

NIST Notified Body (NB) Assessment Checklist – Radio Equipment Directive (RED)

November 15, 2015 (Version 1.0)

Checklist to Assess U.S Conformity Assessment Bodies (CABs) for Compliance to the EU Radio Equipment Directive (RED) 2014/53/EU Notified Body Requirements Annex III (Module B) – EU Type Examination

1. For the complete list of requirements that must be met in order to be designated (notified) to the EU, please refer to the following document: *NIST Requirements and Application Instructions for U.S. Conformity Assessment Bodies – Notified Body Status for the EU Radio Equipment Directive (Version 1.0)*
2. This NIST **NB Assessment Checklist for the Radio Equipment Directive** should be utilized in conjunction with the *Assessment Guide*¹, which contains technical competency guidance.
3. The first column of this checklist identifies the Radio Equipment Directive requirements (specific to NBs) and **additional NIST requirements** (where needed). The first column also identifies the reference to the relevant clause of the EA 2/17 INF: 2014 cross reference table of the requirements on Decision (EC) 768/2008 and the applicable basic conformity assessment standards.
4. The second column of this checklist provides a place for the CAB to identify the relevant document reference within its quality system (policies, procedures, or other documents as required) that demonstrates compliance.
5. The 3rd, 4th, 5th columns of this checklists are used to indicate whether the CAB meets the particular clause (YES, N/A, NO).
6. The 6th column of this checklist should be used by the Accreditation Body (AB) assessor(s) to record comments.
7. If the CAB is being assessed to both the Radio Equipment Directive and the EMC Directive, the assessor must complete **this checklist** in full and the relevant portions of the *NIST NB Assessment Checklist for the EMC Directive* marked with an “*” in the first column.

¹ RED Notified Body Accreditation/Notification Assessment Guide Document (V1.0c)

Abbreviations:

ADCO	The Administrative Co-operation Working Group
CENELEC	European Committee for Electrotechnical standardization
CEPT	European Committee for Post and Telecommunications
ECO	European Communications Office
EFIS	ECO Frequency Information System
EMCD	Electromagnetic Compatibility Directive 2014/30/EU
EMC WP	EMC Working Party
ETSI	European Telecommunications Standards Institute
LVD	Low Voltage Directive 2014/35/EU
OJEU	Official Journal of the European Union
REFDOCS	Reference Documents issued by the RTTA CA
SRDOCS	ETSI System Reference Documents
TCAM	Telecommunications Conformity Assessment and Market Surveillance Committee
TGNs	Technical Guidance Notes

Table of Contents

NB ASSESSMENT CHECKLIST – CAB INFORMATION	5
GENERAL REQUIREMENTS	6
5.1 LEGAL & CONTRACTUAL.....	6
5.2 IMPARTIALITY	6
5.3 LIABILITY & FINANCING.....	9
5.4 IDENTIFICATION OF NOTIFIED BODY.....	9
STRUCTURAL REQUIRMENTS	10
6.1 ROLE AS NOTIFIED BODY	10
6.2 COOPERATION	11
RESOURCES	12
7.1 PERSONNEL	12
7.2 EQUIPMENT	16
7.3 OUTSOURCING.....	17
INFORMATION REQUIREMENTS & CONFIDENTIALITY.....	18
8.1 INFORMATION REQUIREMENTS.....	18
8.2 CONFIDENTIALITY.....	19

PROCESS REQUIRMENTS.....	19
9.1 GENERAL.....	19
9.2 SCOPE OF ACTIVITIES.....	20
9.3 OPERATIONAL OBLIGATIONS.....	20
9.4 CONFORMITY ASSESSMENT CRITERIA.....	22
9.5 PREPARATION FOR ASSESSMENT AND CONTRACT REVIEW.....	22
9.6 ASSESSMENT OF RADIO EQUIPMENT CONFORMITY.....	23
ANNEX III: MODULE B.....	24
ANNEX V: CONTENTS OF TECHNICAL DOCUMENTATION.....	29
ANNEX VI: EU DECLARATION OF CONFORMITY.....	31
ANNEX VII: SIMPLIFIED EU DECLARATION OF CONFORMITY.....	32

