MEMORANDUM OF UNDERSTANDING

between

The National Institute of Standards and Technology

and

The National Cooperation for Laboratory Accreditation

Preamble

The National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce and the National Cooperation for Laboratory Accreditation (NACLA) hereby state their commitment to develop and maintain a system in the U.S. that will recognize competent laboratory accreditation bodies to accredit testing and calibration laboratories when the services of such laboratories are required to demonstrate compliance with procurement, regulatory, and other requirements of government at all levels – Federal, State, and local – and to meet the needs of the private sector. NIST and NACLA will encourage the use by government and the private sector of such accreditation bodies by informing them of the NACLA recognition process and inviting their participation in that process.

1 Purpose

1.1 NIST and NACLA agree on the need for a coordinated national approach to the accreditation of testing and calibration laboratories to eliminate unnecessary duplication and complexity in the development and promulgation of laboratory accreditation requirements and measures by government at all levels and by the private sector.

1.2 NIST and NACLA recognize the need for improved communication between and within the private and public sectors on laboratory accreditation requirements and practices and the need for affected U.S. government agencies at all levels to contribute to the development, implementation, and use of a system that reduces redundancy and complexity (to the maximum extent possible) while still meeting procurement, regulatory, and other requirements.

1.3 NIST and NACLA agree on the need to monitor reductions in duplicative audits and requirements, as well as savings in resources and improvements in efficiency, that result from the NACLA recognition process and to share their respective findings on an annual basis.

2 NIST Responsibilities

2.1 In accordance with its responsibilities under the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113), NIST will continue to coordinate laboratory accreditation activities of Federal, State, and local entities with those of the private sector and will strive to eliminate unnecessary duplication and complexity in the development and promulgation of such requirements and measures.

2.2 NIST will inform government agencies at all levels of NACLA activities and programs and will encourage agency participation in NACLA, as a means of improving coordination among governmental and private sector conformity assessment activities.

2.3 NIST will work with other U.S. Federal agencies to ensure that agency-unique accreditation requirements are understood by NACLA and incorporated to the extent possible in targeted evaluations by NACLA to minimize duplication and inefficiency in laboratory accreditation activities.

2.4 When requested by an interested Federal agency or agencies, NIST will coordinate with NACLA regarding the incorporation of technical annexes into this MOU outlining or referencing agency-unique accreditation requirements, for reference in NACLA evaluations where relevant. Such technical annexes may be incorporated into the MOU upon agreement between NIST and NACLA. When requested by a Federal agency or agencies, NIST will verify that NACLA evaluation and recognition of laboratory accreditation bodies is carried out in conformance with these agency-unique requirements.

2.5 NIST will encourage laboratory accreditation bodies, including those bodies whose services are used by Federal, State, and local government for procurement, regulatory, trade, and other support purposes, to seek NACLA recognition.

2.6 NIST will work with Federal, State, and local agencies to monitor reductions in duplicative audits and requirements, as well as savings in resources and improvements in efficiency, that result from the NACLA recognition process. NIST will share these findings with NACLA on at least an annual basis.

2.7 NIST representatives will inform NACLA of developments and changes in Federal, State, and local government policy with regard to laboratory accreditation, in a reasonable timeframe whenever NIST becomes aware of such new developments and changes.

3 NACLA Responsibilities

3.1 NACLA will operate a program for recognizing competent laboratory accreditation bodies based on the use of accepted international standards and guides. NACLA will maintain integrity and impartiality in the way it applies relevant standards and guides and judges conformity to them, and will not show undue preference for one competent laboratory accreditation body versus another.

3.2 NACLA will encourage the private sector to specify the use of laboratory accreditation bodies recognized by NACLA when testing and calibration services are required to demonstrate compliance with procurement, regulatory, trade, and other requirements. NACLA will also so encourage the public sector.

3.3 NACLA will encourage laboratory accreditation bodies, including those whose services are used by the private sector to demonstrate compliance with procurement, regulatory, trade, and other requirements, to seek NACLA recognition.

3.4 NACLA will work with the private sector to monitor reductions in duplicative audits and requirements, as well as savings in resources and improvements in efficiency, that result from the NACLA recognition process. NACLA will share these findings with NIST on at least an annual basis.

4 Other Understandings, Agreements, and Arrangements

4.1 Nothing in this MOU precludes either NIST or NACLA from entering into other MOUs, agreements, or arrangements related to laboratory accreditation.

5 Reviews

5.1 Officials of NIST and NACLA will meet at least annually to review this MOU, cooperative efforts of the previous year, and plans for the coming year.

6 Term

6.1 This MOU will remain in effect for a period of 5 (five) years from the date of the last signature below. It may be extended for additional periods by mutual

agreement of the two parties. It may be amended by agreement of the two parties or terminated with 30 (thirty) days written notice by either party.

