

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS Q 17011 : 2005

(ISO/IEC 17011 : 2004)

**Conformity assessment—General
requirements for accreditation
bodies accrediting conformity
assessment bodies**

ICS 03.120.20

Reference number : JIS Q 17011 : 2005 (E)

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee.

This Standard has been made based on **ISO/IEC 17011:2004 *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies*** for the purpose of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

Date of Establishment: 2005-07-20

Date of Public Notice in Official Gazette: 2005-07-20

Investigated by: Japanese Industrial Standards Committee

Conformity Assessment Board

JIS Q 17011: 2005, First English edition published in 2005-11

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

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Printed in Japan

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Conformity assessment— General requirements for accreditation bodies accrediting conformity assessment bodies

Introduction This Japanese Industrial Standard has been prepared based on the first edition of **ISO/IEC 17011:2004** *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies* published in 2004 without modifying the technical contents.

The portions underlined with dots are the matters not stated in the original International Standard.

In the regulatory sector, government authorities implement laws covering the approval of products (including services) for reasons of safety, health, environmental protection, fraud prevention or market fairness. In the voluntary sector, many lines of industry have, both within an economy as well as globally, set up systems for conformity assessment and approval, aiming at achieving a minimum technical level, enabling comparability, and also ensuring competition on equal terms.

A prerequisite for trade on equal terms is that any product (including services), accepted formally in one economy, must also be free to circulate in other economies without having to undergo extensive re-testing, re-inspection, re-certification, etc. This should be the case regardless of whether the product (including services) falls wholly or partly under the regulatory sector.

In today's society it is often required to state objectively conformity of products (including services) to specified requirements. Conformity assessment bodies (CABs) can objectively state such conformity. These CABs perform conformity assessment activities that include certification, inspection, testing and, in the context of this Standard, calibration.

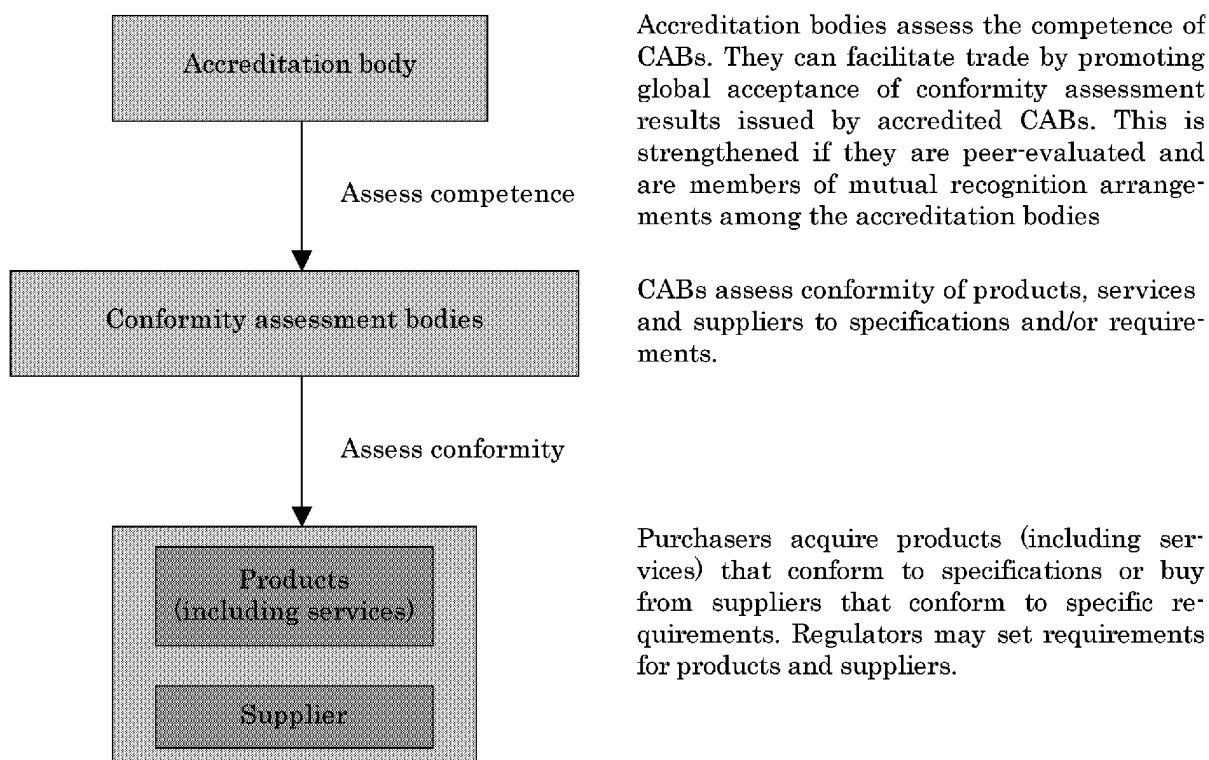
It is important for the purchaser, regulator and the public to know that these CABs are competent to perform their tasks. For that reason there is an increasing demand for impartial verification of their competence. Such verification is done by authoritative accreditation bodies that are impartial in relation to both the CABs and their clients, and which normally operate in a non-profit distributing manner (see figure 1).

