MUTUAL RECOGNITION AGREEMENT

ON CONFORMITY ASSESSMENT

BETWEEN

THE GOVERNMENT OF AUSTRALIA

AND

THE GOVERNMENT OF THE REPUBLIC OF SINGAPORE

THE GOVERNMENT OF AUSTRALIA AND THE GOVERNMENT OF THE REPUBLIC OF SINGAPORE (hereinafter referred to as the Parties)

CONSIDERING the traditional links of friendship that exist between them,

CONSIDERING their shared commitments to protect, *inter alia*, human health and safety, animal and plant life and health and the environment,

CONSIDERING their shared commitment to trade facilitation,

DESIRING to conclude an agreement providing for the mutual recognition of the results of conformity assessment activities required for access into their respective markets,

DESIRING to encourage greater international harmonisation of standards and regulations,

DESIRING to encourage and complement the momentum of cooperation undertaken in the Asia Pacific Economic Cooperation fora of which Australia and Singapore are members,

BEARING IN MIND their status as Contracting Parties to the Marrakesh Agreement Establishing the World Trade Organization, and conscious of their rights and obligations under the Agreement on Technical Barriers to Trade annexed thereto (hereafter the TBT Agreement),

HAVE AGREED as follows:

PART I

Article 1
Definitions

1. All general terms concerning standards and conformity assessment used in this Agreement shall have the meaning given in the definitions contained in ISO/IEC Guide 2:1996 "General terms and their definitions concerning standardization and related activities" of the International Organization for Standardization and International Electrotechnical Commission unless the context requires otherwise. In addition, the following terms and definitions shall apply for the purpose of this Agreement:

accept means the use of the results of conformity assessment activities as a basis for regulatory actions such as approvals, licences, registrations and post-market assessments of conformity;

acceptance has an equivalent meaning to *accept*;

conformity assessment means any activity concerned with determining directly or indirectly that relevant Mandatory Requirements are fulfilled;

Conformity Assessment Body means a body that conducts conformity assessment activities and includes test facilities and certification bodies. A Regulatory Authority may be a Conformity Assessment Body under this Agreement;

Certification Body means a body, including product or quality systems certification bodies, that may be designated by one Party's Designating Authority in accordance with this Agreement to conduct certification to the other Party's Mandatory Requirements;

Designating Authority means a body as specified under this Agreement established in the territory of a Party with the necessary authority to designate, monitor, suspend, remove suspension or withdraw designation of Conformity Assessment Bodies within its jurisdiction;

designation means the authorisation by a Designating Authority of a Conformity Assessment Body to undertake specified conformity assessment activities;

designate has an equivalent meaning to *designation*;

Inspection Service means a body responsible for the inspection of manufacturers of products and the granting of manufacturing licences and/or certificates;

Mandatory Requirements means the legislative, regulatory and administrative requirements, that are the subject of this Agreement, of the Party into which the product is being supplied

Regulatory Authority means 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;

Sectoral Annex is an annex to this Agreement which specifies the implementation arrangements in respect of a specific product sector. Each Sectoral Annex shall specify whether Parts II and/or III of this Agreement apply to that specific sector;

Stipulated Requirements means the criteria set out in a Sectoral Annex for the designation of Conformity Assessment Bodies; and

Test Facility means a facility, including independent laboratories, manufacturers' own test facilities or government testing bodies, that may be designated by one Party's Designating Authority in accordance with this Agreement to undertake tests to the other Party's Mandatory Requirements.

2. For the purposes of this Agreement the singular should be read to include the plural and vice-versa when appropriate.

Article 2
Scope of this Agreement

1. This Agreement shall apply, on the one hand, to the territory of Australia and, on the other hand, to the territory of the Republic of Singapore.

2. Agreements 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, save where there is an express agreement between the Parties to do so.

3. This Agreement 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 harmonisation or equivalence of their respective Mandatory Requirements, where appropriate and where consistent with good regulatory practice. Where both Parties agree that the standards or technical regulations are harmonised 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.

Article 3
Exchange of information

1. The Parties shall exchange information concerning their Mandatory Requirements, conformity assessment procedures and regimes.

2. Each Party shall inform the other Party of any proposed changes to its Mandatory Requirements. Except where considerations of health, safety and environmental protection warrant more urgent action, each Party shall notify the other Party of the changes within the time set out in the relevant Sectoral Annex or, if no time is specified, at least 60 calendar days before the changes enter into force.

3. The Parties may agree on the provision of other information for a specific sector in the relevant Sectoral Annex.

PART II

Article 4
Application and scope of this Part

1. The provisions of this Part shall apply to a specific sector only if the relevant Sectoral Annex so provides.

2. This Part applies to conformity assessment of products specified in the relevant Sectoral Annexes carried out in the territories of the Parties regardless of the origin of those products unless otherwise stated in the relevant Sectoral Annex.

Article 5
Obligations of this Part

1. Each Party recognises that the Conformity Assessment Bodies designated by the other Party in accordance with this Agreement are competent to undertake the conformity assessment activities necessary to demonstrate compliance with its Mandatory Requirements.