NB ASSESSMENT CHECKLIST – CAB INFORMATION

CAB Name	
CAB Location	
<p>Identify Applicable Directives</p> <ul style="list-style-type: none"> - Select one of the options and complete the appropriate checklist(s) as noted in the instructions. 	<p>___ Radio Equipment Directive Only</p> <p>Instructions: Complete this checklist in full.</p>
	<p>___ Radio Equipment Directive and EMC Directive</p> <p>Instructions:</p> <ul style="list-style-type: none"> - Complete <i>this checklist</i> in full; and - Complete selected portions of the <i>NIST NB Assessment Checklist for the EMC Directive</i> marked with an * in the first column.
Date(s) of the Assessment	
Assessment Type (New or Renewal)	
Assessment Location (On-Site or Remote)	
Name of the Assessor(s)	
Assessor Signature (s)	

NB Assessment Checklist – Radio Equipment Directive

Knowledge Area / Requirement	NB Reference Document	Y	N A	N	Assessor Notes
GENERAL REQUIREMENTS					
5.1 LEGAL & CONTRACTUAL					
<p>RED Art. 26.2</p> <p>A conformity assessment body (CAB) shall be established under the national law of Member State and have legal personality in the United States.</p> <p><i>NIST Requirement: U.S. CAB seeking notification as an NB shall be a legal entity in the United States.</i></p> <p>(EA 2/17, 5.1.1)</p>					
5.2 IMPARTIALITY					
<p>RED Art. 26.3</p> <p>A CAB shall be a third-party body independent of the organisation or the radio equipment it assesses.</p> <p>(EA2/17 5.2.1)</p>					

<p>RED Art. 26.4 (1st Para)</p> <p>A CAB, 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 radio equipment which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed radio equipment that is necessary for the operation of the conformity assessment body or the use of such radio equipment for personal purposes.</p> <p>(EA 2/17 5.2.2)</p>					
<p>RED Art. 26.4 (2nd Para)</p> <p>A CAB, 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 that radio equipment, 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.</p> <p>(EA 2/17 5.2.2)</p>					

<p>RED Art. 26.4 (3rd Para)</p> <p>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.</p> <p>(EA 2/17 5.2.4)</p>					
<p>RED Art. 26.5</p> <p>CABs 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.</p> <p>(EA2/17 5.2.5)</p>					
<p>RED Art. 26.8</p> <p>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.</p> <p>The remuneration of the top level management and personnel responsible</p>					

<p>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.</p> <p>(EA2/17 5.2.5)</p>					
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5.3 LIABILITY & FINANCING

<p>RED Art. 26.9</p> <p>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.</p> <p><i>NIST Requirement: The Notified Body shall have professional liability insurance or errors and omissions insurance in an amount that is sufficient in coverage to protect the NB from lawsuits arising from its activities.</i></p> <p>(EA2/17 5.2.5)</p>	<p>Just added – add to requirements document also</p>				
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5.4 IDENTIFICATION OF NOTIFIED BODY

<p>RED Art. 20.3</p> <p>The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Annex IV is applied.</p>					
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<p>The identification number of the notified body shall have the same height as the CE marking.</p> <p>The identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative.</p> <p>NIST Requirements: <i>The CAB shall be aware of when the NB number should be applied to the label. The NB number shall not be applied to the label under Module B.</i></p> <p>(EA 2/17 5.4.1)</p>					
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STRUCTURAL REQUIRMENTS

6.1 ROLE AS NOTIFIED BODY

<p>RED Art. 26.6 (1st para + b)</p> <p>A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by <u>Annexes III and IV</u> 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. The CAB shall have at its disposal the necessary:</p> <p>(b) descriptions of procedures in accordance with which conformity</p>					
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<p>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.</p> <p>(EA 2/17 6.1.1)</p>					
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6.2 COOPERATION

<p>RED Article 26.11</p> <p>Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, <u>the relevant standardisation activities, the regulatory activities in the area of radio equipment and frequency planning, and the activities of the notified body coordination group</u> established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.</p> <p><i>NIST Requirement: The CAB (or one of its related bodies located in the United States) shall maintain membership in the Radio Equipment Directive Compliance Association (RED CA).</i></p>					
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(EA 2/17 6.2.1)					
RESOURCES					
7.1 PERSONNEL <i>The depth of knowledge of the CAB's technical personnel shall be assessed based on the technical elements listed in the NIST Program Requirements (Section XXXX) and the Assessment Guide – Section 7.1</i>					
<p>RED Art. 26.6 (1st para + a)</p> <p>A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV 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. The CAB shall have at its disposal the necessary:</p> <p>(a) Personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks.</p> <p>(EA 2/17 7.1.1)</p>					

