Union du Maghreb Arabe (UMA)

UMA Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment

Date

INTRODUCTION

(A preamble with references to UMA and MRAs. A number of points are suggested below)

The implementation of a Mutual Recognition Arrangement for telecommunications equipment will promote rapid and economical access for new telecommunications equipment to UMA, while assuring continued compliance with national Technical Regulations. This would benefit UMA Member States' efforts to upgrade national and regional telecommunications infrastructure and services.

The World Trade Organization (WTO) Agreement on Technical Barriers to Trade provides that WTO Members "shall ensure, whenever possible, that results of conformity assessment procedures in other WTO Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures."

The WTO Arrangement on Technical Barriers to Trade also provides that "where a positive assurance of conformity with a technical regulation or standard is required, Members shall, wherever practicable, formulate and adopt international systems for conformity assessment and become members thereof or participate therein," and that "Members are encouraged to permit participation of conformity assessment bodies located in the territories of other Members in their conformity assessment procedures under conditions no less favorable than those accorded to bodies located within their territory or the territory of any other country."

One essential precondition for mutual recognition is an importing Party's confidence in the competence of Conformity Assessment Bodies of another Party to test or assess conformity to the importing Party's requirements, including confidence that physical standards of measurement are maintained to a high degree of accuracy and are traceable to international standards, that instruments in laboratories and test facilities are properly calibrated, and that inspectors and assessors are technically competent to carry out tests and to interpret results and are familiar with and able to put in place all necessary tests and procedures.

Confidence building can be facilitated in various ways, including through technical cooperation and assistance which can help to develop institutional structures on measurement, testing and other conformity assessment skills, and also by means of courses, seminars, personnel exchanges, intercomparisons, joint audits and the like. Such technical cooperation and assistance can help to develop a greater familiarity with other Parties' requirements and a greater commonality of approach.

Confidence building is promoted by the development within each member state of rigorous systems of accreditation for Conformity Assessment Bodies, using international standards such as ISO/IEC standards or recommendations issued by international bodies. Parties to this Arrangement may rely

on mutual recognition agreements between such accreditation systems to secure and simplify their participation in this Arrangement.

This Arrangement is not intended to displace private sector agreements among Conformity Assessment Bodies, or to displace regulatory regimes allowing for manufacturers' self-assessments and declarations of conformity. This Arrangement represents a statement of intention on the part of the member states of UMA in the sense that they commit themselves to make progress in their territories for the adoption of measures needed to start the implementation of the set of criteria and procedures as long as they are prepared to do so. This document is flexible enough so that the member states may apply the criteria established in the Arrangement in one or both Phases according to their needs and possibilities. Likewise, as provided for in the Arrangement, the member states are free to withdraw from it, or to limit their participation, without legal consequences.

The Parties to this Arrangement mutually decide as follows:

1. PURPOSE OF THE ARRANGEMENT

This Arrangement is intended to streamline the conformity assessment procedures for a wide range of telecommunications and telecommunications-related equipment and thereby to facilitate trade among the Parties. It provides for the mutual recognition by the importing Parties of Conformity Assessment Bodies and mutual acceptance of the results of testing and equipment certification undertaken by those bodies in assessing conformity of equipment to the importing Parties' own Technical Regulations.

In cases where homologation is required, Parties will grant homologation under transparent terms, conditions, and timeframes no less favorable than those accorded to like products of national origin or originating in any other country. Homologation shall not have the effect of creating unnecessary obstacles for international trade in telecommunications equipment.

2. GENERAL PROVISIONS

- 2.1 The requirements that the Parties will apply to designate and monitor testing laboratories and certification bodies as Conformity Assessment Bodies are found in Appendix A to this Arrangement, "Designation and Monitoring Requirements of Conformity Assessment Bodies."
- 2.2 The procedures that the Parties will use to mutually recognize Conformity Assessment Bodies and to mutually accept the results of Conformity Assessment Procedures produced by those Bodies are set forth in two additional appendices:

Appendix B – "Phase I Procedures for Mutual Recognition of Testing Laboratories As Conformity Assessment Bodies and Mutual Acceptance of Test Reports" (Phase I Procedures).

Appendix C – "Phase II Procedures for Mutual Recognition of Certification Bodies as Conformity Assessment Bodies and Mutual Acceptance of Equipment Certifications" (Phase II Procedures).

3. DEFINITIONS AND INTERPRETATIONS

3.1 General terms concerning test reports and Conformity Assessment Procedures used in this Arrangement have the meaning given to those terms in ISO/IEC 17000:2004 Conformity Assessment – Vocabulary and General Principles. In addition, the following definitions apply to this Arrangement:

Administrative Arrangements means any publicly available procedures or permission or legal or contractual agreements within a Party's jurisdiction which impact on the Conformity Assessment Procedures for the telecommunications equipment within the scope of this Arrangement, as described in paragraph 4 of this Arrangement.

Conformity Assessment Body means a body, which may include a third party or a supplier's testing laboratory, or a certification body, that performs conformity assessment to an importing Party's Technical Regulations.

Designation means the act by a Designating Authority of designating a Conformity Assessment Body to perform Conformity Assessment Procedures under this Arrangement.

Certification means a procedure by which a third party gives written assurance that a product, process, or service conforms to specify requirements.

Approval /Homologation means permission for a product, process or service to be marketed or used for stated purposes or under stated conditions.

Party means a UMA member state that chooses to join this Arrangement.

Public Telecommunications Network means public telecommunications infrastructure that permits telecommunications between defined network termination points.

Technical Regulations means those technical requirements, legislative and regulatory provisions, and Administrative Arrangements that a Party has specified under Annex I of the Phase I or Phase II Procedures pertaining to the registration, testing or certification of equipment with respect to which compliance is mandatory.

