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Conformity assessment — Conformity
assessment for Japanese Industrial
Standards — General guidance on a
third-party certification system for
products and these processing
technology

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Foreword

This Japanese Industrial Standard has been revised by the Minister of Economy, Trade and Industry, through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Act. This edition replaces the previous edition (**JIS Q 1001:2015**), which has been technically revised.

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Conformity assessment — Conformity assessment for Japanese Industrial Standards — General guidance on a third-party certification system for products and these processing technology

Introduction

This Japanese Industrial Standard is based on **ISO/IEC Guide 28** which specifies the third-party certification system for products in accordance with Scheme type 5¹⁾ defined in **ISO/IEC 17067** among other International Standards and Guides on conformity assessment procedures.

Note¹⁾ For the industrial and mineral products or the industrial and mineral products worked with processing technologies, the method is defined as the product certification system Scheme type 5, in which the audit of conformity with the Japanese Industrial Standard (hereafter referred to as JIS) is performed by the product test, and the certification is performed by the audit of the quality control system of the factory or business establishment which manufactures or processes the industrial and mineral products concerned. After the certification is granted, the certification maintenance surveillance is performed to maintain the certification concerned.

This Standard specifies the matters serving as the criteria when the registered certification body performs the certification service (hereafter referred to as guidance on certification) regarding **JIS** for the industrial and mineral products and processing technology thereof under the conformity certification for **JIS** (hereafter referred to as **JIS** mark scheme), and aims to enhance the understanding among the related parties concerning the certification of the **JIS** mark scheme not only by harmonizing with the Industrial Standardization Act and the applicable provisions of competent Ministerial Ordinance of the said act but also by describing these provisions again in accordance with **ISO/IEC Guide 28** and adding the cases obtained from the relevant International Standard, etc.

In addition, the applicable provisions of the competent Ministerial Ordinance refers to the criteria of certification service (limited to the criteria between a registered certification body and an applicant or a licensee, and including the criteria of audit of marking and quality control system), and does not include other criteria specified in the Ministerial Ordinance concerned (those between the registered certification body and the Japanese laws and regulations, such as registration).

The guidance on certification consists of the general guidance on certification specified in order to apply in common to all of the industrial and mineral products or processing technologies thereof to be the object of certification and the sectoral guidance

on certification specified when it is necessary to specify the matter of a special case for the general guidance on certification according to the characteristics of the industrial and mineral products or processing technologies thereof to be the object of certification.

The registered certification body shall stipulate the provisions concerning the certification service in accordance with the general guidance on certification and the sectoral guidance on certification in the case where there is the sectoral guidance on certification specified in relation to the industrial and mineral products and processing technologies thereof concerning the certification.

1 Scope

This Standard specifies the criteria of certification service under the **JIS** mark scheme (limited to industrial and mineral products and processing technologies thereof), and the fundamental and cross-sectoral matters of criteria of audit as the general guidance on certification.

The sectoral guidance on certification shall be specified as the special matters for the general guidance on certification aside from this Standard according to the characteristics of the industrial and mineral products or processing technologies thereof to be the object of certification. The sectoral guidance on certification shall be in accordance with the matters and the form specified in Annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS Q 9001 *Quality management systems — Requirements*

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

JIS Q 17025 *General requirements for the competence of testing and calibration laboratories*

ISO 9001 *Quality management systems — Requirements*

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purpose of this Standard, the terms and definitions given in **JIS Q 17000**, and the following apply.

3.1

registered certification body

those registered in accordance with Article 30, paragraph (1) and paragraph (2), Article 31, paragraph (1), and Article 37, paragraph (1) to paragraph (3) of the Industrial Standardization Act

3.2

industrial and mineral products, etc.

industrial and mineral products or industrial and mineral products processed with processing technologies thereof to be the object of certification

3.3

JIS mark

marking of the form specified in Article 1, paragraph (1) to paragraph (3) of the Ministerial Ordinance Concerning Certification of Conformity with Japanese Industrial Standards concerning industrial and mineral products and processing technologies thereof in accordance with the Industrial Standardization Act, and also called the certification mark

3.4

JIS mark, etc.

generic term of **JIS** mark, number of conforming **JIS**, type or grade of conforming **JIS** and name or designation of the registered certification body which has performed the certification

3.5

applicant

those who fall into the following and request the registered certification body to grant the certification in accordance with the respective articles

