analysis; sampling
	Need to evaluate suppliers ability to supply product to meet organizations requirements	Descriptive statistics; design of experiments; process capability analysis; regression analysis; sampling
7.4.2 Purchasing information	None identified	
7.4.3 Verification of purchased product	Need to establish and implement inspection and other activities to ensure that purchased product meets specified requirements	Descriptive statistics; hypothesis testing; measurement analysis; process capability analysis; reliability analysis; sampling
7.5 Production and service provision		
7.5.1 Control of production and service provision	Need to monitor and control production and service activity	Descriptive statistics; measurement analysis; process capability analysis; regression analysis; reliability analysis; sampling; SPC charts; time series analysis
7.5.2 Validation of processes for production and service provision	Need to validate, monitor, and control processes whose output cannot be readily measured	Descriptive statistics; process capability analysis; regression analysis; sampling; SPC charts; time series analysis
7.5.3 Identification and traceability	None identified	
7.5.4 Customer property	Need to verify characteristics of customer property	Descriptive statistics; sampling
7.5.5 Preservation of product	Need to monitor the effect of handling, packaging and storage on product quality	Descriptive statistics; regression analysis; reliability analysis; sampling; SPC charts; time series analysis
7.6 Control of monitoring and measuring devices	Need to ensure that monitoring and measurement process and equipment is consistent with requirement.	Descriptive statistics; measurement analysis; process capability analysis; regression analysis; sampling; SPC charts; statistical tolerancing; time series analysis
	Need to assess the validity of previous measurements, where required	Descriptive statistics; hypothesis testing; measurement analysis; regression analysis; sampling; statistical tolerancing; time series analysis
8 Measurement, analysis and improvement		
8.1 General	None identified	
8.2 Monitoring and measurement		
8.2.1 Customer satisfaction	Need to monitor and analyse information pertaining to customer perception	Descriptive statistics; sampling