

Updates in EU Conformity Assessment

MIC MRA International Workshop 2023 Tokyo 16 March 2023

Speaker

Holger Bentje Chairperson REDCA



http://www.redca.eu/

MIC MRA International Workshop 2023, Tokyo, Japan, 16 March 2023





Content

- Blue Guide 2022
- Update RED Harmonised Standards
- Update Cybersecurity
- Common Charger-New Directive
- REDCA Technical Guidance Notes (TGNs)
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Blue Guide 2022 General Information



- On June 29, 2022, the EU Commission published the Guide for the Implementation of EU 2022 Product Regulations ("Blue Guide") in the Official Journal of the EU.
 EUR-Lex - 52022XC0629(04) - EN - EUR-Lex (europa.eu)
- The Blue Guide 2022 is designed to help understand the basic principles of CE-marking that the European Union uses to write regulations and directives under the "New Legislative Framework".
- The legally non-binding guidance document on EU product law harmonization regulations is intended to serve as an interpretation aid for authorities and economic operators.
- The revision of the document, which was last updated in 2016, had become necessary because the European legislator adopted some new regulations on product law.



- Important for all manufacturers of products in the harmonized area is certainly the fact that the Blue Guide emphasizes that a risk assessment must basically be carried out for all products.
- The new Guide considers recent changes in legislation and the adoption of a new regulation on market surveillance (EU) 2019/1020. <u>EUR-Lex 32019R1020 EN EUR-Lex (europa.eu)</u>
- The term "end user" is defined, which plays a central role in some places in product law.
- The steadily growing area of provision and placing on the market in distance and online sales was included.



- The section on "Repairs and modifications to products" has been amended and supplemented. This section also deals primarily with the so-called "Significant change".
- Changes have also been made to the topic of "Handling software".
- Information on the United Kingdom's withdrawal from the EU.
- Valuable information on the economic and trade agreement CETA between the EU and Canada.



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RED Harmonized Standards Changes in the publication of HS



- "Harmonized standard" means a European standard adopted based on a mandate from the European Commission (EC) for the implementation of Union harmonization legislation.
- New listings of Harmonized Standards (HS) are via a formal European Commission Implementing Decision.
- Published in the L (legislation) series of the EU Official Journal (OJEU).
- Harmonized Standards shall specify precise performance criteria, technical specifications and tests ("legal certainty").
- Equipment not covered by a specific part of an HS cannot benefit from "Presumption of Conformity".
- The EC provides a summary list of HS. The list reproduces information already published in the OJEU L or C. Radio equipment (europa.eu)

RED Harmonized Standards

Commission Implementing Decision (EU) 2022/2191



- The Commission Implementing Decision (EU) 2022/2191 will repeal all previous legal acts on RED HS (C-Series and L-Series) and merge them into one.
 EUR-Lex - 32022D2191 - EN - EUR-Lex (europa.eu)
- This new structure does not modify the currently cited HS.
- Some restrictions applied:
 - Tolerances for the set-up are not permitted.
 - Lack of alignment with EU legal acts on radio spectrum.
 - Discretionary tests are not permitted.

RED Harmonized Standards

Commission Implementing Decision (EU) 2022/2191 – Updated Standards

Categories of radio equipment in the new or updated ETSI Harmonized Standards included in the Decision:

Article 3.1.b EMC	Article 3.2 Radio
Satellite earth stations	Wireless microphones
Cellular communication user equipment	Transport and traffic telematics
	VHF radiotelephone equipment
	IMT cellular equipment
	Advanced surface movement guidance and control system
	Broadcast sound receivers
	Meteorological radars
	Air traffic control surveillance radars

RED

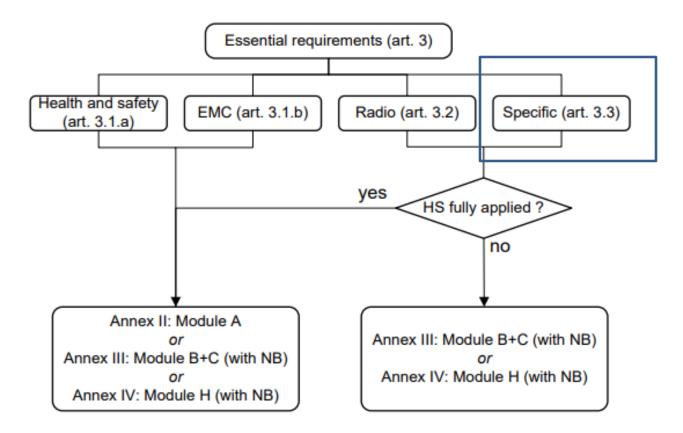


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Radio Equipment Directive Article 3(3) Conformity Assessment Procedures





