



Updates in EU Conformity Assessment

MIC MRA International Workshop
16-17 March 2021

Speaker

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Chairman REDCA



<http://www.redca.eu/>

MIC MRA International Workshop 2021 (Online), Tokyo, Japan, 16-17 March 2021





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- **Risk Assessment**
- RED Harmonised Standards
- New Technical Guidance Notes
- Upcoming Article 3.3 Changes
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Risk Assessment

Information in the Blue Guide

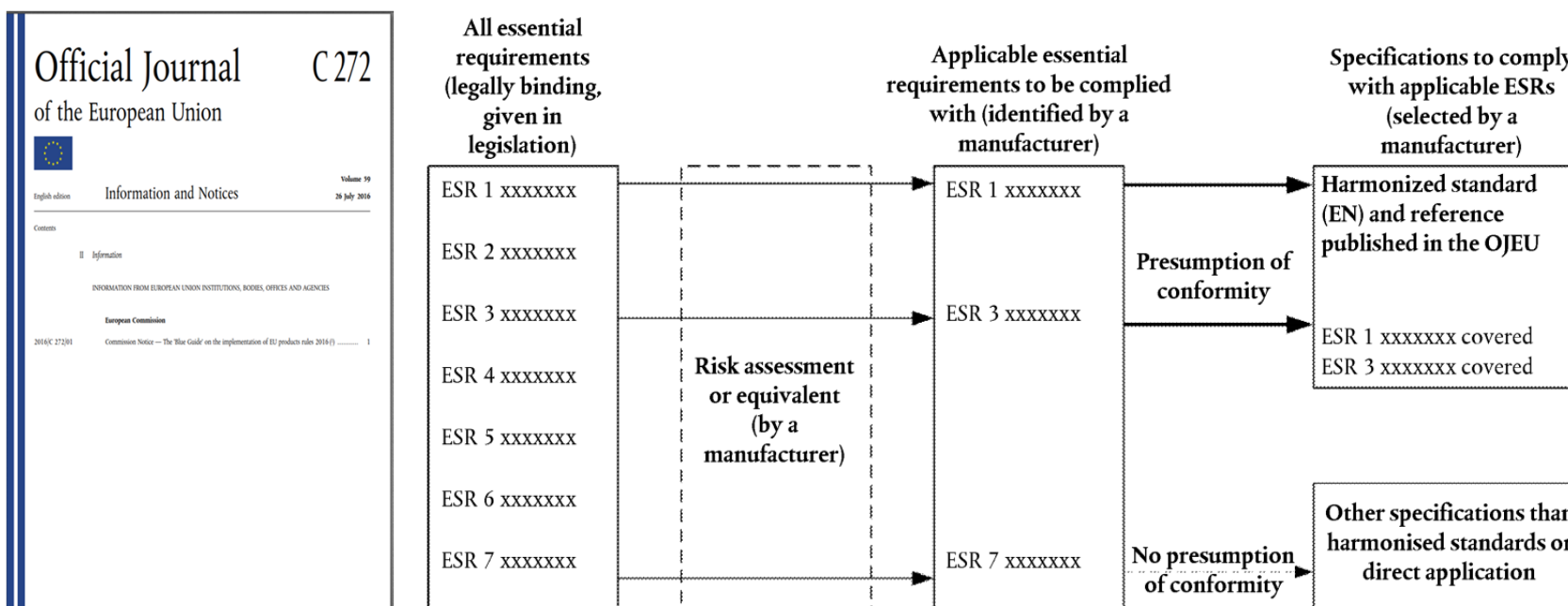


- The European product rules are risk oriented
 - More than 30 European Directives have been published
 - The Radio Equipment Directive 2014/53/EU is one of them.
- Risk assessment is a horizontal issue over all Directives.
- The requirements are described in the „Blue Guide“ under clause 4.1.2.2 and clause 4.3.
- Additional information is available in the „RED Guide“.

Risk Assessment Information in the Blue Guide



The figure given in 4.1.2.2 of the “Blue Guide” can be used as guidance.