3.2 In the event of any inconsistency between a definition in ISO/IEC 17000:2004 and a definition in this Arrangement, the definition in this Arrangement will prevail.

4. SCOPE

4.1 <u>Scope of Technical Regulations</u> - This Arrangement applies to Technical Regulations listed separately by each Party under Annex I concerning conformity assessment of equipment. The Technical Regulations will concern equipment subject to network terminal attachment or other telecommunications regulation. Where network terminal attachment or other telecommunications regulation pertains, the Arrangement applies to the Technical Regulations

- listed in Annex I concerning conformity assessment, including electromagnetic compatibility (EMC) and electrical safety.
- 4.2 <u>Equipment Scope</u> The equipment scope covers network terminal attachment and other equipment subject to telecommunications regulation of each Party, including wire and wireless equipment, and terrestrial and satellite equipment, whether or not connected to a Public Telecommunications Network.
- 4.3 Nothing contained in this Arrangement precludes the Parties from entering into agreements under the International Telecommunication Union Memorandum of Understanding on Global Mobile Personal Communications by Satellite (GMPCS).
- 4.4 This Arrangement does not constitute an acceptance of the standards or technical regulations of a Party by the other Parties, or mutual recognition of the equivalence of such standards or technical regulations.
- 4.5 Agreements concluded by any Party with a Member State that is not a Party to this Arrangement (including non-UMA member states) will not impose any obligation upon any other Parties.

5. DESIGNATING AUTHORITIES

- Parties will ensure that their Designating Authorities have the authority and competence to designate, list, verify the compliance of, limit the Designation of, and withdraw the Designation of Conformity Assessment Bodies within their jurisdictions. Parties also will ensure that their Designating Authorities have the authority and competence to recognize Conformity Assessment Bodies outside their jurisdictions.
- 5.2 Designating Authorities will take such measures as necessary to ensure that their designated Conformity Assessment Bodies maintain the necessary technical competence to undertake the Conformity Assessment Procedures for which they have been designated.
- 5.3 The Designating Authority also may appoint an accreditation body to accredit Conformity Assessment Bodies while maintaining full responsibility as a Designating Authority under this Arrangement.
- 5.4 Each Party will list, under Annex II, its Designating Authorities and accreditation bodies.

6. DESIGNATION OF CONFORMITY ASSESSMENT BODIES AND APPOINTMENT OF ACCREDITATION BODIES

6.1 Each Designating Authority listed in Annex II may designate Conformity Assessment Bodies to perform conformity assessment of equipment subject to another Party's Technical Regulations.

- 6.2 In making such Designations, a Designating Authority will observe the procedures set out in Appendix A to this Arrangement.
- A Conformity Assessment Body will publish and maintain a list of equipment certifications, and upon a request by a Party, will identify all equipment certified by that Conformity Assessment Body to the Party's Technical Regulations. The Designating Authority that designated the Conformity Assessment Body will enforce the request, as necessary.

7. RECOGNITION OF CONFORMITY ASSESSMENT BODIES AND MUTUAL ACCEPTANCE OF THE RESULTS OF CONFORMITY ASSESSMENT PROCEDURES

Under the conditions and procedures specified in the Phase I or Phase II Procedures, a Party will recognize the Conformity Assessment Bodies designated by another Party's Designating Authority and accept the results of Conformity Assessment Procedures performed by those bodies.

8. VERIFICATION OF CONFORMITY ASSESSMENT BODIES

- 8.1 Parties concerned have the right to contest the technical competence of Conformity Assessment Bodies, as well as the Conformity Assessment Bodies' conformity with Appendix A. This right will be exercised under exceptional circumstances only.
- 8.2 The contesting Party will provide written notice of its contest to the exporting Party. The contest will include an objective and reasoned written description of the basis for the contest, including a description of the available evidence and opinions supporting the contest. The relevant Designating Authority, accreditation body, and the Conformity Assessment Body will be given prompt notice of the contest and not less than (a suggestion of sixty days) from receipt of the notice to present information refuting the contest or correcting the deficiencies which form the basis of the contest.
- 8.3 Where verification of the Conformity Assessment Body's technical competence or conformity with Appendix A is required to resolve the issue, it will be carried out in a timely manner jointly by the Parties concerned with the participation of the relevant Designating Authority and accreditation body.
- Parties will ensure that their Conformity Assessment Bodies are available for verification of their technical competence and their conformity with Appendix A.
- 8.5 The results of this verification will be discussed by the Parties, the relevant Designating Authority, accreditation body, and the Conformity Assessment Body concerned with a view to resolving the issue as soon as possible. Where, as a result of the verification, the Conformity Assessment Body is found to be not in conformity with Appendix A, *the* contesting Party will give the Conformity Assessment Body prompts notice. The Conformity Assessment Body

- will present, not less than sixty days from receipt of the notice information refuting the findings of the verification or correcting the deficiencies, which form the basis of the contest.
- 8.6 Where, as a result of the verification and subsequent response by the Conformity Assessment Body, the contesting Party intends to withdraw or limit to certain Technical Regulations its recognition of the Conformity Assessment Body, the contesting Party will provide (a suggestion of sixty days) advance notice of its intent, including a written explanation of its reasons, to the Conformity Assessment Body concerned, to the relevant Designating Authority, accreditation body, and the exporting Party.
- 8.7 Upon mutual consent of one or more contesting Parties and the relevant Designating Authority and accreditation body, matters relating to the conformity of the Conformity Assessment Body with Appendix A may be referred to a review process recognized by those Parties, or to a subcommittee of the Joint Committee, comprised of the Parties involved, for evaluation and assistance in resolution of technical issues.
- When a Party withdraws or limits to certain Technical Regulations recognition of a Conformity Assessment Body, that Party will continue to accept the results of Conformity Assessment Procedures performed by the Conformity Assessment Body prior to the withdrawal or limitation, unless that Party has good cause for not accepting such results.
- 8.9 If the Party determines not to accept such results, it will provide (*a suggestion of sixty days*) advance notice including a written explanation of the reason to the Conformity Assessment Body concerned, to the relevant Designating Authority, accreditation body, and the exporting Party.
- 8.10 The withdrawal or limitation will remain in effect until agreement has been reached by the Parties upon the future status of the Conformity Assessment Body.

