



Requirements & Application
for
U.S. Conformity Assessment Bodies
Seeking
Electromagnetic Compatibility (EMC)
Directive 2014/30/EU
Notified Body Status

For questions related to this document, please send your inquiry to mra@nist.gov.

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Section 1: Introduction

Scope

This document identifies the requirements for U.S. conformity assessment bodies (CABs) seeking Notified Body¹ status for the EU **EMC Directive 2014/30/EU - Annex III – Part A (Module B: EU-Type Examination)**.

To be designated by NIST to the European Commission for consideration as a Notified Body for the EMC Directive, the applicant CAB shall demonstrate compliance with the requirements specified in the EMC Directive and in this document.

Notified Body Role

The role of the Notified Body under Module B is to examine a manufacturer's technical documentation and supporting evidence to verify and attest that the technical product design meets the relevant legislative requirements.

For the EMC Directive, the Notified Body examines the technical design of an apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in Annex I (1) of the EMC Directive as follows:

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

The Notified Body then writes an evaluation report (that may be released only upon agreement with the manufacturer), and issues an EU-Type Examination Certificate.

The manufacturer maintains the EU-Type Examination in the technical documentation that supports its Declaration of Conformity.

Under the EMC Directive, use of a Notified Body is voluntary. [Article 14 of the EMC Directive does not identify any circumstances where an EU-Type Examination Certificate is mandatory.]

In the role as Notified Body, the CAB does not test or certify the apparatus (equipment/device).

¹ A Notified Body (NB) is a third-party conformity assessment body notified to perform specific conformity assessment tasks as described in a directive.

NIST Role

The United States is a signatory to telecommunication mutual recognition agreements (Tel MRAs) with the European Union (EU)² and the European Economic Area (EEA) European Free Trade Association (EFTA) States³. NIST serves as the *Notifying Authority*⁴ and is responsible for designating (notifying) to the European Commission qualified U.S. CABs seeking Notified Body status and for monitoring on-going compliance of these Notified Bodies.

Exclusions

The following topics are not addressed in this document:

EMC Directive Module C – EMC Directive Annex III Part B refers to Module C: Conformity to Type based on Internal Production Control. This module is carried out by the manufacturer. This module relies on the EU-Type Examination Certificate provided by the Notified Body.

Radio Equipment Directive: U.S. CABs are eligible to apply for notification as a Notified Body for the European Union’s Radio Equipment Directive (2014/53/EU). The requirements that U.S. CABs must meet to apply under the RED are covered in a separate NIST document.

Disclaimers

In the event there is a discrepancy between the contents of this document and the EMC Directive 2014/30/EU, the EMC Directive takes precedence.

The hyperlinks included in this document were valid at the time of publication. If a hyperlink is broken or no longer points to the correct document, please contact mra@nist.gov for further guidance.

NIST reserves the right to change the requirements for application and notification, and to update this document as needed to reflect the current interpretations of the EMC Directive as issued by the European Commission, the European Union Association of Notified Bodies (EUANB – Group of Notified Bodies for the EMC Directive), and related stakeholder groups.

² Agreement on Mutual Recognition Between the European Community and the United States of America (Telecommunications Equipment and EMC annexes) – 1998

³ Agreement on Mutual Recognition Between the European Community and the European Economic Area (EEA) European Free Trade Association (EFTA) States (Telecommunications Equipment and EMC annexes) – 1998

⁴ The Notifying Authority (NA) notifies NBs to the European Commission. There is an appointed NA in each member state and in each country that has signed a telecom MRA with the EU. Other MRAs utilize the term Designating Authority.

