Australian Standard®

Quality system guidelines

Part 1: Guidelines to AS 3901/NZS 9001/ISO 9001 for the chemical and allied industries

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Chemical manufacturers

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Australian Standard®

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Part 1: Guidelines to AS 3901/NZS 9001/ISO 9001 for the chemical and allied industries

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PREFACE

These Guidelines were prepared by a Committee convened by the Australian Chemical Industry Council comprising chemical manufacturers and quality systems certification bodies.

These Guidelines have been prepared for the chemical and allied industries and are based on the Chemical Industries Association (U.K.) publication, ISO 9001, EN 29001, BS 5750: Part 1: 1987 Guidelines for use by the Chemical and Allied Industries. The cooperation of the CIA (U.K.) in making this document available is gratefully acknowledged.

The Guidelines are considered relevant to those organizations involved in process industries such as petroleum, food, mining, building materials, adhesives and sealants, detergents, cosmetics, pharmaceuticals, inks, paints, etc.

While a copy of the Standard AS 3901/NZS 9001/ISO 9001, *Quality systems for design/development, production, installation and servicing*, to which these Guidelines are directed is not enclosed, it can be obtained from any Standards Australia office (addresses on back cover). Copies of ISO 8402, *Quality vocabulary* and AS 3904.1/NZS 9004.1/ISO 9004, *Quality management and quality system elements – Guidelines* (referred to within the Guidelines) can also be obtained from Standards Australia.

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FOREWORD

These Guidelines are intended to be used by a company in the role of a supplier as an aid to the interpretation of the requirements of AS 3901 for the chemical and allied industries. Where AS 3901 is referenced in this document it implies ISO 9001 and NZS 9001. AS 3901 includes AS 3902/NZS 9002/ISO 9002 and AS 3903/NZS 9003/ISO 9003. In these Guidelines, supplier and company are synonymous.

It is suggested that these Guidelines may also be used, with few alterations, for other process industries.

This edition addresses AS 3901 (which includes all the requirements of AS 3902 and AS 3903), though AS 3902 remains the Standard most suited to the majority of chemical industry businesses when manufacturing rather than development is the main focus.

Attention is drawn to AS 3904.1/NZS 9004.1/ISO 9004 which is a general guide to quality management and quality system elements, although no guidance specific to the chemical and allied industries is given. This gives guidance to the application of AS 3901, AS 3902 and AS 3903. Such guidance will not be specific to any particular industrial sector, whereas these Guidelines are particular to the chemical and allied industries.

The requirements relating to health, safety and environment are limited to those under the heading of Design Control (see Clause 4.4). However, since these have become an integral part of the operations, they should, of necessity, form part of all relevant procedures.

The requirements relating to product liability are limited to those under the heading of Design Control (see Clause 4.4).

Where documents are part of a requirement, the electronic equivalent is acceptable.

In the appendices to this document, guidance is given in relation to the operation of third party registration schemes. This information is intended for use as broad guidance only and reference should be made to the appropriate certification body in individual circumstances.

DEFINITIONS

In addition to the definitions of ISO 8402–1986, the following definitions are useful in relation to the chemical industry. Individual usage of the terms may differ from company to company but the definitions listed are those used throughout these Guidelines.

Agent

A person or company appointed by a principal to sell product on a commission basis. An agent does not have ownership of the product.

Batch

In a batch process, this is the quantity of finished chemical produced at one time. In a continuous or semi-continuous process, it is not possible to define a batch in the above sense and consequently it is usual to talk in terms of a lot (q.v.).

Certificate of analysis

A statement relating specifically to results of testing of a sample drawn from the material to be delivered. It incorporates test results, the detail of which should be agreed between customer and supplier.

Certificates of analysis should be requested by the supplier for the quality system only where specific use is to be made of the information—for example, in statistical examination of performance and in the absence of any statistical control by the subcontractor.

It is appreciated that, with exports, firms are sometimes requested to provide certificates of analysis which, for diverse reasons, cannot meet the above definitions.

Certificate of conformity

A statement of conformity to specification.

The provision of a certificate of conformity is not a requirement of the Standard although customers may request suppliers to provide this document. See the guidance notes to Clauses 4.3 and 4.6.

A certificate of conformity does not imply that the actual material delivered has been tested but that all the material from which the delivery has been made up has, at some stage, been inspected and tested according to the requirements of the established quality system and found to conform to specification.

Consignment stock

A quantity of product owned by the supplier but kept in the customer's store for that customer's specific use and the ownership is transferred when used. Consignment stock may be either packed or bulk product.

Design

In the chemical industry, the term 'design' includes all the operations that are normally included in research and development activities where these include the development of both products and processes.