Criteria for Qualification of U.S. Conformity Assessment Bodies under the US-EU Mutual Recognition Agreement

Electromagnetic Compatibility

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On July 20, 2007, European Community Directive 89/336/EEC on Electromagnetic Compatibility (EMC) will be repealed, and a new EMC Directive, 2004/108/EC, will apply. This will terminate the status of all Competent Bodies, or Conformity Assessment Bodies (CABs), and the role that they served prior to this date under Article 10.2 of EMC Directive 89/336/EEC. However, there is still a limited role for CABs under the new Directive as Notified Bodies, but current CABs will not automatically transition to that status. Designating Authorities shall review bodies seeking designation under Directive 2004/108/EC and will nominate qualified Conformity Assessment Bodies to serve as Notified Bodies.

In the United States, NIST serves as the Designating Authority under the Agreement on Mutual Recognition between the United States of America and the European Community, hereinafter referred to as the US-EU Mutual Recognition Agreement (MRA). Designating Authorities under the MRA have the authority to designate, monitor, suspend, remove the suspension of, or to withdraw Conformity Assessment Bodies.

Any U.S. body seeking to serve as a CAB under this Agreement shall meet all applicable required criteria in order to be nominated by NIST. All nominations shall be officially validated by the European Commission. Validated CABs will be assigned a Notified Body number.[1] Such U.S. CABs operating under EMC Directive 2004/108/EC Annex III will be equivalent to other Notified Bodies in the EU or any other country operating under the same directive.

Role of a Notified Body

Under the Electromagnetic Compatibility (EMC) Directive 2004/108/EC, a manufacturer is not under any circumstance required to employ the services of a Notified Body; such use is completely voluntary. However, a manufacturer may nonetheless wish to seek the expertise of a Notified Body and is free to do so.

The role of the Notified Body is outlined in Article 7 and Annex III of the EMC Directive and Section 6.2 of the Guide for the EMC Directive 2004/108/EC[2]. A Notified Body may assist the manufacturer (or his authorized representative in the European Community) by reviewing the technical documentation[3] for apparatus as drawn up by the manufacturer.

The Notified Body shall:

[1] U.S. CABs currently designated under the Telecommunications Annex of the MRA will use the same Notified Body number. Newly designated Notified Bodies will receive a new number.
[2] A Web link to the final version will be included here when available.
[3] See Annex IV of the Directive.

- Accept requests for assessment of technical documentation only from manufacturers or the manufacturer's authorized representative in the European Community. A manufacturer may be located anywhere in the world. The manufacturer defines which aspects of the essential requirements are to be assessed by the Notified Body.

- Review the technical documentation for the apparatus and assess whether that technical documentation properly demonstrates that the relevant aspects of the essential requirements of the EMC Directive have been met.

- Issue a Notified Body Statement to the manufacturer or his authorized representative if the compliance of the apparatus is confirmed for the requirements assessed. The Notified Body will limit the Statement to those aspects of the essential requirements of the apparatus that have been requested by the manufacturer and assessed by the Notified Body.

- If compliance of the apparatus is not confirmed, the Notified Body may provide a negative response describing the grounds on which the technical documentation of the apparatus fails to demonstrate compliance to the EMC Directive.[4]

The Directive allows all covered products to be placed on the EU market based on a Supplier's Declaration of Conformity (SDOC). A CAB cannot issue the SDOC for a product and does not need to state such conformance. The SDOC shall be issued by the manufacturer or his authorized representative. However, the manufacturer shall add the Statement of the Notified Body to the technical documentation.

Criteria for Notified Bodies

The general criteria for Notified Bodies are outlined in Annex VI of the Directive. Specific NIST criteria shall also be met in order for a body to qualify as a U.S. CAB. In particular, an organization shall be located in the United States and shall be able to sufficiently demonstrate the required level of competence, independence, impartiality, and integrity.

All supporting information will be subject to expert technical review, both for evidence of general technical competence and claimed specific competence. Additional documentation or supporting evidence may be requested as necessary during the review process.[5] U.S. bodies seeking designation shall submit information to NIST for review pertaining to the following:

I.) Independence
II.) Separation of Functions
III.) Professional Integrity
IV.) Impartiality
V.) Confidentiality/Professional Secrecy
VI.) Professional Liability Insurance
VII.) Technical Competence

[4] The manufacturer may consult more than one Notified Body in respect to any apparatus. The opinion of a Notified Body is not binding.
[5] In some cases a site visit may be necessary.

