

Australian Standard<sup>®</sup>

---

**Quality system guidelines**

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

---

This Australian Standard was prepared by Committee QR/-/2, Chemical Guidelines Quality Committee. It was approved on behalf of the Council of Standards Australia on 1 November 1991 and published on 11 November 1991.

---

The following interests are represented on Committee QR/-/2:

Australian Chemical Industry Council

Chemical manufacturers

Quality systems certification bodies

---

**Review of Australian Standards.** To keep abreast of progress in industry, Australian Standards are subject to periodic review and are kept up to date by the issue of amendments or new editions as necessary. It is important therefore that Standards users ensure that they are in possession of the latest edition, and any amendments thereto.

Full details of all Australian Standards and related publications will be found in the Standards Australia Catalogue of Publications; this information is supplemented each month by the magazine 'The Australian Standard', which subscribing members receive, and which gives details of new publications, new editions and amendments, and of withdrawn Standards.

Suggestions for improvements to Australian Standards, addressed to the head office of Standards Australia, are welcomed. Notification of any inaccuracy or ambiguity found in an Australian Standard should be made without delay in order that the matter may be investigated and appropriate action taken.

AS 3905.1—1991

Australian Standard<sup>®</sup>

---

**Quality system guidelines**

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

---

First published as AS 3905.1—1991.

PUBLISHED BY STANDARDS AUSTRALIA  
(STANDARDS ASSOCIATION OF AUSTRALIA)  
1 THE CRESCENT, HOMEBUSH, NSW 2140

ISBN 0 7262 7181 0

## 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.

## © Copyright — STANDARDS AUSTRALIA

Users of Standards are reminded that copyright subsists in all Standards Australia publications and software. Except where the Copyright Act allows and except where provided for below no publications or software produced by Standards Australia may be reproduced, stored in a retrieval system in any form or transmitted by any means without prior permission in writing from Standards Australia. Permission may be conditional on an appropriate royalty payment. Requests for permission and information on commercial software royalties should be directed to the head office of Standards Australia.

Standards Australia will permit up to 10 percent of the technical content pages of a Standard to be copied for use exclusively in-house by purchasers of the Standard without payment of a royalty or advice to Standards Australia.

Standards Australia will also permit the inclusion of its copyright material in computer software programs for no royalty payment provided such programs are used exclusively in-house by the creators of the programs.

Care should be taken to ensure that material used is from the current edition of the Standard and that it is updated whenever the Standard is amended or revised. The number and date of the Standard should therefore be clearly identified.

The use of material in print form or in computer software programs to be used commercially, with or without payment, or in commercial contracts is subject to the payment of a royalty. This policy may be varied by Standards Australia at any time.

## CONTENTS

	<i>Page</i>
FOREWORD .....	4
0 INTRODUCTION .....	6
1 SCOPE AND FIELD OF APPLICATION .....	6
1.1 Scope .....	6
1.2 Field of application .....	6
2 REFERENCES .....	6
3 DEFINITIONS .....	6
4 THE ELEMENTS OF THE STANDARD .....	6
4.1 Management responsibility .....	6
4.2 Quality system .....	7
4.3 Contract review .....	8
4.4 Design control .....	9
4.5 Document control .....	10
4.6 Purchasing .....	10
4.7 Purchaser supplied product .....	12
4.8 Product identification and traceability .....	12
4.9 Process control .....	12
4.10 Inspection and testing .....	13
4.11 Inspection, measuring and test equipment .....	14
4.12 Inspection and test status .....	15
4.13 Control of non-conforming product .....	15
4.14 Corrective action .....	15
4.15 Handling, storage, packaging and delivery .....	16
4.16 Quality records .....	16
4.17 Internal quality audits .....	16
4.18 Training .....	16
4.19 Servicing .....	17
4.20 Statistical techniques .....	17
APPENDICES	
A GUIDANCE NOTES RELATING TO REGISTRATION SCHEMES OPERATED BY ACCREDITED CERTIFICATION BODIES FOR THE CHEMICAL AND ALLIED INDUSTRIES .....	18
B ‘RULES OF REGISTRATION’ UNDER WHICH REGISTRATION OF A FIRM’S COMPLETE BUSINESS ACTIVITY MAY OCCUR .....	19
C CHECKLIST FOR CONSUMERS AGAINST A SUPPLIER’S CLAIM OF ‘REGISTRATION AGAINST AS 3901, AS 3902 OR AS 3903’ .....	20

## 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.