

法規名稱：MUTUAL RECOGNITION ARRANGEMENT ON CONFORMITY ASSESSMENT FOR INDUSTRIAL PRODUCTS BETWEEN THE TAIPEI ECONOMIC AND CULTURAL OFFICE IN THE PHILIPPINES AND THE MANILA ECONOMIC AND CULTURAL OFFICE

簽訂日期：民國 106 年 12 月 07 日

生效日期：民國 106 年 12 月 07 日

This Mutual Recognition Arrangement (MRA) is entered into by and between:

The TAIPEI ECONOMIC AND CULTURAL OFFICE IN THE PHILIPPINES (TECO), hereinafter referred to as “TECO,”

- and -

The MANILA ECONOMIC AND CULTURAL OFFICE (MECO), hereinafter referred to as “MECO,”

WHEREAS, on 12 February 2009, the TECO and MECO signed a Memorandum of Understanding on cooperation in the field of Standardization and Conformity Assessment stating that any arrangements therein will be implemented by the Bureau of Standards, Metrology and Inspection (BSMI) of the Ministry of Economic Affairs of Taiwan and the Bureau of Philippine Standards (BPS) of the Department of Trade and Industry of the Philippines;

WHEREAS, relative to the MOU, a Letter of Intent (LOI) was likewise issued reflecting both Parties' desire to determine the feasibility of establishing an appropriate and effective cooperation framework for negotiating MRA;

WHEREAS, in line with the said MOU and LOI, greater international harmonization of standards and technical regulations is further encouraged;

NOW, THEREFORE, this Mutual Recognition Arrangement on Conformity Assessment for Industrial Products is hereby executed and entered into in recognition of the Parties' shared commitments to protect inter alia the environment and the life, health and safety of humans, animals and plants and shall be implemented by BSMI for TECO and BPS for MECO.

## ARTICLE I

### GENERAL PROVISIONS

Section 1. Objectives - The general objectives of this Arrangement are as follows:

- 1.1 To enhance cooperation through information exchange between the Parties to ensure safety and quality of products covered by this Arrangement;
- 1.2 To facilitate trade between the Parties through the mutual recognition of the results of conformity assessment activities issued by the designated Conformity Assessment Bodies required for access into their respective markets;
- 1.3 To affirm the Parties' commitments to the Agreement on Technical Barriers to Trade (TBT) of the World Trade Organization (WTO).

Section 2. Definitions - All general terms concerning standards and conformity assessment used in this Arrangement shall adopt the definitions provided in the ISO/IEC Guide 2:2004 "Standardization and Related Activities - General Vocabulary" and ISO/IEC 17000:2004 "Conformity Assessment - Vocabulary and General Principles" published by the International Organization for Standardization and International Electrotechnical Commission (ISO/IEC), unless the contrary requires otherwise.

In addition, for purposes of this Arrangement, the

following shall mean -

- 2.1 Accept - The use of the results of conformity assessment as a basis for regulatory actions such as approval, licences, registrations and post market assessments of conformity;
- 2.2 Conformity Assessment - Any activity which involves determining directly or indirectly that relevant Mandatory Requirements are fulfilled;
- 2.3 Conformity Assessment Body - A body that conducts conformity assessment activities including testing laboratories, and inspection bodies;
- 2.4 Designating Authority - A body as specified in this Arrangement established in the territory of a Party with the necessary authority to designate, monitor, suspend, lift suspension or withdraw designation of Conformity Assessment Bodies within its jurisdiction;
- 2.5 Designation - The authorization issued by a Designating Authority to a Conformity Assessment Body to undertake specified conformity assessment activities;
- 2.6 Inspection Body - A body that may be designated in accordance with this Arrangement to conduct inspection and sampling pursuant to the relevant Mandatory Requirements;
- 2.7 Mandatory Requirements - Legislative, regulatory and administrative requirements of the Party into which the product is being supplied that are subject of this Arrangement;
- 2.8 Regulatory Authority - An entity that exercises a legal right to control the import, use or supply of products within a Party ' s jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with that Party ' s Mandatory Requirements;
- 2.9 Stipulated Requirements - The criteria set out for the designation of Conformity Assessment Bodies;
- 2.10 Testing Laboratories - Independent laboratories or

government testing bodies that may be designated by one Party ' s Designating Authority in accordance with this Arrangement to undertake tests to the other Party ' s Mandatory Requirements.