Signed on behalf of NACLA on this 24th day of September 2003:

Louis T. Dixon
President
NACLA

Signed on behalf of NIST on this 24th day of September 2003:

Richard F. Kayser
Director, Technology Services
NIST
Technology Administration
U.S. Department of Commerce

ANNEX A

NIST REQUIREMENTS FOR NACLA RECOGNITION OF ACCREDITATION BODIES SUPPORTING INTERNATIONAL AGREEMENTS AND ARRANGEMENTS

1. Under the provisions of Section 286.2(b)(3) of Title 15 of the U.S. Code of Federal Regulations, NIST has determined after public consultation that recognition of laboratory accreditation bodies by NACLA provides a suitable alternative to direct NIST recognition under National Voluntary Conformity Assessment System Evaluation (NVCASE) procedures. This Annex outlines the process by which NIST will verify that NACLA recognition of the competence of laboratory accreditation bodies located in the United States to accredit testing laboratories to meet the technical requirements for their acceptance under the international agreements and arrangements listed below meets NIST requirements as a designating authority under those agreements and arrangements.

2. Appendix I of this Annex lists specific technical requirements for each of the following agreements and arrangements: the Electromagnetic Compatibility (EMC) Annex of the Agreement on Mutual Recognition between the United States of America and the European Community, the Inter-American (CITEL) Mutual Recognition Agreement for Conformity Assessment of Telecommunications Equipment, and the Asia-Pacific Economic Cooperation (APEC) Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment. Individual laboratories located in the United States and accredited by a NACLA-recognized laboratory accreditation body accepted by NIST may apply to NIST for designation as Conformity Assessment Bodies (CABs) under these agreements and arrangements, subject to the terms and conditions of each.

3. The NIST process will include the following elements:

   a) NIST will conduct a document review to verify that the NACLA recognition program takes into account the supplemental technical criteria listed in Appendix I of this Annex. This document review will be updated periodically, taking into account any additions to the NACLA recognition program to address expansions of scope for recognized accreditation bodies.

   b) NIST will review NACLA's process to ensure that interested accreditation bodies and laboratories have copies and understand the technical requirements set forth in the intergovernmental agreements covered in this Annex.

   c) A NIST representative will participate as an observer or as an evaluation-team member for all initial evaluations and re-evaluations of laboratory accreditation bodies seeking recognition for any activity or activities covered under the provisions of this Annex.

d) A NIST representative will participate on NACLA acceptance panels considering laboratory accreditation bodies for recognition for any activity or activities covered under the provisions of this Annex.

APPENDIX I

SPECIFIC TECHNICAL REQUIREMENTS FOR INTERNATIONAL AGREEMENTS AND ARRANGEMENTS

Presently, the United States is signatory to three Mutual Recognition Agreements/Arrangements as follows:

- The Asia-Pacific Economic Cooperation Telecommunications and Information (APEC Tel) Mutual Recognition Arrangement (APEC Tel MRA),
- the Inter-American Telecommunications Commission (CITEL) Mutual Recognition Agreement (MRA), and
- the United States of America and the European Community Mutual Recognition Agreement (U.S.-EU MRA).

Specific requirements of each MRA are described below.

1. APEC Tel MRA

This is a multi-lateral, single sector MRA for telecommunications equipment only, with 21 signatory economies. The MRA has two phases. In Phase I, the actively participating economies mutually accept test data for telecommunications equipment subject to the regulatory requirements. The MRA requires that the designated conformity assessment bodies (CABs) must be accredited to ISO/IEC Standard 17025: *General Requirements for the Competence of Testing and Calibration Laboratories,* and the importing economy's technical requirements, by a NIST-recognized accreditor that complies with ISO/IEC Guide 58, *Calibration and testing laboratory accreditation systems – General requirements for operation and recognition*. The United States requires that an APEC economy desiring to implement the MRA sign an exchange letter that includes the names of the pertinent contact organizations, the relevant personnel within those organizations, and the technical requirements as required by the MRA. Thus far, within the APEC Tel framework, the United States has implemented this MRA with four economies namely,

a) Australia (Australian Communications Authority; *http://www.aca.gov.au*),
b) Canada (Industry Canada; *http://strategis.ic.gc.ca*),
c) Chinese-Taipei (Bureau of Standards, Metrology, and Inspection; *http://www.bsmi.gov.tw* & Directorate General of Telecommunications; *http://www.dgt.gov.tw*), and
d) Singapore (Infocomm Development Authority; *http://www.ida.gov.sg*).

Each of these economies has a single Regulatory Authority with the exception of Chinese Taipei that has two Regulatory Authorities – one for Telecommunications & Radio Equipment and one for Information Technology equipment. In the future, the United

States will be implementing the MRA with additional APEC economies.

Under Phase II of this MRA, the actively participating economies accept each other's product approvals. The designated CABs must be accredited to ISO/IEC Standard 17025 for the telecommunications equipment standards of the importing economy by a NIST-recognized accreditor who complies with ISO/IEC Guide 58. [Note: In addition, a Phase-II a designated CAB must be accredited to ISO/IEC Guide 65 by a NIST-recognized accreditor.]

