

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





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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

Refer to page 4



1.Requirement to CAB

2. Requirement to Manufacturers

3. Technical Requirement

ISO/IEC 17025 is not a condition of a CAB



1. Quality manual

(including detailed description)

2. Personnel

(Certification, Factory Audit)

1. Testing Personnel

2. Test Equipments

3. Subcontracting

2. Conformity with ISO/IEC Guide 65



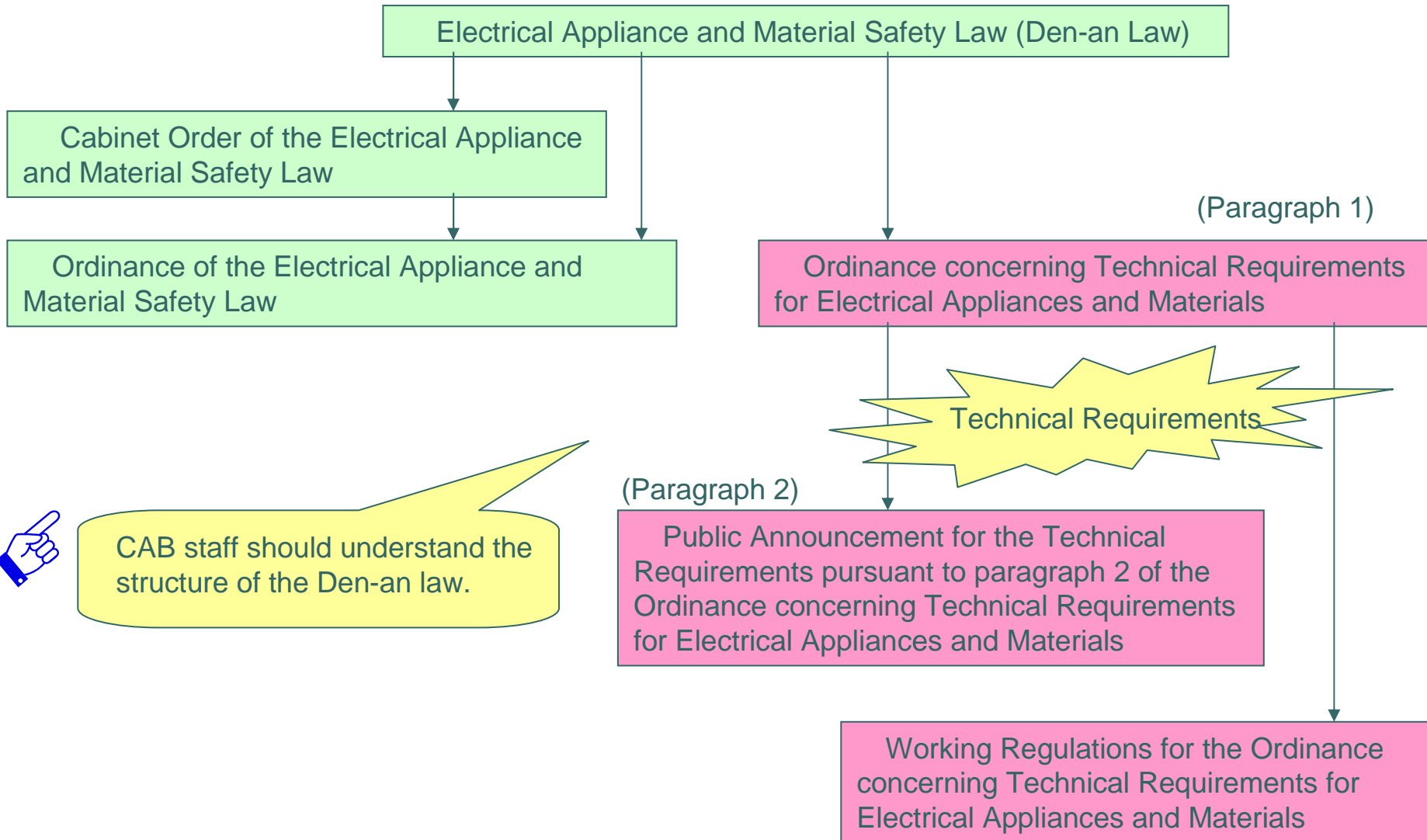
Refer to page 6



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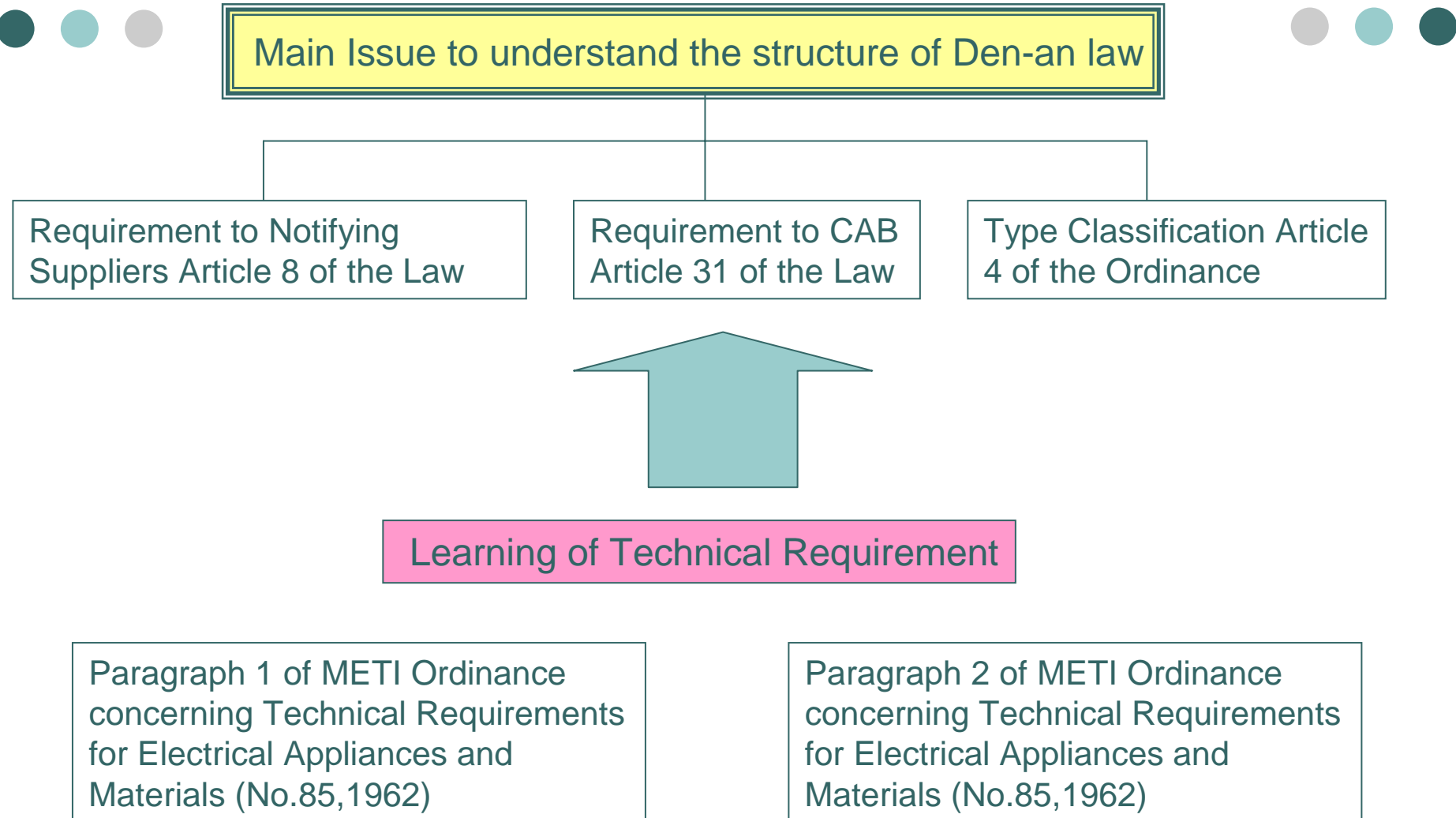
3.Conformity with ISO/IEC 17025

1.Understanding of the legal structure Den-an Law



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

1. Understanding of Den-an Law



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

Management Requirement

Technical Requirement

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.