<p>RED Art. 26.7 (a-d)</p> <p>The personnel responsible for carrying out conformity assessment tasks shall have the following:</p> <p>(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;</p> <p>(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;</p> <p>(c) appropriate knowledge and understanding of the essential requirements set out in Article 3, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;</p> <p><i>[NIST Comment – See Article 3 below.]</i></p> <p>(d) the ability to draw up EU-type examination certificates or quality system approvals, records and reports demonstrating that assessments have been carried out.</p> <p>(EA 2/17 7.1.2)</p>					
<p>RED Article 3</p> <p><i>NIST Requirement: The CAB shall demonstrate appropriate knowledge of</i></p>					

<p><i>all essential requirements in Article 3 as follows:</i></p>					
<p>RED Art. 3.1</p> <p>Radio equipment shall be constructed so as to ensure:</p> <ul style="list-style-type: none"> a) the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying; b) an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU. 					
<p>RED Art. 3.2</p> <p>Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.</p>					
<p>RED Art. 3.3</p> <p>Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:</p>					

<ul style="list-style-type: none"> a) radio equipment interworks with accessories, in particular with common chargers; b) radio equipment interworks via networks with other radio equipment; c) radio equipment can be connected to interfaces of the appropriate type throughout the union; d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; f) radio equipment supports certain features ensuring protection from fraud; g) radio equipment supports certain features ensuring access to emergency services; h) radio equipment supports certain features in order to facilitate its use by users with a disability; i) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the 					
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<p>compliance of the combination of the radio equipment and software has been demonstrated.</p> <p>The Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories or classes of radio equipment are concerned by each of the requirements set out in points (a) to (i) of the first subparagraph of this paragraph.</p>					
<p>7.2 EQUIPMENT</p>					
<p>RED Art. 26.6 (1st para + last para)</p> <p>A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV 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.</p> <p>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.</p> <p>(EA 2/17 7.2.1)</p>					

7.3 OUTSOURCING

RED Art. 28.1
 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 26 and shall inform the notifying authority accordingly.
 (EA 2/17 7.3.1)

RED Art. 28.2
 Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
 (EA 2/17 7.3.2)

RED Art. 28.3
 Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
 (EA 2/17 7.3.3)

RED Art. 28.4
 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or

<p>the subsidiary and the work carried out by them under Annexes III and IV. (EA 2/17 7.3.4)</p>					
<p>INFORMATION REQUIREMENTS & CONFIDENTIALITY</p>					
<p>8.1 INFORMATION REQUIREMENTS</p>					
<p>RED Art. 36.1 Notified bodies shall inform the notifying authority of the following: (a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval in accordance with the requirements of Annexes III and IV; (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. (EA 2/17 8.1.1)</p>					
<p>RED Art. 36.2</p>					

<p>Notified bodies shall, in accordance with the requirements of Annexes III and IV, provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same categories of radio equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.</p> <p>(EA 2/17 8.1.2)</p>					
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8.2 CONFIDENTIALITY

<p>RED Art. 26.10</p> <p>The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes III and IV or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.</p> <p>(EA 2/17 8.2.1)</p>					
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PROCESS REQUIRMENTS

9.1 GENERAL

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<p>RED Art. 26.6 (1st para + para c)</p> <p>A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV 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.</p> <p>(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 radio equipment technology in question and the mass or serial nature of the production process.</p> <p>(EA 2/17 9.1.2)</p>					
<p>9.2 SCOPE OF ACTIVITIES – Intentionally left blank in EA 2/17</p>					
<p>9.3 OPERATIONAL OBLIGATIONS</p>					
<p>RED Art. 34.1</p> <p>Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III and IV.</p> <p>(EA 2/17 9.3.1)</p>					
<p>RED Art. 34.2</p>					

<p>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 radio equipment technology in question and the mass or serial nature of the production process.</p> <p>In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the radio equipment with this Directive.</p> <p>(EA 2/17 9.3.2)</p>					
<p>RED Art. 34.3</p> <p>Where a notified body finds that the essential requirements set out in Article 3 or corresponding harmonised 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 an EU-type examination certificate or a quality system approval.</p> <p>(EA 2/17 9.3.3)</p>					
<p>RED Art. 34.4</p> <p>Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality</p>					

<p>system approval, a notified body finds that radio equipment no longer complies; it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate or the quality system approval if necessary.</p> <p>(EA 2/17 9.3.4)</p>					
<p>RED Art. 34.5</p> <p>Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates or quality system approvals, as appropriate.</p> <p>(EA 2/17 9.3.5)</p>					
<p>RED Art. 36.3</p> <p>Notified bodies shall fulfil information obligations under Annexes III and IV.</p> <p><i>[NIST Comment: As applicable only – not all NBs will seek Annex IV notification.]</i></p> <p>(EA 2/17 9.3.1)</p>					
<p>9.4 CONFORMITY ASSESSMENT CRITERIA Intentionally left blank in EA 2/17</p>					
<p>9.5 PREPARATION FOR ASSESSMENT AND CONTRACT REVIEW Intentionally left blank in EA 2/17</p>					

9.6 ASSESSMENT OF RADIO EQUIPMENT CONFORMITY

RED Art. 10.2

Manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.