- a) manufacturer of the industrial and mineral products in Article 30, paragraph (1) of the Industrial Standardization Act
- b) importer or dealer of the industrial and mineral products in Article 30, paragraph (2) of the said act
- c) processor of the industrial and mineral products in Article 31, paragraph (1) of the said act
- d) manufacturer, exporter or processor of the industrial and mineral products, which carries out a business overseas in Article 37, paragraph (1) to paragraph (3) of the said act

3.6

factory audit

audit on the production quality control system of the industrial and mineral products concerning the certification (which refers to the manufacturing facility, inspection facility, inspection method, quality control method and other necessary technological production condition for quality maintenance), or audit on process quality control system of the processing technologies concerning the certification (which refers to the processing facility, inspection facility, inspection method, quality control method and other necessary technological production condition for quality maintenance)

The production quality control system and the process quality control system are collectively called quality control system. The factory audit performed when requested from the applicant to perform the certification is referred to as the initial factory audit.

3.7

product test

test, analysis or measurement concerning the industrial and mineral products performed in accordance with **JIS** to determine the conformity with **JIS**

The product test performed when requested from the applicant to perform the certification is referred to as the initial product test.

3.8

licensee

those who have received the certification of the industrial and mineral products or processing technologies thereof from the registered certification body

3.9

certification maintenance surveillance

surveillance for judging whether the certification which the registered certification body is performing can be maintained or not

There are the periodic certification maintenance surveillance and the temporary certification maintenance surveillance.

The factory audit performed in the certification maintenance surveillance is referred to as the certification maintenance factory audit, and the product test performed for the certification maintenance surveillance is referred to as the certification maintenance product test.

3.10

lot certification

certification concerning the specific number or the quantity of the industrial and mineral products actually manufactured or processed in accordance with **JIS** of the industrial and mineral products or processing technologies thereof concerning the certification

4 Conditions of certification

The registered certification body shall perform the certification by confirming that the industrial and mineral products or processing technologies thereof to be the object of certification conform to **JIS** and the quality control system of the applicant meets all the applicable criteria as a result of the audit performed in accordance with the **JIS** concerning the certification, the general guidance on certification, the sectoral guidance on certification for the industrial and mineral products or processing technologies thereof concerning the certification, if specified and the provisions on the certification service which the registered certification body stipulates.

Furthermore, in order for a licensee to perform the marking of **13.1** and **13.2** on the industrial and mineral products, etc., the actually effective certification agreement between the licensee and the registered certification body shall be concluded.

5 Application for certification

5.1 Object standard

The standard to be the object of certification shall be the **JIS** which is applied to the conformity certification of the industrial and mineral products or processing technologies thereof.

5.2 Division of certification

The registered certification body shall coordinate with the applicant and decide the division of the industrial and mineral products or processing technologies thereof (hereafter referred to as division of certification) for which the applicant is requesting a certification in accordance with the sectoral guidance on certification and/or the provisions related to the certification service stipulated by the registered certification body.

The division of certification shall be usually by the applicable **JIS**.

The division of certification may be any of the following.

- a) By the type or grade specified in **JIS**
- b) By the industrial and mineral products or processing technologies thereof defined by the applicant (type specified by the applicant, etc.)
- c) Group of industrial and mineral products concerning more than one **JIS**

5.3 Application form

The registered certification body shall request the applicant to submit data of **b)** and **c)** together with the application form which includes at least the matter of the following **a)**.

- a) Entry made on application form
 - 1) Name or designation (including name of a representative for a corporate body) and address of applicant
 - 2) Designation of the industrial and mineral products or processing technologies thereof
 - 3) Number of **JIS** concerning the certification
 - 4) Division of certification (omissible in the case of the same number as that of **JIS**)
 - 5) For the lot certification, number or quantity concerned
 - 6) Designation and address of factory or business establishment concerning the certification [omissible in the case of **5)**]
- b) Document describing the quality management implementation condition concerning the initial factory audit of the industrial and mineral products or processing

technologies thereof (which refers to the document which explains that the quality control system of the factory or business establishment concerning the industrial and mineral products or processing technologies thereof to be certified conforms to the criteria of audit in Annex B based on the company standard or other information on manufacture or processing presented by the applicant)

- c) Data explaining conformity with requirements which the registered certification body stipulates

6 Initial factory audit and initial product test

6.1 General

The registered certification body shall coordinate with the applicant and decide the implementation plan concerning the initial factory audit and the initial product test in accordance with the division of certification of the applied industrial and mineral products or processing technologies thereof.