METI is to assess whether the CAB fulfills the designation criteria stipulated in the Article 31 of the Den-an Law



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)

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

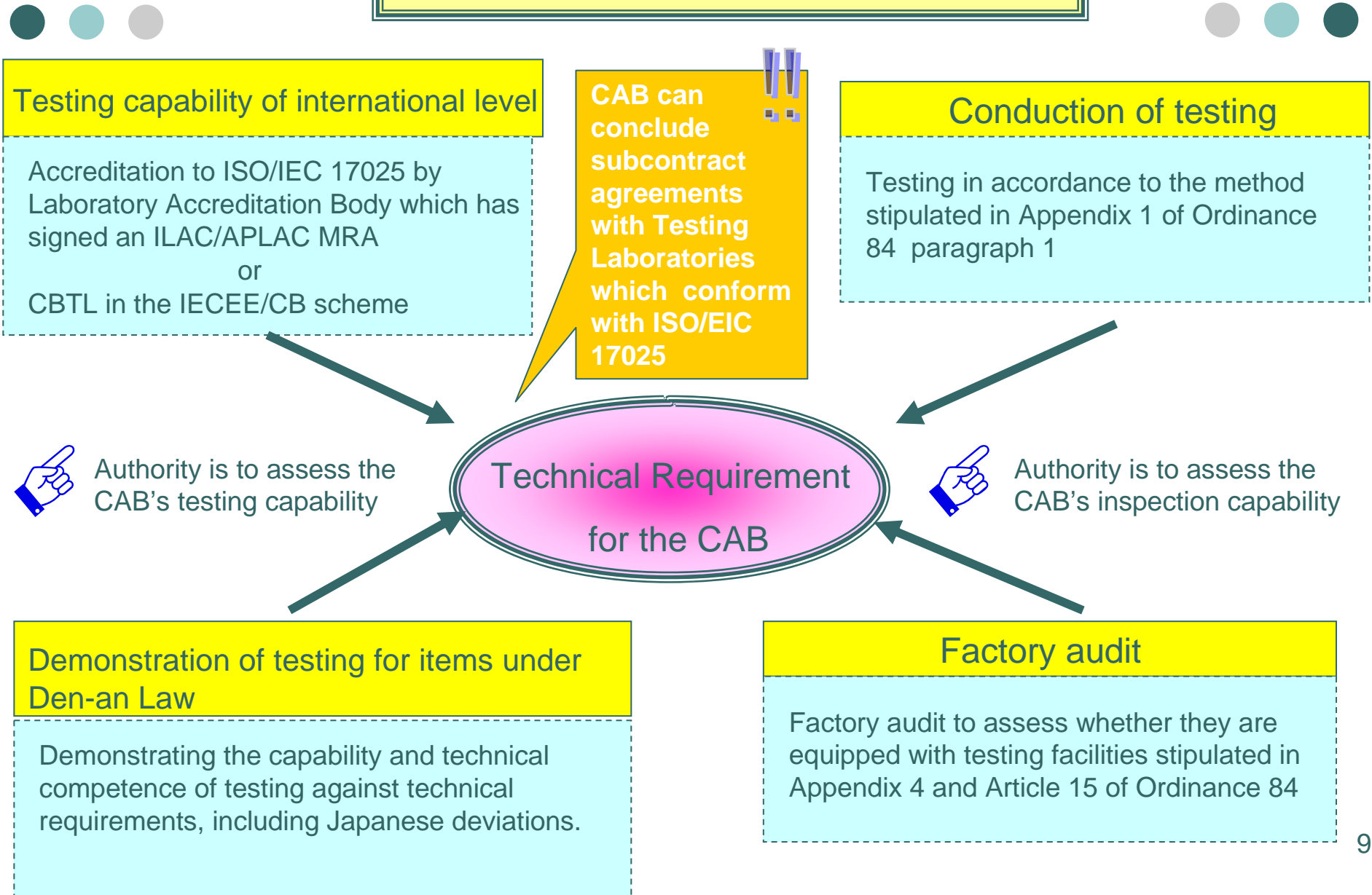
- Competency for Certification -