NIST Requirement: The CAB shall demonstrate their understanding of this requirement.

RED Art. 10.8

Manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended.

Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

NIST Requirement: The CAB shall demonstrate their understanding of this requirement.

<p>RED Art. 10.10</p> <p>In cases of restrictions on putting into service or of requirements for authorisation of use, information available on the packaging shall allow the identification of the Member States or the geographical area within a Member State where restrictions on putting into service or requirements for authorisation of use exist. Such information shall be completed in the instructions accompanying the radio equipment.</p> <p><i>NIST Requirement: The CAB shall demonstrate their understanding of this requirement.</i></p>					
<p>ANNEX III: MODULE B</p> <p>Annex III, Module B.1 and B.2</p> <p>1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.</p> <p>2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).</p>					
<p>Annex III Module B.3</p> <p>The application shall include:</p>					

<p>(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;</p> <p>(b) a written declaration that the same application has not been lodged with any other notified body;</p> <p>(c) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's 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 radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;</p> <p>(d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.</p>					
Annex III Module B.4					

<p>The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the radio equipment.</p>					
<p>Annex III Module B.5</p> <p>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 as provided in point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.</p>					
<p>Annex III Module B.6</p> <p>Where the type meets the requirements of this Directive that apply to the radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain:</p> <ol style="list-style-type: none"> 1. the name and address of the manufacturer 2. the conclusions of the examination 3. the aspects of the essential requirements covered by the examination 4. the conditions (if any) for its validity and 5. the necessary data for identification of the assessed type. <p>The EU-type examination certificate may have one or more annexes attached.</p>					

<p>6. The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control.</p> <p>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.</p>					
<p>Annex III Module B.7</p> <p>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.</p> <p>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 radio equipment 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.</p>					
<p>Annex III Module B.8</p>					

<p>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.</p> <p>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.</p> <p>Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the Official Journal of the European Union have not been applied or not been fully applied.</p> <p>The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto.</p> <p>On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.</p>				
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<p>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 for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.</p>					
<p>Annex III Module B.9</p> <p>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 radio equipment has been placed on the market.</p>					
<p>Annex III Module B.10</p> <p>The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9 [above], provided that they are specified in the mandate.</p>					
<p>ANNEX V: CONTENTS OF TECHNICAL DOCUMENTATION</p> <p>The technical documentation shall, wherever applicable, contain at least the following elements:</p>					
<p>(a) a general description of the radio equipment including:</p> <p>(i) photographs or illustrations showing external features, marking and internal layout;</p>					

(ii) versions of software or firmware affecting compliance with essential requirements; (iii) user information and installation instructions;					
(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;					
(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment;					
(d) a list of the harmonised 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 harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;					
(e) copy of the EU declaration of conformity;					
(f) where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;					
(g) results of design calculations made, examinations carried out, and other relevant similar elements;					
(h) test reports;					

(i) an explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10).					
ANNEX VI: EU DECLARATION OF CONFORMITY					
<i>NIST Requirement: The CAB shall demonstrate knowledge of the required content of the EU Declaration of Conformity (DoC) as follows:</i>					
1. Radio equipment (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 the radio equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the radio equipment):					
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: Directive 2014/53/EU Other Union harmonisation legislation where applicable					

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared. References must be listed with their identification number and version and, where applicable, date of issue:					
7. Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the EU-type examination certificate: ...					
8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:					
9. Additional information: Signed for and on behalf of: ... (place and date of issue): (name, function) (signature):					
ANNEX VII: SIMPLIFIED EU DECLARATION OF CONFORMITY					
<i>NIST Requirement: The CAB shall demonstrate knowledge of the required content of the simplified EU Declaration of Conformity (DoC) as follows:</i>					
The simplified EU declaration of conformity referred to in Article 10(9) shall be provided as follows:					

<p>Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/53/EU.</p> <p>The full text of the EU declaration of conformity is available at the following internet address:</p>					
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