9. COMMENCING THE ARRANGEMENT AND INITIATING PARTICIPATION IN PHASE I OR PHASE II PROCEDURES

- 9.1 This Arrangement does not, in and of itself, create legally binding obligations. Two Parties may enter into legally binding bilateral agreements between themselves incorporating this Arrangement.
- 9.2 Member states that are preparing to initiate participation in Phase I or Phase II Procedures will notify the UMA Secretariat at any time when they are prepared to do so. Such notification will generally be given(a suggestion of six months) prior to the date that the member state intends to initiate participation in Phase I or Phase II Procedures, or both, so that other Parties have the opportunity to begin learning about the member state's Technical Regulations, and vice versa. No later than (a suggestion of one month) after receiving a notification from a member state under this paragraph, the UMA Secretariat will identify the Member State to the other member states.

- 9.3 Once the UMA Secretariat has identified a Party under paragraph 9.2, the Party will supply to the other Parties the following information in writing:
 - a) The list of Technical Regulations for which it will recognize the test reports and equipment certifications from other Parties' Conformity Assessment Bodies in accordance with the respective Phase I and Phase II Procedures. The list will be provided in the format specified in Annex I to the procedures.
 - b) The list of Designating Authorities in the notifying Party's jurisdiction that will be responsible for designating Conformity Assessment Bodies in accordance with Appendix A. The list will be provided in the format specified in Annex II to the Phase I and Phase II Procedures. The list will include any accreditation bodies that the Designating Authority intends to appoint for accrediting Conformity Assessment Bodies as provided under paragraphs 5.3 of this Arrangement.
 - c) The contact persons to be responsible for the activities under this Arrangement.

The other Parties will supply the new Party with the same information.

- 9.4 The information relating to designation and recognition of Conformity Assessment Bodies will be provided in the format specified in Annex III and IV to the Phase I and Phase II Procedures and in accordance with Appendix B and C.
- 9.5 Parties will enjoy full and equal benefits and responsibilities under this Arrangement immediately upon initiating participation in accordance with this Arrangement.

10. INFORMATION EXCHANGE

- 10.1 Each Party will maintain a publicly available list of Technical Regulations under Annex I of the Phase I and Phase II Procedures and will make those Technical Regulations publicly available. Except where more urgent action is required, each Party will make publicly available any amendments to the Technical Regulations included in the Parties' list of Technical Regulations or any changes to its list of Technical Regulations within sixty days of publication of the amended or new regulation. In the event of any need for interpretation of such provision, the official language in which the provision was prepared will be used.
- 10.2 The Parties will consult as necessary to ensure the maintenance of confidence in Conformity Assessment Procedures and to ensure that all Technical Regulations are identified and are satisfactorily addressed.
- 10.3 Each Party will provide public notice of any new or amended technical regulations within the scope of the respective Phase I and Phase II Procedures. The Party will provide any interested person, including manufacturers of other Parties, an opportunity to comment, unless expressly prohibited under a Party's law, on the relevant part of the new or amended technical regulations in advance of their adoption. When the new or amended technical regulations come into effect, the Party will amend its list accordingly.

10.4 Each Party will promptly notify the other Parties of any changes to its list of Designating Authorities and accreditation bodies (Annex II), list of designated Conformity Assessment Bodies (Annex IV).

11. JOINT COMMITTEE

- The Parties hereby establish a Joint Committee, consisting of representatives of each Party. The Joint Committee will meet at the request of the UMA Secretariat, or more frequently as agreed by the Joint Committee, to assist in the effective implementation of the Arrangement. The Joint Committee will determine its own rules of procedure. All decisions of the Joint Committee will be made by consensus, unless the Parties mutually decide otherwise.
- 11.2 To assist in the effective implementation of this Arrangement, the Joint Committee may appoint one or more subcommittees in which the representatives of a Party may include persons from the business/private sector including suppliers, manufacturers and Conformity Assessment Bodies.

12. ADDITIONAL PROVISIONS

- 12.1 Each Party will endeavor to use international standards, or the relevant parts of international standards, as the basis for its Technical Regulations, where applicable international standards exist or when their completion is imminent, except when such international standards or relevant parts would be ineffective or inappropriate. Examples include, but are not limited to, fundamental climatic or geographic considerations or fundamental technical problems.
- An importing Party may specify the language in which test reports, equipment certifications, notices of designation and recognition, and other pertinent documents shall be submitted. An importing Party will issue Technical Regulations in the language of its choice.

13. CONFIDENTIALITY

- An importing Party will not require a Designating Authority, accreditation body or Conformity Assessment Body to disclose a supplier's proprietary information except where necessary to demonstrate conformity with an importing Party's Technical Regulations.
- 13.2 A Party, in accordance with its applicable laws, will protect the confidentiality of any proprietary information disclosed to it in connection with Conformity Assessment Procedures.

14. PRESERVATION OF REGULATORY AUTHORITY

14.1 Each Party retains all authority under its laws to interpret and implement its Technical Regulations governing equipment included within the scope of this Arrangement.