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



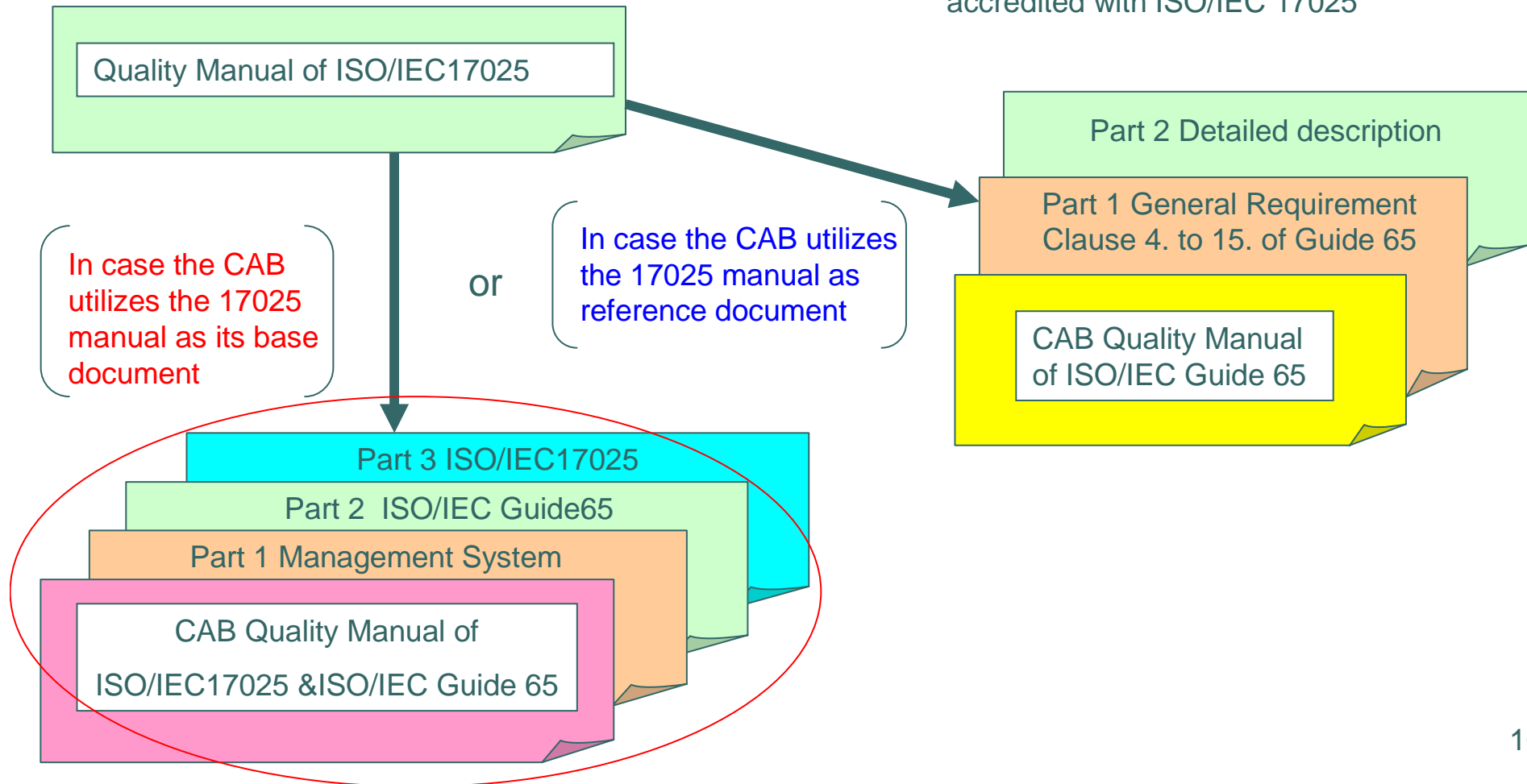
CAB should start to review the quality manual and the current status of certification body and personnel regarding the conformity with ISO/IEC Guide 65 as soon as possible.