Section 3. Scope of the MRA - The MRA shall cover the following  
:

- 3.1 Industrial products manufactured in the Parties ' territories that are specified, by agreement of the Regulatory Authorities, under Annex I on which either Party has prescribed Mandatory Requirements applicable to imports as set out in the applicable laws, regulations and administrative provisions listed in Annex II except for the following:
  - 3.1.1 Telecommunication equipment; and
  - 3.1.2 Medical devices.
- 3.2 Duly designated Testing Laboratories and Inspection Bodies.
- 3.3 Third party conformity assessment activities particularly testing by accredited testing laboratories and inspection and sampling by accredited inspection bodies.

## ARTICLE II

### OBLIGATIONS, DESIGNATIONS AND QUALIFICATIONS

Section 1. Obligations of the Parties - TECO and MECO are obliged as follows:

- 1.1 To exchange information concerning their Mandatory Requirements, conformity assessment procedures and regimes covered in this Arrangement;
- 1.2 To inform the other Party of any proposed changes to its Mandatory Requirements at least sixty (60) calendar days before the changes enter into force, except where considerations of health, safety and environmental protection warrant more urgent action;
- 1.3 To ensure that their Designating Authorities have the

necessary authority and competence to carry out their obligations within their respective jurisdictions as stated in this Arrangement;

- 1.4 To ensure that their designated and recognized Conformity Assessment Bodies are available for verification of their technical competence and compliance with the relevant Stipulated Requirements;
- 1.5 To accept results of conformity assessment activities stipulated herein that demonstrate compliance with their respective Mandatory Requirements when the conformity assessment activities are undertaken by Conformity Assessment Bodies designated by BPS and recognized by BSMI and vice versa in accordance with Articles II and III of this Arrangement. Upon receipt of the results, BPS or BSMI, shall complete the relevant product approval processes within ten (10) working days;
- 1.6 When requested, to make copies of their Mandatory Requirements, and intended changes thereto, available in English;
- 1.7 To give consideration to any request for consultations on issues relating to the interpretation and implementation of this Arrangement. Such consultations shall take place within sixty (60) calendar days after the date of the receipt of the request with the objective of finding mutually acceptable solutions. One or more consultation/s may be convened and conducted through a method as may be agreed upon.

Section 2. Designating Authorities - The BSMI and BPS, in their capacity as designating authorities shall consult, as necessary, with their counterparts to ensure the maintenance of confidence in conformity assessment processes and procedures. This consultation may include joint participation in audits related to conformity assessment activities or assessments of

designated Conformity Assessment Bodies, where such participation is appropriate, technically possible and within reasonable cost.

Section 3. Basis for Designating Conformity Assessment Bodies (CABs) – The Designating Authorities shall consider the following in designating a CAB:

- 3.1 Technical competence and relevant experience to undertake the conformity assessment activities for which they are designated based on:
  - 3.1.1 Technological knowledge of the relevant products, processes or services;
  - 3.1.2 Understanding of the technical standards and the general risk protection requirements for which designation is sought;
  - 3.1.3 Experience relevant to the applicable Mandatory Requirements;
  - 3.1.4 Physical capability to perform the relevant conformity assessment activities;
  - 3.1.5 Adequate management of the conformity assessment activities concerned; and
  - 3.1.6 Any other circumstance necessary to give assurance that the conformity assessment activities shall be adequately performed on a consistent basis;
- 3.2 With legal personality in the relevant jurisdiction;
- 3.3 Scope of conformity assessment activities; and
- 3.4 Not adversely influenced by a body that manufactures or trades in industrial products specified under Annex I, impartial and provision of services in a manner that does not compromise the objectivity of their conformity assessment activities and decisions.

Section 4. Basis for Designating Testing Laboratories – The following shall be the basis for designating a Testing Laboratory:

4.1 Accredited to ISO/IEC 17025 ( “ General requirements for the competence of testing and calibration laboratories ” )by an accreditation body that is a signatory to the Asia-Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement.