Risk Assessment

REDCA Technical Guidance Note TGN 30



- The risk assessment is an activity for the manufacturer alone to perform.
- The risk analysis and assessment should consider and document at least the following steps:
 - Clearly identifying
 - the intended user groups (e.g., professional, consumer, children etc.)
 - and the operating environment (e.g., Indoor/outdoor, temperature, altitude, etc.).
 - Identifying the Essential Requirement(s).
 - Identifying which Harmonised Standard(s) or equivalent documentation has been applied to minimize the risk of non-compliance to the Essential Requirements.

Risk Assessment

REDCA Technical Guidance Note TGN 30



- Identifying if there are special product characteristics or features
 - which might be not included in the current Harmonised Standard(s) and
 - how these features are still considered to comply with the Essential Requirements.
- Specifically explaining how the additional risks in not following the available Harmonised Standards giving a presumption of conformity or not using alternative compliance methods and standards have been mitigated to demonstrate compliance to the Essential Requirements.



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- **RED Harmonised Standards**
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RED Harmonised Standards



Some changes in the publication of HS

- New listings of Harmonised Standards (HS) are via a formal European Commission Implementing Decision.
- Published on the L (legislation) series of the Official Journal.
- Harmonised Standards shall specify precise performance criteria, technical specifications and tests (legal certainty).
- ETSI has split many HS into specific sub-parts.
- Equipment not covered by a specific part of an HS cannot benefit from “Presumption of Conformity”.
- Measurement Uncertainty may be included in the informative part of a HS but shall not affect normative elements.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167



- The last FULL list of HS was published on 14 September 2018.
- New lists of HS were published in the Official Journal (OJ) on
 - 06 February 2020
 - 21 April 2020 and
 - 26 October 2020.
 - https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/red_en
- The Commission provides a summary list. It reproduces information already published in the OJ L or C.

27.10.2020 Official Journal of the European Union L 357/24

COMMISSION IMPLEMENTING DECISION (EU) 2020/167

of 26 October 2020

amending Implementing Decision (EU) 2020/167 as regards harmonised standards for certain radio equipment concerning advanced surface movement guidance and control systems, primary surveillance radar, broadcast sound receivers, international mobile telecommunication equipment and fixed radio systems

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directive 89/686/EEC and Directive 94/9/EC, 94/12/EC, 95/16/EC, 97/23/EC, 98/14/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (1), and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 16 of Directive 2014/53/EU of the European Parliament and of the Council (2), radio equipment which is in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, is to be presumed to be in conformity with the essential requirements set out in Article 3 of that Directive, covered by those standards or parts thereof.
 - (2) By Implementing Decision (EU) 2020/167 (3), the Commission made a request to the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI) for the drafting and revision of harmonised standards for radio equipment in support of Directive 2014/53/EU.
 - (3) On the basis of the request set out in Implementing Decision (EU) 2020/167, ETSI drafted harmonised standards EN 303 213-5-1 V1.1.1, EN 303 145-5 V1.1.1, EN 303 145-5 V1.1.1, for broadcast sound receivers, and EN 303 146-3 V1.1.1, for primary surveillance radars.
 - (4) On the basis of the request set out in Implementing Decision (EU) 2020/167, ETSI revised harmonised standards EN 303 908-2 V1.1.1, EN 303 908-13 V1.1.1, EN 302 217-2 V1.1.1 and EN 303 213-6-1 V1.1.1, the references of which are published in the C series of the Official Journal of the European Union (4). This resulted in adoption of, respectively, harmonised standards EN 303 908-2 V1.1.1 for user equipment for international mobile telecommunication, EN 303 908-13 V1.1.1 for user equipment for evolved universal terrestrial radio access, EN 302 217-2 V1.2.2 for fixed radio systems and EN 303 213-6-1 V1.1.1 for advanced surface movement guidance and control systems.
 - (5) The Commission, together with ETSI, has assessed whether those harmonised standards comply with the request set out in Implementing Decision (EU) 2020/167.
 - (6) Harmonised standards EN 303 213-5-1 V1.1.1 and EN 303 908-2 V1.1.1 satisfy the essential requirements which they aim to cover and which are set out in Directive 2014/53/EU. It is therefore appropriate to publish the references of those standards in the Official Journal of the European Union.
 - (7) Implementing Decision (EU) 2020/167 provides, in Annex B (3)(b), that "radio performance is also of particular importance for mobile terminals, in particular antenna performance, and for communication equipment used in safety of life applications". Harmonised standard EN 303 908-13 V1.1.1 does not include specifications with respect to antenna performance. The reference of that harmonised standard should therefore be published in the Official Journal of the European Union with restriction.
- (1) OJ L 316, 14.11.2012, p. 12.
(2) 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 (2014/53/EU).
(3) Commission Implementing Decision (EU) 2020/167 of 26 October 2020 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute in regard to radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.
(4) OJ L 28, 14.2.2018, p. 14.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167 of 5 February 2020