Technical Requirements for the CAB



Review of the CAB Quality Manual

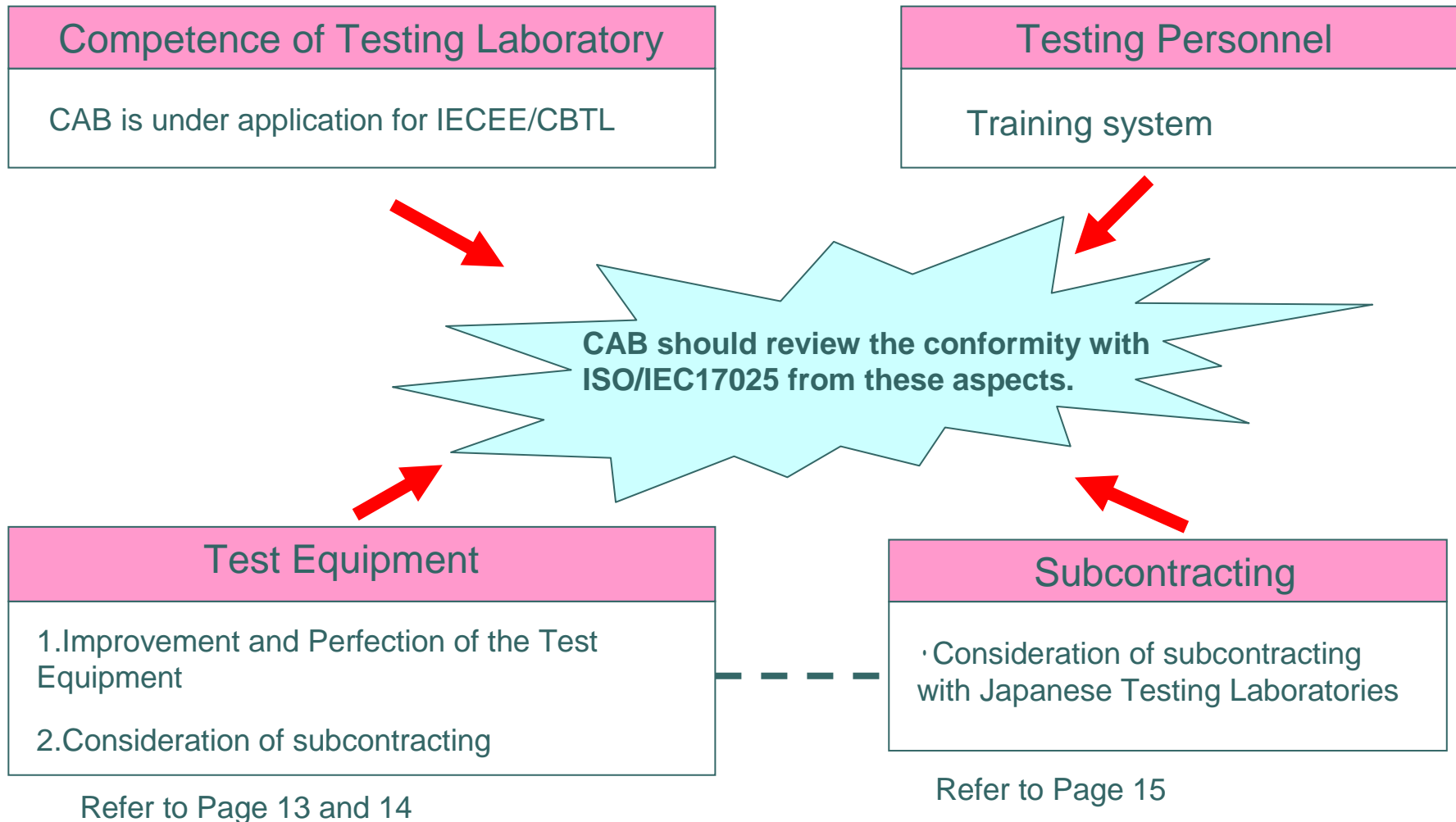
*) In case the CAB has already been accredited with ISO/IEC 17025



