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

Radio &Telecommunications Terminal Equipment

July 2009

European Community Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment (the R&TTE Directive) entered into force in April, 1999. The R&TTE Directive applies to all radio equipment irrespective of its intended use and to telecommunications terminal equipment intended to be connected to the public telecommunications networks.[1] The R&TTE Directive outlines "essential requirements", which are mandatory provisions for the protection of the public and the radio spectrum and are designed to ensure a high level of protection. Apparatus is required to comply with the essential requirements referenced in Article 3 of the Directive.

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 review bodies seeking designation under Directive 1999/5/EC and nominate qualified Conformity Assessment Bodies (CABs) to serve as Notified Bodies. Designating Authorities under the MRA have the authority to designate, monitor, suspend, remove the suspension of, or to withdraw CABs.

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.[2] Such U.S. CABs operating under R&TTE Directive 1999/5/EC Annex III, Annex IV, and/or Annex V will be equivalent to other Notified Bodies in the EU or any other country operating under the same directive.

Role of a Notified Body

The Directive allows all products to be placed on the market based on a Supplier's Declaration of Conformity (SDOC). However, there is still a role for a Notified Body, which is outlined in Annexes III, IV and V of the Directive and Section 6.2 and Section 8 in the Guide to the R&TTE Directive 1999/5/EC[3]. A Notified Body under the R&TTE Directive may be designated to perform up to three conformity assessment tasks following the procedures in Annex III, IV, and V of the Directive:

[1] Exceptions are listed in Annex I of the Directive and Section 1.1.3 of the Guide to the R&TTE Directive 1999/5/EC.
[2] U.S. CABs currently designated under the Electromagnetic Compatibility Annex of the MRA will use the same Notified Body number. Newly designated Notified Bodies will receive a new number.
[3] R&TTE Guide: http://www.rtteca.com/Guide_R_TTE_DIR_1999-5-EC_2009-04-20.pdf

1. Annex III – Identify the Essential Radio Test Suites

Annex III (Internal Production Control plus Specific Apparatus Tests) requires that a Notified Body be consulted when the radio test suites considered to be essential are not defined in the harmonized standards. The sole function of the Notified Body is to review, evaluate, and advise the manufacturer of the proper tests that should be performed in order to meet the essential requirements of the Directive. This will require evaluating such items as details of the product for its usage and general parameters and determining any specific requirements of the territory of intended usage (e.g., spectrum allocation, frequency band requirements).

2. Annex IV – Review and Issue Opinions on Technical Documentation

Annex IV (Technical Construction File) requires that a Notified Body be able to review a Technical Construction File (TCF) for apparatus comprising technical documentation, test reports and SDOC and issue an opinion as to whether or not, on the basis of the documentation, the correct testing was performed (see Annex III above) and the requirements of the Directive have been met. The applicant specifies which aspects of the essential requirements the Notified Body is to assess.

3. Annex V – Assess and Perform Periodic Surveillance of Manufacturers' Full Quality Assurance Systems

Annex V (Full Quality Control**)** requires that a manufacturer have its quality system audited by a Notified Body. The Notified Body must be competent to perform a thorough evaluation of a manufacturers quality system per the requirements noted in Annex V of the Directive. Where the manufacturer's quality system, has already been registered by an appropriate Quality organization, the Notified Body will normally not duplicate assessments of compliance with those requirements, but will seek assurance that the Directive-specific issues have been taken into account.

Criteria for Notified Bodies

The general criteria for Notified Bodies are outlined in Annex VI of the Directive. In order to qualify for designation by NIST, a CABs must be located in the United States, must meet the all of the criteria outlined in Annex VI of the Directive, and must meet all of the applicable criteria in this document, depending upon the scope of designation.

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.[4]

It should be noted that a CAB cannot, in its role as a Notified Body: carry out testing; prepare test reports; design equipment; sign or issue a manufacturer's declaration of conformity; act as an agent for the manufacturer; or perform notifications pursuant to Article 6(4) of the Directive.

[4] In some cases a site visit may be necessary.

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

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 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 other words, if a different part of the organization performs any testing or TCF development the organization must be able to show how separation of the functions (supplying test data or developing a TCF vs. review and evaluation of a TCF) occurs such that the person(s) evaluating a TCF are not involved in producing the TCF or any test results being reviewed.

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)[5], 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 radio technology and telecommunications terminal equipment;
- Appropriate knowledge and understanding of interpretations, guidelines, and policies of the European Commission with regard to the R&TTE Directive;
- Thorough knowledge and understanding of, and relevant experience with, the essential requirements of the R&TTE 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;

[5] *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.

- 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 of Opinion necessary to demonstrate that the assessments have been carried out.

In order to demonstrate Technical Competence, please submit:

8. Current valid NVLAP or A2LA accreditation certificate and scope for ISO/IEC 17025 and/or ANSI or A2LA certificate and scope for ISO/IEC Guide 65. The scope should cover a representative set of European radio test methods (transmitter characteristics);
9. Current resume for each key technical personnel performing conformity assessment tasks as a Notified Body under the R&TTE Directive, including dates and describing their background and experience in performing the type of engineering judgment necessary to evaluate technical documentation under the R&TTE 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. Information identifying specific technically competent individuals utilized by the body and describing their background and experience in performing the type of engineering judgements needed to analyze a specific proposal for a product and recommend a proper test suite (Annex III) and review and evaluate technical documentation (Annex IV);[6]
11. 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;
12. Policy and procedures for initial and ongoing training of key technical personnel relevant to the R&TTE Directive;
13. 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 R&TTE 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;
14. Sample Notified Body Statement of Opinion[7].

[6] More specific information on personnel qualifications for Annex V is outlined below in the section on Scope of Designation.

[7] A NB shall issue a Notified Body Opinion 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 Opinion 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 R&TTE Directive. The NB Opinion is not to be confused with the Supplier's Declaration of Conformity (SDOC). The Directive allows all covered products to be placed on the EU market based on a 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 Opinion of the Notified Body to the technical documentation.

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 R&TTE 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 R&TTE 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:

15. 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;
16. A list of locations where additional personnel are utilized;
17. 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. [8]

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

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

X. Scope of Designation

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

In order to demonstrate compliance under **Annex III** of R&TTE Directive 1999/5/EC, please submit:

20) A detailed documented procedure to follow when analyzing a product to determine the proper test suite to recommend.

In order to demonstrate compliance under **Annex IV** of R&TTE Directive 1999/5/EC, an organization must be able to fulfill the conditions noted above for Annex III, plus additional requirements. Please submit:

21) A detailed documented procedure on how to perform TCF evaluations;

22) A detailed documented procedure for training staff to perform TCF evaluations;

23) Information identifying specific technically competent individuals by describing their background and experience in performing the type of engineering judgements needed to evaluate TCFs under the R&TTE Directive including their knowledge of associated requirements (e.g., EMC and/or LVD/safety);

In order to demonstrate compliance under **Annex V** of R&TTE Directive 1999/5/EC, please submit:

24) Evidence of general competence in quality management system operation and basic technical understanding. This can be demonstrated by supplying a current valid certificate of accreditation to ISO/IEC 17021, with a scope covering a representative set of appropriate technology;

25) A detailed documented procedure on how the body performs quality system reviews under the R&TTE Directive;

26) A detailed documented procedure for training staff to perform evaluations of quality management systems under the R&TTE Directive;

27) Information identifying specific technically competent individuals and describing their background and experience in performing the type of judgements needed to perform the functions described above.