

Ordinance for Designated Evaluation Bodies, Etc. Pursuant to the Act for Implementation of the Mutual Recognition between Japan and Foreign States in Relation to Results of Conformity Assessment Procedures of Specified Equipment (MIC/METI Ordinance No. 2 of 2001)

Pursuant to the provisions of the Act for Implementation of the Mutual Recognition between Japan and the European Community in Relation to Conformity Assessment of Specified Equipment (Act No. 111 of 2001) and the Order for Enforcement of the Act for Implementation of the Mutual Recognition between Japan and the European Community in Relation to Conformity Assessment of Specified Equipment (Cabinet Order No. 355 of 2001), and for the enforcement of the Act, the Ordinance for Designated Evaluation Bodies, Etc. Pursuant to the Act for Implementation of the Mutual Recognition between Japan and the European Community in Relation to Conformity Assessment of Specified Equipment is established as follows.

Ordinance for Designated Evaluation Bodies, Etc. Pursuant to the Act for Implementation of the Mutual Recognition between Japan and Foreign States in Relation to Results of Conformity Assessment Procedures of Specified Equipment

Article 1 (Terminology)

The terminology used in this Ordinance shall be based on the terminology used in the Act for Implementation of the Mutual Recognition between Japan and Foreign States in Relation to Results of Conformity Assessment Procedures of Specified Equipment (hereinafter referred to as “the Act”) and the Order for Enforcement of the Act for Implementation of the Mutual Recognition between Japan and Foreign States in Relation to Results of Conformity Assessment Procedures of Specified Equipment (Cabinet Order No. 355 of 2001; hereinafter referred to as “the Order”).

Article 2 (Application for Evaluation)

(1) When any person who intends to obtain the designation set forth in Article 3 paragraph (1) of the Act or the renewal of the designation (hereinafter referred to as “designation, etc.”) or approval for a change set forth in Article 7 paragraph (1) of the Act applies for the evaluation which is conducted by a designated evaluation body pursuant to the provision of Article 14 paragraph (3) of the Act, he shall submit to the designated evaluation body an written application using Form 1 describing the following matters:

(i) Name and address of the applicant and in the case of a juridical person, the names of the representative person and officers as well

(ii) Category of overseas conformity assessment business

(iii) Distinction of application for either designation, renewal or approval for a change

(iv) Outline of facilities used for overseas conformity assessment business

(v) Rules and procedures for conducting overseas conformity assessment business

(vi) In the case of a person intending to be designated for activities limited in scope pursuant to the provision of Article 3 paragraph (2) of the Act, the type of specified equipment for export and scope of activities

(2) The written application set forth in the preceding paragraph shall be submitted with a document which explains conformity to the criteria for designation prescribed in items of Article 3 of the Ordinance for Enforcement of the Act for Implementation of the Mutual Recognition between Japan and Foreign States in Relation to Results of Conformity Assessment Procedures of Specified Equipment (MIC/METI Ordinance No. 3 of 2001; referred to as “the Enforcement Ordinance” in paragraph (3)) attached thereto.

(3) When a person who intends to obtain designation, etc. seeks administrative rationalization (which means to evaluate whether the overseas conformity assessment business conforms to the quality system requirements among the criteria for designation prescribed in Article 5 paragraph (1) of the Act by confirming that he has obtained the designation for overseas conformity assessment business pertaining to any item of Article 2 of the Order (excluding any overseas conformity assessment business for which he intends to undergo an evaluation) or that he has obtained or renewed the designation or registration set force in any item of Article 20 of the Enforcement Ordinance) in the evaluation, he must submit the written application set forth in paragraph (1) with the documents prescribed in the main clause of Article 19 or Article 21 of the Enforcement Ordinance attached thereto.

