



Current Status of the Certification System in Europe

MIC MRA International Workshop 2024

Tokyo

06 March 2024

Speaker



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Chairperson REDCA

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



Content

- **Introduction RED**
- New HS: Vector Probes for SAR Measurements
- Cybersecurity, Privacy and Fraud – Conformity Assessment
- Radio Equipment in Vehicles
- REDCA Technical Guidance Notes (TGNs)
- REDCA Information

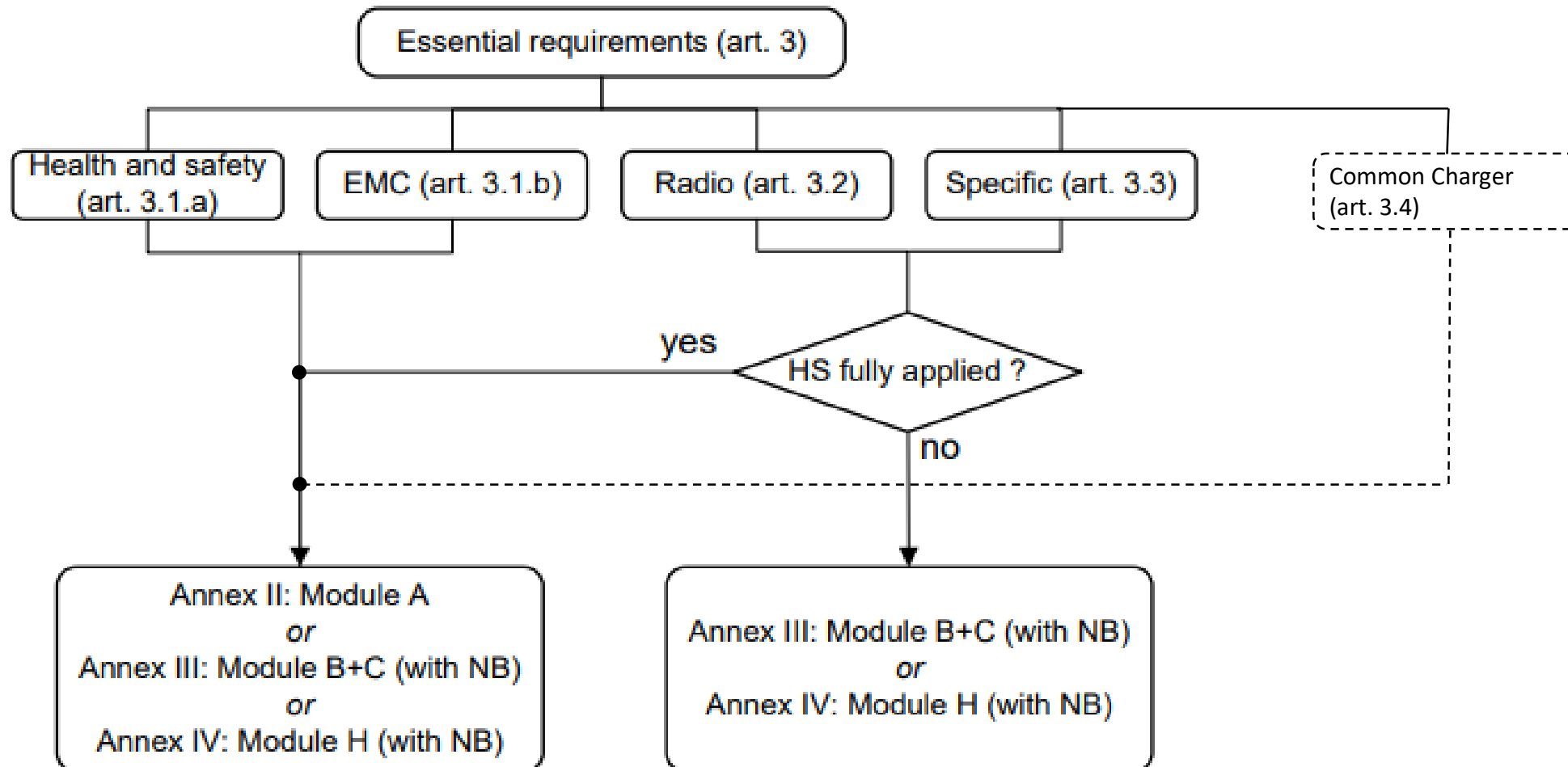
Introduction RED



- The radio equipment directive 2014/53/EU (RED) establishes a regulatory framework for placing radio equipment on the European market.
- It ensures a single market for radio equipment by setting essential requirements for
 - safety and health,
 - electromagnetic compatibility, and
 - the efficient use of the radio spectrum.
- It also provides the basis for further regulation governing some additional aspects. These include technical features
 - for the protection of privacy, personal data and against fraud,
 - to increase the level of cybersecurity, and
 - for the access to emergency services.



Essential Requirements in Article 3 Conformity Assessment Procedures





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Article 3.1(a): Specific Absorption Rate

Advanced measurement systems employing vector probe arrays



- Wireless devices operating near or in contact with the human body need additional assessment of the amount of EM-fields that may be absorbed by the human tissue.
- European standards defining SAR-measurement methodologies have been based on conventional measurement systems (IEC 62209-1/-2, now IEC/IEEE 62209-1528).
- New measurement systems employing vector measurement systems making the SAR testing less time consuming (IEC 62209-3:2019), especially for products with many transmission modes like Smartphones.

Equivalence of SAR Testing Methodologies

JRC Study



- The Joint Research Centre (JRC) of the European Commission performed a study to analyse the equivalence of the two testing methodologies on IEC 62209-1/-2 and IEC 62209-3 for the measurement of the Specific Absorption Rate (SAR) in 2023.