2. The Government of Australia shall accept the results of conformity assessment activities to demonstrate conformity of products with its Mandatory Requirements when the conformity assessment activities are undertaken by Conformity Assessment Bodies designated by Singapore's Designating Authorities in accordance with this Agreement.

3. The Government of the Republic of Singapore shall accept the results of conformity assessment activities to demonstrate conformity of products with its Mandatory Requirements when the conformity assessment activities are undertaken by Conformity Assessment Bodies designated by Australia's Designating Authorities in accordance with this Agreement.

4. Each Party shall, in accordance with Article 2.4 of the TBT Agreement, use international standards, or the relevant parts of international standards, as the basis for its Mandatory Requirements where applicable international standards exist or when their completion is imminent, except when such international standards or their relevant parts are ineffective or inappropriate.

5. The Sectoral Annexes may provide mechanisms for the completion of registration and/or licensing activities that are based on conformity assessment activities covered by this Agreement.

Article 6
Designating Authorities

1. The Parties shall ensure that their Designating Authorities have the necessary authority to designate, monitor, suspend, remove suspension and withdraw designation of the Conformity Assessment Bodies within their respective jurisdictions.

2. Designating Authorities shall consult, as necessary, with their counterparts in the other Party 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 other assessments of designated Conformity Assessment Bodies, where such participation is appropriate, technically possible and within reasonable cost.

Article 7
Designation of Conformity Assessment Bodies

1. In designating Conformity Assessment Bodies, Designating Authorities shall observe the relevant procedures and Stipulated Requirements.

2. Designating Authorities shall specify the scope of the conformity assessment activities for which a Conformity Assessment Body has been designated.

3. Each Party shall give the other Party advance notice of at least seven calendar days, or such other time period as may be specified in the relevant Sectoral Annex, of any changes, including suspensions, to their list of designated Conformity Assessment Bodies.

4. The results of conformity assessment activities undertaken by a designated Conformity Assessment Body shall be valid for acceptance for the purposes of Articles 5.2 and 5.3 from the date of effect of their designation.

5. The Parties shall ensure that their designated Conformity Assessment Bodies maintain the necessary technical competence to undertake conformity assessment activities that demonstrate the conformity of a product with the Mandatory Requirements for which they have been designated.

6. The Parties shall exchange information concerning the procedures used to ensure that the designated Conformity Assessment Bodies are technically competent and comply with the relevant Stipulated Requirements.

7. The Parties shall ensure that their designated Conformity Assessment Bodies participate in appropriate proficiency testing programs and other comparative reviews, such as non-government to government mutual recognition agreements, so that confidence in their technical competence to undertake the required conformity assessment activities is maintained.

8. Each Party shall inform the other Party, in an expeditious manner, of any changes that affect a designated Conformity Assessment Body's technical competence or compliance with the relevant Stipulated Requirements.

Article 8
Verification, suspension and withdrawal of Conformity Assessment Bodies

1. The Parties shall ensure that their designated Conformity Assessment Bodies are available for verification of their technical competence and compliance with the relevant Stipulated Requirements.

2. Each Party retains the right to challenge a designated Conformity Assessment Body's technical competence and compliance with the relevant Stipulated Requirements. This right shall be exercised only in exceptional circumstances and where supported by relevant expert analysis and/or evidence. A Party shall exercise this right by notifying the other Party in writing. Such notification shall be accompanied by the supporting expert analysis and/or evidence.

3. Except in urgent circumstances, the Parties shall, prior to a challenge under paragraph 2, enter into consultations with a view to seeking a mutually satisfactory solution. In urgent circumstances, consultations shall take place immediately after the right to challenge has been exercised.

4. The consultations referred to in paragraph 3 shall be conducted expeditiously with a view to resolving all issues and seeking a mutually satisfactory solution within the time period specified in the relevant Sectoral Annex. If this is not achieved, the Joint Committee established under Article 11 shall be convened to resolve the matter.

5. The Sectoral Annexes may provide for additional procedures, such as verification and time limits, to be followed in relation to a challenge.

6. Unless the Parties decide otherwise, the designation of the challenged designated Conformity Assessment Body shall be suspended by the relevant Designating Authority for the relevant scope of designation from the time its technical competence or compliance was challenged, until either:

(a) the challenging Party is satisfied as to the competence and compliance of the Conformity Assessment Body; or

(b) the designation of the Conformity Assessment Body has been withdrawn.

7. The results of conformity assessment activities, undertaken by a designated Conformity Assessment Body on or before the date of its suspension or withdrawal, shall remain valid for acceptance for the purposes of Articles 5.2 and 5.3 unless otherwise agreed to by the Joint Committee.

8. The Parties shall compare methods used to verify that the designated Conformity Assessment Bodies comply with the Stipulated Requirements.

PART III

Article 9
Application and scope of this Part

1. The provisions of this Part shall apply to a specific sector only if the relevant Sectoral Annex so provides.

2. This Part applies to assessments of manufacturers of products specified in the relevant Sectoral Annexes carried out in the territories of the Parties regardless of the origin of those products unless otherwise stated in the relevant Sectoral Annex.