Article 3 (Report of Evaluation Results)

The reporting of the evaluation results to the competent minister pursuant to the provision of Article 14 paragraph (4) of the Act shall be made with a written report

using Form 2 describing the following matters:

(i) Name and address of the applicant who has applied for the evaluation and in the case of a juridical person, the names of the representative person and officers as well

(ii) Category of the overseas conformity assessment business related to the application for evaluation

(iii) Summary and results of the evaluation (in cases where administrative rationalization was conducted in the evaluation, the report should include a note to that effect)

Article 4 (Application for Designation)

(1) Any person who intends to apply for the designation set forth in Article 15 of the Act shall submit to the competent minister an written application using Form 3 describing the following matters for each category of the overseas conformity assessment business related to the application:

(i) Name and address of the applicant and in the case of a juridical person, the names of the representative person and officers as well

(ii) Location of the office where the evaluation activities will be conducted

(iii) Planned starting date of the evaluation activities

(2) The following documents shall be attached to the application set forth in the preceding paragraph:

(i) In the case of an application for designation in respect of the category of overseas conformity assessment business pertaining to item (i) through item (vii) of Article 2 of the Order

(a) The articles of incorporation or the articles of endowment and a certified copy of the register book, or equivalents of these

(b) An inventory of assets and the balance sheet for the last business year, or equivalents of these

(c) Document which shows the distinction between the matters related to the evaluation activities and the matters related to other activities in the business plan and a revenue and expenditure plan for both the business year including the day of application and the following business year

(d) Document which explains that the applicant does not fall under any item of Article 16 of the Act

(e) Document describing the following matters:

1. If the applicant is a juridical person, the names of the officers and their brief personal histories as well as the names of the constituent members set forth in Article 5 paragraph (2) according to the type of juridical person

2. Matters related to the organization and management

3. Record of activities similar to the evaluation related to the application for the designation

4. If the applicant conducts activities other than the evaluation activities, the type and outline of those activities

5. Plan for conducting the evaluation activities

6. Names and personal histories of the persons who conduct the evaluation

7. Any other reference matters

(ii) In the case of an application for designation in respect of the category of overseas conformity assessment business pertaining to Article 2 item (viii) of the Order

(a) The articles of incorporation or the articles of endowment and a certified copy of the register book, or equivalents of these

(b) Document which explains conformity to the provision of Article 5 paragraph (1)

(c) Document which explains that the applicant does not fall under any item of Article 16 of the Act

(d) Document describing the following matters:

1. If the applicant is a juridical person, the names of the officers and their brief personal histories as well as the names of the constituent members set forth in Article 5 paragraph (2) according to the type of juridical person

2. Matters related to the organization and management

3. Record of activities similar to the evaluation related to the application for the designation

4. If the applicant conducts activities other than the evaluation activities, the type and outline of those activities

5. Any other reference matters

(3) When any change has occurred to the following matters, the designated evaluation body shall submit to the competent minister a written notification using Form 4 describing the matters which have been changed, date of the change and reason for the change.

(i) In the case of the designated evaluation body that conducts evaluation in respect of the category of overseas conformity assessment business pertaining to item (i) through item (vii) of Article 2 of the Order, matters set forth in item (i) (e) 1 (limited to matters related to the names of the constituent members), or item (i) (e) 4 or item (i) (e) 6 of the preceding paragraph

(ii) In the case of the designated evaluation body that conducts evaluation in respect of the category of overseas conformity assessment business pertaining to Article 2 item (viii) of the Order, matters set forth in item (ii) (b) (limited to matters related to the names and personal histories of the persons who conduct evaluation), or item (ii) (d) 1 (limited to matters related the names of the constituent members) or item (ii) (d) 4 of the preceding paragraph

Article 5 (Criteria for Designation)

(1) The criteria for examination set forth in Article 17 item (i) of the Act shall be as

follows:

(i) In the case of an application for designation in respect of the category of overseas conformity assessment business pertaining to Article 2 item (i) through item (vii) of the Order

(a) With regard to the financial basis, the criteria for examination shall be those listed in Appended Table 1.

(b) With regard to technical competence, the criteria for examination shall be those listed in Appended Table 2.

(ii) In the case of an application for designation in respect of the category of overseas conformity assessment business pertaining to Article 2 item (viii) of the Order, the criteria shall be those regarding the financial basis or technical competence among the criteria provided in the standards for accreditation bodies accrediting conformity assessment bodies prescribed by the International Organization for Standardization and the International Electrotechnical Commission pertaining to the overseas conformity assessment business.