The registered certification body shall not perform the certification when there is any matter which is judged as nonconformity in the initial factory audit and the initial product test. If the applicant has proved to the registered certification body that the action has been taken to correct the matter pointed out within the period designated by the registered certification body, the registered certification body shall repeat the evaluation of Clause 7 for the matter concerned to perform the certification.

When the applicant cannot prove that the matter concerned is corrected within the designated period, the registered certification body shall not perform the certification.

The registered certification body shall confirm before the certification decision that the quality of the industrial and mineral products, etc. is stable through the investigation of production records for at least six months (or usually at least one year after restructuring of the quality system, in the case of reviewing the certification which has been cancelled in accordance with Clause 15).

When the lot certification is applied by the applicant, the registered certification body may perform the certification by omitting the on-site investigation specified in 6.2.1 from the initial factory audit. Furthermore, when performing the initial product test on all the lot concerned (one hundred percent test), the registered certification body may omit the initial factory audit.

6.2 Initial factory audit

6.2.1 Method of initial factory audit

The registered certification body shall perform the on-site investigation on all the factories or business establishments concerning the certification while performing the paper audit on the document describing the quality management implementation condition submitted by the applicant, and shall judge whether the quality control system of the factory or business establishment of the applicant conforms to the criteria of audit of the quality control system specified in Annex B.

In addition, the applicant may select whether the audit will be in accordance with

Criterion (A) or Criterion (B) of audit of the quality control system specified in Annex B.

The registered certification body shall request the applicant to describe the information necessary for explaining that the quality control system of the factory or business establishment conforms to the criteria of audit in Annex B in the document describing the quality management implementation condition, and simultaneously make a request so that the registered certification body can confirm the necessary information such as relevant company standards, administrative records, testing and inspection records concerning raw materials, industrial and mineral products, etc.

6.2.2 Others

In the case where the applicant applies for the certification in accordance with the Criterion (B) of audit specified in Annex B, the applicant may attach to the application the copy of the registration certificate and the copy of the registration report obtained from the audit registration body accredited by the accreditation body which signs MLA (Multilateral Recognition Arrangement) of IAF (International Accreditation Forum).

6.3 Initial product test

6.3.1 Sampling

The registered certification body shall perform the sampling of the industrial and mineral products, etc. for the test (hereafter referred to as sample) to perform the initial product test. The samples concerned shall be taken randomly in the number or quantity necessary to perform all the product tests specified in **JIS** concerning the industrial and mineral products or processing technologies thereof for certification.

The sample shall represent the manufacture or work process of industrial and mineral products to be the object of certification.

In addition, the registered certification body may perform the initial product test with the samples which it selected from the trial products when it is judged to be appropriate. In this case, all or a part of the product tests shall be performed on the samples taken from the manufactured or processed industrial and mineral products, etc. promptly after the start of the manufacturing or processing of the object industrial and mineral products.

The registered certification body may perform the sampling before the on-site investigation of the initial factory audit. However, when the quality control system has been altered after the sampling concerned and it influences the audit of conformity with **JIS** of the industrial and mineral products, etc. for the test concerned, the system shall not be examined by using the results of the product test concerned.

6.3.2 Implementation of initial product test

The initial product test may be implemented by the testing personnel of the registered certification body using the test facilities thereof, or by one or the combination of the following.

- a) Implementation by the testing personnel of the registered certification body at the

testing laboratory of the applicant

- b) Implementation by the testing personnel of the applicant at the testing laboratory of the applicant in the presence of the registered certification body
- c) Utilization of data of test performed by the third-party testing body
- d) Utilization of data of test performed by the testing personnel of the applicant at the testing laboratory of the applicant

In the case of the method [a) or b)] by e.g. the presence of the registered certification body, the registered certification body shall confirm that the necessary testing facility of the applicant, the testing personnel, etc. meet the applicable requirements in **ISO/IEC 17025** or **JIS Q 17025**. Furthermore, in the case of the method [c) or d)] which utilizes the test data provided by the testing laboratory, etc. other than the registered certification body, the registered certification body shall follow the procedure in **6.3.3**.

6.3.3 Utilization of testing laboratories, etc. other than registered certification body

In the case of c) or d) of **6.3.2**, the registered certification body shall confirm that the third-party testing body concerned or the testing laboratory of the applicant has the capability of satisfying the relevant requirements in **ISO/IEC 17025** or **JIS Q 17025** according to the test required.