Remark: Art. 3.4 is not mentioned in the RED Guide Source: Guide to the Radio Equipment Directive 2014/53/EU

RED Delegated Regulation EU 2022/30 Activates RED requirements 3(3)(d)(e)(f)

- 3(3)(d) "radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service"
- 3(3)(e) "radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected"
- 3(3)(f) "radio equipment supports certain features ensuring protection from fraud"

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. 7/6	EN	Official Journal of the European Union	12.1.2022			
	COMMISSION DELEGATED REGULATION (EU) 2022/30					
		of 29 October 2021				
	supplementing Directive 2014/53JEU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive					
	(Text with EEA relevance)					
п	HE EUROPEAN COMMISSIO	JN,				
Н	aving regard to the Treaty	y on the Functioning of the European Union,				
ha	armonisation of the laws pealing Directive 1999/	ve 2014/53/EU of the European Parliament and of the Council of 16 April 2 of the Member States relating to the making available on the market of radio equ SJEC (), and in particular Article 3(3), the second subparagraph, in conjunction vints (d), (e) and (l), thereof,	ipment and			
w	/hereas:					

- Protection of the network or its functioning from harm, protection of personal data and privacy of the user and of the subscriber and protection from fraud are elements that support protection against cybersecurity risks.
- (2) As stated in recital 13 of Directive 2014/53/EU, the protection of personal data and privacy of users and of subscribers of radio equipment and the protection from fraud may be enhanced by particular features of radio equipment. According to that recital, radio equipment should therefore in appropriate cases be designed in such a way that it supports those features.
- (3) 5G will play a key role in the development of the Union digital economy and society in the years to come and will potentially affect almost every aspect of Union citizens' lines. The document with title ("Detrocurity of 5G networks EU Toolbox of risk mitigating measures" (") identifies a possible common set of measures which are able to mitigate the main cyberecentry risks of 5G networks and provides guidance for the selection of measures which should be prioritised in mitigation plans at national and at Union level. In addition to those measures, it is very important to follow a harmosel approach to essential requirements relating to elements of cybersecurity protection on the Inion market.
- (4) The level of security applicable under Union essential requirements set out in Article 3(3)(d), (e) and (f) to ensure network protection, safeguards for the protection of personal data and privacy and protection from fraud shall not undermine the high level of security requested at national level for decentralised smart grids in the field of energy where smart meters subject to those requirements are to be used, and for 5G network equipment used by providers of public electronic communications networks and publicly available electronic communications services within the meaning of in Directive (EU) 2018/1972 of the European Parliament and of the Council (¹).
- (5) Numerous concerns have also been expressed in relation to increasing cybersecurity risks as a result of the increased use by profesionals and consumers, including children, of radio equipment which: (i) is capable itself to communicate over the internet, regardless if it communicates directly or via any other equipment (internet-connected radio equipment), (i), es uch internet-connected equipment, (i) can be either a toy with radio function which also functions of the second second second second second construction of the second second second second (i) or is designed or intended exclusively for childcare, such as child monitore; or (iii) is designed or intended, whether exclusively or not exclusively, to be worn on, strapped to, or hung from any part of the human body functualing the

⁽⁾ OJ L 153, 22.5.2014, p. 62

^(*) Cybersecurity of 5G networks - EU Toolbox of risk mitigating measures, 29 January 2020. https://ec.europa.eu/digital-singlemarket

en linis-cooperation-group () Directive (EU) 2018/1972 of the European Parliament and of the Council of 11 December 2018 establishing the European Electronic Communications Code (0) [J 121, 17.12.2018, p. 36).

