

AS/NZS 3905.14:1998

Australian/New Zealand Standard™

Quality system guidelines

**Part 14: Guide to AS/NZS ISO 9001,
9002 and 9003 for health services**

AS/NZS 3905.14:1998

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee QR/2, Quality of Service.

The objective of this Guide is to provide assistance to organizations which provide health services and those involved in a health services environment in understanding ISO 9000 and to offer guidance on developing and implementing a quality system based on the ISO 9000 series of Standards.

In this Guide, Clauses from AS/NZS ISO 9001 are given in a box. This is followed by guidance on that Clause which explains how it can be implemented, and offers examples.

For ease of reading, the guidance is set out under the 20 headings which correspond to the headings of AS/NZS ISO 9001:1994, referred to herein as the Standard. However, when implementing a quality system, each organization should start by identifying its key processes and building on existing procedures and management and control systems, in order to develop a quality system which is suitable for, and is structured to reflect, the services it supplies and the processes and specific practices it employs.

The examples given should not be taken as prescriptive or exhaustive, or as preferred methods. There are many ways of achieving the intent of the Standard, and the health services provider should adopt those approaches that best suit its mode of operation.

In addressing AS/NZS ISO 9001, this Guide also provides all the necessary guidance for AS/NZS ISO 9002:1994, which many health service organizations may find suitable for their needs. (Clause 4.4, Design control, does not apply to AS/NZS ISO 9002.)

Attention is drawn to AS/NZS ISO 9004.1:1994, *Quality management and quality system elements*, Part 1: *Guidelines*, which is a general guide to quality management and quality assurance systems. Information on other Standards which may be relevant is provided in Appendix B.

The term 'informative' has been used in this Standard to define the application of the appendix to which it applies. An 'informative' appendix is only for information and guidance.

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