Article 10
Obligations of this Part

1. The Government of Australia shall accept the results of conformity assessment activities to demonstrate conformity of manufacturers with its Mandatory Requirements when the conformity assessment activities are undertaken by Inspection Services appointed by Singapore in accordance with this Agreement.

2. The Government of the Republic of Singapore shall accept the results of conformity assessment activities to demonstrate conformity of manufacturers with its

Mandatory Requirements when the conformity assessment activities are undertaken by Inspection Services appointed by Australia in accordance with this Agreement.

3. Each Party shall, in accordance with Article 2.4 of the TBT Agreement, use international standards, or the relevant parts of international standards, as the basis for its Mandatory Requirements, where applicable international standards exist or when their completion is imminent, except when such international standards or their relevant parts are ineffective or inappropriate.

PART IV

Article 11
Joint Committee

1. A Joint Committee shall be established.

2. The Joint Committee shall be led by co-chairs representing the Parties and shall comprise an equal number of senior representatives from both Parties with an understanding of this Agreement, its objectives and application and with the relevant expertise. A representative:

(a) may be accompanied by advisers at meetings of the Joint Committee; and

(b) shall not hold a position which may give rise to a conflict of interest.

3. The Joint Committee shall:

(a) be responsible for administering and facilitating the effective functioning of this Agreement and the Sectoral Annexes including:

(i) facilitating the extension of this Agreement, including the addition of new Sectoral Annexes or an increase in the scope of existing Sectoral Annexes;

(ii) resolving any questions or disputes relating to the application of this Agreement and its Sectoral Annexes; and

(iii) the discharge of such other functions as provided for in this Agreement;

(b) be the contact point for the Parties unless otherwise specified in the relevant Sectoral Annexes;

(c) determine its own rules of procedure;

(d) make its decisions and adopt its recommendations by consensus; and

(e) meet as and when required for the discharge of its functions, including upon the request of either Party.

4. The Joint Committee may establish *ad hoc* groups to undertake specific tasks, where necessary.

5. The Parties shall bring into effect the relevant decisions of the Joint Committee.

Article 12
Confidentiality

1. 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 Conformity Assessment Bodies and conformity with the relevant Stipulated Requirements.

2. 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 13
Preservation of Regulatory Authority

1. Each Party retains all authority under its laws to interpret and implement its Mandatory Requirements.

2. This Agreement does not limit the authority of a Party to determine the level of protection it considers necessary with regard to health, safety and the environment.

3. This Agreement does not limit the authority of a Party to take all appropriate measures whenever it ascertains that products may not conform with its Mandatory Requirements. Such measures may include withdrawing products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, initiating legal proceedings or otherwise preventing the recurrence of such problems, including through a prohibition on imports. If a Party takes such measures, it shall notify the other Party within fifteen calendar days of taking the measures, providing its reasons.

Article 14
Entry into force and duration

1. This Agreement shall enter into force on the first day of the second month following the date on which the Parties have exchanged notes confirming the completion of their respective procedures for the entry into force of this Agreement.

2. Either Party may terminate this Agreement in its entirety or any one or more of the Sectoral Annexes by giving the other Party six months' advance notice in writing.

3. Following termination of this Agreement or any Sectoral Annex, a Party shall continue to accept the results of conformity assessment activities performed by designated Conformity Assessment Bodies or Inspection Services prior to termination,

unless that Party decides otherwise based on health, safety and environmental protection considerations.

Article 15
Final provisions

1. Any amendment to this Agreement shall be by mutual agreement.

2. The Parties shall conclude Sectoral Annexes which shall provide the implementing arrangements for this Agreement.

3. Amendments to the Sectoral Annexes shall be agreed to by the Parties through the Joint Committee.

4. Where a Party changes its Mandatory Requirements for products covered by a Sectoral Annex, its obligations under Articles 5.2, 5.3, 10.1 or 10.2 of this Agreement, 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 the relevant Conformity Assessment Bodies have been designated or the relevant Inspection Services have been appointed in accordance with this Agreement.

5. This Agreement is drawn up in two originals in the English language.

IN WITNESS WHEREOF the undersigned, being duly authorised by their respective Governments, have signed this Agreement.

DONE at on 2001.

FOR THE GOVERNMENT OF AUSTRALIA:

FOR THE GOVERNMENT OF THE REPUBLIC OF SINGAPORE:

SECTORAL ANNEX ON ELECTRICAL AND ELECTRONIC EQUIPMENT

Pursuant to the Mutual Recognition Agreement on Conformity Assessment between Australia and Singapore ("the Agreement"), the Parties agree on this Sectoral Annex for Electrical and Electronic Equipment.

1. Scope

1.1 The products to which this Sectoral Annex applies are new electrical and electronic equipment that are intended to be either directly connected or plugged-in to the low voltage supply or are battery powered, and which are:

(a) not subject to the Sectoral Annex on Telecommunications Equipment; and

(b) not medical equipment.