^(*) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

RED Delegated Regulation EU 2022/30 Scope 1/2



- RED Article 3.3(d) to ensure network protection applies to:
 - radio equipment that can communicate itself over the internet, whether it communicates directly or via any other equipment ('internet-connected radio equipment')
- RED Article 3.3(e) to ensure safeguards for the protection of personal data and privacy
 - applies to the following equipment when capable of processing personal data or traffic data and location data:
 - a) internet-connected radio equipment other than referred to in points b), c) or d);
 - b) radio equipment designed or intended exclusively for childcare;
 - c) radio equipment falling under the Toys Directive (2009/48/EC);
 - d) radio equipment designed or intended, whether exclusively or not exclusively, to be worn on, strapped to, or hung from the body or clothing worn by human beings
- RED Article 3.3(f) to ensure protection from fraud applies to:
 - internet-connected radio equipment, if that equipment enables the holder or user to transfer money, monetary value or virtual currency.

RED Delegated Regulation EU 2022/30 Scope 2/2



The following radio equipment is exempted from RED Articles 3.3(d), 3.3(e) and 3.3(f)

• Medical devices under Regulation (EU) 2017/745 and (EU) 2017/746

The following radio equipment is exempted from RED Articles 3.3(e) and 3.3(f), but article 3.3(d) still applies:

- Radio equipment under Regulation (EU) 2018/1139 (civil aviation)
- Radio equipment under Regulation (EU) 2019/2144 (motor vehicles)
- Radio equipment under Directive (EU) 2019/520 (road toll systems)

DELEGATED REGULATION (EU) 2022/30 Article 3



The DELEGATED REGULATION (EU) 2022/30 on Cybersecurity shall apply from **1 August 2024**.

Standardization Request Timeline



- 12 January 2022: Delegated Regulation (EU) 2022/30 published
- 5 August 2022: Standardization Request to CEN/CENELEC
- 7 September 2022: Request accepted; Standards work started
 - CEN/CENELEC JTC 13/WG 8 "Special Working Group RED Standardization Request"
 - WG8 currently has 131 committee members and 16 liaison members (ANEC, APPLIA, ETSI, ESMIG, EURALARM, EUROSMART and CENELEC).
- Original Plan: Publication of standards 30 September 2023

Standardization Request CEN/CENELEC JTC 13/WG 8



Three standards will be delivered to the European Commission for citation in the Official Journal (OJEU):

- Common security requirements for internet connected radio equipment.
- Common security requirements for equipment processing personal data.
- Common security requirements for internet connected radio equipment processing virtual money or monetary value

CEN/CENELEC JTC 13/WG 8 Timeline

- JTC 13/WG8 was established on July 7, 2022, to address the RED Standardization Request.
- The goal is to develop three standards by the end of the year (best case scenario).
- A first early draft was circulated in February to collect stakeholders' input.
 - Not included: 5G network equipment, smart meters, eIDAS
- REDCA members have access to this document.



CEN/CENELEC JTC 13/WG 8 Headlines of 17 main requirements



Access control mechanism Authentication mechanism Secure update mechanism Secure storage mechanism Secure communication mechanism Logging mechanism Deletion mechanism Resilience mechanism Attack surface reduction-Network Network monitoring mechanism Traffic control mechanism User notification mechanism CSP generation mechanism General equipment capabilities Cryptography Physical protection Smart meters 5G Network equipment

Working draft requirement sections

Next Step:

Cyber Resilience Act (Proposal)



- The European Commission presented on 14 September 2022 a proposal for a new Cyber Resilience Act to protect consumers and businesses from products with inadequate security features.
 - Wide-ranging scope: Digital products, including hardware and software.
 - Whole lifecycle of the product is covered.
- In order to avoid a regulatory overlap, it is envisaged that the European Commission would repeal or amend the RED Delegated Regulation with respect to the radio equipment covered by the proposed Regulation.



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Common Charger

History



- In January 2020, the European Parliament adopted a resolution calling for the urgent adoption of a standard for a common charger for mobile phones in order to avoid further internal market fragmentation.
- The resolution called on the European Commission to adopt a legislative measure, if necessary, to establish a common charger.

