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 only designate, and accreditation bodies will only accredit, 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 will encourage harmonization of 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. Where accreditation bodies participate in the Designation process they will be encouraged to participate in mutual recognition arrangements among accreditation bodies.

6. To ensure consistency of the Designation process, 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 guides will be applied:
a) ISO/IEC Guide 58:1993 - Calibration and Testing Laboratory Accreditation Systems - general requirements for operation and recognition;
b) ISO/IEC Guide 25:1990 - General requirements for the competence of calibration and testing laboratories;
c) ISO/IEC Guide 61:1996 - General requirements for assessment and accreditation of certification/registration bodies ; and
d) ISO/IEC Guide 65:1996 - General requirements for bodies operating equipment 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, or both Designating Authorities and accreditation bodies, to accredit and designate testing laboratories that are capable of performing

conformity assessment to an importing Party's Technical Regulations.
a) A Designating Authority selected by an exporting Party will be capable of using the requirements and conditions of ISO/IEC Guide 58 to the maximum extent necessary to accredit testing laboratories.
b) Any accreditation body appointed will meet the requirements and conditions of ISO/IEC Guide 58.

2. Requirements for Designating Testing Laboratories

2.1 A testing laboratory may be accredited and 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 Guide 25 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 and be capable of determining compliance. A specialized test, if necessary, may be performed in accordance with the provisions for subcontracting in ISO/IEC Guide 25. The laboratory also will be familiar with the applicable Technical Regulations for the equipment under test.

2.2 When accreditation is not available under paragraph 2.1, or when special circumstances apply, the Designating Authority may require the Conformity Assessment Bodies to demonstrate their competence through other means such as:
a) Participation in regional/international mutual recognition arrangements or certification systems;
b) Regular peer evaluations;
c) Proficiency testing and
d) Comparisons between test facilities.

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

a) The Designating Authority selected by an exporting Party will be capable of using the requirements and conditions of ISO/IEC Guide 61 to the maximum extent necessary to accredit certification bodies.

b) The accreditation body appointed will meet the requirements and conditions of ISO/IEC Guide
61.

c) 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 accredited and 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 Guide 65 in conjunction with the Technical Regulations specified for Phase II Procedures and based on type testing as identified in sub-clause 1.2(a).

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 will have the technical expertise and capability to test the equipment it will certify. Alternatively, the certification body may enter into contractual arrangements 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 Guides 25 and 65. 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 a 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 4.4 of ISO/IEC Guide 65, the testing of equipment, or a portion thereof, may be performed by a sub-contractor of a designated certification body, including a supplier's testing laboratory. In accordance with the Technical Regulations of the importing Party, the testing laboratory will be accredited to ISO/IEC Guide 25, or the testing laboratory will

be evaluated by the certification body to be competent in accordance with ISO/IEC Guide 25.
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 which designated the certification body, followed by four additional alpha-numeric 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 Guide 65 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 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.