1.2 Part II of the Agreement shall apply to this Sectoral Annex.

1.3 For the purpose of this Sectoral Annex:

low voltage has the same meaning as that defined in Band II of International Electrotechnical Commission Standards 60449:1979 - Voltage bands for electrical installations in buildings (IEC 60449:1979); and

Registration Assessment Body means a body that may be designated by one Party in accordance with this Sectoral Annex to undertake assessments of compliance with the other Party's Mandatory Requirements for registration or approval by Regulatory Authorities. A Regulatory Authority may be a Registration Assessment Body under this Sectoral Annex.

1.4 The Mandatory Requirements to which this Sectoral Annex applies shall be third party conformity assessment processes or requirements for product testing for the equipment referred to in Section 1.1 of this Annex.

1.5 The Conformity Assessment Bodies which may be designated under this Sectoral Annex shall be:

(a) Test Facilities;

(b) Certification Bodies; or

(c) Registration Assessment Bodies.

1.6 The conformity assessment activities for which Conformity Assessment Bodies may be designated under this Sectoral Annex are:

(a) testing by designated Test Facilities;

(b) product surveillance activities undertaken in accordance with the relevant Mandatory Requirements by designated Certification Bodies, the results of which are supplemented by test results from designated Test Facilities; and

(c) assessments of compliance with Mandatory Requirements by Registration Assessment Bodies for registration or approval by Regulatory Authorities.

2. Obligations

2.1 Australia shall accept test reports that demonstrate compliance with its Mandatory Requirements issued by Test Facilities designated by Singapore's Designating Authorities in accordance with Section 5 of this Annex.

2.2 Singapore shall accept test reports that demonstrate compliance with its Mandatory Requirements issued by Test Facilities designated by Australia's Designating Authorities in accordance with Section 5 of this Annex.

2.3 Australia shall accept the results of product surveillance activities undertaken in accordance with its Mandatory Requirements by Certification Bodies designated by Singapore's Designating Authorities in accordance with Section 5 of this Annex. Such results shall be supplemented by test results from Test Facilities designated by Singapore's Designating Authorities.

2.4 Singapore shall accept the results of product surveillance activities undertaken in accordance with its Mandatory Requirements by Certification Bodies designated by Australia's Designating Authorities in accordance with Section 5 of this Annex. Such results shall be supplemented by test results from Test Facilities designated by Australia's Designating Authorities.

2.5 Australia's Regulatory Authorities shall accept assessments of compliance with Australia's Mandatory Requirements for approval undertaken by Registration Assessment Bodies designated by Singapore's Designating Authorities in accordance with Section 5 of this Annex. Upon receipt of such assessments, Australia's Regulatory Authorities shall complete the relevant product approval processes within 7 calendar days or 5 working days, whichever is the longer.

2.6 Singapore's Regulatory Authorities shall accept assessments of compliance with Singapore's Mandatory Requirements for registration undertaken by Registration Assessment Bodies designated by Australia's Designating Authorities in accordance with Section 5 of this Annex. Upon receipt of such assessments, Singapore's Regulatory Authorities shall complete the

relevant product registration processes within 7 calendar days or 5 working days, whichever is the longer.

3. Exchange of Information

3.1 The Parties' relevant Regulatory Authorities shall notify each other, the Joint Committee and the relevant Designating Authorities of any proposed changes to their relevant Mandatory Requirements. Except where considerations of health, safety and the environment warrant more urgent action, such notification shall take place at least 60 calendar days before the entry into force of the changes.

4. Designating Authorities

4.1 For the purpose of this Sectoral Annex, Australia's Designating Authorities shall be:

(a) the National Association of Testing Authorities, Australia, for Test Facilities;

(b) the Joint Accreditation System of Australia and New Zealand, for Certification Bodies; and

(c) the Electrical Regulatory Authorities Council, for Registration Assessment Bodies.

4.2 For the purpose of this Sectoral Annex, Singapore's Designating Authorities shall be:

(a) the Singapore Accreditation Council - Singapore Laboratory Accreditation Scheme (SINGLAS), for Test Facilities;

(b) the Singapore Accreditation Council, for Certification Bodies; and

(c) the Public Utilities Board of Singapore and the Singapore Productivity and Standards Board jointly, for Registration Assessment Bodies.

5. Designation of Conformity Assessment Bodies and Stipulated Requirements

5.1 Designating Authorities shall give advance notice of at least 7 calendar days of any changes, including suspension, to their list of designated Conformity Assessment Bodies.

5.2 Designating Authorities shall specify the scope of the conformity assessment activities for which a Conformity Assessment Body has been designated. When a Conformity Assessment Body is designated to undertake conformity assessment activities with regard to particular Mandatory Requirements, the relevant obligations of acceptance shall be

limited to the results of assessments in relation to those particular Mandatory Requirements.

5.3 Designating Authorities shall only designate Conformity Assessment Bodies where the Conformity Assessment Body, or the organisation of which the Conformity Assessment Body is a part, is a legal person in the relevant jurisdiction.

