

NIST TEL MRA Program Office

NB Reporting/Information Obligations

(addresses record retention and monitoring obligations as well)

EMC Directive 2014/30/EU & Radio Equipment Directive 2014/53/EU

Initial Release - 7/12/2016

This document has been prepared by NIST to help prospective NBs understand and comply with the reporting/information obligations in the EMC and Radio Equipment Directives. NBs also have monitoring obligations – see page 4.

EMC Directive 2014/30/EU Article 34	Radio Equipment Directive 2014/53/EU Article 36	NIST Instructions
1. Notified bodies shall inform the notifying authority (NIST) of the following	1. Notified bodies shall inform the notifying authority (NIST) of the following	
a) any refusal, restriction, suspension or withdrawal of a certificate;	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];	NIST will NOT have access to the NB Database. This is a confidential tool to be used by NBs only. Notify NIST when entering information into the NB Certificate Database. Address in NB procedures. Follow appropriate EUANB and REDCA Procedures for NB Certificate Database Participation.
b) any circumstances affecting the scope of or conditions for notification;	c) any circumstances affecting the scope of or conditions for notification;	Notify NIST via mra@nist.gov when relevant. For example, if the accreditation is no longer valid.
c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;	d) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;	Notify NIST via mra@nist.gov as soon as NB is contacted by a Market Surveillance Authority. Address in NB procedures.
d) on request , conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.	e) on request , conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.	Respond to NIST requests for this information.
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	2. 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.	Participate in the NB Certificate Database process as required for NBs by the EUANB and the RED CA. This is mandatory. Address participation in the NB Database within NB procedures and disclose to clients in client contract. Follow appropriate EUANB and REDCA Procedures for NB Certificate Database Participation.

EMC Directive 2014/30/EU	Radio Equipment Directive 2014/53/EU	NIST Instructions
Annex III (8)	Annex III (8)	
<p>Paragraph 1</p> <p>Each notified body shall inform its notifying authority (NIST) concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn...</p>	<p>Paragraph 1</p> <p>Each notified body shall inform its notifying authority (NIST) concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn....</p>	<p>Partial compliance (for withdrawn, refused, suspended and restricted certificates) for Paragraph 1 will be met if following 1 (a) above.</p> <p>The requirement calls for informing NIST of <u>all certificates issued</u>. It does not identify the timing of such notification or the information to provide. See below.</p>
<p>...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>...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>NIST will ask NBs to provide the list to NIST periodically, [frequency and details to be determined.]</p> <p>This is condition for continued notification. NBs should confirm that they will provide a list to upon request to NIST.</p> <p>Address in procedures.</p>
<p>Paragraph 2</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....</p>	<p>Paragraph 2</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,</p>	<p>Participate in the NB Certificate Database process as required for NBs by the EUANB and the REDCA.</p> <p>Address in procedures and disclose to client in client contract.</p>
<p>...upon request, concerning such certificates and/or additions thereto which it has issued.</p>	<p>upon request, concerning such certificates and/or additions thereto which it has issued.</p>	<p>Provide upon request to other notified bodies.</p>
<p>Paragraph 3</p>	<p>Paragraph 3</p> <p>Each notified body <u>shall</u> inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonized 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>For RED NBs only.</p> <p>Provide this information to NIST. NIST will provide it to the Member States via a mechanism agreed upon by the Commission.</p> <p>Notification must be made to NIST, along with a copy of the EU Type Examination Certification, whenever existing harmonized standards (could have been but) were not used or only used in part. Address in the RED NB's procedures.</p>

EMC Directive 2014/30/EU	Radio Equipment Directive 2014/53/EU	NIST Instructions
The Commission , the Member States and the other notified bodies may, <u>on request</u> , obtain a copy of the EU-type examination certificates and/or additions thereto.	The Member States, the Commission and the other notified bodies may, <u>on request</u> , obtain a copy of the EU-type examination certificates and/or additions thereto.	Provide upon request to the requesting party.
On request, the Commission and the Member States may obtain a copy of the <u>technical documentation</u> and the <u>results of the examinations</u> carried out by the notified body.	On request, the Member States and the Commission may obtain a copy of the <u>technical documentation</u> and the <u>results of the examinations</u> carried out by the notified body.	Provide upon request to the requesting party.
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.	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>NBs must define in their own terms when the EU Type Examination Certificate expires.</p> <p>One option is to include an expiration date. However, even if this is included - at any time that either the technical requirements or the product changes, the <u>EU Type Examination Certificate may no longer be valid</u>. Some of the relevant requirements for monitoring obligations are included at the end of this table.</p> <p>RED NBs: Address the 10 year record retention date in the NB procedures.</p>

NBs and the client manufacturers have on-going obligations to each other to ensure that the EU Type Examination Certificates that are issued continue to remain valid for products being placed on the market in the EU.

Relevant Requirements in the EMC Directive

EMC D – Annex III (7)

The notified body shall keep itself apprised of any changes in the **generally acknowledged state of the art** {NIST Comment – track standards development activities} 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. {NIST Comment – require this of client in the contract.}

EMC Directive Article 32

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

{NIST Comment – then enter information into the NB Certificate Database.}

Relevant Requirements in the Radio Equipment Directive

RED Annex III

7. The notified body shall keep itself apprised of any changes in the **generally acknowledged state of the art** {NIST Comment – Track relevant standards development activities} 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 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 {NIST Comment – require this of client in the contract.}

RED Article 34 (4)

4. Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality 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.

5. 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. {NIST Comment – then enter information into the NB Certificate Database.}