(2) The constituent members specified by the applicable ministerial ordinance set forth in Article 17 item (ii) of the Act shall be the persons prescribed in the following items for each type of juridical person:

(i) A incorporated association established pursuant to the provision of Article 34 of the Civil Code (Act No. 89 of 1896): Members of staff

(ii) A general partnership company, a limited partnership company, and a limited liability company: Members of staff

(iii) A stock company: Shareholders with 5/100 or more of the total number of issued shares

(iv) Other juridical persons: Those equivalent to the members prescribed in the preceding three items corresponding to the type of juridical persons concerned

(3) The criteria specified in the applicable ministerial ordinance set forth in Article 17 item (iii) of the Act shall be that the organization conducting evaluation, the method of evaluation, the method of calculating the fees, and any other system required for conducting evaluation activities are prepared to conform to the following matters:

(i) They shall not treat specific persons with undue discrimination.

(ii) They shall not be affected by any business relationship or any other interest with the person who is evaluated.

(iii) In addition to matters listed in the preceding two items, they shall not hinder fair conduct of evaluation activities.

Article 6 (Notification of Change of Name, Etc.)

When a designated evaluation body intends to notify the competent minister of a change pursuant to the provision of Article 18 paragraph (2) of the Act, it shall submit a written notification using Form 5 describing the following matters:

(i) New name, new address or new location of the office where the evaluation activities will be conducted

(ii) Planned date of the change

Article 7 (Renewal of Designation)

The provisions of Article 4 paragraph (1) and paragraph (2) and Article 5 shall apply mutatis mutandis to the renewal of designation of a designated evaluation body set forth in Article 19 paragraph (1) of the Act.

Article 8 (Notification of Appointment and Dismissal of Officers)

(1) When a designated evaluation body intends to notify the competent minister of appointment or dismissal of officers pursuant to the provision of Article 22 of the Act, it shall submit a written notification using Form 6 describing the following matters:

(i) Names of the officers who have been appointed or dismissed

(ii) Reasons for appointment or dismissal

(iii) Date of appointment or dismissal

(2) The following documents shall be attached to the written notification set forth in the preceding paragraph:

(i) Document which certifies the determination of intent with regard to the appointment or dismissal

(ii) In the case of the notification of appointment, brief personal histories of the appointed officers

Article 9 (Application, Etc. for Approval of Rules and Procedures for Evaluation)

(1) When a designated evaluation body intends to obtain approval for the rules and procedures for evaluation pursuant to the provision of the first sentence in Article 23 paragraph (1) of the Act, it shall submit to the competent minister a written application using Form 7 with the rules and procedures for evaluation attached thereto.

(2) When a designated evaluation body intends to obtain approval for a change in the rules and procedures for evaluation pursuant to the provision of the second sentence in Article 23 paragraph (1) of the Act, it shall submit to the competent minister a written application using Form 8 describing the following matters with the new rules and procedures for evaluation attached thereto:

(i) Planned change

(ii) Planned date of change

(iii) Reasons for the change

Article 10 (Matters to be Provided in the Rules and Procedures for Evaluation)

The matters specified by the applicable ministerial ordinance set forth in Article 23 paragraph (2) of the Act shall be as follows:

- (i) Matters related to the business hours for conducting evaluation activities and holidays
- (ii) Matters related to the office where evaluation activities are conducted
- (iii) Matters related to the methods for conducting evaluation activities
- (iv) Matters related to the handling of fees
- (v) Matters related to the appointment, dismissal or placement of the persons who conduct the evaluation
- (vi) Matters related to the maintenance of confidentiality with regard to the evaluation activities
- (vii) Matters related to the control of books and records and documents concerning the evaluation activities
- (viii) Matters related to accounting procedures
- (ix) Matters related to the disclosure, etc. of annual business reports
- (x) Matters related to the report to the competent minister prescribed in Article 14 paragraph (4) of the Act (limited to the designated evaluation bodies in respect of the category of the overseas conformity assessment business pertaining to Article 2 item (viii) of the Order)
- (xi) In addition to the matters listed in the preceding items, the matters required for the proper conduct of evaluation activities

Article 11 (Books and Records)

(1) The matters specified by the applicable ministerial ordinance set forth in Article 24 of the Act shall be as follows:

- (i) Name and address of the applicant who has applied for the evaluation and in the case of a juridical person, the name of the representative person as well
- (ii) Date when the application for the evaluation was received
- (iii) Category of the overseas conformity assessment business related to the application for the evaluation
- (iv) Date when the evaluation was conducted
- (v) Name of the person who conducted the evaluation
- (vi) Summary and results of the evaluation (in the cases where administrative rationalization was conducted in the evaluation, the report should include a note to that effect)
- (vii) Date of report of results of the evaluation

(2) The books and records set forth in Article 24 of the Act shall be maintained in each office where the evaluation activities are conducted and shall be kept for ten years starting from the date when entries are made therein.