- 14.2 Nothing in this Arrangement will be construed to limit the authority of a Party to determine the level of protection it considers appropriate with regard to safety, the protection of consumers, and otherwise with regards to risks of concern to the Party.
- 14.3 Nothing in this Arrangement will be construed to limit the authority of a Party to take all appropriate measures whenever it ascertains that equipment may not meet the Party's Technical Regulations. Such measures may include carrying out surveillance activities, prohibiting connection of the equipment to the Public Telecommunications Network, withdrawing the equipment from the market, prohibiting their placement on the market, restricting their free movement, initiating an equipment recall, or otherwise preventing the recurrence of such problems, including through a prohibition on imports. If a Party takes such action, it will notify the affected Parties within (a suggestion of fifteen days) of taking such action, providing its reasons.

15. FEES

The Parties will ensure that any fees imposed by the Parties for determining compliance of Conformity Assessment Bodies with the Designation requirements under paragraph 6 of this Arrangement will be non-discriminatory, transparent, and reasonable.

16. AMENDMENT AND TERMINATION OF ARRANGEMENT

- 16.1 This Arrangement may be amended by the mutual, written consent of the Parties provided, however, that a Party may modify its respective lists of Technical Regulations (Annex I), Designating Authorities and accreditation bodies (Annex II), designated Conformity Assessment Bodies (Annex III), and recognized Conformity Assessment Bodies (Annex IV).
- 16.2 Any Party may terminate its participation in this Arrangement or only in the Phase I or Phase II Procedures, as applicable, by giving to all other Parties (*a suggestion of six months*) notice in writing.
- 16.3 Following termination by a Party of its participation in this Arrangement or only in the Phase I or Phase II Procedures, as applicable, a Party will continue to accept the results of Conformity Assessment Procedures performed by Conformity Assessment Bodies under this Arrangement prior to termination, unless the Party decides otherwise, and so advises other Parties in its termination notice.

17. FINAL PROVISIONS

- 17.1 This Arrangement includes:
 - Appendix A, "Designation and Monitoring Requirements for Conformity Assessment Bodies":

- Appendix B, "Phase I Procedures for Mutual Recognition of Testing Laboratories as Conformity Assessment Bodies and Mutual Acceptance of Test Reports";
- Appendix C, "Phase II Procedures for Mutual Recognition of Certification Bodies as Conformity Assessment Bodies and Mutual Acceptance of Equipment Certifications";
- Annex I, "List of Technical Regulations For [Name of Party]";
- Annex II, "List of Designating Authorities and Accreditation Bodies For [Name of Party]";
- Annex III, "List of Conformity Assessment Bodies (CAB) Designated by [Name of Party]"; and
- Annex IV, "List of Conformity Assessment Bodies (CAB) Recognized by [Name of Party]".
- 17.2 In the event of any inconsistency between a provision in this Arrangement and a provision in one of the Appendices, the Appendices will prevail, to the extent of the inconsistency.

APPENDIX A DESIGNATION AND MONITORING REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES

This Appendix specifies the Designation and monitoring requirements for two categories of Conformity Assessment Bodies -- testing laboratories and certification bodies.

A Conformity Assessment Body for electrical safety may require different Designation procedures depending on the Technical Regulations of the importing Party.

A. COMMON REQUIREMENTS

- 1. The Designating Authority may designate a testing laboratory or a certification body as a Conformity Assessment Body. The Designating Authority may appoint an accreditation body to accredit Conformity Assessment Bodies, while maintaining full responsibility as a Designating Authority under this Arrangement.
- 2. Designating Authorities will designate and accreditation bodies will accredit, only legally identifiable entities as Conformity Assessment Bodies.
- 3. Designating Authorities will only designate Conformity Assessment Bodies able to demonstrate by means of accreditation that the Conformity Assessment Bodies understand, have experience relevant to, and are competent to apply the Conformity Assessment Procedures pertaining to the Technical Regulations, as well as interpretations and policies of the other Party.
- 4. The technical competence of Conformity Assessment Bodies will be demonstrated by means of accreditation and including the following areas:
 - a) Technological knowledge of the relevant equipment, processes and services;
 - b) Understanding of the Technical Regulations and the general protection requirements for which Designation is sought;
 - c) The knowledge relevant to the applicable Technical Regulations;
 - d) The practical capability to perform the relevant Conformity Assessment Procedures;
 - e) An adequate management of the Conformity Assessment Procedures concerned; and
 - f) Any other evidence necessary to give assurance that the Conformity Assessment Procedures will be adequately performed on a consistent basis.
- 5. Parties are encouraged to harmonize Designation and Conformity Assessment Procedures through cooperation between Designating Authorities and Conformity Assessment Bodies by

means of coordination meetings, participation in mutual recognition arrangements, and working group meetings.

6. To ensure consistency of the Designation and Accreditation processes, the international guides for conformity assessment will be used in conjunction with the Technical Regulations of the importing Party to determine the technical competency of an accreditation body, testing laboratory, or certification body.

The following list of relevant ISO/IEC standards will be applied:

- a) ISO/IEC 17011: 2004 Conformity assessment General requirements for accreditation bodies accrediting conformity assessment bodies
- b) ISO/IEC 17025:2005/Cor 1:2006 General requirements for the competence of testing and calibration laboratories
- c) ISO/IEC 17065:2012 General requirements for bodies operating product certification systems

B. DESIGNATION OF TESTING LABORATORIES

The following requirements, conditions, and procedures will apply for the Designation of testing laboratories:

1. Requirements for a Designating Authority or Accreditation Body.

The exporting Party may use one or more Designating Authorities or one or more accreditation bodies to accredit and designate testing laboratories that are capable of performing conformity assessment to an importing Party's Technical Regulations.

