Technical information on procedures for overseas CABs to be designated under the Electrical Appliance and Material Safety Law (‘Den-an Law’)

Ministry of Economy, Trade and Industry
Japan
1. Understanding of legal structure to become CAB of the Den-an Law

2. Conformity with ISO/IEC Guide 65

3. Conformity with ISO/IEC 17025

4. Procedure for the Designation of the CAB

5. Miscellaneous
Main Issues for the Prospective CAB of Den-an law

1. Understanding of legal structure of Den-an law

1. Requirement to CAB

2. Requirement to Manufacturers

3. Technical Requirement

1. Quality manual
   (including detailed description)

2. Personnel
   (Certification, Factory Audit)

ISO/IEC 17025 is not a condition of a CAB

2. Testing Personnel

3. Test Equipments

3. Subcontracting

2. Conformity with ISO/IEC Guide 65

3. Conformity with ISO/IEC 17025

Refer to page 4

Refer to page 6

Refer to page 12
1. Understanding of the legal structure Den-an Law

- Electrical Appliance and Material Safety Law (Den-an Law)
  - Cabinet Order of the Electrical Appliance and Material Safety Law
  - Ordinance of the Electrical Appliance and Material Safety Law

- Ordinance concerning Technical Requirements for Electrical Appliances and Materials

  (Paragraph 1)

- Public Announcement for the Technical Requirements pursuant to paragraph 2 of the Ordinance concerning Technical Requirements for Electrical Appliances and Materials

  (Paragraph 2)

- Working Regulations for the Ordinance concerning Technical Requirements for Electrical Appliances and Materials

CAB staff should understand the structure of the Den-an law.
1. Understanding of Den-an Law

Main Issue to understand the structure of Den-an law

- Requirement to Notifying Suppliers Article 8 of the Law
- Requirement to CAB Article 31 of the Law
- Type Classification Article 4 of the Ordinance

Learning of Technical Requirement

- Paragraph 1 of METI Ordinance concerning Technical Requirements for Electrical Appliances and Materials (No.85,1962)
- Paragraph 2 of METI Ordinance concerning Technical Requirements for Electrical Appliances and Materials (No.85,1962)
2. Conformity with ISO/IEC Guide 65

General Requirements of ISO/IEC Guide 65

4.1 General Provision
4.2 Organization
4.3 Operation
4.4 Subcontracting
4.5 Quality System
4.6 Conditions and Procedure for Granting Certification
4.7 Internal Audit and Management Review
4.8 Documentation
4.9 Records
4.10 Confidentiality
5. Personnel

6. Changes in the Certification Requirements
7. Appeals, Complaints and Disputes
8. Application
9. Preparation for Evaluation
10. Evaluation
11. Evaluation Report
12. Decision on Certification
13. Surveillance
14. Use of License, Certificates and Marks
15. Complaints to Suppliers
2. Conformity with ISO/IEC Guide 65

Criteria for Designation of CAB
- Article 31 of the Den-an Law -

Conformity with ISO/IEC Guide 65

The applicant fulfills the requirements for bodies operating product certification systems stipulated by International Organization for Standardization and International Electronic Commission.

How should the CAB prove the conformity with ISO/IEC Guide 65 actually?

Elimination of Unfairness

The applicant does not fall into any of the following items as being controlled by Notifying Suppliers who manufacture or import Specified Electrical Appliance and Materials for which conformity assessment is required in accordance with Article 9, Paragraph 1 (hereinafter called "supplier which may apply for conformity assessment")

**Condition**

- A supplier which may apply for conformity assessment is the Parent Company if the applicant is publicly-traded company or private limited company,
- The percentage of board members of a supplier which may apply for conformity assessment in the board members of the applicant exceeds 50 percent.
- The applicant is a board member or an employee of a body which applies for conformity assessment (including the case where it was a board member or an employee in the preceding two years)
2. Conformity with ISO/IEC Guide 65

Key issues to tackle first

(unofficial recommendation)

Review of Quality manual

Based on clause 4.5.3 of ISO/IEC Guide 65

- CAB should prepare the manual in English (or Japanese)
- CAB should prepare the contents of quality manual and the following description in English (or Japanese) for the audit.

- CAB may prepare the below description as the associated quality procedure in English (or Japanese)

Detailed description of the evaluation and certification procedure

Qualification criteria

Personnel

- Competency for Certification -

- Certification body personnel
- Auditor for factory audit
- Training system

CAB should start to review the quality manual and the current status of certification body and personnel regarding the conformity with ISO/IEC Guide 65 as soon as possible.
2. Conformity with ISO/IEC Guide 65

Technical Requirements for the CAB

Testing capability of international level
Accreditation to ISO/IEC 17025 by Laboratory Accreditation Body which has signed an ILAC/APLAC MRA or CBTL in the IECEE/CB scheme

Conduction of testing
Testing in accordance to the method stipulated in Appendix 1 of Ordinance 84 paragraph 1

Technical Requirement for the CAB

CAB can conclude subcontract agreements with Testing Laboratories which conform with ISO/IEC 17025

Factory audit
Factory audit to assess whether they are equipped with testing facilities stipulated in Appendix 4 and Article 15 of Ordinance 84

Demonstration of testing for items under Den-an Law
Demonstrating the capability and technical competence of testing against technical requirements, including Japanese deviations.