(3) The books and records set forth in the preceding paragraph may be kept by means of electromagnetic form (an electronic means, magnetic means, or any other means not recognizable to human perception).

Article 12 (Application for Authorization of Suspension or Abolition of the Evaluation Activities)

When a designated evaluation body intends to obtain authorization set forth in Article 26 paragraph (1) of the Act, it shall submit to the competent minister an written application using Form 9 describing the following matters:

- (i) The scope of the evaluation activities which it intends to suspend or abolish
- (ii) Planned date to suspend or abolish the evaluation activities, and in case of suspension, planned period of suspension
- (iii) Reasons for the suspension or abolition

Article 13 (Transfer of the Evaluation Activities)

A designated evaluation body shall conform to the following items when any event prescribed in Article 28 paragraph (3) of the Act has occurred:

- (i) Transfer the evaluation activities to the competent minister
- (ii) Transfer the books and records and documents concerning the evaluation activities to the competent minister
- (iii) Other matters which the competent minister deems necessary

Article 14 (Application, Mutatis Mutandis to the Evaluation by NITE)

The provisions of Article 2 paragraph (1), Article 3 and the preceding Article shall apply mutatis mutandis to the evaluation by NITE. In this case, the term “Article 14 paragraph (3) of the Act” and the term “designated evaluation body” in Article 2 paragraph (1) shall be deemed to be replaced with “Article 14 paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 36 paragraph (2) of the Act” and “NITE,” respectively; the term “Article 14 paragraph (4) of the Act” in Article 3 shall be deemed to be replaced with “Article 14 paragraph (4) of the Act, as applied mutatis mutandis pursuant to Article 36 paragraph (2) of the Act”; the term “Article 28 paragraph (3) of the Act” in the preceding Article shall be deemed to be replaced with “Article 36 paragraph (3) of the Act”; and the term “competent minister” in item (i) and item (ii) in the same Article shall be deemed to be replaced with “NITE.”

Article 15 (Public Notice)

The public notice set forth in Article 18 paragraph (1) and paragraph (3), Article 26 paragraph (2), Article 27 paragraph (2), Article 28 paragraph (2), and Article 36 paragraph (4) of the Act shall be made by a notification in the Official Gazette.

Article 16 (Details of Expenses Required for Conducting Evaluation Activities)

The matters specified by the applicable ministerial ordinance set forth in Article 12 paragraph (1) of the Order shall be personnel expenses, administration and other expenses, travel expenses (railway fare, vessel fare, air fare, and vehicle fare), daily allowance and accommodation fees, which serve as the bases for calculating the fees

for which a designated evaluation body intends to obtain the approval, and the method of calculating the fees for which it intends to obtain the approval.

Article 17 (Application Form, Etc. for the Approval of Fees)

(1) The written application set forth in the first sentence in Article 12 paragraph (1) of the Order shall use Form 10.

(2) The written application for approval of the change set forth in the third sentence in Article 12 paragraph (1) of the Order shall use Form 11.

Article 18 (Procedure of Application, Etc.)

Application, etc. to the competent minister pursuant to the provisions of the Order or this Ordinance shall be made by submitting one original application document to the Minister for Internal Affairs and Communications with regard to an application pertaining to Article 13 item (i) of the Order, by submitting one original application document and a duplicate of it to either of the Minister for Internal Affairs and Communications or the Minister of Economy, Trade and Industry with regard to an application pertaining to Article 13 item (ii) of the Order, or by submitting one original application document to the Minister of Economy, Trade and Industry with regard to an application pertaining to Article 13 item (iii) of the Order.

Supplementary Provisions

(Effective Date)

(1) This Ordinance shall come into effect as from the date on which the Act comes into effect; provided, however, that the provision of the following paragraph shall come into effect as from the date on which Supplementary Provisions Article 2 of the Act comes into effect (November 17, 2001).