- a) Any accreditation body appointed will meet the requirements and conditions of ISO/IEC 17011.
- 2. Requirements for Designating Testing Laboratories
- 2.1 A testing laboratory may be designated by a Designating Authority. The Designating Authority may appoint an accreditation body to accredit a testing laboratory. In either case,
 - a) The testing laboratory will be accredited against ISO/IEC 17025 in conjunction with the Technical Regulations specified for Phase I Procedures, and
 - b) The testing laboratory will have the technical expertise and capability for testing against the standards covered in the scope of the accreditation. A specialized test, if

necessary, may be performed in accordance with the provisions for subcontracting in ISO/IEC 17025. The laboratory also will be familiar with the applicable Technical Regulations for the equipment under test.

3. Additional Designation Requirements

The exporting Party will assign to each testing laboratory designated under paragraph 2, a unique six-character identifier, consisting of two letters identifying the party, which designated the testing laboratory, followed by four additional alpha-numeric characters.

C. DESIGNATION OF CERTIFICATION BODIES

The following requirements, conditions, and procedures will apply for the Designation of certification bodies:

1. Requirements for a Designating Authority or Accreditation Body

The exporting Party may use one or more Designating Authorities or one or more accreditation bodies to accredit and designate Certification Bodies that are capable of performing conformity assessment to an importing Party's Technical Regulations.

- a) The accreditation body appointed will meet the requirements and conditions of ISO/IEC 17011.
- b) The accreditation body will appoint a team of qualified experts to perform the assessment covering all of the elements within the scope of accreditation. For assessment of telecommunications equipment, the areas of expertise to be used during the assessment will include, but not be limited to: Electro-magnetic compatibility, telecommunications equipment (wire and wireless), and electrical safety.

2. Requirements for Designating Certification Bodies in the Area of Equipment Certification

The certification body may be designated by a Designating Authority. The Designating Authority may appoint an accreditation body to accredit a certification body. In either case:

- a) The certification body will be accredited against ISO/IEC 17065 in conjunction with the Technical Regulations specified for Phase II Procedures.
- b) The type testing normally will be based on testing no more than one unmodified representative sample of each equipment type for which certification is sought. Additional samples may be requested if clearly warranted for technical regulatory purposes, such as in cases where certain tests are likely to render a sample inoperative. According to generally accepted conformity assessment practices, all samples,

- components and parts will be returned to the supplier unless the supplier has requested otherwise in writing.
- c) The certification body will, by means of accreditation, demonstrate for each equipment type, expert knowledge of the Technical Regulations identified in Annex I of Phase II of the Arrangement, as well as interpretations and policies for each equipment type with respect to which the certification body seeks Designation.
- d) To ensure that the certification body has current technical competence, knowledge and expertise to evaluate the test data, and test reports, and to reach the appropriate conclusion in conformity assessment work with respect to applicable Technical Regulations, the certification body must have the technical expertise and capability to test the equipment it will certify. Alternatively, the certification body may enter into contractual agreements with designated testing laboratories such that the personnel of the certification body has access to personnel and facilities capable of performing the required testing and can oversee and supervise the testing so as to maintain current expertise and understanding of the applicable Technical Regulations.
- e) The certification body will demonstrate, through assessment, general competence, efficiency, experience, and familiarity with Technical Regulations and equipment included in those Technical Regulations as well as conformity with applicable parts of the ISO/IEC 17025 and 17065. The certification body also will demonstrate an ability to recognize situations where interpretations of the Technical Regulations or Conformity Assessment Procedures may be necessary. The appropriate key certification personnel will demonstrate knowledge of the responsible officials of the importing Party to contact to obtain current and correct Technical Regulation interpretations. The competence of the certification body will be demonstrated by assessment.
- f) A certification body also will participate in any reasonable consultative activities, identified by the regulatory authority of the importing Party, to establish a common understanding and interpretation of applicable regulations. After Designation, designated certification bodies will continue to participate in such consultative activities.

3. Sub-contracting

- a) In accordance with the provisions of sub-clause 6.2.2 of ISO/IEC 17065, a sub-contractor of a designated certification body, including a supplier's testing laboratory may perform the testing of equipment or a portion thereof. In accordance with the Technical Regulations of the importing Party, the testing laboratory will be accredited to ISO/IEC 17025 or the testing laboratory will be evaluated by the certification body to be competent in accordance with ISO/IEC 17025.
- b) When a subcontractor is used, the certification body remains responsible for the tests and will maintain appropriate oversight of the subcontractor to ensure reliability of the

test reports. A Party may require that such oversight will include periodic audits of equipment that have been tested.

4. Additional Designation Requirements

- a) The exporting Party will assign to each certification body designated under paragraph 2, a unique six-character identifier, consisting of two letters identifying the party that designated the certification body, followed by four additional alphanumeric characters.
- b) In the case of a concern and before making a determination to recognize a certification body under paragraph 2 of Phase II Procedures, a Party may request and receive within thirty days of said request a complete copy of the evaluation report prepared in the course of designating the certification body. The confidentiality provisions of paragraph 13 of the Arrangement apply to evaluation reports.

5. Post-certification Requirements

- a) The surveillance activities required under ISO/IEC 17065 will be based on type testing a few samples of the total number of equipment types, which the certification body has certified. Other types of surveillance activities of equipment that has been certified are permitted, provided they are no more onerous than type testing. The importing Party may request and receive copies of equipment certification reports.
- b) If during post market surveillance of certified equipment, a certification body determines that equipment fails to comply with the applicable Technical Regulations, the certification body will immediately notify the supplier and the appropriate importing Party. A follow-up report also will be provided within (*a suggestion of thirty days*) of the action taken by the supplier to correct the situation.

c) Where concerns arise, the certification body will make every effort to provide a copy of the equipment certification report within thirty days upon request by a Party to the certification body and the manufacturer. If the certification report is not provided within thirty days, a statement will be provided to the Party as to why such a report cannot be provided. This could be ground for revocation of the equipment certification or other steps, as specified in this Arrangement. The confidentiality provisions of paragraph 13 of the Arrangement apply to equipment certification reports.