A system to accredit CAB conformity assessment services should provide confidence to the purchaser and regulator. Such a system should facilitate cross-border trade, as pursued by trade authorities and organizations. The ultimate goal is to achieve one-stop accreditation and one-stop conformity assessment.

A "cross border" trade facilitating system can work well if accreditation bodies and CABs all operate to globally accepted requirements in an equivalent manner and take into account the interests of all parties concerned.

This Standard specifies the general requirements for accreditation bodies. Peer evaluation mechanisms have been created at regional and international levels, through which assurance is provided that accreditation bodies are operating in accordance with this Standard. Those who have passed such an evaluation can become members of mutual recognition arrangements. Through regular re-evaluations, the continued adherence to this Standard is assured.

These mutual recognition arrangement members facilitate the one-stop process, through recognition, promotion and acceptance of each other's accredited conformity assessments. This means that a CAB in an economy should not need to be accredited more than once for the same scope by different accreditation bodies.



NOTE : The word supplier is used to mean provider of products (including services).

Figure 1 Flowchart

1 Scope This Standard specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies.

Accreditation bodies operating in accordance with this Standard do not have to offer accreditation to all types of CABs.

For the purposes of this Standard, CABs are organizations providing the following conformity assessment services: testing, inspection, management system certification, personnel certification, product certification and, in the context of this Standard, calibration.

Information : "Management system certification" is also referred to as "Management system assessment and registration".

NOTES 1 General requirements for these bodies have been established in Japanese Industrial Standards.

2 The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21.

ISO/IEC 17011:2004 *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies* (IDT)

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. If the indication of the year publication is given to these referred standards, only the edition of indicated year constitutes the provision of this Standard but the revision and amendment made thereafter do not apply. The normative references without the indication of the year of coming into effect apply only to the most recent edition (including amendments).

JIS Q 9000 *Quality management systems—Fundamentals and vocabulary*

NOTE : ISO 9000:2000 *Quality management systems—Fundamentals and vocabulary* is identical with the said standard.

JIS Q 17000 *Conformity assessment—Vocabulary and general principles*

NOTE : ISO/IEC 17000:2004 *Conformity assessment—Vocabulary and general principles* is identical with the said standard.

VIM:1993 *International vocabulary of basic and general terms in metrology*, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

3 Terms and definitions For the purposes of this Standard, the terms and definitions given in **JIS Q 17000** and the following apply. Where the terms and definitions are neither included in this document nor in **JIS Q 17000**, the terms and definitions of **JIS Q 9000** or the International vocabulary of basic and general terms in metrology (VIM) apply. If different definitions for specific metrological terms are given, the definitions of VIM have preference.

3.1 accreditation third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

3.2 accreditation body authoritative body that performs accreditation

NOTE : The authority of an accreditation body is generally derived from government.

3.3 accreditation body logo logo used by an accreditation body to identify itself

3.4 accreditation certificate formal document or a set of documents, stating that accreditation has been granted for the defined scope

3.5 accreditation symbol symbol issued by an accreditation body to be used by accredited CABs to indicate their accredited status

NOTE : "Mark" is to be reserved to indicate direct conformity of an entity against a set of requirements.

3.6 appeal request by a CAB for reconsideration of any adverse decision made by the accreditation body related to its desired accreditation status

NOTE : Adverse decisions include

- refusal to accept an application,
- refusal to proceed with an assessment,
- corrective action requests,
- changes in accreditation scope,
- decisions to deny, suspend or withdraw accreditation, and
- any other action that impedes the attainment of accreditation.

