AS ISO 10017—2006

Australian Standard®

Guidance on statistical techniques for ISO 9001:2000 (ISO/TR 10017, Ed. 2.0 (2003) MOD)

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- Main Roads Department, Queensland
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PREFACE

This Standard was prepared by the Australian members of Joint Standards Australia/New Zealand Committee QR-008, Quality Systems. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australia/New Zealand Standard.

The objective of this Standard is to provide organizations with guidance on the selection of statistical techniques that may assist in developing, implementing, maintaining and improving a quality management system and its component processes.

For clarity the guidance provided is limited to well-known techniques and is aligned with AS/NZS ISO 9001. This does not imply preference for the particular techniques mentioned, or that they are essential for compliance with AS/NZS ISO 9001. In all cases the use of statistical techniques requires care in selection and application and an understanding of the process under investigation.

This Standard is an adoption with national modifications and has been reproduced from ISO/TR 10017, Ed. 2.0 (2003), *Guidance on statistical techniques for ISO 9001:2000*, and has been varied as indicated to take account of Australian/New Zealand conditions.

Variations to ISO/TR 10017, Ed. 2.0 (2003) are indicated at the appropriate places throughout this standard. Strikethrough (~~example~~) identifies ISO text, tables and figures which, for the purposes of this Australian Standard, are deleted. Where text, tables or figures are added, each is set in its proper place and identified by shading (example). Added figures are not themselves shaded, but are identified by a shaded border.

As this Standard is reproduced from an international standard, the following applies:

(a) Its number appears on the cover and title page while the international standard number appears only on the cover.

(b) In the source text 'ISO/TR 10017' should read 'AS ISO/TR 10017'.

(c) A full point substitutes for a comma when referring to a decimal marker.

The Bibliography provides additional information on ISO and IEC publications related to statistical techniques and reliability analysis, some of which are identified as having been adopted as Australian or Australian/New Zealand Standards.

The reader seeking further guidance on selection and an overview of all reference Standards, guides and technical reports developed by the ISO Technical Committee on Applications of statistical methods, ISO/TC 69, may wish also to refer to—

AS ISO 13462.1—2004, *Guidelines for implementation of statistical process control (SPC) Part 1: Elements of SPC*

AS ISO 13425—2004 (ISO/TR 13425:2003), *Guidelines for the selection of statistical methods in standardization and specification.*

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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.

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Any table, figure or text of the international standard that is struck through is not part of this standard. Any Australian table, figure or text that is added is part of this standard and is identified by shading.

1 Scope

This Technical Report provides guidance on the selection of appropriate statistical techniques that may be useful to an organization in developing, implementing, maintaining and improving a quality management system in compliance with ISO 9001. This is done by examining those requirements of ISO 9001 that involve the use of quantitative data, and then identifying and describing the statistical techniques that can be useful when applied to such data.

The list of statistical techniques cited in this Technical Report 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 Technical Report 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.

This Technical Report 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 9001:2000 requirements. The justification for using statistical techniques is that their application would help to improve the effectiveness of the quality management system.

NOTE 1 The terms “statistical techniques” and “statistical methods” are often used interchangeably.

NOTE 2 References in this Technical Report to “product” are applicable to the generic product categories of service, software, hardware and processed materials, or a combination thereof, in accordance with the definition of “product” in ISO 9000:2000.

2 Normative references

The following referenced documents are indispensable for the application 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.

References to international standards that are struck through in this clause are replaced by references to Australian or Australian/New Zealand Standards that are listed immediately thereafter and identified by shading. Any Australian or Australian/New Zealand Standard that is identical to the International Standard it replaces is identified as such.

~~ISO 9001:2000, *Quality management systems—Requirements*~~

AS/NZS ISO 9001, *Quality management systems—Requirements* (identical to ISO 9001)