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Interim Australian Standard®
AS 3911.3(Int)—1990 (Expires 1 March 1992)

Guidelines for auditing quality systems

Part 3: Managing audit programs

3911.3—1992 Management of audit programs
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(In Professional Package 46) *

Provides basic guidelines for managing quality system audit programs. These guidelines can be used to establish and maintain an audit program function when performing quality systems audits in accordance with AS 3911.1 and AS 3911.2. This Standard is identical with and reproduced from



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.

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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 3: Managing audit programs*.

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 such that references to 'ISO 10011' are read as 'AS 3911'.

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 The date of expiry for comment is 1 March 1992, at which time this interim Australian Standard will either be withdrawn or revised in the light of public comment, with the view to the preparation of an Australian Standard.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

	<i>Page</i>
0 INTRODUCTION	4
1 SCOPE	5
2 NORMATIVE REFERENCE	5
3 DEFINITIONS	5
4 MANAGING AN AUDIT PROGRAM	5
5 CODE OF ETHICS	6

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Introduction

Any organization which has an ongoing need to carry out audits of quality systems should establish a capability to provide overall management of the entire process. This part of ISO 10011 describes the activities which should be addressed by such an organization.

Guidelines for auditing quality systems

Part 3: Managing audit programs

1 Scope

This part of ISO 10011 provides basic guidelines for managing quality system audit programs.

These guidelines should be used to establish and maintain an audit program management function when performing quality systems audits to ISO 10011—Part 1 and ISO 10011—Part 2.

2 Normative reference

The following Standards contain 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*

ISO 10011 *Guidelines for auditing quality systems*
Part 1: *Auditing*
Part 2: *Qualification criteria for auditors*

3 Definitions

For the purposes of this part of ISO 10011, the definitions given in ISO 8402 and ISO 10011—Part 1 together with the following apply:

3.1 Audit program management

That organization, or function within an organization, which has been given the responsibility to plan and carry out a programmed series of quality system audits.

4 Managing an audit program

4.1 Organization

Any organization which has an ongoing need to carry out audits of quality systems should establish a capability to provide overall management of the entire process. This function should be independent from direct responsibility for implementing such quality systems.

4.2 Standards

Audit program management should determine the quality system standards they may be expected to audit against and develop capabilities to enable them to effectively audit against such standards.

4.3 Qualification of staff

4.3.1 Audit program management

Management of the audit program should be carried out by those who have practical knowledge of quality audit procedures and practices.

4.3.2 Auditors

Audit program management should employ auditors who meet the requirements of ISO 10011—Part 2. Such auditors should be certified by an evaluation panel, acceptable to audit program management, which meets the requirements of ISO 10011—Part 2.

4.4 Suitability of team members

Audit program management should consider the following factors when selecting auditors and lead auditors for particular assignments in order to ensure that the skills brought to each assignment are appropriate:

- the type of quality system standard against which the audit is to be conducted (for example manufacturing, computer software or service standards);
- the type of service or product and its associated regulatory requirements (for example health care, food, insurance, computers, instrumentation, nuclear devices);
- the need for professional qualifications or technical expertise in a particular discipline;
- the size and composition of the audit team, the concurrent need for skill in managing such teams and the ability to make effective use of the skills of the various audit team members;
- the personal skills needed to deal with a particular auditee;
- required language skills;
- absence of any real or perceived conflict of interest;
- other relevant factors.

4.5 Monitoring and maintenance of auditor performance

4.5.1 Performance evaluations

Audit program management should continually evaluate the performance of their auditors, either through observation of audits, or other means. Such information should be used to improve auditor selection and performance and to identify unsuitable performance. Audit program management should make this information available to evaluation panels, where required.