VIII.) If Applicable, Use of Personnel within an Organization at Locations not Designated by NIST as a U.S. CAB
IX.) CAB Declaration

Specific information on each provision follows below:

I.) Independence

The specific role of a Notified Body is to provide public confidence in a high level of protection, which requires, as a general rule, safeguarding the complete objectivity of their judgments. Annex VI, Criteria for the Assessment of the Bodies to be Notified, states that a CAB shall be independent in preparing the reports and performing the verification function provided for in the Directive and that there shall be independence of staff and technical personnel in relation to all interested parties, groups, or persons directly or indirectly concerned with the equipment in question.

Specifically, and in order to qualify for designation as a U.S. CAB; the body, its top level management, and the personnel responsible for carrying out the conformity assessment task shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user, or maintainer of the products which they assess, nor the authorized representative of any of these parties. They shall not become directly involved in the design, manufacturer/construction, marketing, installation, use or maintenance of these products, nor represent the parties engaged in these activities. They shall not provide consultancy related to the conformity assessment activities for which they are notified and relating to products intended to be placed on the market and/or put into service in the EU. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body and the use of the assessed products that are necessary for the operations of the body. The body shall ensure that activities of related bodies do not affect the confidentiality, objectivity, and impartiality of its conformity assessment activities.

In addition, an in-house body (e.g., a manufacturer's laboratory) that forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use, or maintenance of the products it assesses, and has been established, in part, to supply conformity assessment services to its parent organization, shall meet the following criteria: The body and its personnel shall be organizationally identifiable and have reporting methods within the parent organization that ensure and demonstrate its impartiality. They shall not be responsible for the design, manufacture, supply, installation, use, or maintenance of the products that they assess, and shall not engage in any activities that might conflict with their independence of judgment and integrity in relation to their assessment activities.

In order to demonstrate independence, please submit:

1. Current and detailed organization chart;
2. Policy and procedure demonstrating compliance with the above provision.

II.) Separation of Functions

Annex VI, Criteria for the Assessment of the Bodies to be Notified, states that there shall be independence of staff and technical personnel in relation to all interested parties, groups, or

persons directly or indirectly concerned with the equipment under consideration. If another part of the organization performs the product testing, or is involved in the development of the manufacturer's technical documentation, the organization shall be able to show a separation of these functions (e.g., supplying test data or involvement in the developing the manufacturer's technical documentation vs. review and evaluation of the manufacturer's technical documentation). Those who review and/or evaluate the technical documentation may not be involved in product testing or developing the manufacturer's technical documentation.

In order to demonstrate a separation of functions, please submit:

3. Policy and/or procedure demonstrating compliance with the above provision.

III.) Professional Integrity

The Notified Body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and shall be free from all pressures and inducements, including financial, that might influence their judgment or the results of their conformity assessment activities, especially with respect to persons or groups of persons with an interest in the results of these activities. The procedures under which a Notified Body operates shall be administered in a non-discriminatory manner.

In order to demonstrate professional integrity, please submit:

4. Policy and/or procedure demonstrating compliance with the above provision.

IV.) Impartiality

The impartiality of the Notified Body, its top level management, and assessment personnel shall be guaranteed. The remuneration of the body's top level management and assessment personnel shall not depend on the number of assessments carried out, nor on the results of such assessments.

In order to demonstrate impartiality, please submit:

5. Policy and/or procedure demonstrating compliance with the above provision.

V.) Confidentiality/Professional Secrecy

The personnel of the Notified Body shall be bound to observe confidentiality with regard to all information gained in carrying out its tasks as a Notified Body.

In order to demonstrate confidentiality/professional secrecy, please submit:

6. Policy and/or procedure demonstrating compliance with the above provision.

VI.) Professional Liability Insurance

Notified Bodies shall be adequately insured to cover their professional activities. Therefore, a Notified Body shall have Civil Liability Insurance (in the United States, a.k.a. professional

liability insurance or errors and omissions insurance)[6], in an amount that is sufficient in coverage to protect itself from lawsuits arising from its activities. A body shall be able to demonstrate evidence that it has such insurance and the coverage limits.

In order to demonstrate Professional Liability Insurance or Errors and Omissions Insurance, please submit:

7. Current insurance policy showing proof that the organization has obtained Professional Liability Insurance or Errors and Omissions Insurance.

VII.) Technical Competence

The Notified Body shall be capable of carrying out all conformity assessment tasks that it accepts and for which it has been designated, whether those tasks are carried out by the designated Notified Body itself or on its behalf and under its responsibility. At all times and for each conformity assessment procedure and kind(s)/category of products for which it is notified, the body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks. It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment and facilities.