(Preparatory Actions)

(2) The designation, related procedures and other necessary actions prescribed in Supplementary Provisions Article 2 of the Act shall be undertaken based on the provisions of Article 4, Article 5, Article 9, Article 10, Article 15 and Article 18 of this Ordinance even if prior to the enforcement of this Ordinance.

Supplementary Provisions (MIC/METI Ordinance No.3 – July 26, 2002)

This Ordinance shall come into effect as from the date on which the Act for Partial Revision of the Act for Implementation of Mutual Recognition between Japan and the European Community in Relation to Conformity Assessment of Specified Equipment comes into effect.

Supplementary Provisions (MIC/METI Ordinance No. 6 – October 1, 2004)

This Ordinance shall come into effect as from the day of promulgation.

Supplementary Provisions (MIC/METI Ordinance No. 1 – March 7, 2005)

This Ordinance shall come into effect as from the date on which the Act on Development, Etc. of Related Acts upon the Enforcement of Real Estate Registration Act comes into effect (March 7, 2005).

Supplementary Provisions (MIC/METI Ordinance No. 1 – April 20, 2006)

This Ordinance shall come into effect as from the date on which the Companies Act (Act No. 86 of 2005) comes into effect (May 1, 2006).

Supplementary Provisions (MIC/METI Ordinance No. 4 – November 16, 2007)

This Ordinance shall come into effect as from the date on which the Act for Partial Revision of the Act for Implementation of the Mutual Recognition between Japan and the European Community and the Republic of Singapore in Relation to Conformity Assessment of Specified Equipment (Act No. 92 of 2007) comes into effect (November 20, 2007); provided, however, that the provision of Article 2 shall come into effect as from the date on which the Agreement on Mutual Recognition of Results of Conformity Assessment Procedures between Japan and the United States of America enters into force.

別表第一（第五条関係）

Appended Table 1 (Re: Article 5)

	Items	Criteria for Examination
(i)	Organization	<ol style="list-style-type: none">1. The applicant shall have the financial stability and resources (which mean the facilities, technology, knowledge and skills that individuals have, and any other resources to be used for the evaluation activities) required for conducting evaluation activities.2. The applicant shall have appropriate arrangements to cover liabilities arising from the evaluation activities.
(ii)	Establishment of a quality management system	<ol style="list-style-type: none">1. Objectives for the quality of the evaluation activities (limited to activities related to the financial basis; hereinafter the same shall apply in this table) (hereinafter referred to as “quality” in this table) and a policy for quality (referred to as “quality policy” hereinafter in this table) shall be defined and documented by the person who is responsible for quality (hereinafter referred to as “person responsible for quality” in this table).2. The quality policy shall be clearly understood, implemented and maintained by the officers and members of staff.3. Procedures for conducting the evaluation activities shall be established explicitly and systematically

		<p>based on the quality policy and the evaluation activities shall be appropriately conducted according to the procedures.</p> <p>4. A person who is authorized to exercise power related to the following matters shall be designated under the control of the person responsible for quality and independently from the section which is engaged in the evaluation activities.</p> <p>(a) To establish, implement and maintain a quality management system which conforms to the requirements prescribed in 1 through 3 above</p> <p>(b) To report on the performance of the quality management system to the person responsible for quality</p>
(iii)	Review of the quality management system	<p>The policy and procedures to review the quality management system at sufficient intervals to ensure the continuing adequacy and effectiveness shall be established by the person responsible for quality. The quality management system shall be reviewed based on the policy and procedures, and records of such reviews shall be maintained.</p>
(iv)	Document control	<p>1. The following matters shall be established as internal standards and shall be periodically renewed:</p> <p>(a) Information on the body's legal status</p> <p>(b) General explanation of the evaluation activities</p> <p>(c) Means for securing financial stability</p> <p>(d) Information on the procedure for dealing with complaints</p> <p>2. The following matters shall be established as internal standards:</p> <p>(a) The procedures for conducting the evaluation activities set forth in (ii) 3 above</p> <p>(b) The procedures for reviewing the quality management system set forth in (iii) above</p> <p>(c) The procedures for safeguarding confidentiality set forth in (v) 3 below</p> <p>(d) The procedures for dealing with complaints on the evaluation activities set forth in (vi) 1 below</p> <p>(e) The procedures for dealing with non-conformity related to the evaluation activities set forth in (vi) 3 below</p> <p>(f) The procedures for conducting internal audits set</p>