5.4 Designated Conformity Assessment Bodies shall not be adversely influenced by a body that manufactures or trades in electrical and electronic equipment. Furthermore, designated Conformity Assessment Bodies shall be impartial. Any other services offered by the Conformity Assessment Body shall be provided in a manner that does not compromise the objectivity of its conformity assessment activities and decisions.

5.5 Designating Authorities shall only designate Conformity Assessment Bodies that are able to demonstrate that they understand, have experience relevant to and are technically competent to undertake the conformity assessment activities for which they are designated.

5.6 Demonstration of technical competence shall be based on:

(a) technological knowledge of the relevant products, processes or services;

(b) understanding of the technical standards and the general risk protection requirements for which designation is sought;

(c) the experience relevant to the applicable Mandatory Requirements;

(d) the physical capability to perform the relevant conformity assessment activities;

(e) an adequate management of the conformity assessment activities concerned; and

(f) any other circumstance necessary to give assurance that the conformity assessment activities shall be adequately performed on a consistent basis.

5.7 The basis for designating Test Facilities shall be:

(a) Accreditation to ISO/IEC Guide 25:1996 or ISO/IEC 17025:1999, which shall constitute sufficient proof of technical competence to undertake conformity assessment activities that demonstrate conformity with the Mandatory Requirements for which they are to be designated provided that:

(i) the accreditation process is conducted in compliance with ISO/IEC Guide 58:1993; and

(ii) the accreditation body participates in mutual recognition arrangements, such as the Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement, where they are subject to peer evaluation of the competence of accreditation bodies and the Test Facilities accredited by them.

OR

(b) Membership in the IECEE CB Scheme.

5.8 The basis for designating Certification Bodies shall be:

(a) Accreditation to ISO/IEC Guide 65:1996, which shall constitute sufficient proof of technical competence to undertake conformity assessment activities that demonstrate conformity with the Mandatory Requirements for which they are to be designated provided that:

(i) the accreditation process is conducted in compliance with ISO/IEC Guide 61:1996; and

(ii) the accreditation body is recognised by the designating Party.

OR

(b) Membership in the IECEE CB/FC Scheme.

5.9 The basis for designating Registration Assessment Bodies shall be:

(a) participation in the regulatory process in the jurisdiction in which they reside;

(b) participation in training in the other Party's Mandatory Requirements and relevant regulatory processes; and

(c) understanding of the Mandatory Requirements and relevant regulatory processes of the other Party.

5.10 Registration Assessment Bodies shall be Regulatory Authorities or their appointed agents.

5.11 When designating a Conformity Assessment Body, the Designating Authority shall provide to the other Party the following details in respect of each Conformity Assessment Body it designates:

(a) the name;

(b) the postal address;

(c) the facsimile (fax) number;

(d) email address (if available);

(e) name and telephone number of the contact person;

(f) scope of designation detailing range of products, reference standards, methods of certification, capability and other relevant details;

(g) designating procedure used; and

(h) date of effect of designation.

6. Verification, Suspension and Withdrawal of Conformity Assessment Bodies

6.1 For the purpose of this Sectoral Annex, the time period specified in Article 8.4 of the Agreement shall be 70 calendar days.

7. Entry Into Force

7.1 This Sectoral Annex shall enter into force on the day on which the Agreement enters into force.

8. Transitional Provisions

8.1 Notwithstanding any provision in this Sectoral Annex, the provisions of this section shall apply for a period of 18 months from the date of entry into force of this Sectoral Annex in accordance with Section 7 ("the transitional period").

8.2 During the transitional period, the obligations set out in Sections 2.3 to 2.6 shall apply only to electrical and electronic equipment which has been exported from the territory of one Party to the other. The production of relevant bills of lading, airway bills or other similar documents containing statements as to the country of export shall constitute sufficient evidence for this purpose.

8.3 During the transitional period, the Regulatory Authorities shall not be bound to complete the relevant product regulatory processes within the time limits set out in Sections 2.5 and 2.6 but shall do so expeditiously and, in any event, within 21 calendar days upon receipt of the assessments. The regulatory process may include verification of the technical competence or compliance of the designated conformity assessment body with the Stipulated Requirements set out in this Sectoral Annex.

SECTORAL ANNEX FOR TELECOMMUNICATIONS EQUIPMENT

Pursuant to the Mutual Recognition Agreement on Conformity Assessment between Australia and Singapore ("the Agreement"), the Parties agree on this Sectoral Annex for Telecommunications Equipment.

1. Scope

1.1 This Sectoral Annex applies to network terminal attachment and other equipment subject to network terminal attachment or other telecommunications regulation, including wire and wireless equipment, and terrestrial and satellite equipment, whether or not connected to a Public Telecommunications Network.

1.2 Part II of the Agreement shall apply to this Sectoral Annex.

1.3 For the purpose of this Sectoral Annex:

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

1.4 The Conformity Assessment Bodies which may be designated under this Sectoral Annex shall be:

(a) Test Facilities; or

(b) Certification Bodies.