Comparison of Management Requirements between Guide 65 and 17025

ISO/IEC Guide 65	Common Items	
<p><u>4.1 General Provision</u></p> <p><u>4.6 Conditions and Procedure for Granting Certification</u></p> <p><u>6. Changes in the Certification Requirements</u></p> <p><u>8. Application</u></p> <p><u>9. Preparation for Evaluation</u></p> <p><u>10. Evaluation</u></p> <p><u>11. Evaluation Report</u></p> <p><u>12. Decision on Certification</u></p> <p><u>13. Surveillance</u></p> <p><u>14. Use of License, Certificates and Marks</u></p> <p><u>15. Complaints to Suppliers</u></p>	<p><u>4.2 Organization</u></p> <p><u>4.3 Operation</u></p> <p><u>4.4 Subcontracting</u></p> <p><u>4.5 Quality System</u></p> <p><u>4.7 Internal Audit and Management Review</u></p> <p><u>4.8 Documentation</u></p> <p><u>4.9 Records</u></p> <p><u>4.10 Confidentiality</u></p> <p><u>5. Personnel</u></p> <p><u>7. Appeals, Complaints and Disputes</u></p>	<p><u>4.4 Review of Requests, Tenders and Contracts</u></p> <p><u>4.6 Purchasing Services and Suppliers</u></p> <p><u>4.7 Service to Client</u></p> <p><u>4.9 Control of Nonconforming Testing and /or Calibration Work</u></p> <p><u>4.10 Corrective Action</u></p> <p><u>4.11 Preventive Action</u></p>
		<p>ISO/IEC 17025</p>

3.Conformity with ISO/IEC 17025



CAB Self-assessment of Testing Equipment

- Paragraph 1 of METI Ordinance -

Testing Equipment List to Purchase (in case of electrical wires)

- | | |
|-----------------------------|-------------------------------|
| (1) Bending Test | (7) Tear Resistance Test |
| (2) Snatch Test | (8) Impact Resistance Test |
| (3) Heat Deformation Test | (9) Vibration Resistance Test |
| (4) Bending Strength Test | (10) Tilted Impact Test |
| (5) Winding Strength Test | (11) Cold Resistance Test |
| (6) Torsional Strength Test | (12) Twisting Strength Test |

purchase

Alternative Measures

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

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.

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)

- | | |
|-----------------------------|---|
| 1. IEC 60227 & 60811 | 2. IEC 60245 |
| (1) Bending Test | (1) Solderability Test |
| (2) Snatch Test | (2) Three Pulley Flexing Test |
| (3) Cold Elongation Test | (3) Kink Test |
| (4) Impact Test | (4) Test for Resistance to heat of textile braids |
| (5) Static Flexibility Test | (5) Tensile Test |

purchase

Alternative Measure

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

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.

Technical Training conducted at the CAB site of Japan or Japanese local factory of your country