		<p>forth in (vii) below</p> <p>(g) The procedures for controlling all the documents and the recording media by electromagnetic means related to the evaluation activities (hereinafter referred to as “all the documents” in this table)</p> <p>3. All the documents shall be properly controlled according to the procedures set forth in 2 (g) so that the applicant for the evaluation (which means the person who applies for the evaluation pursuant to the provision of Article 14 paragraph (3) of the Act; the same shall apply hereinafter), the officers and members of staff may use all the appropriate documents.</p>
(v)	Records	<p>1. Records concerning the evaluation activities shall be systematically maintained.</p> <p>2. The records of the evaluation activities shall satisfy the following matters:</p> <p>(a) The records shall be identified, managed, and disposed of in such a way as to ensure the appropriateness of the procedure for the evaluation activities and the confidentiality of the information.</p> <p>(b) The records shall be kept for longer than the valid period of the designation granted to the respective overseas conformity assessment business of the applicant for the evaluation.</p> <p>3. The policy and procedures for safeguarding confidentiality shall be established in respect of the policy and procedures for maintaining the records and the use of the records.</p>
(vi)	Dealing with complaints and non-conformity	<p>1. The policy and procedures for dealing with complaints about the evaluation activities made by an applicant for the evaluation or its relevant person shall be established, and the complaints shall be dealt with according to the policy and procedures.</p> <p>2. The following matters shall be taken when dealing with the complaints:</p> <p>(a) All complaints concerning the evaluation activities shall be recorded.</p> <p>(b) Appropriate corrective actions and preventive actions shall be taken.</p>

		<p>(c) The actions taken shall be documented and their effectiveness shall be assessed.</p> <p>3. Rules and procedures for dealing appropriately with non-conformity related to the evaluation activities shall be established.</p>
(vii)	Internal audits	<p>Rules and procedures for conducting internal audits shall be established pursuant to the provisions of the Japanese Industrial Standards (hereinafter referred to as “JIS”) Q19011 under the Industrial Standardization Act (Act No. 185 of 1949), and internal audits shall be periodically and appropriately conducted according to the rules and procedures.</p>

Appended Table 2 (Re: Article 5)

	Items	Criteria for Examination
(i)	Organization	<p>1. The applicant shall secure a sufficient number of personnel having the education, training, technical knowledge and practical experience necessary for conducting appropriately the evaluation activities (limited to activities related to technical competence; the same shall apply hereinafter).</p> <p>2. The applicant for designation in respect of the category of the overseas conformity assessment business pertaining to Article 2 item (iii) (limited to the overseas conformity assessment business related to a conformity assessment body prescribed in Article 1 (5) of the Council Directive 89/336/EEC of 3 May 1989 on the approximation of the Acts of the Member States relating to electromagnetic compatibility), item (v) or item (vi) of the Order (which means a person who intends to obtain the designation set forth in Article 14 paragraph (1) of the Act; the same shall apply hereinafter) shall establish a committee to deal with technical matters related to the document evaluation and the on-site (which means a place where the applicant for the evaluation conducts the overseas conformity assessment business; the same shall apply hereinafter) evaluation (hereinafter referred to as “document evaluation, etc.”).</p>
(ii)	Establishment of a quality management system	<p>1. Objectives for the quality of the evaluation activities (hereinafter referred to as “quality”) and a policy for quality (hereinafter referred to as “quality policy”) shall be defined and documented by the person who is responsible for quality (hereinafter referred to as</p>