The exchange letters describe the technical requirements of individual APEC economies actively participating in the MRA with the United States for both Phases I and II. Copies of these exchange letters can be obtained from NIST or the United States Trade Representative (USTR). The technical requirements for a particular APEC economy can be obtained from the websites listed above. It is imperative that designated CABs visit each APEC economy's website on a regular basis to check the latest technical requirements. Further information about the APEC Tel Working Group can be obtained at *http://www.apectelwg.org/apec/main.html*. A copy of the APEC Tel MRA can be accessed at *http://ts.nist.gov/mra*.

2. CITEL MRA

The CITEL MRA is similar to the APEC Tel MRA. It is also a multi-lateral, single sector MRA for the telecommunications equipment, with a Phase I and II, and has 35 signatory countries within the Americas. At present, the United States has not implemented this MRA with any of the CITEL countries. Further information about CITEL organization can be obtained at *http://www.citel.oas.org/citel_i.asp*. A copy of the CITEL MRA can be accessed at *http://ts.nist.gov/mra*.

3. U.S.-EU MRA

The U.S.-EU MRA is a bilateral, multi-sector MRA that covers six sectors, namely; Electromagnetic Compatibility (EMC), Telecommunications (or Telecom), Recreational Craft, Electrical Safety, Medical Devices, and Pharmaceuticals. Currently, there are 15 member countries that coordinate their MRA activities through a single organization known as the European Commission, Directorate General (DG) – Enterprise. NIST serves as the Designating Authority for the EMC, Telecom, and Recreational Craft sectors of the MRA. A copy of the US-EU MRA can be accessed at *http://ts.nist.gov/mra*.

EMC Sector: A designated CAB under this sector shall be accredited by an accreditor that has been recognized by NIST to be in conformance with ISO/IEC Guide 58. The CAB must operate in accordance with ISO/IEC Standard 17025. A CAB may use any appropriate technical standard that it, or the manufacturer, chooses to test the product.

The scope of accreditation must include test methods covered in the CAB's scope of accreditation.

The equipment requirements subject to EMC phenomena are described in Council Directive 89/336/EEC. Article 10.2 describes the requirements for the equipment subject to EMC requirements. Under this sector of the MRA, United States' CABs are equivalent to Competent Bodies in Europe. A CAB must also demonstrate its capability to evaluate data relevant to assess the conformity of products covered by the EMC directive. In addition to be capable of evaluating an apparatus to national and harmonized standards, a CAB must be able to ensure conformity of an apparatus to relevant protection requirements when no standards have been applied by the manufacturer. In this case, the CAB must be able to develop or evaluate a technical construction file (TCF) that describes the apparatus and the procedures used to evaluate it. NIST will continue to be responsible for ensuring the technical competence of CABs for these additional activities, which are not covered by accreditation to ISO/IEC Standard 17025. Guidelines for application of the EMC Directive and list of EMC harmonized standards can be accessed at http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/emc.html. Designated CABs must visit this website and review the Official Journal of the European Communities on a regular basis to keep abreast of the latest developments.

Telecom Sector: The designated CAB under this sector shall be accredited by an accreditor that has been recognized by NIST to be in conformance with ISO/IEC Guide 58. The CAB must operate in accordance with ISO/IEC Standard 17025. A CAB may use any appropriate technical standard that it, or the manufacturer, chooses to test the product. The scope of accreditation must include test methods relevant to the claimed scope of competence of the CAB.

The equipment requirements subject to the Telecom sector are described in Council Directive 1999/5/EC. Article 1.4 and Annex I describe the equipment covered by this Directive. Article 10 and Annexes II through V describe the conformity assessment procedures. Annex VI describes the minimum criteria for qualifying Notified Bodies (or U.S. CABs). Under this sector of the MRA the U.S. CABs are equivalent to Notified Bodies in Europe. A CAB must also demonstrate its capability to evaluate data relevant to assess the conformity of products covered by the Radio Equipment & Telecommunications Terminal Equipment (R&TTE) Directive. In addition to be capable of evaluating an apparatus to national and harmonized standards, a CAB must be able to ensure conformity of an apparatus to relevant protection requirements when no standards have been applied by the manufacturer. In this case, the CAB must be able to develop or evaluate a technical construction file (TCF) that describes the apparatus and the procedures used to evaluate it. NIST will continue to be responsible for ensuring the technical competence of CABs for these additional activities, which are not covered by accreditation to ISO/IEC Standard 17025. A list of harmonized standards for the R&TTE Directive can be accessed at http://europa.eu.int/comm/enterprise/rtte/harstand.htm.

Designated CABs must visit this web site and review the Official Journal of the European Communities on a regular basis to keep abreast of the latest developments.