1.5 The conformity assessment activities for which Conformity Assessment Bodies may be designated under this Sectoral Annex are:

(a) testing by designated Test Facilities; and

(b) certifications that equipment complies with relevant Mandatory Requirements by designated Certification Bodies (hereinafter known as "equipment certifications").

2. Obligations

2.1 Australia shall accept test reports that demonstrate compliance with its Mandatory Requirements issued by Test Facilities designated by Singapore's Designating Authorities in accordance with Section 5 of this Annex.

2.2 Singapore shall accept test reports that demonstrate compliance with its Mandatory Requirements issued by Test Facilities designated by Australia's Designating Authorities in accordance with Section 5 of this Annex.

2.3 Australia shall accept equipment certifications that demonstrate compliance with its Mandatory Requirements issued by Certification Bodies designated by Singapore's Designating Authorities in accordance with Section 5 of this Annex.

2.4 Singapore shall accept equipment certifications that demonstrate compliance with its Mandatory Requirements issued by Certification Bodies designated by Australia's Designating Authorities in accordance with Section 5 of this Annex.

3. Exchange of Information

3.1 The Parties' relevant Regulatory Authorities shall notify each other, the Joint Committee and the relevant Designating Authorities of any proposed changes to their relevant Mandatory Requirements. Except where considerations of health, safety and the environment warrant more urgent action, such notification shall take place at least 60 calendar days before the entry into force of the changes.

4. Designating Authorities

4.1 For the purpose of this Sectoral Annex, Australia's Designating Authorities shall be:

(a) the National Association of Testing Authorities, Australia, for Test Facilities; and

(b) the Joint Accreditation System of Australia and New Zealand, for Certification Bodies.

4.2 For the purpose of this Sectoral Annex, Singapore's Designating Authorities shall be:

(a) the Singapore Accreditation Council - Singapore Laboratory Accreditation Scheme (SINGLAS), for Test Facilities; and

(b) the Singapore Accreditation Council, for Certification Bodies.

5. Designation of Conformity Assessment Bodies and Stipulated Requirements

5.1 Designating Authorities shall give advance notice of at least 7 calendar days of any changes (including suspension) to their list of designated Conformity Assessment Bodies.

5.2 Designating Authorities shall specify the scope of the conformity assessment activities for which a Conformity Assessment Body has been designated. When a Conformity Assessment Body is designated to undertake conformity assessment activities with regard to particular

Mandatory Requirements, the relevant obligations of acceptance shall be limited to the results of assessments in relation to those particular Mandatory Requirements.

5.3 Designating Authorities shall only designate Conformity Assessment Bodies where the Conformity Assessment Body, or the organisation of which the Conformity Assessment Body is a part, is a legal person in the relevant jurisdiction.

5.4 Designated Conformity Assessment Bodies shall not be adversely influenced by a body that manufactures or trades in telecommunications equipment. Furthermore, designated Conformity Assessment Bodies shall be impartial. Any other services offered by a Conformity Assessment Body shall be provided in a manner that does not compromise the objectivity of its conformity assessment activities and decisions.

5.5 Designating Authorities shall only designate Conformity Assessment Bodies that are able to demonstrate that they understand, have experience relevant to and are technically competent to undertake the conformity assessment activities for which they are designated.

5.6 Demonstration of technical competence shall be based on:

(a) technological knowledge of the relevant products, processes or services;

(b) understanding of the technical standards and the general risk protection requirements for which designation is sought;

(c) the experience relevant to the applicable Mandatory Requirements;

(d) the physical capability to perform the relevant conformity assessment activities;

(e) an adequate management of the conformity assessment activities concerned; and

(f) any other circumstance necessary to give assurance that the conformity assessment activities shall be adequately performed on a consistent basis.

5.7 The basis for designating Test Facilities shall be accreditation to ISO/IEC Guide 25:1996 or ISO/IEC 17025:1999, which shall constitute sufficient proof of technical competence to undertake conformity assessment activities that demonstrate conformity with the Mandatory Requirements for which they are to be designated provided that:

(a) the accreditation process is conducted in compliance with ISO/IEC Guide 58:1993; and

(b) the accreditation body participates in mutual recognition arrangements, such as the Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement, where they are subject to peer evaluation of the competence of accreditation bodies and the Test Facilities accredited by them.

5.8 The basis for designating Certification Bodies shall be accreditation to ISO/IEC Guide 65:1996, which shall constitute sufficient proof of technical competence to undertake conformity assessment activities that demonstrate conformity with the Mandatory Requirements for which they are to be designated provided that:

(a) the accreditation process is conducted in compliance with ISO/IEC Guide 61:1996; and

(b) the accreditation body is a member of the Pacific Accreditation Cooperation and is a signatory to a mutual recognition arrangement where they are subject to peer evaluation of the competence of accreditation bodies and the Certification Bodies accredited by them.

5.9 When designating a Conformity Assessment Body, the Designating Authority shall provide to the other Party the following details in respect of each Conformity Assessment Body it designates:

(a) the name;

(b) the postal address;

(c) the facsimile (fax) number;

(d) email address (if available);

(e) name and telephone number of the contact person;

(f) scope of designation detailing range of products, reference standards, methods of certification, capability and other relevant details;

(g) designating procedure used; and

(h) date of effect of designation.