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

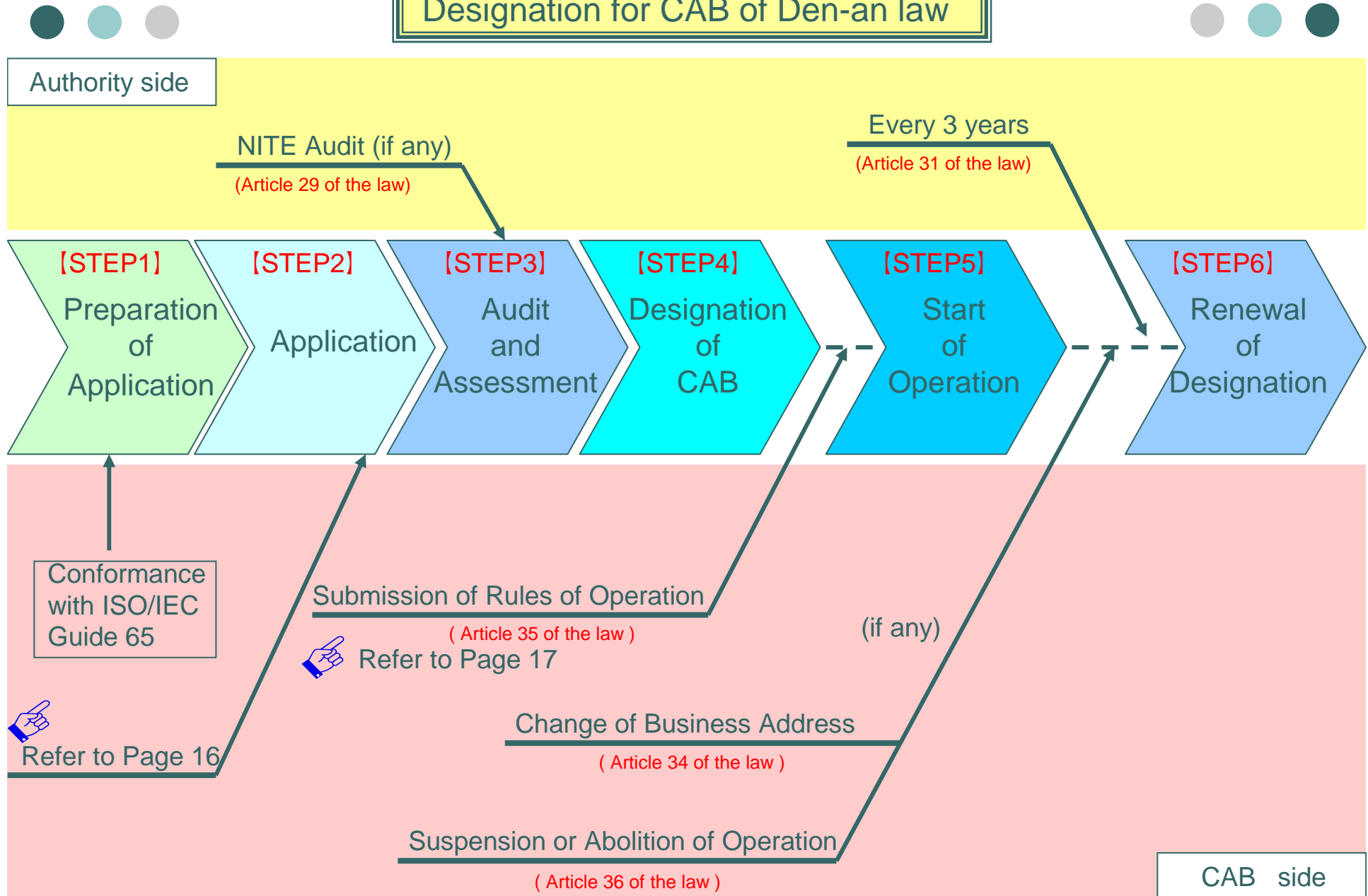
Critical issue for CAB

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



Application to become a CAB under Den-an Law

Application form in Japanese

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

様式第11 (第20条、第23条関係)

登録(登録の更新)申請書

年月日

経済産業大臣 殿

住所

氏名又は名称及び法人にあ

つてはその代表者の氏名 印

電気用品安全法第29条第1項(第32条第2項において準用する第29条第1項)の規定により同法第9条第1項(第32条第1項)の登録(登録の更新)を受けたいので、次のとおり申請します。

1 適合性検査を行う特定電気用品の区分

2 事業所の名称及び所在地

(備考) 1 この用紙の大きさは、日本工業規格A4とすること。

2 氏名を記載し、押印することに代えて、署名することができる。

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)

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) of the Electrical Appliance and Material Safety Law and therefore apply as follows pursuant to the provisions of Article 29 (or Article 29 to be applied mutatis mutandis according to Article 32, Paragraph 2) of the Law:

9) Classification of specified electrical appliances and materials which undergo conformity assessment

10) Name and address of place of business

(Notes)

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

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

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.

and

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3. Document explaining that the applicant conforms to the provisions of the items of Article 31, Paragraph 1

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

[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

(*)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

Obligation of the CAB - Article 27 of the Ordinance -



CAB should modify the present book of record for Den-an law

[Book of Record]

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.

Noe 2. The period for which the record books must be stored pursuant to the provisions of Article 42, Paragraph 2 of the Law 19 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.