4.1.1 The scope of accreditation shall cover the Mandatory Requirements of Regulatory Authority of the other Party;

4.2 Compliant with the particular requirements set out in the applicable laws, regulations and administrative provisions, and with the stipulated criteria for designation as set out in Annex IV.

4.2.1 The manufacturers ’ own testing laboratories may be designated by one Party ’ s Designating Authority to undertake electromagnetic compatibility tests to the other Party ’ s Mandatory Requirements only.

Section 5. Basis for Designating Inspection Bodies - The following shall be the basis for designating an Inspection Body:

5.1 Accredited to ISO/IEC 17020 ( “ Conformity assessment - Requirement for the operation of various types of bodies performing inspection ” )by an accreditation body that is a signatory to the Asia-Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement;

5.1.1 The scope of accreditation shall cover the Mandatory Requirements of Regulatory Authority of the other Party; and

5.1.2 Compliant with the particular requirements set out in the applicable laws, regulations and administrative provisions, and with the stipulated criteria for designation as set out in Annex IV.

### ARTICLE III

#### RECOGNITION AND SUSPENSION OF CONFORMITY ASSESSMENT BODIES

Section 1. Required Details - When designating a Conformity Assessment Body, the Designating Authority shall provide the other Party with the following details in respect of each Conformity Assessment Body it designates:

- 1.1 registered name;
- 1.2 postal address;
- 1.3 facsimile (fax) number;
- 1.4 email address (if available);
- 1.5 name and telephone number of declared contact person;
- 1.6 scope of designation detailing range of products, reference standards, capability and other relevant details;
- 1.7 designating procedure used; and
- 1.8 date of designation.

Section 2. Recognition Procedure - The following procedure shall apply the recognition of a conformity assessment body:

- 2.1 Each Party shall make a proposal to the other Party that a CAB duly designated in accordance herewith be recognized under this Arrangement, by presenting to the latter such proposal in writing, supported by necessary documents.
- 2.2 The other Party shall determine whether the proposed CAB complies with the criteria for designation set out in its applicable laws, regulations and administrative provisions as specified in the Annexes after which shall indicate its position thereon within ninety (90) working days from the receipt of the proposal referred to above. In such consideration, such other Party should assume that the proposed conformity assessment body complies with the aforementioned criteria.
- 2.3 In the event that the other Party is unable to make a decision on the recognition of the proposed conformity assessment body within the prescribed period under Section 2.2 of this Article, the proposing Party may request the

other Party that a joint verification of the CAB under consideration be conducted. After the completion of such verification, both Parties shall make the decision regarding the recognition of the CAB under consideration, furnishing each other a copy of the written decision within fifteen (15) working days from the completion of the joint verification.

Section 3. Procedure for any Changes - The following procedure shall apply to any changes made, viz:

3.1 Each Party shall give the other Party an advance notice of any changes in the list of duly designated CABs, including suspensions, at least seven (7) working days prior to said change.

3.2 Each Party shall inform the other Party within fifteen (15) working days of any changes that affect a designated CAB's technical competence or compliance with the relevant Stipulated Requirements.

#### ARTICLE IV

#### RIGHTS AND REMEDIES OF PARTIES

Section 1. Rights of the Parties - The Parties shall have the following rights:

1.1 In exceptional circumstances, a Party retains the right to challenge a designated CAB's technical competence and compliance with the relevant Stipulated Requirements, provided that it is supported by relevant expert analysis and/or evidence. The Parties may further agree on additional guidelines for the exercise of this right.

1.2 A Party whose designated CAB is being challenged has the right to be notified of the challenge in writing and be provided with copies of supporting expert analysis and/or evidence.

1.3 Except in urgent circumstances, the Parties shall, prior to

a challenge, enter into consultations with a view to seeking a mutually satisfactory solution. Consultation shall be conducted expeditiously with a view to resolving all issues and seeking a mutually satisfactory solution within ninety (90) working days from commencement thereof.

In urgent circumstances, consultations shall take place immediately after the right to challenge has been exercised.

#### Section 2. Suspension, Withdrawal or Revocation of Designation

- The designation of the challenged designated CAB may be suspended, or revoked by the relevant Designating Authority for the relevant scope of designation from the time its technical competence or compliance was challenged, unless the Parties decide otherwise based on any of the following grounds:

- 2.1 The challenging Party is satisfied with the competence and compliance of the Conformity Assessment Body; or
- 2.2 The designation of the Conformity Assessment Body has been withdrawn prior to suspension or revocation.