APPENDIX B PHASE I PROCEDURES FOR MUTUAL RECOGNITION OF TESTING LABORATORIES AS CONFORMITY ASSESSMENT BODIES AND MUTUAL ACCEPTANCE OF TEST REPORTS

1. Scope

The procedures in this Appendix address the mutual recognition of testing laboratories as Conformity Assessment Bodies and mutual acceptance of test reports relating to the conformity of equipment with the Parties' respective Technical Regulations identified in Annex I. The term "Conformity Assessment Bodies" as used in the Phase I Procedures refers to testing laboratories.

2. Designation and Recognition of Conformity Assessment Bodies

2.1 Each Party may designate and recognize Conformity Assessment Bodies using the procedures in paragraph 2.2 or paragraph 2.3, or both.

2.2 Designating Authority Procedures

- 2.2.1 The Designating Authority of an exporting Party will designate Conformity Assessment Bodies as being competent to perform testing of equipment subject to the Technical Regulations specified in Annex I by an importing Party. In accordance with paragraph 5.3 of this Arrangement, the Designating Authority may appoint an accreditation body to accredit Conformity Assessment Bodies. The requirements for designation and accreditation of Conformity Assessment Bodies are contained in Appendix A to this Arrangement.
- 2.2.2 The notification of the Designation of a Conformity Assessment Body to an importing Party will include: the testing laboratory's name, the unique six-character identifier, physical address, mailing address, contact person, contact person's telephone and telefax numbers and e-mail address, and the scope of the accreditation. Thereafter, the Designating Authority will update each Designation as necessary, for example, to revise the scope of a Conformity Assessment Body's accreditation.
- 2.2.3 The importing Party, upon receipt of a Designation from the exporting Party, will evaluate and make a determination on recognizing the Conformity Assessment Body under terms and conditions no less favorable than those accorded to the bodies of the importing Party that apply for recognition as a Conformity Assessment Body. Designations performed in accordance with Appendix A normally will be recognized.
- 2.2.4 The importing Party must notify the other Parties its acceptance of a designated Conformity Assessment Body within (a suggestion of sixty days) from receipt of the Designation. If the importing Party does not recognize a designated Conformity Assessment Body, in whole or in part, the importing Party will provide, within (a suggestion of sixty days)

- receipt of the Designation, a written explanation to the Designating Authority and the designated Conformity Assessment Body, including the basis for that decision.
- 2.2.5 The Designating Authority and the designated Conformity Assessment Body will be provided a period of not less than (a suggestion of sixty days) from receipt of the importing Party's explanation to present additional factual information in order to resolve the concerns or to correct the deficiencies which form the basis of the importing Party's decision.
- 2.2.6 The importing Party will have up to (a suggestion of thirty days) to evaluate and act upon the additional information under terms and conditions no less favorable than those accorded to the bodies of the importing Party that apply for recognition as a Conformity Assessment Body.
- 2.2.7 Upon mutual consent of the two or more Parties directly involved, matters relating to the designation of the Conformity Assessment Body in accordance with Appendix A may be referred to a review process recognized by the Parties concerned, or to a subcommittee of the Joint Committee, comprised of the Parties involved, for evaluation and assistance in resolution of technical issues.
- 2.3 Information Relating to Designation and Recognition of Conformity Assessment Bodies
- 2.3.1 Under paragraph 2.2, the exporting Party will specify in its Annex III to these procedures all Conformity Assessment Bodies that it has designated.
- 2.3.2 The importing Party will specify in its Annex IV to these procedures all Conformity Assessment Bodies that it has recognized.

3. Participation in Phase I Procedures

A Party may participate in these Phase I Procedures exclusively for the purpose of enabling other exporting Parties to designate Conformity Assessment Bodies as being competent to perform testing of equipment subject to the Technical Regulations specified in Annex I to these procedures by the importing Party. Such a Party will provide the information specified in Annex I, List of Technical Regulations, and Annex IV, List of Conformity Assessment Bodies Recognized, as provided in paragraphs 9 and 10 of this Arrangement.

4. Transition Periods

4.1 After a Party has notified other Parties of its intention to initiate participation in these Phase I Procedures as specified in paragraph 9 of the Arrangement, the notifying Party may indicate its desire to enter into a transition period with one or more of the other Parties or any of the other Parties may indicate their desire to enter into a transition period with the notifying Party, within (a suggestion of ninety days) of the exchange of information pursuant to paragraph 9 of the Arrangement. Otherwise, these procedures will apply at

the end of the (a suggestion of ninety-day) period, or other time as mutually decided by the Parties

- 4.2 The Parties may agree to conduct familiarization activities, e.g., permitting the importing Party the opportunity to participate in evaluations of Conformity Assessment Bodies and to review the Conformity Assessment Body evaluation reports, during the transition period for the benefit of the Designating Authorities and Conformity Assessment Bodies. The transition period normally will last no more than (a suggestion of twelve months) from the date of mutual agreement regarding the commencement of such activities.
- 4.3 Upon the satisfactory completion of any agreed transition period, the Parties involved will recognize the Conformity Assessment Bodies designated by each exporting Party whose technical competence has been determined through accreditation to the technical requirements of the importing Party. The importing Party will accept the test reports prepared by Conformity Assessment Bodies recognized in accordance with procedures specified in paragraph 5.

