

SAA HB18.28—1991
SANZ HB18.28—1991
ISO/IEC Guide 28—1982

Guidelines for third-party
certification and accreditation

**Guide 28—
General rules for a
model third-party
certification
system for
products**

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PREFACE

This handbook is presented as a series of separate publications, each of which is identical with the corresponding guide published either jointly by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) or solely by ISO. It has been issued as a joint publication under the terms of the Memorandum of Understanding between Standards Australia and the Standards Association of New Zealand.

The information contained in the various guides making up this handbook is intended to assist organizations in understanding the basis of product certification and third-party certification systems and how the various bodies operating such schemes should function. Coverage is also given in some instances to guidance on the establishment and operation of laboratory accreditation bodies as well as the type of information that such bodies will require of testing laboratories, including those carrying out calibration, when making application for accreditation. It is anticipated that these guides will become of greater importance when the forthcoming Joint Accreditation Scheme—Australia and New Zealand (JAS—ANZ) becomes operational. Reference should also be made to the Standards for quality systems which are published jointly in Australia and New Zealand as the AS 3900/NZS 9000/ISO 9000 series.

The other guides covered in this handbook are as follows:

- Guide 7: *Requirements for standards suitable for product certification*
- Guide 16: *Code of principles on third-party certification systems and related standards*
- Guide 22: *Information on manufacturer's declaration of conformity with standards or other technical specifications*
- Guide 23: *Methods of indicating conformity with standards for third-party certification systems*
- Guide 25: *General requirements for the competence of calibration and testing laboratories*
- Guide 27: *Guidelines for corrective action to be taken by a certification body in the event of either misapplication of its mark of conformity to a product, or products which bear the mark of the certification body being found to subject persons or property to risk*
- Guide 39: *General requirements for the acceptance of inspection bodies*
- Guide 40: *General requirements for the acceptance of certification bodies*
- Guide 42: *Guidelines for a step-by-step approach to an international certification system*
- Guide 43: *Development and operation of laboratory proficiency testing*
- Guide 44: *General rules for ISO or IEC international third-party certification schemes for products*
- Guide 48: *Guidelines for third-party assessment and registration of a supplier's Quality System*
- Guide 53: *An approach to the utilization of a supplier's quality system in third-party product certification*
- Guide 54: *Testing laboratory accreditation systems—General recommendations for the acceptance of accreditation bodies*
- Guide 55: *Testing laboratory accreditation systems—General recommendations for operation*
- Guide 56: *An approach to the review by a certification body of its own internal quality system*

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General rules for a model third-party certification system for products

0 Introduction

These model general rules are valid for the following type of certification system:

A third party certification system of determining conformity with product standards through initial testing and assessment of a factory quality management system and its acceptance followed by surveillance that takes into account the factory quality management system and the testing of samples from the factory and the open market.

NOTE — This model system corresponds to system No. 5 as described in ISO/ITC Publication, *Certification — Principles and practice*. This system was chosen because it was the most comprehensive and could thus offer the best basis for the eventual development of other systems.

The identification of conformity may be in the form of a certificate of conformity or a mark of conformity. (See ISO/IEC Guide 23.)

A certification body operating the system at national level shall as a minimum have a suitable organizational structure¹⁾ and utilize personnel, equipment, and operating procedures that comply with the criteria given in ISO Guide 24 and ISO/IEC Guide 25 (latest edition).

Any certification scheme under the system requires as a prerequisite a standard that is suitable for certification purposes. (See ISO/IEC Guide 7.)

1 References

ISO Guide 2, *General terms and their definitions concerning standardization and certification*.

ISO/IEC Guide 7, *Requirements for standards suitable for product certification*.

ISO/IEC Guide 23, *Methods of indicating conformity with standards for third-party certification systems*.

ISO Guide 24, *Guidelines for the acceptance of testing and inspection agencies by certification bodies*.

ISO/IEC Guide 25, *General requirements for the technical competence of testing laboratories*.

2 Definitions

The relevant definitions of ISO Guide 2-1980 and its Addendum 1-1981 are applicable.

3 Basic conditions

The basic conditions for obtaining and retaining the licence²⁾ to issue a certificate of conformity or to use a mark of conformity are that the applicant/licensee follows these General Rules and the Specific Rules³⁾ of the relevant scheme and that he applies the identification of conformity only to products that are within the scope of his licence and are in conformity with the relevant standard(s).

4 Application for licence

The application shall be made on a special form obtainable from the certification body. An example of such a form is given in annex B.

The application relates to the specific product or group of products determined by the certification scheme and specified in the Specific Rules. It should normally cover products coming from one factory only.

1) Guidelines on this subject are in preparation within ISO/CERTICO.

2) For the purpose of this document the words "licence" and "licensee" are used although the granting of a licence is only one of several means of indicating that the applicant concerned has been accepted by the certification body.

3) For Specific Rules, see annex A.

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