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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.

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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.

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