Section 2: Reference Documents

The CAB shall maintain (or have access to) the following documents:

[Blue Guide](#)⁵ - on Implementation of EU Product Rules (2014) – Version 1.1 – July 15, 2015

[EA-2/17 INF:2014](#)⁶ – European Cooperation for Accreditation (EA) Document on Accreditation for Notification Purposes (November 2014 Revision 2; re-published June 2015)

[Electromagnetic Compatibility Directive](#)⁷ 2014/30/EU

Guide for the EMC Directive 2014/30/EU *(As of 11/15/2015, this document is not yet published by the Commission)*

[Technical Guidance Notes issued by the EUANB](#)⁸ (Hosted on the RED CA website)

[List of Harmonized Standards applicable for the EMC Directive](#)⁹ as published in the Official Journal of the European Union. *(This link is to the list of Harmonized Standards for the current EMC Directive. Please be sure to use the updated list provided for EMC Directive 2014/30/EU as soon as it is made available.)*

[Low Voltage Directive](#)¹⁰ 2014/35/EU

⁵ <http://ec.europa.eu/DocsRoom/documents/12661>

⁶ <http://www.european-accreditation.org/publication/ea-2-17-inf>

⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_096_R_0079_01&qid=1396511671603&from=EN

⁸ http://www.rtteca.com/html/download_area.htm

⁹ http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/electromagnetic-compatibility/index_en.htm

¹⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_096_R_0357_01&from=EN

Section 3: Application Process

The CAB shall obtain accreditation in accordance with the requirements included in *Section 4, Accreditation for Notified Body Activities*.

The CAB shall submit the NB Application Form (refer to Appendix I) and the supporting documents to NIST at mra@nist.gov.

The CAB's supporting documents, including policies and procedures, shall contain the CAB's unique information on how the requirements contained in the EMC Directive are being met by the CAB through specific references and adequate detail.

NIST will review CAB application documents in the order in which they are received.

If the supporting documents are incomplete and/or do not address all requirements, NIST will notify the CAB of the elements that still need to be addressed and will place the application on hold until additional information is provided.

NIST will process a notification to the European Commission for qualified organizations that have demonstrated that all requirements have been met. The European Commission conducts a review of all notifications.

A CAB becomes a Notified Body only once the information on the Notified Body's name and the tasks for which the Notified Body has been notified are published on the public

New Approach Notified and Designated Organizations (NANDO) website:
<http://ec.europa.eu/enterprise/newapproach/nando/index.cfm>

CABs that successfully obtain Notified Body status must continue to meet the requirements of the EMC Directive and this document.

A periodic renewal of the notification is required. Refer to *Section 9, Maintaining Notified Body Status*.

Section 4: Accreditation for Notified Body Activities

The CAB shall obtain formal accreditation for its Notified Body activities.

Acceptable Accreditation Bodies

NIST will maintain a list of U.S. accreditation bodies (ABs) that have been evaluated to ensure that the assessment and accreditation process meets requirements to support the accreditation of Notified Bodies for the purposes of notification. Refer to *Section 10, Accreditation Body Requirements*.

CABs shall use an accreditation body included on the NIST list of U.S. accreditation bodies acceptable for Notified Body accreditation for the purposes of notification.

Preferred Basic Conformity Assessment Standards: ISO/IEC 17020 or ISO/IEC 17065

The [Blue Guide](#) identifies the following two basic conformity assessment standards as most appropriate¹¹ for Module B assessment: ISO/IEC 17020 and ISO/IEC 17065.

[EA-2/17 INF: 2014](#)¹² further specifies that for Module B, supplemental (secondary basic standard requirements) apply as follows:

Option I: ISO/IEC 17065 plus the following secondary basic standard requirements

- ISO/IEC 17025 Clause 5
- ISO/IEC 17020 Clauses 6.1.2, 6.1.3 and 6.1.6 to 6.1.10
(Ability to make professional judgments related to product requirements where required.)

Option II: ISO/IEC 17020 plus the following secondary basic standard requirements

- ISO/IEC 17025 Clause 5

CABS accredited to ISO/IEC 17020 or ISO/IEC 17065 that wish to seek NB status can apply to NIST under the process covered in EMC Directive Article 27.2. The notification process is simplified in this case, with minimal information having to be forwarded to the Commission. The Commission's decision will normally take two weeks if there are no objections from Member States.

