

NIST TEL MRA Program Office
 Notified Body Reporting/Information Obligations
 &
 Annual Reporting Obligations to NIST

(This document also addresses record retention and monitoring obligations)

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

Version 3.0 - 01/08/2020

This document has been prepared by NIST to help NBs understand and comply with the reporting/information obligations in the EMC and Radio Equipment Directives.

For the monitoring obligations – please refer to page 4 of this document.

EMC Directive 2014/30/EU	Radio Equipment Directive 2014/53/EU	NIST Instructions Applicable to NBs
Article 34	Article 36	
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];	<i>NBs shall provide this information to NIST on an annual basis, by no later than January 31 of each year, for the NB activities conducted during the prior year (from January 1 to December 31).</i>
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 For example, if the accreditation is no longer valid.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.
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.	NBs shall respond to NIST requests for this information in a timely manner (within 30 days).

EMC Directive 2014/30/EU	Radio Equipment Directive 2014/53/EU	NIST Instructions
<p>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</p>	<p>2. Notified bodies shall, in accordance with the requirements of Annexes III <i>and</i> 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>NBs must participate in the NB Certificate Database process as required for NBs by the EUANB and the REDCA. This is mandatory.</p> <p>NBs shall address their participation in the NB Database in their NB procedures.</p> <p>NBs shall follow the appropriate EUANB and REDCA Procedures for NB Certificate Database participation. NBs shall disclose their participation in the NB Database to their clients in the client contract/agreement.</p> <p>For further information, please see the following documents:</p> <p>EUANB</p> <p>EUANB (16) 018 – <i>NB Certificate Database for Module B/C Assessments According to EMCD 2014/30/EU</i></p> <p>EUANB (16) 018a – <i>Form to Acquire Access Rights to NB Certificate Database</i></p> <p>REDCA</p> <p>REDCA (18) 32 – Draft - <i>RED NB refused Certificate Database process For Module B assessments according to RED 2014/53/EU</i></p> <p><i>REDCA (17) 26a Form to Acquire Access rights to REDCA NB Certificate Database (updated April 2018)</i></p> <p>NOTE</p> <p>NIST does NOT have access to database information. This is a confidential tool to be used by NBs only.</p>

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>NBs shall provide this information to NIST on an annual basis, by no later than January 31 of each year, for the NB activities conducted during the prior year (from January 1 to December 31).</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>NBs shall provide this information to NIST on an annual basis, by no later than January 31 of each year, for the NB activities conducted during the prior year (from January 1 to December 31).</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>NBs must participate in the NB Certificate Database process as required for NBs by the EUANB and the REDCA. This is mandatory.</p> <p>NBs shall address this requirement in their procedures and shall disclose this requirement to the clients in client contract/agreement.</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>NBs shall provide this information to other notified bodies upon request.</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>This requirement applies to the RED NBs only.</p> <p>NBs shall follow the procedure established by the REDCA:</p> <p>ADCO RED has made available the following non-person specific email address that should be used to submit this information to one address (to ADCO RED) instead of having to separately provide the information to each Member State National Authority: ADCO-RED@bakom.admin.ch</p> <p>[Reference: REDCA (18) 48]</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 must address the 10 year record retention date in the NB procedures.</p>

NB MONITORING OBLIGATIONS

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 – 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 – Enter the relevant information into the NB Certificate Database.}

Revision Notes for Version 3.0 (January 8, 2020)

- Removed 2018 NB reporting due date
- Removed highlights from text