

This is a preview of "ISO 10017:2021". [Click here to purchase the full version from the ANSI store.](#)

First edition
2021-07

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

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



Reference number
ISO 10017:2021(E)

© ISO 2021

This is a preview of "ISO 10017:2021". [Click here to purchase the full version from the ANSI store.](#)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

This is a preview of "ISO 10017:2021". [Click here to purchase the full version from the ANSI store.](#)

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Statistical techniques in the implementation of ISO 9001	1
5 Quantitative data and associated statistical techniques in ISO 9001	2
6 Applicability of selected techniques	9
7 Description of statistical techniques	9
7.1 Descriptive statistics.....	9
7.1.1 General description.....	9
7.1.2 Benefits.....	11
7.1.3 Limitations and cautions.....	11
7.1.4 Examples of applications.....	12
7.2 Design of experiments.....	12
7.2.1 General description.....	12
7.2.2 Benefits.....	12
7.2.3 Limitations and cautions.....	13
7.2.4 Examples of applications.....	13
7.3 Hypothesis testing.....	13
7.3.1 General description.....	13
7.3.2 Benefits.....	14
7.3.3 Limitations and cautions.....	14
7.3.4 Examples of applications.....	14
7.4 Measurement system analysis.....	14
7.4.1 General description.....	14
7.4.2 Benefits.....	15
7.4.3 Limitations and cautions.....	15
7.4.4 Examples of applications.....	15
7.5 Process capability analysis.....	15
7.5.1 General description.....	15
7.5.2 Benefits.....	16
7.5.3 Limitations and cautions.....	16
7.5.4 Examples of applications.....	17
7.6 Regression analysis.....	17
7.6.1 General description.....	17
7.6.2 Benefits.....	18
7.6.3 Limitations and cautions.....	18
7.6.4 Examples of applications.....	19
7.7 Reliability analysis.....	19
7.7.1 General description.....	19
7.7.2 Benefits.....	20
7.7.3 Limitations and cautions.....	20
7.7.4 Examples of applications.....	20
7.8 Sampling.....	21
7.8.1 General description.....	21
7.8.2 Benefits.....	21
7.8.3 Limitations and cautions.....	21
7.8.4 Examples of applications.....	22
7.9 Simulation.....	22
7.9.1 General description.....	22
7.9.2 Benefits.....	22

This is a preview of "ISO 10017:2021". [Click here to purchase the full version from the ANSI store.](#)

7.9.3	Limitations and cautions	23
7.9.4	Examples of applications	23
7.10	Statistical process control	23
7.10.1	General description	23
7.10.2	Benefits	24
7.10.3	Limitations and cautions	25
7.10.4	Examples of applications	25
7.11	Statistical tolerance	25
7.11.1	General description	25
7.11.2	Benefits	26
7.11.3	Limitations and cautions	26
7.11.4	Examples of applications	26
7.12	Time series analysis	26
7.12.1	General description	26
7.12.2	Benefits	27
7.12.3	Limitations and cautions	27
7.12.4	Examples of applications	28
Bibliography		29

This is a preview of "ISO 10017:2021". [Click here to purchase the full version from the ANSI store.](#)

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.