¹¹ Blue Guide (2015), Section 10.6 – Annex 6 – 3.2 (Module B), page 129

¹² EA Document on Accreditation For Notification Purposes (3.1, page 6): <http://www.european-accreditation.org/publication/ea-2-17-inf>

Other Basic Conformity Assessment Standard: ISO/IEC 17025

EA-2/17 INF: 2014 also includes basic conformity assessment standard ISO/IEC 17025 under Module B (with the following additional secondary basic standard requirements):

Option III: ISO/IEC 17025 plus the following secondary basic standard requirements

- ISO/IEC 17065 Clauses 4.1, 7.5 and 7.6
(Capability of and procedures for judging and deciding based on results of tests, if the essential requirements are fulfilled and / or the Harmonized Standards have been applied when required.)

CABs accredited to ISO/IEC 17025 (only) that wish to seek NB status must follow an alternative path for notification since this basic conformity assessment standard is not considered sufficient on its own for Module B (per the Blue Guide). The alternative path is described in Article 27.3 of the EMC Directive. The alternative path includes the following additional steps:

- Submittal of key NB application documentation by NIST to the Commission for review by Member States
- Longer Commission decision process for initial NB notification (two months if no objections are expressed by Member States after review of NB information)
(EMC Directive Article 28.5)

The continued formal ISO/IEC 17025 accreditation ensures that the NB will be monitored regularly. (EMC Directive Article 28.4)

Under this option, NIST requires that the ISO/IEC 17025 Scope of Accreditation contains the NB activities and reference to EA 2/17 INF: 2014 (*as long as this document references ISO/IEC 17025 for Module B*). Refer to EA 2/17 Annex A, *Description of the Accreditation Scope of Notified Bodies*.

Technical Competency Assessment

The technical competency assessment of NBs is the same regardless of the basic conformity assessment standard used. The technical assessment will include use of the *NIST NB Assessment Checklist (EMC Directive)*.

Scope of Accreditation

The CAB's Scope of Accreditation shall cover the Notified Body activities.¹³

The publicly available Scope of Accreditation shall include at least the following information:

- (a) The basic conformity assessment standard (ISO/IEC 17020, ISO/IEC 17065, or ISO/IEC 17025) which is used as reference and applied in full for the accreditation of the CAB.
- (b) A reference to EA-2/17 INF: 2014 (or most current version) to confirm that the NB complies with the additional requirements stated therein, and to confirm that the accreditation may be considered suitable for notification purposes;
- (c) Identification of the directive (EMC Directive 2014/30/EU)
- (d) Identification of the conformity assessment procedure used (Module B)
- (e) products/category – family – homogeneous groups of products [refer to Article 24.6]

Examples of categories of apparatus include:

Telecom Terminal Equipment
Power supplies
Micro-controllers
PC cards

Note: Equipment regulated by other EU Directives covering EMC do not fall under the EMC Directive and should not be listed in the products/category section of the Scope of Accreditation.

¹³ EA 2/17 INF: 2014 – Annex A (pages 9 and 10)

Section 5: Assessment Tools

NIST NB Assessment Checklist (EMC Directive)

NIST NB Assessment Checklist

NIST has developed a ***NB Assessment Checklist - EMC Directive*** that contains (1) the EMC Directive normative requirements and (2) any additional NIST requirements applicable to the Notified Bodies.

Accreditation Bodies shall use the NIST ***NB Assessment Checklist – EMC Directive*** to document the compliance information obtained during the on-site assessment.

Section 6: EMC Directive and NIST Requirements for Notified Bodies

The articles and annexes of the EMC Directive that are specific to Notified Bodies have been reproduced (presented in order in which these appear in the EMC Directive). In some cases, it has been necessary for NIST to specify an additional requirement or to clarify an article.

These requirements are also reproduced in the NIST *NB Assessment Checklist – EMC Directive*.

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EMC Directive - ARTICLE 6

Essential Requirements

The equipment shall meet the essential requirements set out in Annex I.

NIST Requirement: The CAB shall demonstrate appropriate knowledge of the essential requirements in Annex I.

EMC Directive ANNEX I

1. General requirements

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

- (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
- (b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

2. Specific requirements for fixed installations

Installation and intended use of components

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the essential requirements set out in point 1.

EMC Directive - ARTICLE 24

Requirements Relating to Notified Bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law of a Member State and have legal personality.

NIST Requirement: A U.S. CAB seeking notification as an NB shall be a legal entity in the United States.