Authority is to assess the CAB’s testing capability

Authority is to assess the CAB’s inspection capability
Review of the CAB Quality Manual

Quality Manual of ISO/IEC 17025

2. Conformity with ISO/IEC Guide 65

*) In case the CAB has already been accredited with ISO/IEC 17025

Part 1 General Requirement Clause 4. to 15. of Guide 65

Part 2 Detailed description


Part 3 ISO/IEC 17025

Part 2 ISO/IEC Guide 65

Part 1 Management System


In case the CAB utilizes the 17025 manual as its base document

In case the CAB utilizes the 17025 manual as reference document

or
Comparison of Management Requirements between Guide 65 and 17025

ISO/IEC Guide 65

4.1 General Provision
4.6 Conditions and Procedure for Granting Certification
6. Changes in the Certification Requirements
8. Application
9. Preparation for Evaluation
10. Evaluation
11. Evaluation Report
12. Decision on Certification
13. Surveillance
14. Use of License, Certificates and Marks
15. Complaints to Suppliers

Common Items

4.2 Organization
4.3 Operation
4.4 Subcontracting
4.5 Quality System
4.7 Internal Audit and Management Review
4.8 Documentation
4.9 Records
4.10 Confidentiality
5. Personnel
7. Appeals, Complaints and Disputes

ISO/IEC 17025

4.4 Review of Requests, Tenders and Contracts
4.6 Purchasing Services and Suppliers
4.7 Service to Client
4.9 Control of Nonconforming Testing and/or Calibration Work
4.10 Corrective Action
4.11 Preventive Action

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3. Conformity with ISO/IEC 17025

- Competence of Testing Laboratory
  - CAB is under application for IECEE/CBTL

- Testing Personnel
  - Training system

- Test Equipment
  - 1. Improvement and Perfection of the Test Equipment
  - 2. Consideration of subcontracting

- Subcontracting
  - Consideration of subcontracting with Japanese Testing Laboratories

CAB should review the conformity with ISO/IEC 17025 from these aspects.

Refer to Page 13 and 14

Refer to Page 15
### CAB Self-assessment of Testing Equipment
- Paragraph 1 of METI Ordinance -

<table>
<thead>
<tr>
<th>Testing Equipment List to Purchase (in case of electrical wires)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Bending Test</td>
</tr>
<tr>
<td>(2) Snatch Test</td>
</tr>
<tr>
<td>(3) Heat Deformation Test</td>
</tr>
<tr>
<td>(4) Bending Strength Test</td>
</tr>
<tr>
<td>(5) Winding Strength Test</td>
</tr>
<tr>
<td>(6) Torsional Strength Test</td>
</tr>
</tbody>
</table>

CAB is responsible for the evaluation of the test result from Testing Laboratories.

Testing personnel of CAB must learn how to conduct these equipments, even if the CAB does not actually possess them.

Subcontracting with Testing Laboratories which can conduct test based on the technical requirement of Den-an law.

Technical Training conducted at the CAB site of Japan or Japanese local factory of your country.
## CAB Self-assessment of Testing Equipment

- **Paragraph 2 of METI Ordinance** -

### LIST of Testing Equipment to Purchase (in case of electric wires)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>1. IEC 60227 &amp; 60811</strong></td>
<td><strong>2. IEC 60245</strong></td>
</tr>
<tr>
<td>(1) Bending Test</td>
<td>(1) Solderability Test</td>
</tr>
<tr>
<td>(2) Snatch Test</td>
<td>(2) Three Pulley Flexing Test</td>
</tr>
<tr>
<td>(3) Cold Elongation Test</td>
<td>(3) Kink Test</td>
</tr>
<tr>
<td>(4) Impact Test</td>
<td>(4) Test for Resistance to heat of textile braids</td>
</tr>
<tr>
<td>(5) Static Flexibility Test</td>
<td>(5) Tensile Test</td>
</tr>
</tbody>
</table>

- **CAB is responsible for the evaluation of the test result from Testing Laboratories.**

- **CAB testing personnel must learn how to conduct the above equipments, even if the CAB does not possess them.**

- **Subcontracting with Testing Laboratories which can conduct test base on the technical requirement of IEC 60245**

- **Technical Training conducted at the CAB site of Japan or Japanese local factory of your country**
3. Conformity with ISO/IEC 17025

Subcontracting with Testing Laboratories

Subcontracting

CAB can conclude subcontracting agreements with Testing Laboratories.
CAB is responsible for the evaluation of the test result from Testing Laboratories.

