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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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

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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.