The key technical personnel responsible for carrying out the conformity assessment activities shall have:

- General competence in quality management system operation and an understanding of EMC technology;
- Appropriate knowledge and understanding of interpretations, guidelines, and policies of the European Commission with regard to the EMC Directive;
- Thorough knowledge and understanding of, and relevant experience with, the essential requirements of the EMC Directive, the applicable and relevant harmonized standards, and all other relevant provisions of the Directive;
- Sound technical and vocational training covering the conformity assessment activities for which the body is designated;
- Through direct and/or indirect participation, access to the most current and relevant regulatory, standardization, and conformity assessment issues and activities in the industry (e.g., EU industry associations, standardization bodies, and/or other forums);
- The ability to create Notified Body Statements necessary to demonstrate that the assessments have been carried out.

In order to demonstrate Technical Competence, please submit:

[6] *General Liability Insurance* will protect an organization in the event the insured party causes bodily injury or property damage to others and becomes legally obligated to pay damages. Liability for Bodily Injury can occur when a physical injury to a person is caused by third party. Liability for Property Damage can occur when a third party causes direct or indirect damage (such as loss of use of property) to another person's property. *Professional Liability Insurance* is designed to provide coverage for claims arising out of their professional activities or services provided to clients. It is also called *Errors and Omissions Insurance* or E&O.

8. Current valid NVLAP or A2LA accreditation certificate and scope for ISO/IEC 17025 and/or ANSI certificate and scope for ISO/IEC Guide 65. The scope should cover a representative set of appropriate EMC technology for immunity and/or emissions;
9. Current resume for each key technical personnel performing conformity assessment tasks as a Notified Body under the EMC Directive, including dates and describing their background and experience in performing the type of engineering judgment necessary to evaluate technical documentation under the EMC Directive. Each organization will submit documentation for at least two key technical personnel per location. The same personnel may be utilized at more than one location;
10. For each key technical personnel, additional collateral documentation substantiating prior technical education. This may include copies of college and/or university diplomas, NARTE certificates, or other relevant credentials;
11. Policy and procedures for initial and ongoing training of key technical personnel relevant to the EMC Directive;
12. Record of training for key technical personnel demonstrating compliance with documented procedures for initial and ongoing training. Training records should cover the last 12-24 months, including dates. Training should be specific and relevant to the technical requirements, interpretations, guidelines, policies, and harmonized standards of the EMC Directive. Training may include: 1) attendance at relevant events, such as NIST MRA workshops and industry symposiums, conferences, seminars, and meetings; 2) specific internal training (hands-on and/or instructional); 3) frequent reviews of relevant websites, publications, correspondence from NIST; and 4) other documented self study or specific and relevant training;
13. Sample Notified Body Statement of Opinion.

VIII.) Use of Personnel within an Organization at Locations not Designated by NIST as a U.S. CAB

If a Notified Body subcontracts specific tasks connected with the assessment of conformity as it relates to the EMC Directive and its role as a Notified Body, it shall follow the provisions set out in ISO/IEC 17025 and/or Guide 65 with regards to subcontracting.

In addition, a Notified Body may choose to allocate specific tasks connected with the assessment of conformity as it relates to the EMC Directive and its role as a Notified Body to personnel at other location(s) within its organization that have not been designated as a U.S. CAB by NIST. However, a Notified Body shall ensure and be able to sufficiently demonstrate that all provisions in this document are maintained. A Notified Body shall keep all relevant documentation pertaining to this provision on file at the designated location(s), and this information shall be made available to NIST upon request.

This does not release the Notified Body from responsibility for the proper performance of the tasks performed. In particular, a Notified Body shall maintain its responsibility for the determination of conformity and shall have the necessary competence to form an independent assessment of the results of these tasks. A Notified Body Statement shall only be issued by the designated Notified Body. Use of the Notified Body number shall be authorized only by the designated Notified Body.

If applicable, in order to demonstrate compliance with the above provision, please submit:

14. Appropriate policies and procedures to ensure that all provisions within this document are maintained with regard to use of personnel within an organization at locations not designated by NIST as a U.S. CAB;
15. A list of locations where additional personnel are utilized;
16. If available, for each location where personnel are utilized, a current valid accreditation certificate and scope for ISO/IEC 17025 and/or certificate and scope for ISO/IEC Guide 65, and/or EN 45011 and/or the equivalent.

IX.) CAB Declaration

Each organization nominated to be a CAB is required to sign a statement declaring its commitment to the requirements and responsibilities of designation as a U.S. CAB. By signing this declaration, the organization agrees to the terms of the MRA and the terms of designation.[7]

In order to demonstrate compliance with the NIST CAB Declaration, please submit:

17. NIST CAB Declaration, signed and dated by the primary and alternate contacts of the organization;
18. Policy and procedure demonstrating compliance with the NIST CAB Declaration.

[7] This includes electronic signatures when specified by NIST.