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**General requirements for bodies
operating product certification
systems**

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Descriptors : quality assurance, quality assurance systems, non-profit-marking bodies,
certification (approval), certification bodies, general conditions

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of International Trade and Industry through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law.

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General requirements for bodies operating product certification systems

0 Introduction

0.1 This Japanese Industrial Standard has been prepared based on the first edition of ISO/IEC GUIDE 65 General requirements for bodies operating product certification systems published in 1996 without modifying the technical contents.

Portions underlined with dots are the matters not stated in the original Guide.

0.2 Certification of a product (a term used to include a process or service) is a means of providing assurance that it complies with specified standards and other normative documents. Some product certification systems may include initial testing of a product and assessment of its suppliers' quality systems, followed by surveillance that takes into account the factory quality system and the testing of samples from the factory and the open market. Other systems rely on initial testing and surveillance testing, while still others comprise type testing only.

This Standard specifies requirements, the observance of which is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis and so furthering international trade.

The requirements contained in this Standard are written, above all, to be considered as general criteria for organizations operating product certification systems; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account.

Assertion of conformity to the appropriate standards or other normative documents will be in the form of certificates or marks of conformity. Systems for certifying particular products or product groups to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

While this Standard is concerned with third-parties providing product certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.

The diversity in certification systems may at first seem unnecessary and even confuse newcomers in the field, clients and operators alike. The ISO/IEC publication *Certification and related activities* is available for background reading and will help to answer questions regarding the practices of the worldwide conformity assessment community.

NOTE: Subclause 0.2 corresponds to Introduction of the original Guide.

1 Scope

1.1 This Standard specifies general requirements that a third-party operating a product certification system shall meet if it is to be recognized as competent and reliable.

In this Standard the term "certification body" is used to cover any body operating a product certification system. The word "product" is used in its widest sense and includes processes and services; the word "standard" is used to include other normative documents such as specifications or technical regulations.

1.2 The certification system used by the certification body may include one or more of the following, which could be coupled with production surveillance or assessment and surveillance of the supplier's quality system or both, as described in **ISO/IEC Guide 53**:

- a) type testing or examination;
- b) testing or inspection of samples taken from the market or from supplier's stock or from a combination of both;
- c) testing or inspection of every product or of a particular product, whether new or already in use;
- d) batch testing or inspection;
- e) design appraisal.

NOTE 1 **ISO/IEC Guide 28** may be consulted for a model of one form of a third-party product certification system.

2 Normative references

ISO 8402:1994 *Quality management and quality assurance — Vocabulary*

JIS Z 9911-1:1996 *Guidelines for auditing quality systems — Part 1: Auditing*

NOTE: ISO 10011-1:1990 *Guidelines for auditing quality systems — Part 1: Auditing* is identical with the said standard.

ISO/IEC Guide 2:1996 *Standardization and related activities — General Vocabulary*

ISO/IEC Guide 7:1994 *Guidelines for drafting of standards suitable for use for conformity assessment*

ISO/IEC Guide 23:1982 *Methods of indicating conformity with standards for third-party certification systems*

JIS Z 9325-1996 *General requirements for the competence of calibration and testing laboratories*

NOTE: ISO/IEC Guide 25:1990 *General requirements for the competence of calibration and testing laboratories* is identical with the said standard.

ISO/IEC Guide 27:1983 *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*

ISO/IEC Guide 28:1982 *General rules for a model third-party certification system for products*

ISO/IEC Guide 39:1988 *General requirements for the acceptance of inspection bodies*

ISO/IEC Guide 53:1988 *An approach to the utilization of a supplier's quality system in third-party product certification*

ISO/IEC Guide 62:1996 *General requirements for bodies operating assessment and certification/registration of quality systems*

3 Definitions For the purposes of this Standard, the relevant definitions given in **ISO/IEC Guide 2** and **ISO 8402** apply, together with the following definition.

3.1 supplier The party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.

4 Certification body

4.1 General provisions

4.1.1 The policies and procedures under which the certification body operates and their administration shall be non-discriminatory and shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this Standard.

4.1.2 The certification body shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the supplier or membership of any association or group, nor shall certification be conditional upon the number of certificates already issued.

4.1.3 The criteria against which the products of a supplier are evaluated shall be those outlined in specified standards. Requirements for standards suitable for this purpose are contained in **ISO/IEC Guide 7**. If explanation is required as to the application of these documents for a specific certification system, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the certification body.

4.1.4 The certification body shall confine its requirements, evaluation and decision on certification to those matters specifically related to the scope of the certification being considered.

4.2 Organization The structure of the certification body shall be such as to foster confidence in its certifications. In particular, the certification body shall

- a) be impartial;
- b) be responsible for decisions relating to its granting, maintaining, extending, suspending and withdrawing of certification;
- c) identify the management (committee, group or person) which shall have overall responsibility for all of the following:
 - 1) performance of testing, inspection, evaluation and certification as defined in this Standard,
 - 2) formulation of policy matters relating to the operation of the certification body.
 - 3) decisions on certification,
 - 4) supervision of the implementation of its policies,