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

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

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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.

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

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

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

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

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

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

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

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

Introduction

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

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

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

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

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

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

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

1 Scope

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

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

2 Normative references

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

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

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

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

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

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

3 Terms and definitions

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

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

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

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

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

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

4 Statistical techniques in the implementation of ISO 9001

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

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

— descriptive statistics (see 7.1);

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

— hypothesis testing (see 7.3);

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

— process capability analysis (see 7.5);

— regression analysis (see 7.6);

— reliability analysis (see 7.7);

— sampling (see 7.8);

— simulation (see 7.9);

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

— statistical tolerance (see 7.11);

— time series analysis (see 7.12).

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

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

5   Quantitative data and associated statistical techniques in ISO 9001

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

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

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

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

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

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

Table 1 *(continued)*

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

Table 1 *(continued)*

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

Table 1 *(continued)*

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