5. Mutual Acceptance of Test Reports

- After the importing Party has recognized another Party's designated Conformity Assessment Body, the appropriate entities of the importing Party will accept test reports produced by the recognized Conformity Assessment Body of the other Party on terms no less favorable than those accorded to test reports produced by Conformity Assessment Bodies of the importing Party.
- 5.2 The importing Party will take steps to ensure that:
 - a) Upon receipt of a test report, the report is promptly examined for completeness of data and documentation;
 - b) The applicant is informed in writing in a timely, precise and complete manner of any deficiency;
 - c) Any request for additional information is limited to omissions, inconsistencies, and/or variances from the Parties' Technical Regulations; and
 - d) Re-testing or duplicate testing is avoided, e.g., upon a change in commercial distribution agreements, logo, packaging, or minor equipment changes that do not affect compliance with Technical Regulations.
- 5.3 Parties will grant equipment certification, based on test reports produced by recognized Conformity Assessment Bodies, under transparent terms and conditions no less favorable than those accorded to the bodies of the importing Party's recognized Conformity Assessment Bodies.

6. Processing of Applications

Applications for equipment certification accompanied by test reports completed by recognized Conformity Assessment Bodies of the other Parties normally will be processed, and a decision communicated to applicants, within the same time-frames as those applicable to local applicants.

7. Suspension of Mutual Recognition and Acceptance Obligations

- 7.1 A Party may suspend its mutual recognition and acceptance obligations under this Phase I Procedures with respect to a second Party, upon (*a suggestion of sixty days*) written notice, providing the reasons for suspension. Examples of such reasons include the following conditions:
 - a) The suspending Party loses confidence in the Designating Authorities or Conformity Assessment Bodies of the second Party;
 - b) The suspending Party no longer perceives mutual benefits in terms of the facilitation of trade in the equipment within the scope of this Arrangement or
 - c) The suspending Party is dissatisfied with the protection by the other Party of confidential information.
- 7.2 If the two Parties so decide, they may resume their mutual recognition and acceptance obligations at any time.

APPENDIX C

PHASE II PROCEDURES FOR MUTUAL RECOGNITION OF CERTIFICATION BODIES AS CONFORMITY ASSESSMENT BODIES AND MUTUAL ACCEPTANCE OF EQUIPMENT CERTIFICATIONS

1. Scope

The procedures in this Appendix address the mutual recognition of certification bodies as Conformity Assessment Bodies and mutual acceptance of equipment certifications relating to the conformity of equipment with the Parties' respective Technical Regulations identified in Annex I. The term "Conformity Assessment Bodies" as used in the Phase II Procedures refers to certification bodies.

2. Designation and Recognition of Conformity Assessment Bodies

- 2.1 The Parties may designate and recognize Conformity Assessment Bodies using the procedures in paragraph 2.2 or paragraph 2.3, or both.
- 2.2 <u>Designating Authority Procedures</u>
- 2.2.1 The Designating Authority of an exporting Party will designate Conformity Assessment Bodies as being competent to perform certification of equipment subject to the Technical Regulations specified in Annex I by an importing Party. In accordance with paragraph 5.3 of this Arrangement, the Designating Authority may appoint an accreditation body to accredit Conformity Assessment Bodies. The requirements for designation and accreditation of Conformity Assessment Bodies are contained in Appendix A to this Arrangement.
- 2.2.2 The notification of the Designation of a Conformity Assessment Body to an importing Party will include: the certification body's name, the unique six-character identifier, physical address, mailing address, contact person, contact person's telephone and telefax numbers and e-mail address, and the scope of the accreditation. Thereafter, the Designating Authority will update each Designation as necessary, for example, to revise the scope of a Conformity Assessment Body's accreditation.
- 2.2.3 The importing Party, upon receipt of a Designation from the exporting Party, will evaluate and make a determination on recognizing the Conformity Assessment Body under terms and conditions no less favorable than those accorded to the bodies of the importing Party that apply for recognition as a Conformity Assessment Body. Designations performed in accordance with Appendix A normally will be recognized.
- 2.2.4 The importing Party must notify the other Parties its acceptance of a designated Conformity Assessment Body within (*a suggestion of sixty days*) from receipt of the Designation. If the importing Party does not recognize a designated Conformity Assessment Body, in

whole or in part, the importing Party will provide, within (a suggestion of sixty days) of receipt of the Designation, a written explanation to the Designating Authority and the designated Conformity Assessment Body, including the basis for that decision.

- 2.2.5 The Designating Authority and the designated Conformity Assessment Body will be provided a period of not less than (*a suggestion of sixty days*) from receipt of the importing Party's explanation to present additional factual information in order to resolve the concerns or to correct the deficiencies which form the basis of the importing Party's decision.
- 2.2.6 The importing Party will have up to (a suggestion of thirty days) from receipt to evaluate and act upon the additional information under terms and conditions no less favorable than those accorded to the bodies of the importing Party that apply for recognition as a Conformity Assessment Body.
- 2.2.7 Upon mutual agreement of the two or more Parties directly involved, matters relating to the designation of the Conformity Assessment Body in accordance with Appendix A may be referred to a review process recognized by the Parties concerned, or to a subcommittee of the Joint Committee, comprised of the Parties involved, for evaluation and assistance in resolution of technical issues.
- 2.3 Information Relating to Designation and Recognition of Conformity Assessment Bodies
- 2.3.1 Under paragraph 2.2, the exporting Party will specify in its Annex III to these procedures all Conformity Assessment Bodies that it has designated.
- 2.3.2 The importing Party will specify in its Annex IV to these procedures all Conformity Assessment Bodies that it has recognized.

3. Participation in Phase II Procedures

A Party may participate in these Phase II Procedures exclusively for the purpose of enabling other exporting Parties to designate Conformity Assessment Bodies as being competent to perform certification of equipment subject to the Technical Regulations specified in Annex I to these procedures by the importing Party. Such a Party will provide the information specified in Annex I, List of Technical Regulations, and Annex IV, List of Conformity Assessment Bodies Recognized, as provided in paragraphs 9 and 10 of this Arrangement.