5.10 Designated Conformity Assessment Bodies shall maintain a list of telecommunications equipment they have assessed and, on a request of a Party, shall provide the list to that Party.

6. Verification, Suspension and Withdrawal of Conformity Assessment Bodies

6.1 For the purpose of this Sectoral Annex, the time period specified in Article 8.4 of the Agreement shall be 70 calendar days.

7. Entry into Force

7.1 This Sectoral Annex shall enter into force on the day on which the Agreement enters into force.

SECTORAL ANNEX ON MEDICINAL PRODUCTS

Pursuant to the Mutual Recognition Agreement on Conformity Assessment between Australia and Singapore ("the Agreement"), the Parties agree on this Sectoral Annex for Medicinal Products.

1. Scope

1.1 This Sectoral Annex applies to the Good Manufacturing Practice (GMP) inspection of manufacturers of medicinal products carried out in the territories of the Parties.

1.2 The Mandatory Requirements covered by this Sectoral Annex are the mandatory GMP requirements of the Parties.

1.3 Part III of the Agreement shall apply to this Sectoral Annex.

1.4 For the purpose of this Sectoral Annex:

Good Manufacturing Practice (GMP) means that part of quality assurance which ensures that products are consistently produced and controlled during manufacture to the quality standards appropriate to their intended use and as required by the marketing authorisation granted by the importing Party; and

Inspection Service means a Regulatory Authority responsible for the inspection of manufacturers of medicinal products and the granting of manufacturing licences and/or certificates for medicinal products.

2. Obligations

2.1 Australia shall accept the conclusions of GMP inspections of manufacturers carried out by Singapore's Inspection Service and manufacturing certificates issued by Singapore's Inspection Service in accordance with Section 4.

2.2 Singapore shall accept the conclusions of GMP inspections of manufacturers carried out by Australia's Inspection Service and manufacturing certificates issued by Australia's Inspection Service in accordance with Section 4.

2.3 With respect to medicinal products covered by the mandatory GMP requirements of one Party but not the other, manufacturing companies can request that, for the purpose of this Sectoral Annex, an inspection be made by the other Party's Inspection Service.

3. Inspection Services

3.1 For the purpose of this Sectoral Annex, Australia's Inspection Service shall be:

Therapeutic Goods Administration (TGA)
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
AUSTRALIA

3.2 For the purpose of this Sectoral Annex, Singapore's Inspection Service shall be:

National Pharmaceutical Administration
Ministry of Health
No 2 Jalan Bukit Merah
SINGAPORE 169547

4. Certification of Manufacturers

4.1 At the request of an exporter, importer or the regulatory authority of the other Party, the Inspection Service shall assess and, where appropriate, certify that the manufacturer:

(a) is appropriately authorised to manufacture the relevant medicinal product or to carry out the relevant specified manufacturing operation;

(b) is regularly inspected by the authorities; and

(c) complies with the national GMP requirements recognised as equivalent by the two Parties in accordance with Article 2.3 of the Agreement. In cases where different GMP requirements are used as a reference, this is to be mentioned in the certificate.

4.2 Certificates shall also identify the site(s) of manufacture and contract testing laboratories (if any). The format of the certificate is attached as Appendix 1 and may be modified through agreement by the Parties.

4.3 Certificates shall be issued expeditiously and the time taken shall not exceed 30 calendar days. In exceptional cases, such as when a new inspection has to be carried out, this period may be extended to 60 calendar days.

5. Operational Provisions

5.1 Transmission of Inspection Reports

5.1.1 Upon reasoned request, the relevant Inspection Service shall forward a copy of the last inspection report of the manufacturing site or contract testing laboratory in the case where analytical operations are contracted out. The request may concern a "full inspection report" or a "detailed report" (see Section 5.2 below). The requesting Party shall

deal with these inspection reports with the degree of confidentiality requested by the other Party.

5.1.2 If the manufacturing operations of the medicinal product in question have not been inspected recently, i.e. when the last inspection dates back to more than two years or a particular need to inspect has been identified, a specific and detailed inspection may be requested. Parties shall ensure that inspection reports are forwarded in no more than 30 calendar days. Should a new inspection be carried out, this period may be extended to 60 calendar days.

5.2 Inspection Reports

5.2.1 A "full inspection report" comprises a Site Master File (compiled by the manufacturer and verified by the Inspection Service) and a narrative report by the Inspection Service. A "detailed report" responds to specific queries about a manufacturer by the other Party.

5.3 Reference GMP

5.3.1 For the avoidance of doubt, with respect to medicinal products covered by the mandatory GMP requirements of the importing Party but not the exporting one, GMP inspections by the Inspection Service of the exporting Party shall be in relation to the mandatory GMP requirements of the importing Party. This shall also be the case when the mandatory GMP requirements of both Parties are not regarded as equivalent in accordance with Article 2.3 of the Agreement.