		<p>“person responsible for quality”).</p> <p>2. The quality policy shall be clearly understood, implemented and maintained by the officers and members of staff.</p> <p>3. Procedures for conducting the evaluation activities shall be established explicitly and systematically based on the quality policy and the evaluation activities shall be appropriately conducted according to the procedures.</p> <p>4. A person who is authorized to exercise power related to the following matters shall be designated under the control of the person responsible for quality and independently from the section which is engaged in the evaluation activities.</p> <p>(a) To establish, implement and maintain a quality management system which conforms to the requirements prescribed in 1 through 3 above</p> <p>(b) To report on the performance of the quality management system to the person responsible for quality</p>
(iii)	Review of the quality management system	The policy and procedures to review the quality management system at sufficient intervals to ensure the continuing adequacy and effectiveness shall be established by the person responsible for quality. The quality management system shall be reviewed based on the policy and procedures, and records of such reviews shall be maintained.
(iv)	Document control	<p>1. The following matters shall be established as internal standards and shall be periodically renewed:</p> <p>(a) Information on the body’s legal status</p> <p>(b) General explanation of the evaluation activities</p> <p>(c) Information on the procedure for the document evaluation, etc.</p> <p>(d) Information on the application fees for the document evaluation, etc.</p> <p>(e) Rights and duties of the applicant for the evaluation</p> <p>(f) Information on the procedure for dealing with complaints</p>

		<p>2. The following matters shall be established as internal standards:</p> <p>(a) The procedures for conducting the evaluation activities set forth in (ii) 2 above</p> <p>(b) The procedures for reviewing the quality management system set forth in (iii) above</p> <p>(c) The procedures concerning the employment, education, and training of the evaluating personnel set forth in (v) 1 below</p> <p>(d) Appropriate criteria concerning the competence of the evaluating personnel set forth in (v) 2 below</p> <p>(e) The procedures concerning the method of selecting the evaluating personnel set forth in (v) 4 below</p> <p>(f) The procedures concerning the system for monitoring the document evaluation, etc. by the evaluating personnel set forth in (v) 8 below</p> <p>(g) The procedures for conducting the document evaluation, etc. set forth in (vii) 1 below</p> <p>(h) The procedures for maintaining records set forth in (viii) 3 below</p> <p>(i) The procedures for safeguarding confidentiality set forth in (viii) 3 below</p> <p>(j) The procedures for reporting to the competent minister set forth in (ix) below</p> <p>(k) The procedures for dealing with complaints on the evaluation activities set forth in (x) 1 below</p> <p>(l) The procedures for dealing with non-conformity related to the evaluation activities set forth in (x) 3 below</p> <p>(m) The procedures for conducting internal audits set forth in (xi) below</p> <p>(n) The procedures for controlling all the documents and the recording media by electromagnetic means related to the evaluation activities (hereinafter referred to as “all the documents”)</p> <p>3. All the documents shall be properly controlled according to the procedures set forth in 2 (n) so that the applicant for the evaluation, the officers and members of staff may use all the appropriate documents.</p>
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(v)	Evaluating personnel	<ol style="list-style-type: none"> 1. The policy and procedures to employ, educate, and train evaluating personnel (which mean persons who conduct the document evaluation, etc. and experts who guide and advise on technical matters related to the overseas conformity assessment business; the same shall apply hereinafter) shall be established. 2. Appropriate criteria concerning the competence of evaluating personnel shall be established. 3. The evaluating personnel who conduct the document evaluation, etc. shall conform to JIS Q19011. 4. The procedures concerning the method of selecting evaluating personnel shall be established, and the evaluating personnel shall be selected based on the competence, education, training, qualifications useful for the evaluation, practical experience of evaluation, and the evaluation of all of these. 5. The evaluation team (which means a group of evaluating personnel who have been selected to conduct the document evaluation, etc.; the same shall apply hereinafter) shall have a thorough knowledge of the procedures for conducting the document evaluation, etc. set forth in (vii) 1 below and the criteria for designation of the overseas conformity assessment business prescribed in Article 5 paragraph (1) of the Act, and shall have professional knowledge. 6. The evaluation team shall be provided with clear and up-to-date instructions describing the duties and scope of responsibility of each member required for the document evaluation, etc. and all the relevant information concerning the procedures for document evaluation, etc. 7. All evaluating personnel shall be requested to submit a contract written pledge or other document committing that they will maintain confidentiality concerning their document evaluation, etc., and that their document evaluation, etc. will be independent of commercial and other interests, and any prior or present link with the applicant for evaluation. 8. The policy and procedures concerning the system for monitoring the document evaluation, etc. by evaluating personnel shall be established.
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		<p>9. Records including the following matters with regard to the evaluating personnel shall be maintained and be kept up-to-date:</p> <ul style="list-style-type: none"> (a) Name and address (b) Affiliation and position held in the organization (c) Educational qualifications and professional status (d) Practical experience, education, and training (e) Performance appraisal (f) Date of most recent updating of the records
(vi)	Application for document evaluation, etc.	<p>1. A detailed description concerning the procedures for the document evaluation, etc. and the documents describing application fees for the document evaluation, etc. and other methods of document evaluation, etc. shall be maintained up-to-date and shall be provided to the applicant for the evaluation.</p> <p>2. If requested, additional information on the application for the document evaluation, etc. shall be provided to the applicant for the evaluation.</p> <p>3. At least the following information shall be provided by the applicant for the evaluation prior to the on-site assessment:</p> <ul style="list-style-type: none"> (a) Outline of the applicant for the evaluation (b) Organization of and general information on the applicant for the evaluation which intends to conduct the overseas conformity assessment business (c) Internal standards of the applicant for the evaluation <p>4. Information gathered from the applicant for the evaluation in the course of application for document evaluation, etc. shall be treated with appropriate confidentiality.</p>
(vii)	Conducting of document evaluation, etc.	<p>1. The policy and procedures for conducting the document evaluation, etc. shall be established.</p> <p>2. A plan for conducting the document evaluation, etc. shall be prepared.</p> <p>3. An appropriate evaluation team which evaluates all the information gathered from the applicant for the evaluation and conducts the document evaluation, etc. shall be formed.</p> <p>4. The applicant for the evaluation shall be informed of</p>