In the case of the validation of the test data of c) or d) of **6.3.2**, the registered certification body shall specify the test data verification procedure applied to the third-party testing body or the testing laboratory of the applicant, perform the procedure, and confirm that it is appropriate.

7 Assessment

The registered certification body shall assess whether the result of the initial factory audit and the result of the initial product test conform to all of the following items.

- a) Applicable **JIS**
- b) General guidance on certification
- c) Sectoral guidance on certification relevant to the industrial and mineral products or processing technologies thereof concerning the certification, if there is any.
- d) Requirements stipulated in the provisions of the certification service specified by the registered certification body

8 Decision of certification

The registered certification body shall decide whether to perform the certification or not with regard to the industrial and mineral products or processing technologies thereof of which the certification has been applied for according to the assessment specified in Clause 7.

The registered certification body shall notify the applicant of the decision for the certification concerned.

9 Certification agreement

9.1 Conclusion of certification agreement

The registered certification body shall conclude the certification agreement with the applicant when it decides to perform the certification in accordance with Clause 8.

After concluding the certification agreement, the registered certification body shall officially announce the following items without delay.

- a) Items of a) to h) in Clause 10
- b) Items of Clause 13

This announcement shall be made until the date when the certification agreement terminates. In the case of lot certification, this announcement shall be made for one year from the date when the certification agreement is concluded. Furthermore, the announcement concerned shall be not only provided for public reading during working hours at all the offices of the registered certification body where the certification is performed, but also provided for browsing by using the Internet.

9.2 Content of certification agreement

When the registered certification body specifies the form of certification agreement, at least the following matters shall be included.

- a) Agreement concerning the certification in accordance with the provision of Article 30, paragraph (1) or paragraph (2), Article 31, paragraph (1), or Article 37, paragraph (1), paragraph (2) or paragraph (3) of the Industrial Standardization Act
- b) Term of validity of certification agreement where specified
- c) Items of Clause 13
- d) Following conditions which enable marking of 13.1
 - 1) When the licensee attests to the third-party by the advertisement and other methods that the certification has been granted by the registered certification body for its industrial and mineral products or processing technologies thereof, those products or technologies having been certified shall be discriminated from those not certified.
 - 2) In order to confirm that the service of the licensee concerning the certification is appropriately performed, the registered certification body can request a report from the licensee, or can enter the factory, business establishment and other necessary places of the licensee to examine the industrial and mineral products, or industrial and mineral products processed with processing technologies, their raw materials or the quality control system, concerning the certification.
 - 3) Frequency of audit of 2), the expense burden, and other conditions
- e) When the industrial and mineral products concerning the certification are manufactured or processed at a plural number of factories or business establishments, matters concerning the method for identifying the factory or business establish-

ment concerned

- f) Matters on the action taken when the licensee alters the specification or the quality control system of the industrial and mineral products or processing technologies thereof concerning the certification
- g) Matters on the action taken when the licensee receives complaints from the third-party on the industrial and mineral products or processing technologies thereof concerning the certification
- h) Matters on confidentiality of the registered certification body and the licensee
- i) Matters on the appeal which the licensee lodges with regard to the action taken by the registered certification body
- j) Items on the request, cancellation of certification and termination of certification agreement specified in Clause 15

An reference example of the certification agreement is given in Annex C.

9.3 Termination of certification agreement

The registered certification body, when the certification agreement terminates, shall announce the following matters without delay.

- a) Date (year, month, day) on which the certification agreement terminates, and certification number
- b) Name or designation, and address of the licensee concerning the terminated certification agreement
- c) Items of c) to f) and h) of Clause 10
- d) Items of Clause 13

This announcement shall be made for one year from the date when the certification agreement terminates. Furthermore, the registered certification body shall make the announcement concerned be not only provided for public reading during working hours at all of its offices, but also provided for browsing by using the Internet.

10 Issuance of certificate

The registered certification body shall issue the certificate on which the following items are described (hereafter referred to as certificate) when concluding the certification agreement specified in Clause 9 with the applicant.

- a) Date (year, month, day) on which the certification agreement is concluded, and certification number
- b) Name or designation, and address of the licensee
- c) Number of JIS concerning the certification, and the type or grade when specified in JIS
- d) Designation of industrial and mineral products or processing technologies thereof