Section 3. Effect of Suspension, Withdrawal or Revocation - The results of conformity assessment activities undertaken by a suspended, withdrawn or revoked CAB before the date of its suspension, withdrawal or revocation shall remain valid for acceptance for purposes of performing a Party's obligations under this MRA.

- 3.1 The Parties shall compare methods used to verify that the designated Conformity Assessment Bodies complied with the Stipulated Requirements.

ARTICLE V

CONFIDENTIALITY

Section 1. Non-Disclosure - A Party shall not be required to disclose confidential proprietary information to the other Party except where such disclosure would be necessary for the Party to demonstrate the competence of its designated CAB and the latter ' s conformity to the relevant Stipulated Requirements.

A Party shall, in accordance with its applicable laws, protect the confidentiality of any proprietary information disclosed to it in connection with conformity assessment activities and/or designation procedures.

## ARTICLE VI

### FINAL PROVISIONS

Section 1. Preservation of Regulatory Authority - Each Party retains all authority under its laws and implementing rules to interpret and enforce its Mandatory Requirements.

### Section 2. Binding Effect of the Arrangement

2.1 Arrangements concluded by either Party with a third party shall not impose any obligation on the other Party to accept the results of conformity assessment undertaken in the third party except when there is written agreement between the Parties to do so.

2.2 This Arrangement does not require mutual acceptance of the Mandatory Requirements of each Party, or mutual recognition of the equivalence of such Mandatory Requirements. The Parties shall, however, give consideration to increasing the degree of harmonization or equivalence of their respective Mandatory Requirements. Where both Parties agree that the standards or technical regulations are harmonized or established as equivalent, a Party shall be able to assess

compliance with its own Mandatory Requirements and this shall be deemed acceptable by the other Party.

2.3 The Mandatory Requirements to which this Arrangement applies shall be third party conformity assessment activities except product certification for the product referred to in Section 3.1 of Article I of this Arrangement. The applicable laws, regulations and administrative provisions are set out in Annex III.

Section 3. Amendments/Revisions to this Arrangement - Any amendments and/or revisions to this Arrangement shall be mutually agreed upon by the Parties in writing.

Section 4. Amendments/Revisions to Mandatory Requirements - Where a Party changes its Mandatory Requirements for products covered by this Arrangement, its obligations under Article II hereof as applicable, shall extend to accepting the results of conformity assessment activities in relation to the changed Mandatory Requirements if these fall within the scope of activities for which relevant Conformity Assessment Bodies have been designated in accordance with this Arrangement.

Section 5. Effectivity and Duration of the MRA - This Arrangement shall take effect upon signing, which shall be valid for a period of five (5) years and shall be automatically renewed for another five (5) years unless either Party proposes to re-negotiate not earlier than six (6) months before its termination.

Section 6. Termination of MRA - Either Party may terminate this Arrangement within the validity of the Arrangement by giving the other Party six months' advance notice

in writing.

Following termination of this Arrangement, a Party shall cease to accept the results of conformity assessment activities performed by designated Conformity Assessment Bodies.

Section 7. Contact Points - The contact points for the respective Regulatory Authorities shall be as follows:

7.1 For the Philippines: The Bureau of Philippine Standards of the Department of Trade and Industry;

7.2 For Taiwan: The Bureau of Standards, Metrology and Inspection of the Ministry of Economic Affairs.

Done in duplicate in the Chinese and English languages, both texts having equal validity. In case of divergence in interpretation of this Arrangement, the English text will prevail.

The Taipei Economic  
and Cultural Office in  
the Philippines

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Song-Huann Lin  
Representative

Date: 7 December 2017  
Place: Manila

The Manila Economic  
and Cultural Office

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Angelito Tan Banayo  
Representative

Date: 7 December 2017  
Place: Manila

Witnessed by:

Bureau of Standards,

Bureau of Philippine



Metrology and  
Inspection, Ministry of  
Economic Affairs

Standards, Department  
of Trade and Industry

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Dr. Ming-Jong Liou  
Director General

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Ernesto V. Perez  
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