Common Charger

Reasons



Reasons for a regulatory change for chargers (External Power Supply (EPS)) of mobile phones and similar devices:

- Harmonization of the charging port and the fast-charging protocol will benefit consumer (reduce the number of charging solutions).
- Introduce requirements so that end-users are not obliged to purchase a new charging device whenever they purchase a new mobile phone or similar item of radio equipment.
- Charging characteristics to be displayed will strengthen customers' knowledge of interoperability of their devices.

Common Charger Amendment of the RED

Directive (EU) 2022/2380, amending the Radio Equipment Directive 2014/53/EU, introduces these requirements of the 'common charging' solution on 07 December 2022

Publications Office (europa.eu)



315/30	EN	Official Journal of the European Union	7.12.20

DIRECTIVES

DIRECTIVE (EU) 2022/2380 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 November 2022 amending Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof

Having regard to the proposal from the European Commission

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

- (1) One of the objectives of Directive 2014/53/EU of the European Parliament and of the Council () is to ensure the proper functioning of the internal marker. Pursuant to Article 3(3), point (a), of that Directive, one of the essential requirements that radio equipment is to comply with is that it interworks with accessories, in particular with common chargers. In that respect, Directive 2014/53/EU indicates that interoperability between radio equipment and accessories such as the arger simplifies the use of radio equipment and reduces unnecessary wate and costs and that developing a common charger for particular categories or classes of radio equipment is necessary, in particular for the benefit of consumers and other end-users.
- (2) Since 2009, efforts have been made at Union level to limit the fragmentation of the market for charging interfaces for mobile phones and similar items of radio equipment. Although recent voluntary initiatives have increased the level of convergence of charging devices, which are the external power supply part of chargers, and decreased the number of different charging solutions available on the market, those initiatives do not fully meet the Union policy objectives of ensuring consumer convenience, reducing electronic waste (e-waste) and avoiding fragmentation of the market for charging devices.
- (3) The Union is committed to boosting the efficient use of resources by moving to a clean, circular economy through the introduction of initiatives such as Directive 2012/19/EU of the European Parliament and of the Council (1) and more recently through the introduction of the European Green Deal, as set out by the Commission in its communication of 11 December 2019. This Directive is aimed at reducing the e-waste generated by the sale of radio equipment, and at reducing the extraction of raw materials and the CO₂ emissions generated by the production, transportation and disposal of chargers, thereby promoting a circular economy.

(*) OJ C 152, 6.4.2022, p. 82.

Position of the European Parliament of 4 October 2022 (not yet published in the Official Journal) and decision of the Council of 24 October 2022.

^(*) Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (O) L 153, 22.5.2014 p. 62).

^(*) Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (O) L 197, 24.7.2012, p. 38).

Common Charger

Scope



The requirements will apply to

- Handheld mobile phones,
- Tablets,
- Digital cameras,
- · Headphones, headsets, portable speakers,
- Handheld videogame consoles, e-readers,
- Earbuds, keyboards, mice, and
- Portable navigation systems as of 2024.

These requirements will also apply to laptops as of 2026.

Common Charger

A harmonized Charging Port



- USB-C will be the common port
 - This will allow consumers to charge their devices with the same USB-C charger, regardless of the device brand
- Unbundling the sale of a charger from the sale of the electronic device
 - Consumers will be able to purchase a new electronic device without a new charger
- Improved information for consumers
 - Manufacturers will need to provide relevant information about charging performance



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- **REDCA**, only **RED** Notified Bodies are allowed to vote on TGNs.
- TGNs are related to activities carried out by **RED Notified Bodies.**
- TGNs are published on the REDCA website **REDCA Documents**

TGN Voting Process

REDCA Technical Guidance Notes

- Technical Guidance Notes are developed by **REDCA** members.
- The development usually takes place in working groups.
- According to the approved rules of the

4. Technical Guidance Notes

The REDCA publishes Technical Guidance Notes (TGNs) which are related to activities carried out by RED Notified Bodies, listed on NANDO.

REDCA TGNs must be understood as giving general guidance to facilitate comprehension and practical implementation of the conformity assessment procedures of the Radio Equipment Directive 2014/53/EU. They have no legal force but are often considered to be State of the Art

REDCA TGNs related to the RED only, will appear in this section 4.

DISCLAIMER

No responsibility or liability can be accepted by the European Commission or the REDCA or any of its officers or members for the contents, specifications and/or advice referred to or contained in REDCA Technical Guidance Notes and/or any action taken as a result of information contained in REDCA Technical Guidance Notes



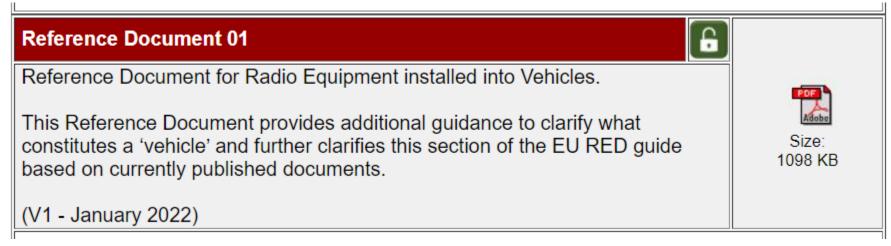


REDCA Technical Guidance Notes

TGNs on Development 1/2



- TGN 33 RED as applied to vehicles
 - The document is published as a Reference Document.



It is still a work in progress.

REDCA Technical Guidance Notes TGNs on Development 2/2



• TGN 29 is in the revision progress

Technical Guidance Note 29	FOF
Guidance related to NB EU-TEC updates	Adobe
	Size:
(V2.0a March 2020)	358 KB

REDCA Technical Guidance Notes Updated TGNs



- TGN 30 Risk analysis/assessment guide
 - Update version May 2022 is available



- ETSI has started to produce a risk assessment guide for manufacturers. It will be limited to the requirements of article 3.1b) (EMC) and article 3.2 (radio).
 - ETSI TR 103 879 Guidance on risk assessment and risk reduction for radio equipment according the Radio Equipment Directive 2014/53/EU



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REDCA Information

Last and next Meeting



- The last REDCA meeting was an Online event with more than 220 participants in November 2022.
- We had very good attendance from RED Notified Bodies, laboratories and manufacturers located in North America and especially Asia.
- The next REDCA meeting will be a meeting in presence in **Frankfurt, Germany in the week commencing 9 May 2022**.
- Depending on the venue, a hybrid meeting is foreseen.



Thank you for listening

Any Question? c/o PHOENIX TESTLAB GmbH, Koenigswinkel 10, 32825 Blomberg, Germany

Annex: REDCA – Who are we 1/2



- The Radio Equipment Directive Compliance Association provides a forum for people concerned with the compliance of radio equipment with regulations and technical standards in the European Economic Area, as well as in the Countries that have a Mutual Recognition Agreement with the EU, such as the USA, Canada, Japan, Switzerland, New Zealand and Australia.
- In particular formed under the requirements of the Radio Equipment Directive 2014/53/EU specifically for Article 26.11 and Article 38 for Notified Bodies (sectorial group of notified bodies).
- Members are:
 - Notified Bodies, Manufacturers,
 - Testing Laboratories & Consulting Companies
 - Member states and administrations
 - Authorities from MRA regions, etc.
 - and they all need to follow the aims and objectives set out in the Associations Rules and Constitution.
- Annual fee for REDCA Membership is € 600.-.

Annex: REDCA – Who are we 2/2



- REDCA offers the following activities and information (and is not limited to these)
 - Rapid access to the constantly changing EU legislation/regulation and EU Standards development.
 - (Draft) material often available before general public gets it. (e.g., Guides, Implementing Acts, etc.)
 - Liaison with EU Commission, ADCO, ETSI, ECC, TCAM etc.
 - Possibility to get answers from fellow experts on specific RED (technical) questions.
 - Special Workshops.
- REDCA publishes Technical Guidance Notes and reference Doc's
 - See website http://www.redca.eu
- The Association meets twice a year in a location within the European Economic Area (EEA)
 - The meeting is for members only.
 - Closed session for Notified Bodies.
 - Representatives of the EU-Commission, ECC, ETSI, CENELEC, ADCO RED and authorities from MRA countries.
 - Next meeting May 2023, in Frankfurt, Germany.
- Has a mail server for members where they can ask questions that will trigger answers and comments from the experts within the Association
- Has a specific protected area on the CIRCABC website for all working documents.
- Maintains the Notification data base to other Notified Bodies as required by RED Annex III clause 8, on CIRCABC.