DRAFT INTERNATIONAL STANDARD

# ISO/DIS 10017

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| ISO/TC **176**/SC **3** | Secretariat: **NEN** |
| Voting begins on: **2020-04-10** | Voting terminates on: **2020-07-03** |

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

ICS: 03.120.30; 03.120.10





This document is circulated as received from the committee secretariat.

Reference number
ISO/DIS 10017:2020(E)



ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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# Foreword

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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 document cancels and replaces ISO/TR 10017. By decision of ISO/TC 176/SC 3 this work is now revised as a full guidance standard and aligned with ISO 9001:2015.

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

Statistical techniques can be employed to benefit a wide spectrum of activities and sectors.

The value of statistical techniques follows from the variability that 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 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 could stem from such variability.

The analysis of available data using statistical techniques can assist in decision making and thereby help to improve the performance of processes and the resulting products and/or services, to provide benefits in productivity and cost.

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 ISO standard is to assist an organization to identify statistical techniques against the elements of a quality management system as defined by ISO 9001:2015, which may help to improve processes and the resulting products and services.

This document may be also used to support other management systems and supporting standards such as, for example, environmental management system, health/safety management system or other management systems.

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

## 1 Scope

This document provides guidance on the selection of appropriate statistical techniques that may be useful to an organization, irrespective of size or complexity, in developing, implementing, maintaining and improving a quality management system in compliance with ISO 9001:2015.

Note 1 This standard 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 9001:2015 requirements.

Note 2 This standard 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: Probability and general statistical terms*

ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Statistical quality control*

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*

ISO 9001:2015, *Quality management systems — Requirements*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534, Parts 1, 2 ,3 and 4 and in 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**
methodology for the analysis of quantitative data (ISO 9000:2015, 3.8.1) associated with variation in products, processes, services and phenomena under study to provide information (ISO 9000:2015, 3.8.2) 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

Note 2 to entry: For the purposes of this document, the term “statistical techniques” are interchangeable with “statistical methods”

## 4 Statistical techniques in the implementation of ISO 9001

The justification for using statistical techniques is that their application could help to improve the effectiveness of the quality management system.

Statistical techniques, or families of techniques, that find useful and ready application in the implementation of ISO 9001 are listed below (in alphabetical order)

— descriptive statistics;

— design of experiments;

— hypothesis testing;

— measurement system analysis;

— process capability analysis;

— regression analysis;

— reliability analysis;

— sampling;

— simulation;

— statistical process control;

— statistical tolerance;

— time series analysis.



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 standard 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 standard 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.

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

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

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

The statistical techniques cited in this guidance standard 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 may be useful in the context of that clause.

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

| Clause/sub-clause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| **1 Scope** | Not applicable | |
| **2 Normative references** | Not applicable | |

**Table 1** *(continued)*

| Clause/sub-clause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| **3 Terms and definitions** | Not applicable | |
| **4. Context of the organization** | — | |
| **4.1 Understanding the organization and its context** | Data regarding internal and external issues, for example:<br>• Financial<br>• Market research<br>• Sales<br>• Product and service performance<br>• Competition / benchmarking | Descriptive statistics<br>Statistical process control<br>Sampling<br>Time series analysis |
| **4.2 Understanding the needs and expectations of Interested parties** | Subjective and objective data regarding expectations of interested parties (e.g. market research) | Descriptive statistics<br>Sampling<br>Time series analysis |
| **4.3 Determining the scope of the quality management system** | None identified | |
| **4.4 Quality management system and its processes** | — | |
| **4.4.1** | None identified | |
| **4.4.2** | None identified | |
| **5. Leadership** | — | |
| **5.1 Leadership and commitment** | — | |
| **5.1.1 General** | None Identified | |
| **5.1.2 Customer focus** | None identified | |
| **5.2 Policy** | — | |
| **5.2.1 Establishing the quality policy** | None identified | |
| **5.2.2 Communicating the quality policy** | Data to determine extent to which policy is understood | Descriptive statistics<br>Sampling |
| **5.3 Organizational roles, responsibilities and authorities** | None identified | |
| **6 Planning** | — | |
| **6.1 Actions to address risks and opportunities** | — | |
| **6.1.1** | Business data to assess risks | Descriptive statistics |
| **6.1.2** | Business data to assess effectiveness of actions | Descriptive statistics |
| **6.2 Quality objectives and planning to achieve them** | — | |
| **6.2.1** | None identified | |
| **6.2.2** | None identified | |
| **6.3 Planning of changes** | None identified | |
| **7 Support** | — | |
| **7.1 Resources** | — | |

**Table 1** *(continued)*

| Clause/sub-clause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| 7.1.1 **General** | Summary data on capability | Descriptive statistics |
| 7.1.2 **People** | None identified | |
| *7.1.3 Infrastructure* | Quantitative data related to the performance and reliability of equipment (hardware and software) and transportation | Descriptive statistics<br>Process capability analysis<br>Reliability analysis |
| *7.1.4 Environment for the operation of processes* | Data on the environment, for example:<br>• Contamination levels<br>• Antistatic controls<br>• Temperatures (e.g. bacteria control)<br>• Morale (e.g. absenteeism) | Descriptive statistics<br>Measurement system analysis<br>Process capability analysis<br>Sampling<br>Statistical process control<br>Time series analysis |
| 7.1.5 **Monitoring and measuring resources** | — | |
| 7.1.5.1 **General** | Data relating to measurement capability | Descriptive statistics<br>Measurement system analysis<br>Statistical tolerance |
| 7.1.5.2 **Measurement traceability** | Data relating to stability of measurement systems | Descriptive statistics<br>Time series analysis |
| 7.1.6 **Organizational knowledge** | None identified | |
| 7.2 **Competence** | Quantitative data on training and effectiveness of training | Descriptive statistics |
| 7.3 **Awareness** | None identified | |
| 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 communications** | None identified | |

**Table 1** *(continued)*

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

**Table 1** *(continued)*

| Clause/sub-clause of ISO 9001:2015 | Quantitative data involved | Statistical technique(s) |
|---|---|---|
| **8.3.6 Design and development changes** | Data re verification of impact of changes | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Regression analysis<br>Sampling<br>Simulation |
| **8.4 Control of externally provided processes, products and services** | — | |
| **8.4.1 General** | None identified | |
| **8.4.2 Type and extent of control** | Incoming control data | Descriptive statistics<br>Measurement system analysis<br>Regression analysis<br>Sampling<br>Time series analysis |
| | Supplier process control data | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Reliability analysis<br>Sampling<br>Statistical process control<br>Statistical tolerances<br>Time series analysis |
| **8.4.3 Information for external providers** | None identified | |
| **8.5 Production and service provision** | — | |
| **8.5.1 Control of production and service provision** | Production and service data | Descriptive statistics<br>Design of experiments<br>Hypothesis testing<br>Measurement system analysis<br>Process capability analysis<br>Regression analysis<br>Sampling<br>Statistical process control<br>Time series analysis |
| **8.5.2 Identification and traceability** | None identified | |