Review of Subcontracting

Critical issue for CAB

The treatment of testing which CAB cannot conduct based on paragraph 1 and 2 of METI Ordinance
4. Procedure for the Designation of the CAB

Road Map to become CAB of Den-an law (14)

Procedure from Application to Designation for CAB of Den-an law

**STEP 1** Preparation of Application

**STEP 2** Application

**STEP 3** Audit and Assessment

**STEP 4** Designation of CAB

**STEP 5** Start of Operation

**STEP 6** Renewal of Designation

- Authority side
  - NITE Audit (if any)
    - (Article 29 of the law)
  - Every 3 years
    - (Article 31 of the law)

- CAB side
  - Conformance with ISO/IEC Guide 65
  - Submission of Rules of Operation
    - (Article 35 of the law)
    - Refer to Page 17
  - Change of Business Address
    - (Article 34 of the law)
  - Suspension or Abolition of Operation
    - (Article 36 of the law)
  - Refer to Page 16
**Application to become a CAB under Den-an Law**

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### Application form in Japanese

**Form 11 APPLICATION FOR REGISTRATION (or RENEWAL OF REGISTRATION)**  
(Related to Article 20 and Article 23)

1. APPLICATION FOR REGISTRATION (or RENEWAL OF REGISTRATION)
2. Date
3. To: Minister of Economy, Trade, and Industry
4. Address
5. Name, and name of representative (in case of legal person)
6. Address of business
7. Seal
8. We would like to obtain registration as a body stipulated in Article 9 (or renew the registration as stipulated in Article 32, Paragraph 1)
9. Classification of specified electrical appliances and materials which undergo conformity assessment
10. Name and address of place of business

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### Attached documents stipulated in Article 20 of Ordinance 84

1. Extract copy of registration  
   e.g. Certificate by Ministry of Commerce in your country
2. Document explaining that the applicant does not fall under the provisions of the items of Article 30 (Disqualification) of the Law
3. Document explaining that the applicant conforms to the provisions of the items of Article 31, Paragraph 1

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### Notes

1. The size of the paper shall be Japan Industrial Standard A4.
2. Signature is permitted instead of describing the name and seal stamp.

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Any person who has been under punishment for the following for the past 2 years shall not be allowed to be registered.

*) Under sentence to a fine or severer penalty for violating this LAW or disposition pursuant to this Law.

**) Whose Designation has been cancelled under this Law and any legal person having a staff who comes under these items mentioned above.
Contents of the Rules of Operation

1. Matters relating to the hours of work for conformity assessment and holidays
2. Matters relating to the locations of work for conformity assessment
3. Matters relating to the stationing of assessors
4. Matters relating to the calculation of fees relating to conformity assessments
5. Matters relating to the issuance of certificates relating to conformity assessments
6. Matters relating to the appointment and dismissal of assessors
7. Matters relating to the storage of applications for conformity assessments
8. Matters relating to the method of conformity assessment
9. Contract(*)
10. International commitment(**)
11. Necessary matters other than those given in the preceding items relating to the work of conformity assessment

After Designation

Submission of the CAB Rules of Operation - Article 35 of Den-an Law-

CAB should prepare and submit the Rules of Operation in Japanese after the designation, before the start of operation.

(*) The name of the international commitment, etc. when using the results of testing another business based on an international commitment, etc. defined by public announcement by the Minister of Economy, Trade and Industry.

(**) Name and address of another business, and details of conformity assessment in another business’s charge when the Conformity Assessment Bodies putting a part of a conformity assessment to the contract with that business.
1. The name or legal name and address of the person applying for the conformity assessment and, for a juridical person, the name of its representative

2. The date of receipt of the application for conformity assessment

3. The product relating to the application for conformity assessment and the Type Classification stipulated by the METI Ordinance noted in Article 3, Item 2 of the Law relating to the product

4. The name of the Specified Electrical Appliance and Material assessed for conformity and a description of its construction, material, and performance

5. The date the conformity assessment was performed

6. The name of the assessor performing the conformity assessment

7. A description of the conformity assessment and its results

Note 1. A Domestic Registered Conformity Assessment Body shall write down matters separated for each Specified Electrical Appliance and Material when writing down in books the matters given in each item of the preceding paragraph.

Note 2. The period for which the record books must be stored pursuant to the provisions of Article 42, Paragraph 2 of the Law shall be as given in the right section of Appendix 1 of the Cabinet Order for each Specified Electrical Appliance and Material given in the left section of the Appendix.