Harmonised standards in Annex I

- **EN 300 328 V2.2.2** Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
- **EN 303 098 V2.2.1** Transport and Traffic Telematics (TTT); Dedicated Short Range Communication (DSRC) transmission equipment (500 kbit/s/250 kbit/s) operating in the 5 795 MHz to 5 815 MHz frequency band; Part 2: Harmonised Standard for access to radio spectrum; Sub-part 2: On-Board Units (OBU)
- **EN 300 674-2-2 V 2.2.1** Maritime low power personal locating devices employing AIS; Harmonised Standard for access to radio spectrum

satisfy the essential requirements which they aim to cover and which are set out in Directive 2014/53/EU.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167 of 5 February 2020



Harmonised standards in Annex II

- **EN 300 698 V2.3.1** Radio telephone transmitters and receivers for the maritime mobile service operating in the VHF bands used on inland waterways; Harmonised Standard for access to radio spectrum and for features for emergency services
- **EN 302 065-3 V2.1.1** Short Range Devices (SRD) using Ultra Wide Band technology (UWB); Harmonised Standard covering the essential requirements of Article 3.2 of the Directive 2014/53/EU; Part 3: Requirements for UWB devices for ground based vehicular applications and
- **EN 303 520 V1.2.1** Short Range Devices (SRD); Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz; Harmonised Standard for access to radio spectrum

have been published in the EU-OJ **with restrictions.**

They do not cover a presumption of conformity to the essential requirements.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167 of 5 February 2020



Harmonised standards in Annex III

- EN 300 328 V2.1.1 Date of withdrawal 6 August 2021
- EN 300 698 V2.2.1 Date of withdrawal 6 August 2021
- EN 300 674-2-2 V2.1.1 Date of withdrawal 6 August 2021
- EN 302 065-3 V2.1.1 6 Date of withdrawal 6 February 2020
- EN 302 752 V1.1.1 Date of withdrawal 6 February 2021
- EN 303 098 V2.1.1 Date of withdrawal 6 February 2021
- EN 303 520 V1.1.1 Date of withdrawal 6 August 2021

have been published in the EU-OJ **with a date of withdrawal.**

They will not cover a presumption of conformity to the essential requirements after the date of withdrawal.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167 of 22 April 2020



Harmonised standards in Annex I

- **EN 301 908-1 V13.1.1** IMT cellular networks; Harmonised Standard for access to radio spectrum; Part 1: Introduction and common requirements
- **EN 301 908-3 V13.1.1** IMT cellular networks; Harmonised Standard for access to radio spectrum; Part 3: CDMA Direct Spread (UTRA FDD) Base Stations (BS)
- **EN 301 908-14 V13.1.1** IMT cellular networks; Harmonised Standard for access to radio spectrum; Part 14: Evolved Universal Terrestrial Radio Access (E-UTRA) Base Stations (BS)
- **EN 301 908-18 V13.1.1** IMT cellular networks; Harmonised Standard for access to radio spectrum; Part 18: E-UTRA, UTRA and GSM/EDGE Multi-Standard Radio (MSR) Base Station (BS)'

satisfy the essential requirements which they aim to cover and which are set out in Directive 2014/53/EU.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167 of 22 April 2020



Harmonised standards in Annex III to Implementing Decision

- **EN 301 908-1 V11.1.1** Date of withdrawal 22 October 2021
- **EN 301 908-3 V11.1.3** Date of withdrawal 22 October 2021
- **EN 301 908-14 V11.1.2** Date of withdrawal 22 October 2021
- **EN 301 908-18 V11.1.2** Date of withdrawal 22 October 2021

have been published in the EU-OJ **with a date of withdrawal.**

They do not cover a presumption of conformity to the essential requirements from the date of withdrawal anymore.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167 of 27 October 2020



Harmonised standards in Annex I

- **EN 301 908-2 V13.1.1** IMT cellular networks; Harmonised Standard for access to radio spectrum; Part 2: CDMA Direct Spread (UTRA FDD) User Equipment (UE)
- **ETSI EN 303 213-5-1 V1.1.1** Advanced Surface Movement Guidance and Control System (A-SMGCS); Part 5: Harmonised Standard for access to radio spectrum for Multilateration (MLAT) equipment; Sub-part 1: Receivers and Interrogators’.

satisfy the essential requirements which they aim to cover and which are set out in Directive 2014/53/EU.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167 of 27 October 2020



Harmonised standards in Annex II

- **EN 301 908-13 V13.1.1** IMT cellular networks; Harmonised Standard for access to radio spectrum; Part 13: Evolved Universal Terrestrial Radio Access (E-UTRA) User Equipment (UE)
- **EN 302 217-2 V3.2.2** Fixed Radio Systems; Characteristics and requirements for point-to-point equipment and antennas; Part 2: Digital systems operating in frequency bands from 1 GHz to 86 GHz; Harmonised Standard for access to radio spectrum
- **EN 303 213-6-1 V3.1.1** Advanced Surface Movement Guidance and Control System (A-SMGCS); Part 6: Harmonised Standard for access to radio spectrum for deployed surface movement radar sensors; Sub-part 1: X-band sensors using pulsed signals and transmitting power up to 100 kW
- **EN 303 345-2 V1.1.1** Broadcast Sound Receivers; Part 2: AM broadcast sound service; Harmonised Standard for access to radio spectrum
- **EN 303 345-5 V1.1.1** Broadcast Sound Receivers; Part 5: DRM broadcast sound service; Harmonised Standard for access to radio spectrum
- **EN 303 364-3 V1.1.1** Primary Surveillance Radar (PSR); Harmonised Standard for access to radio spectrum; Part 3: Air Traffic Control (ATC) PSR sensors operating in the frequency band 8 500 MHz to 10 000 MHz (X band)

have been published in the EU-OJ **with restrictions**.

They do not cover a presumption of conformity to the essential requirements.

RED Harmonised Standards

COMMISSION IMPLEMENTING DECISION (EU) 2020/167 of 27 October 2020



Harmonised standards in Annex III

- **EN 301 908-2 V11.1.2** Date of withdrawal 27 October 2021
- **EN 301 908-13 V11.1.2** Date of withdrawal 27 October 2021
- **EN 302 217-2 V3.1.1** Date of withdrawal 27 April 2022
- **EN 303 213-6-1 V2.1.1** Date of withdrawal 27 October 2021
- **EN 303 339 V1.1.1** Date of withdrawal 27 April 2021

have been published in the EU-OJ **with a date of withdrawal.**

They do not cover a presumption of conformity to the essential requirements from the date of withdrawal anymore.