3.7 assessment process undertaken by an accreditation body to assess the competence of a CAB, based on particular standard(s) and/or other normative documents and for a defined scope of accreditation

NOTE : Assessing the competence of a CAB involves assessing the competence of the entire operations of the CAB, including the competence of the personnel, the validity of the conformity assessment methodology and the validity of the conformity assessment results.

3.8 assessor person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a CAB

3.9 complaint expression of dissatisfaction, other than appeal, by any person or organization, to an accreditation body, relating to the activities of that accreditation body or of an accredited CAB, where a response is expected

3.10 conformity assessment body (CAB) body that performs conformity assessment services and that can be the object of accreditation

NOTE : Whenever the word "CAB" is used in the text, it applies to both the "applicant and accredited CABs" unless otherwise specified.

3.11 consultancy participation in any of the activities of a CAB subject to accreditation

Examples :

- preparing or producing manuals or procedures for a CAB;
- participating in the operation or management of the system of a CAB;
- giving specific advice or specific training towards the development and implementation of the management system and/or competence of a CAB;
- giving specific advice or specific training for the development and implementation of the operational procedures of a CAB.

3.12 expert person assigned by an accreditation body to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed

3.13 extending accreditation process of enlarging the scope of accreditation

3.14 interested parties parties with a direct or indirect interest in accreditation

NOTE : Direct interest refers to the interest of those who undergo accreditation; indirect interest refers to the interests of those who use or rely on accredited conformity assessment services.

3.15 lead assessor assessor who is given the overall responsibility for specified assessment activities

3.16 reducing accreditation process of cancelling accreditation for part of the scope of accreditation

3.17 scope of accreditation specific conformity assessment services for which accreditation is sought or has been granted

3.18 surveillance set of activities, except reassessment, to monitor the continued fulfilment by accredited CABs of requirements for accreditation

NOTE : Surveillance includes both surveillance on-site assessments and other surveillance activities, such as the following:

- a) enquiries from the accreditation body to the CAB on aspects concerning the accreditation;
- b) reviewing the declarations of the CAB with respect to what is covered by the accreditation;
- c) requests to the CAB to provide documents and records (e.g. audit reports, results of internal quality control for verifying the validity of CAB services, complaints records, management review records);
- d) monitoring the performance of the CAB (such as results of participating in proficiency testing).

3.19 suspending accreditation process of temporarily making accreditation invalid, in full or for part of the scope of accreditation

3.20 withdrawing accreditation process of cancelling accreditation in full

3.21 witnessing observation of the CAB carrying out conformity assessment services within its scope of accreditation

4 Accreditation body

4.1 Legal responsibility The accreditation body shall be a registered legal entity.

NOTE : Governmental accreditation bodies are deemed to be legal entities on the basis of their governmental status. Where the governmental accreditation body is part of a larger governmental entity, the government is responsible for identifying the accreditation body in a way that no conflict of interest with governmental CABs occur. This accreditation body is deemed to be the "registered legal entity" in the context of this Standard.

4.2 Structure

4.2.1 The structure and operation of an accreditation body shall be such as to give confidence in its accreditations.

4.2.2 The accreditation body shall have authority and shall be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation.

4.2.3 The accreditation body shall have a description of its legal status, including the names of its owners if applicable, and, if different, the names of the persons who control it.

4.2.4 The accreditation body shall document the duties, responsibilities and authorities of top management and other personnel associated with the accreditation body who could affect the quality of the accreditation.

4.2.5 The accreditation body shall identify the top management having overall authority and responsibility for each of the following:

- a) development of policies relating to the operation of the accreditation body;
- b) supervision of the implementation of the policies and procedures;
- c) supervision of the finances of the accreditation body;
- d) decisions on accreditation;
- e) contractual arrangements;
- f) delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management.

4.2.6 The accreditation body shall have access to necessary expertise for advising the accreditation body on matters directly relating to accreditation.

NOTE : Access to the necessary expertise may be obtained through one or more advisory committees (either ad-hoc or permanent), each responsible within its scope.

4.2.7 The accreditation body shall have formal rules for the appointment, terms of reference and operation of committees that are involved in the accreditation process, and shall identify the parties participating.

4.2.8 The accreditation body shall document its entire structure, showing lines of authority and responsibility.

4.3 Impartiality

4.3.1 The accreditation body shall be organized and operated so as to safeguard the objectivity and impartiality of its activities.

4.3.2 For safeguarding impartiality and for developing and maintaining the principles and major policies of operation of its accreditation system, the accreditation body shall have documented and implemented a structure to provide opportunity for effective involvement by interested parties. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.