3. A conformity assessment body shall be a third-party body independent of the organization or the apparatus it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of apparatus which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the apparatus which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed apparatus that are necessary for the operations of the conformity assessment body or the use of such apparatus for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those apparatus, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity

assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex III and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of apparatus in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.

A conformity assessment body 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 or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonized standards and of the relevant provisions of Union harmonization legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for *the conformity assessment*.

NIST Requirement: A Notified Body shall have Civil Liability Insurance (in the United States, this is also known as *professional liability insurance* or *errors and omissions insurance*), 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.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex III or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonization legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group

NIST Requirement: The CAB (or one of its related bodies located in the United States) shall maintain membership in the EUANB.

EMC Directive - ARTICLE 26

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex III.

EMC Directive –ARTICLE 32

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex III.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigor and the level of protection required for the compliance of the apparatus with this Directive.

3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonized standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate.
4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an apparatus no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

EMC Directive - ARTICLE 34

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:
 - (a) any refusal, restriction, suspension or withdrawal of a certificate;
 - (b) any circumstances affecting the scope of or conditions for notification;
 - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same apparatus with relevant information on issues relating to negative and, on request, positive conformity assessment results.

EMC Directive - ARTICLE 36

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

NIST Comment: Refer to additional NIST Requirement under Article 24.11 – membership in the EUANB is required.

EMC Directive - Annex III – Part A

Module B: EU-type examination

ANNEX III

PART A

Module B: EU-type examination

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in point 1 of Annex I.
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation referred to in point 3, without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified by the manufacturer or his authorised representative.
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall specify the aspects of the essential requirements for which examination is requested and shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation. The technical documentation shall make it possible to assess the apparatus conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation shall contain, wherever applicable, at least the following elements:

(i) a general description of the apparatus;

(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;

(iv) a list of the harmonized standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonized standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonized standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out, etc.;

(vi) test reports.

4. The notified body shall examine the technical documentation to assess the adequacy of the technical design of the apparatus in relation to the aspects of the essential requirements for which examination is requested.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive that apply to the apparatus concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured apparatus with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.

10. The manufacturer's authorized representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

EMC Directive - ANNEX IV

EU DECLARATION OF CONFORMITY (No Xxx)

NIST Requirement: The CAB shall demonstrate knowledge of the required content of the EU Declaration of Conformity (DoC)

1. Apparatus model/Product (product, type, batch or serial number):
 2. Name and address of the manufacturer or his authorised representative:
 3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
 4. Object of the declaration (identification of apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus):
 5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
 6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
 7. Where applicable, the notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
 8. Additional information:
- Signed for and on behalf of:
- (place and date of issue):
- (name, function) (signature):

Section 7: Technical Competency Requirements

The CAB personnel shall demonstrate technical competency during the on-site assessment conducted by the accreditation body. The areas of knowledge assessed will include (but are not limited to) the topics listed in the table below:

Area of Knowledge
A correct understanding of the EMC Directive
A correct understanding of the Scope of the EMC Directive and exclusions
A correct understanding of the role of the Notified Body
A working knowledge of the CENELEC ¹⁴ standards system
An understanding of the Essential Requirements in Annex I of the Directive
A working knowledge of Electromagnetic Compatibility requirements
Correct understanding of the harmonized standards listed in the Official Journal of the European Union (OJEU ¹⁵)
Understanding of the meaning of and use of the <i>Date of cessation of presumption of conformity</i>
Understanding of what the manufacturer obligations are under the EMC Directive – Article 7 – all
Understanding of what an EU Declaration of Conformity must include
Knowledge of how to conduct a review of the technical construction file information
Knowledge of what information is to be included in the NB report that supports the EU Type Examination Certificate
Knowledge of how to prepare an EU Type Examination Certificate (contents)
Familiarity with the Technical Guidance Notes and REFDOCs published by the EUANB

Other related technical issues/topics may be assessed as deemed appropriate by the assessor(s).

¹⁴ CENELEC: <http://www.cenelec.eu/>

¹⁵ http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/electromagnetic-compatibility/index_en.htm (to be updated when new EMCD list is available).