4. Transition Periods

4.1 The satisfactory completion of the steps set forth in the Phase I Procedures is not necessarily a prerequisite to initiating the steps set forth in Phase II Procedures.

- 4.2 After a Party has notified other Parties of its intention to initiate participation in these Phase II Procedures as specified in paragraph 9 of the Arrangement, the notifying Party may indicate its desire to enter into a transition period with one or more of the other Parties or any of the other Parties may indicate their desire to enter into a transition period with the notifying Party, within (a suggestion of ninety days) of the exchange of information pursuant to paragraph 9 of the Arrangement. Otherwise, these procedures will apply at the end of the ninety-day period, or other time as mutually decided by the Parties.
- 4.3 The Parties may agree to conduct familiarization activities, e.g., permitting the importing Party the opportunity to participate in evaluations of Conformity Assessment Bodies and to review the Conformity Assessment Body evaluation reports, during the transition period for the benefit of the Designating Authorities and Conformity Assessment Bodies. The transition period normally will last no more than (a suggestion of twelve months) from the date of mutual agreement regarding the commencement of such activities.
- 4.4 Upon the satisfactory completion of any agreed transition period, the Parties involved will recognize the Conformity Assessment Bodies designated by each exporting Party whose technical competence has been determined through accreditation to the technical requirements of the importing Party. The importing Party will accept certificates prepared by Conformity Assessment Bodies recognized in accordance with procedures specified in paragraph 5.

5. Mutual Acceptance of Equipment Certifications

- After the importing Party has recognized another Party's designated Conformity Assessment Body, the appropriate entities of the importing Party will accept equipment certifications produced by the recognized Conformity Assessment Body of the other Party on terms no less favorable than those accorded to equipment certifications produced by Conformity Assessment Bodies of the importing Party.
- Parties will grant equipment certification by a recognized Conformity Assessment Body under transparent terms and conditions no less favorable than those accorded to the importing Party's recognized Conformity Assessment Bodies.

6. Suspension of Mutual Recognition and Acceptance Obligations

- A Party may suspend its mutual recognition and acceptance obligations under these Phase II Procedures with respect to a second Party, upon sixty days written notice, providing the reasons for suspension. Examples of such reasons may include the following conditions:
 - a) The suspending Party loses confidence in the Designating Authorities or Conformity Assessment Bodies of the second Party;
 - b) The suspending Party no longer perceives mutual benefits in terms of the facilitation of trade in the equipment within the scope of this Arrangement or

- c) The suspending Party is dissatisfied with the protection by the other Party of confidential information.
- 6.2 If the two Parties so decide, they may resume their mutual recognition and acceptance obligations at any time.

ANNEX I TO PHASE I AND II PROCEDURES

LIST OF TECHNICAL REGULATIONS FOR [NAME OF PARTY]

PHASE I

The Technica	l Regulations	for whic	n [Name	of Party]	will	accept	test	reports	from	recogn	ized
Conformity A	ssessment Bo	dies desig	nated by	other Part	ties ar	re:					

1.			
2.			
3.			

PHASE II

The Technical Regulations for which [Name of Party] will accept equipment certifications from recognized Conformity Assessment Bodies designated by other Parties are:

recognized Conformity Assessment Bodies designated by other Parties are:
1.
2.
3.

ANNEX II TO PHASE I AND PHASE II PROCEDURES

LIST OF DESIGNATING AUTHORITIES AND ACCREDITATION BODIES FOR [NAME OF PARTY]

PHASE I

Designating Authorities

1. Name of Designating Authority:
ę ę ,
Physical address:
Mailing address
Home page address:
Name/title of contact person:
Phone:
Fax:
E-mail address:

2.

Accreditation Bodies

1. Name of Accreditation Body:

Physical address:

Mailing address:

Home page address:

Name/title of contact person:

Phone:

Fax:

E-mail address:

PHASE II

Designating Authorities

1. Name of Designating Authority:

Physical address:

Mailing address:

Home page address:

Name/title of contact person:

Phone:

Fax:

E-mail address:

2.

Accreditation Bodies

1. Name of Accreditation Body:

Physical address:

Mailing address:

Home page address:

Name/title of contact person:

Phone:

Fax:

E-mail address:

ANNEX III TO PHASE I AND II PROCEDURES

LIST OF CONFORMITY ASSESSMENT BODIES (CAB) DESIGNATED BY [NAME OF PARTY]

PHASE I

1. Name of CAB:

Six-character identifier:
Physical address:
Mailing address:
Name/title of contact person:
Phone:
Fax:
E-mail address:
Parties/technical regulations for which this CAB has been designated:
2.

PHASE II

1. Name of CAB:

Six-character identifier:

Physical address:

Mailing address:

Name/title of contact person:

Phone:

Fax:

E-mail address:

Technical regulations for which this CAB has been designated:

ANNEX IV TO PHASE I AND II PROCEDURES

LIST OF CONFORMITY ASSESSMENT BODIES (CAB) RECOGNIZED BY [NAME OF PARTY]

PHASE I

Conformity Assessment Bodies

Six-character identifier:	
Physical address:	
Mailing address:	
Name/title of contact person:	
Phone:	
r	

Fax:

E-mail address:

1. Name of CAB:

Technical regulations for which this CAB has been designated:

2.

PHASE II

Conformity Assessment Bodies

1. Name of CAB:

Six-character identifier:

Physical address:

Mailing address:

Name/title of contact person:

Phone:

Fax:

E-mail address:

Parties/technical regulations for which this CAB has been designated: