S/S BY A.S. 3911.1-1992

AS 3911.1(Int)—1990

Auditing guidelines adopted! TAS APRIL 1992

Following a two year period in which the AS 3911 series of standards on guidelines for auditing quality systems has been available to Australian organizations in "Interim Standard" form, the relevant tecnical committee (QR/6) has recently been balloted for the adoption of the final texts of ISO 10011, Part 1-Auditing, Part 2-Qualification criteria for quality systems auditors, and Part 3-Management and audit programs.

In addition to the intention to make these available as full, rather than Interim, publications, they will also be issued as joint Australia and New Zealand standards. With the recent advent of the Joint Accreditation System—Australia and New Zealand (JAS-ANZ), the opportunity is being taken to include, in an informative annex, guidance as to the qualifications and experience expected of auditors, and the procedures for obtaining certification.

To facilitate this, JAS-ANZ will be accrediting acceptable auditor training organizations and courses. Final evaluation of the suitability of applicants for auditing certification will be coordinated by the Quality Society of Australasia, and will involve a review of the candidate's education, experience, management capabilities and personal attributes.

Committee: QR/6, Quality Assessments and Audits
Chairman: Mr A B Marshall, Q.A.Consultancy Services Pty Ltd
Executive Officer: John Owen (Sydney)

Interim Australian Standard® AS 3911.1(Int)—1990 (Expires 1 March 1992)

Guidelines for auditing quality systems

Part 1: Auditing

STANDARDS AUSTRALIA

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This Interim Australian Standard was prepared by Committee QR/6, Quality Assessments and Audits. It was approved on behalf of the Council of Standards Australia on 9 January 1990 and published on 12 March 1990.

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.

Interim Australian Standard®
AS 3911.1(Int)—1990

Guidelines for auditing quality systems

Part 1: Auditing

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PREFACE

This interim Australian Standard was prepared by the Standards Australia Committee on Quality Assessments and Audits under the direction of the Quality and Reliability Standards Board. It is identical with ISO/DIS 10011, *Guidelines for auditing quality systems*, Part 1: *Auditing*.

The Australian Committee provided input to the International Committee, ISO/TC 176, in the preparation of Parts 1, 2 and 3 of the draft international Standard (ISO/DIS 10011). Following a review of these drafts, it was decided that they should be adopted as interim Australian Standards in order to facilitate their usage in Australia, and to assist with the introduction of the National Accreditation Scheme for Quality Management Systems.

For the purpose of this interim Australian Standard, the ISO text should be modified by replacement of references to other publications with references to Australian Standards, as follows:

(a) In the Introduction, line 1, *delete* 'ISO 9000 series' and substitute 'AS 3900 series'.

(b) References to 'ISO 10011' are read as 'AS 3911'.

(c) In annex A the cross-references to other publications should be replaced by references to Australian Standards:

Reference to International Standard		*Australian Standard*	
ISO		AS	
9000	Quality management and quality assurance Standards—Guidelines for selection and use	3900	Quality systems—Guide to selection and use
9001	Quality systems—Model for quality assurance in design/development, production, installation and servicing	3901	Quality systems for design/development, production, installation and servicing
9002	Quality systems—Model for quality assurance in production and installation	3902	Quality systems for production and installation
9003	Quality systems—Model for quality assurance in final inspection and test	3903	Quality systems for final inspection and test
9004	Quality management and quality system elements—Guidelines	3904	Quality systems—Guide to quality management and quality system elements

Standards Australia invites comment on this interim Australian Standard from persons and organizations concerned with this subject. The date of expiry for comment is 1 March 1992, at which time this interim Australian Standard will either be withdrawn or revised in the light of public comment, with the view to the preparation of an Australian Standard.

During the life of this document the Committee will monitor all comment or field data as it is received.

Attention is drawn to the fact that this document is an interim Australian Standard only, and should be regarded as a draft Standard and hence liable to alteration after the expiry date.

This document is not to be regarded as an Australian Standard until issued as such by Standards Australia.

CONTENTS

Introduction

The ISO 9000 series emphasizes the importance of quality audit as a key management tool for achieving the objectives set out in the organization's policy.

Audits should be carried out in order to verify whether the various elements within a quality system are effective and suitable in achieving stated quality objectives.

This part of ISO 10011 provides guidelines for performing an audit of a quality system of an organization. It allows users to adjust the guidelines described to suit their needs.

The quality system audit also provides objective evidence concerning the need for the reduction, elimination, and, most importantly, prevention of nonconformities. The results of these audits can be used by management for improving the performance of the organization.

Guidelines for auditing quality systems Part 1: Auditing

1 Scope

This part of ISO 10011 establishes basic audit principles, criteria and practices, and provides guidelines for establishing, planning, carrying out and documenting audits of quality systems.

It provides guidelines for verifying the existence and implementation of elements of a quality system and for verifying the system's ability to achieve defined quality objectives. It is sufficiently general in nature to permit it to be applicable or adaptable to different industries and organizations. Such organizations should develop their own specific procedures for implementing these guidelines.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 10011. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10011 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1986, *Quality—Vocabulary*

3 Definitions

For the purposes of this part of ISO 10011, the definitions given in ISO 8402, together with the following, apply:

3.1 quality audit: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

NOTES

1. The quality audit typically applies, but is not limited, to a quality system or elements thereof, to processes, to products, or to services. Such audits are often called 'quality system audit', 'process quality audit', 'product quality audit', 'service quality audit'.
2. Quality audits are carried out by staff not having direct responsibility in the areas being audited but, preferably, working in cooperation with the relevant personnel.
3. One purpose of the quality audit is to evaluate the need for improvement or corrective action. An audit should not be confused with 'surveillance' or 'inspection' activities performed for the sole purpose of process control or product acceptance.
4. Quality audits can be conducted for internal or external purposes. [ISO 8402]

3.2 quality system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

NOTES

1. The quality system should only be as comprehensive as needed to meet the quality objectives.
2. For contractual, mandatory and assessment purposes, demonstration of the implementation of identified elements in the system may be required. [ISO 8402]

3.3 auditor (quality): A person who has the qualification to perform quality audits.

NOTES

1. To perform a quality audit the auditor must be authorized for that particular audit.
2. An auditor designated to manage a quality audit is called a 'lead auditor'. [ISO 8402 DAD 1]

3.4 client: A person or organization requesting the audit.

NOTES The client can be:

a) the auditee wishing to have its own quality system audited against some quality system standard;

b) a customer wishing to audit the quality system of a supplier using its own auditors or a third party;

c) an independent agency authorized to determine whether the quality system provides adequate control of the products or services being provided (such as food, drug, nuclear, or other regulatory bodies);

d) An independent agency assigned to carry out an audit in order to list the audited organization's quality system in a register.

3.5 auditee: An organization to be audited.

3.6 observation: A statement of fact made as part of the audit process and substantiated by objective evidence.

3.7 objective evidence: Qualitative or quantitative information, records or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement or test and which can be verified.

3.8 nonconformity: The nonfulfilment of specified requirements.

NOTES

1. The definition covers the departure or absence of one or more quality characteristics or quality system elements from specified requirements.
2. The basic difference between 'nonconformity' and 'defect' is that specified requirements may differ from the requirements for the intended use. [ISO 8402]