Section 8: Notifying Authority Obligations

NIST, as the notifying authority of U.S. CABs, must meet the requirements set out in Articles 21, 22, 23 and 30 of the EMC Directive.

The relevant articles of the EMC Directive that are specific to the notifying authority have been reproduced in this Section. In some cases, NIST has provided additional information.

EMCD ARTICLE 21

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.

NIST: NIST fulfills the role as the notifying authority under the terms of the relevant mutual recognition agreements. Refer to *Section 1, Introduction*.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

NIST: The assessment of the CABs seeking Notified Body status shall be carried out by U.S. accreditation bodies that have been deemed competent to assess the notified bodies. The monitoring of notified bodies is carried out by both the accreditation bodies and NIST.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity; that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 22. In addition it shall have arrangements to cover liabilities arising out of its activities.

NIST: Refer to Section 10 (c).

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

EMCD ARTICLE 22

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organized and operated so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organized in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

NIST: The assessment shall be carried out by the accreditation bodies and the notification shall be carried out by NIST.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

EMCD ARTICLE 23

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

NIST: This NIST document reflects the NIST procedures for the assessment, notification, and monitoring of Notified Bodies. This document is available to the public.

EMCD ARTICLE 30

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Section 9: Maintaining Notified Body Status

Notified Bodies are subjected to on-going monitoring and surveillance by the responsible accreditation body and NIST to ensure continued compliance with these requirements.

To maintain Notified Body status, the Notified Body shall:

- Maintain accreditation for Notified Body activities
- Comply with reporting requirements to the notifying authority (NIST)
- Cooperate with other Notified Bodies in accordance with the directive requirements
- Notify NIST of any contact from the market surveillance authorities in the Member States within 30 days.
- Cooperate with market surveillance authorities in the Member States.
- Maintain membership in and stay up-to-date with the EUANB.
- Stay up-to-date with standardization activities and monitor the state of the art
- Maintain technical competence of staff for Notified Body activities
- Maintain required liability insurance per EMCD Article 24.9
- Renew the Notified Body status as required

Notified Bodies in the United States shall renew their Notified Body status through re-application to NIST.

The renewal process will be initiated by NIST in advance of the notification expiration assigned to the NB and identified in the New Approach Notified and Designated Organizations (NANDO) website.

NIST will provide the Notified Body with instructions for the renewal.

This information requested by NIST in support of re-notification will not exceed the requirements noted in this document unless additional issues have been brought to NIST's attention. These additional issues will also need to be addressed by the Notified Body.

Section 10: Accreditation Body Requirements

List of Accreditation Bodies

NIST will maintain a list of U.S. accreditation bodies (ABs) that have been evaluated to ensure that the assessment and accreditation process meets requirements to support the accreditation of Notified Bodies for the purposes of notification.

Accreditation Body Qualifications

To be eligible for inclusion on the NIST list of accreditation bodies (AB) acceptable for Notified Body accreditation for the purposes of notification, the following qualifications shall be demonstrated and met:

- (a) The AB shall be NIST [NVCASE recognized](#) or [NIST Listed](#).

These ABs are located in the United States, are signatories in good standing to an accreditation body peer organization mutual recognition arrangement, and have met the requirements specified in the referenced NIST programs.

- (b) The AB shall ensure that the assessment of the Notified Bodies is conducted in accordance with the requirements of the EMC Directive, EA 2/17 and this document.
- (c) Per Article 21 (3) of the EMC Directive, the AB shall have arrangements to cover liabilities arising out of its activities.
- (d) The AB assessors shall be technical competent to assess Notified Bodies and shall participate in available training on conducting Notified Body assessments.

The AB assessors shall be knowledgeable about EMC Directive interpretations issued by the EUANB and consider these interpretations during the on-site assessment as part of the technical requirements competency assessment (Refer to *Section 7, Technical Competency Requirements*).

Submittal of Documents to NIST

The AB shall submit relevant documents to NIST (mra@nist.gov) as evidence that the qualifications above are met.

The AB shall identify the names, qualifications, and training records of the assessors that will be used to conduct the assessments of Notified Bodies.