RED Harmonised Standards

EMC, Safety & Health



- Furthermore, there is a lack of listed harmonized standards on the essential requirements EMC and safety.
- Listed standards in the scope of EMC:
 - **EN 55035:2017**, Electromagnetic compatibility of multimedia equipment - Immunity requirements
- Listed standards in the scope of EMF:
 - **EN 50360:2017**, Product standard to demonstrate the compliance of wireless communication devices, with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 300 MHz to 6 GHz: devices used next to the ear
 - **EN 50385:2017**, Product standard to demonstrate the compliance of base station equipment with radiofrequency electromagnetic field exposure limits (110 MHz - 100 GHz), when placed on the market
 - **EN 50401:2017**, Product standard to demonstrate the compliance of base station equipment with radiofrequency electromagnetic field exposure limits (110 MHz - 100 GHz), when put into service
 - **EN 50566:2017**, Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body
- Listed standards in the scope of Safety: **No standards listed.**

RED Harmonised Standards

Use of Non-harmonized standards



- If a manufacturer uses non-harmonized standards as part of the conformity assessment, a comprehensive justification is required in the risk assessment as to why the respective essential requirements are met.
- RED Annex V (d) on Technical Documentation:
*...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***



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New Technical Guidance Notes

New TGN Voting Process






- Technical Guidance Notes are developed by REDCA members.
- The development usually takes place in working groups.
- According to the revised approved rules of the REDCA, only RED Notified Bodies are allowed to vote on TGNs.
 - TGNs are related to activities carried out by RED Notified Bodies.
- As a result of this change, all existing TGNs have been re-voted.
 - Slight updates were also made as part of this process.

New Technical Guidance Notes

New TGNs published



- TGN 34 Active Antennas V1.2 (Version 1.2 October 2020)
- TGN 21 On Guidance for Report Checking (V2.0a November 2020)
- TGN 20 SAR Guidance Document (Version 6.5 October 2020)




4. Technical Guidance Notes	
<p>The REDCA publishes Technical Guidance Notes (TGNs) which are related to activities carried out by RED Notified Bodies, listed on NANDO.</p> <p>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.</p> <p>REDCA TGNs related to the RED only, will appear in this section 4.</p> <p>DISCLAIMER</p> <p>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.</p>	
Technical Guidance Note 01	 Size: 381 KB
For Radio Equipment often referred to as Modules, noting the term "Modules" is not defined in the RED. (V1.2a - March 2020)	
Technical Guidance Note 34	 Size: 352 KB
Active Antennas V1.2 (Version 1.2 October 2020)	
Technical Guidance Note 33	 Size: 1071 kb
RED as applied to vehicles; Draft for REDCA member comment Comments to the Technical Secretariat by the 7th February 2021, at that time the comments will be collated for the drafting group to consider. It is hoped we can get this draft TGN 33 to the RED NB for voting in March. If this is passed we are aiming for publication in early April	

New Technical Guidance Notes

TGNs on Development



- TGN 33 RED as applied to vehicles
 - Draft version available
- TGN 30 Risk analysis/assessment guide
 - Update required

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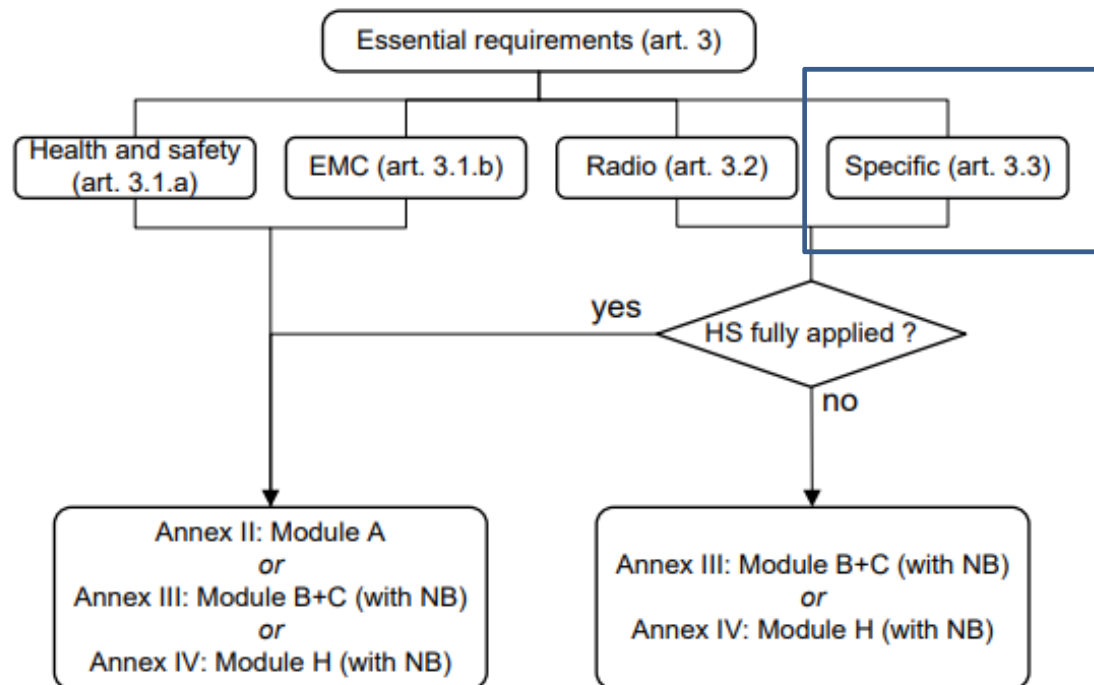