		<p>the names of the members of the evaluation team which carries out the document evaluation, etc. and other information with sufficient notice to appeal against the designated evaluation body.</p> <p>5. The plan for and the date of conducting the document evaluation, etc. shall be agreed with the applicant for the evaluation; and the matters for evaluation to be conducted by the evaluation team shall be clearly defined and made known to the applicant for the evaluation.</p> <p>6. Before proceeding with the document evaluation, etc., the contents of the application from the applicant for the evaluation shall be reviewed in order to ensure the following matters. Records of the review shall be maintained.</p> <p>(a) Any difference in interpretation of the contents of the application for the document evaluation, etc. between the applicant for the evaluation and the evaluation team is solved.</p> <p>(b) The evaluation team has the capability to conduct the document evaluation, etc. with respect to the category and the place of business of the overseas conformity assessment business related to the application for the document evaluation, etc.</p> <p>7. A meeting shall take place between the evaluation team and the applicant for the evaluation after the on-site assessment has been conducted, at which the evaluation team provides a written or oral opinion and provides an opportunity for the applicant for the evaluation to ask questions about the opinion.</p>
(viii)	Records	<p>1. Records concerning the evaluation activities shall be systematically maintained.</p> <p>2. The records of the evaluation activities shall satisfy the following matters:</p> <p>(a) The records shall verify effective implementation of the procedures for the document evaluation, etc.</p> <p>(b) The records shall be identified, managed, and disposed of in such a way as to ensure the appropriateness of the procedure for the evaluation activities and the confidentiality of the information.</p> <p>(c) The records shall be kept for longer than the valid period of the designation granted to the respective overseas conformity assessment business of the applicant for the evaluation.</p>

		3. The policy and procedures for safeguarding confidentiality shall be established in respect of the policy and procedures for maintaining the records and the use of the records.
(ix)	Reporting to the competent minister	Procedure concerning the reporting to the competent minister prescribed in Article 14 paragraph (4) of the Act shall be established.
(x)	Dealing with complaints and non-conformity	<p>1. The policy and procedures for dealing with complaints about the evaluation activities made by an applicant for the evaluation or a its relevant person shall be established, and the complaints shall be dealt with according to the policy and procedures.</p> <p>2. The following matters shall be taken when dealing with the complaints:</p> <p>(a) All complaints concerning the evaluation activities shall be recorded.</p> <p>(b) Appropriate corrective actions and preventive actions for complaints shall be taken.</p> <p>(c) The actions taken shall be documented and their effectiveness shall be assessed.</p> <p>3. Rules and procedures for dealing appropriately with non-conformity related to the evaluation activities shall be established.</p>
(xi)	Internal audits	Rules and procedures for conducting internal audits shall be established pursuant to the provisions of JIS Q19011, and internal audits shall be periodically and appropriately conducted according to the rules and procedures.

Form 1–Form 11 (Omitted)