The AB shall address and resolve any issues raised by NIST regarding the AB's qualifications prior to being included on the NIST list.

Section 11: Document Control

The revision history of this document is maintained below.

Version	Date Issued	Status	Details
V1.0	11/15/2015	FINAL	Initial Release

Appendix I: NB Application Form – EMC Directive

Instructions: Please complete the NB Application Form and submit it along with all supporting documents to NIST via mra@nist.gov.

Part I: General Information

Name of CAB	
Address of main location applying for Notification	
Primary Contact ¹⁶ Name	
Primary Contact E-mail	
Primary Contact Phone Number	
Alternate Contact ¹⁷ Name	
Alternate Contact E-mail	
Name of Person Completing the Application Form	
Signature of Person Completing the Application Form	
Date Completed	

Reserved for CAB comments/other information:

¹⁶ Primary Contact: This person must sign the separate NIST CAB Declaration Form noted in Part II (1) below

¹⁷ Alternate Contact: This person must sign the separate the NIST CAB Declaration Form noted in Part II (1) below.

Part II: Supporting Documents

Please submit the following documents electronically.

	Document	CAB Document Name <u>and</u> page (or other) references
1	NIST CAB Declaration Form signed by the Primary and Alternate Contacts	
2	Section 4 Scope and Certificate of Accreditation	
3	EMCD Article 24.4 Organizational chart that includes all other related bodies/legal entities, <u>along with</u> a description of all types of activities undertaken by the CAB and each other related body/legal entity <u>and</u> a written explanation of how the CAB complies with all three paragraphs of 24.4	
4	EMCD Article 24.6 (b) Procedure to distinguish the CAB's NB tasks and all other types of activities	
5	EMCD Article 24.6 (a) and 24.7 List of all personnel performing NB conformity assessment tasks <u>and</u> a description of their experience and training for NB competency, addressing specifically Articles 24.6 (a) and 24.7 for the essential requirements contained in Annex I	
6	EMCD Article 24.7 and 24.11 Procedure describing how the CAB will maintain NB personnel competence for the elements noted in Article 24.7 and maintains knowledge of the activities noted in 24.11.	
7	EMCD Article 24.9 Valid copy of the current insurance policy as evidence that the CAB has obtained Professional Liability Insurance or Errors and Omissions Insurance. <i>Note: NIST maintains a database of CAB (NB) insurance policy validity dates and requires submittal of an</i>	

	<i>updated, valid copy of the insurance policy when the previous policy has expired.</i>	
8	EMCD Article 34 Procedure addressing Article 34 information obligations (1 to 2) and Annex III information obligations (See Annex III, Module B, 8)	
9	EMCD Annex III – Module B Procedures addressing the full process followed by the CAB for Module B (EU-Type Examination – See Annex III, Part A, Module B)	
10	EMCD Annex III – Module B - 5 Example evaluation report	
11	EMCD Annex III – Module B - 6 Example EU Type Examination Certificate	
12	Example of contract signed by the CAB's client(s) for NB services. <i>Note: Please address all elements requiring release of relevant information to NIST, other NBs, Member States, and Market Surveillance Authorities as specified in the directive and information requirements that the NB is imposing on the manufacturer (reporting of modifications, for example)</i>	

In accordance with Article 22.5 of the EMCD, NIST will maintain the confidentiality of all information received.

Part III: Attestation and Signature of Primary Contact

The CAB's Primary Contact is responsible for ensuring that the CAB complies at all times with the conditions and requirements to apply for and maintain NB status.

I agree with the conditions and requirements specified in NIST CAB Declaration and the NIST document titled *Requirements and Application for U.S. Conformity Assessment Bodies Seeking EU EMC Directive 2014/30/EU Notified Body Status*.

In the event that NIST requires access to additional accreditation documents or information (such as the Assessment Report, Deficiency Report, corrective action responses, and assessment checklists utilized), my organization will authorize the release of such information.

I agree that all the statements made in the supporting documents submitted with this NB Application Form are correct to the best of my knowledge and are made in good faith.

Date	
Name of CAB	
Signature of Primary Contact	
Printed name of Primary Contact	