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Upcoming Article 3.3 Changes

Conformity Assessment Procedures



Source: Guide to the Radio Equipment Directive
2014/53/EU

Upcoming Article 3.3 Changes

Delegated and implementing acts under the RED



- Currently, there are technical requirements according to Article 3.3 (g) of the RED only towards certain marine equipment and avalanche beacons.
 - These requirements have been carried over unchanged from the R&TTE Directive and continue to apply under the RED.
- In addition, the following regulations have been published in the OJ
 - [Commission Implementing Regulation \(EU\) 2017/1354](#) specifies how to present the information provided for in Article 10(10) of Directive 2014/53/EU for printed product documentation.
 - [Commission Delegated Regulation \(EU\) 2019/320](#) of 12 December 2018 with regard to the application of the essential requirements referred to in Article 3(3)(g) of Directive 2014/53/EU in order to ensure caller location in emergency communications from mobile devices.
 - Compliance is **mandatory from 17 March 2022**.
 - ETSI has received a standardisation request. This request was rejected by ETSI.

Upcoming Article 3.3 Changes

Commission Expert Group on Radio Equipment



- The Commission Expert Group on Radio Equipment (EG RE) is expected, among others, to provide recommendations and suggestions which will enable the European Commission to prepare one or more potential delegated acts.
 - The REDCA is a member of this group.
 - <https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3587>
- Currently, the group is working on the following topics.

Upcoming Article 3.3 Changes

Cybersecurity



Discussions are currently underway to apply the following articles to include the topic of cybersecurity in the RED.

- **Article 3(3) (d) (harm to network):** connected devices.
- **Article 3(3) (e) (Protection of personal data):** connected devices, toy devices and wearable devices, in so far as they are capable of processing any information or data covered by Regulation (EU) 2016/679 (GDPR) or Directive 2002/58/EC (ePrivacy).
- **Article 3(3) (f) (protection from fraud):** connected devices, in so far as they enable the holder or user to transfer money, monetary value or virtual currency.

Upcoming Article 3.3 Changes

Other



- The European Commission is studying options including invoking
 - article 3.3(a): radio equipment is compatible with a common charger.
 - invoking articles 3.3(i) and/or 4 of the RED to ensure that radio equipment remains compliant when new or modified software is installed.
- Implementing regulations and standardisation requests may follow.



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REDCA Information

Last and next Meeting



- The last REDCA meeting was an Online event with more than 160 participants in October 2020.
- We had very good attendance from RED Notified Bodies, laboratories and manufacturers located in North America and Asia.
- The next REDCA meeting will be an Online meeting again in the week commencing 17 May 2021.
- We hope to be able to hold our fall meeting again in presence.



Thank you for listening

Any Question?

chairman@redca.eu

You can find some more information on the REDCA attached.

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, 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, ADCO RED and authorities from MRA countries.
 - Next meeting mid May 2021, Online.
- 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 Annex III clause 8, on CIRCABC.