5.3.2 Equivalence of GMP requirements for specific products or classes of products shall be determined according to a procedure established by the Parties.

5.4 Nature of Inspections

5.4.1 Inspection Services shall routinely assess the compliance of the manufacturer with mandatory GMP requirements.

5.4.2 Inspection Services shall, on the request of the other Party, undertake product specific assessments of a manufacturer's compliance with mandatory GMP requirements.

5.5 Safeguard clause for Inspections

5.5.1 Each Regulatory Authority may, subject to the laws and regulations of the other Party, conduct its own inspection of manufacturers in the other Party for reasons identified to the other Party. Such inspections shall be notified in advance to the other Party, which has the option of joining the inspection. Recourse to this safeguard clause shall only be

exercised in exceptional circumstances for the purpose of health and safety and shall only occur with the consent of the manufacturer.

5.6 Exchange of Information between Regulatory Authorities and Harmonisation of Requirements

5.6.1 In accordance with the Agreement, the Parties shall exchange any information necessary for the mutual recognition of inspections.

5.6.2 In addition, the relevant Regulatory Authorities in Australia and in Singapore shall keep each other informed of any new technical guidance or inspection procedure. Each Party shall consult with the other Party before their adoption and shall endeavour to work towards their harmonisation or equivalence.

5.7 Inspectors Training

5.7.1 In accordance with the Agreement, training sessions for inspectors on GMP, organised by the Regulatory Authorities, shall be accessible to inspectors of the other Party. The Parties shall keep each other informed of these sessions.

5.8 Joint Inspections

5.8.1 In accordance with the Agreement, and by mutual agreement between the Parties, joint inspections may be conducted. These inspections are intended to develop common understanding and interpretation of practice and requirements.

5.8.2 The fee for a joint inspection will be charged only by the Regulatory Authority of the Party in whose territory the inspection is carried out if the Inspection Service of the other Party participates in the joint inspection for the purposes of training.

5.9. Alert System

5.9.1 Contact points shall be agreed between the Parties to permit Regulatory Authorities and manufacturers of one Party to inform the Regulatory Authorities of the other Party with appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed.

5.9.2 The Parties shall ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with mandatory GMP requirements and which could affect the protection of public health, is communicated to each other with the appropriate degree of urgency.

5.10 Contact Points

5.10.1 For the purpose of this Sectoral Annex, the contact points for any technical question, such as exchange of inspection reports, inspectors' training sessions and technical requirements, will be:

5.10.2 For Australia:

For GMP:

The Chief GMP Auditor
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
AUSTRALIA

Tel.: 61-2 -6232 8632
Fax: 61-2-6232 8426

For the Alert System:

The Recall Coordinator
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
AUSTRALIA

Tel: 61-2-6232 8636
Fax: 61-2-6232 8687

5.10.3 For Singapore:

For GMP:

Assistant Director (GMP)
National Pharmaceutical Administration
Ministry of Health
No 2 Jalan Bukit Merah
SINGAPORE 169547

Tel: 65-325 5647
Fax: 65-325 5594

For the Alert System:

Divisional Director (Enforcement)

National Pharmaceutical Administration
Ministry of Health
No 2 Jalan Bukit Merah
SINGAPORE 169547

Tel: 65-325 5403
Fax: 65-325 5628

5.11 Divergence of Views

5.11.1 The Regulatory Authorities shall use their best endeavours to resolve any divergence of views concerning *inter alia* compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Joint Committee established under Article 11 of the Agreement.

6. Entry into Force

6.1 This Sectoral Annex shall enter into force on the first day of the second month following the date on which the Parties have exchanged notes confirming the completion of their respective procedures for the entry into force of this Sectoral Annex or the day on which the Agreement enters into force, whichever is the later.

APPENDIX 1
(Letterhead of Competent Authority)

Certificate No: _ _ _/_ _ _/_ _

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

ISSUED UNDER THE PROVISIONS OF THE MUTUAL RECOGNITION AGREEMENT BETWEEN SINGAPORE AND AUSTRALIA

As requested by ……..…….……. on …/…/… (*date*), the competent authority of …….....…… (C*ountry*) confirms the following:

The company ……., whose legally registered address is:

…….
…….

has been authorised, in accordance with ……..., transposed in the following national legislation …….:

under the authorisation reference number …….…….., covering the following site(s) of manufacture:

1. …….

2. …….

to carry out the following manufacturing operations:

+ complete manufacture, or

+ partial manufacture*

of the following medicinal product(s) for human use:
…….

in the following dosage forms/product types (see attached list of categories):
……

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on …/…/… (*date*), it is considered that the company complies with the mandatory Good Manufacturing Practice requirements referred to in the Sectoral Annex for Medicinal Products of the Mutual Recognition Agreement on Conformity Assessment between Australia and Singapore.

This certificate remains valid for three years from the date of last inspection.

…/…/… (*date*)

Name and signature of a responsible officer of the Competent Authority of (*country*)

…….

(name)
(title)
(national authority)
(phone and fax numbers)

_____

(* delete that which does not apply)