- The results are documented in the JRC Technical Report *Chountala C., Cerutti I., Ferragut J., Chareau J.M., Bishop J., Viaud P., Standards for the Measurement of the Specific Absorption Rate, European Commission, Ispra, 2023, JRC134671*

RED Harmonised Standards (HS) Publication in the OJEU



Based on this study, two new harmonised product standards including IEC 62209-3:2019 have been cited in the OJEU (Commission Implementing Decision (EU) 2023/2669, dated 1st December 2023).

[Implementing decision - EU - 2023/2669 - EN - EUR-Lex \(europa.eu\)](#)

Official Journal of the European Union

EN
L series

2023/2669

1.12.2023

COMMISSION IMPLEMENTING DECISION (EU) 2023/2669
of 27 November 2023
amending Implementing Decision (EU) 2022/2191 as regards harmonised standards for wireless communication devices used next to the ear or in close proximity to the human body
(Text with EEA relevance)

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 Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/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 where they are covered by those standards or parts thereof.
- (2) By Commission Implementing Decision C(2015) 5376⁽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 the revision of harmonised standards for radio equipment in support of Directive 2014/53/EU (the request).
- (3) On the basis of the request, Cenelec amended harmonised standards EN 50360:2017 for wireless communication devices used next to the ear, and EN 50566:2017 for wireless communication devices used in close proximity to the human body, the references of which are published in the *Official Journal of the European Union* by Commission Implementing Decision (EU) 2022/2191⁽⁴⁾. This resulted in the adoption of amending harmonised standards EN 50360:2017/A1:2023 and EN 50566:2017/A1:2023.
- (4) The Commission, together with Cenelec, has assessed whether those harmonised standards comply with the request.
- (5) Harmonised standards EN 50360:2017, as amended by EN 50360:2017/A1:2023, and EN 50566:2017, as amended by EN 50566:2017/A1:2023, satisfy the essential requirements which they aim to cover and which are set out in Article 3 of Directive 2014/53/EU. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12, EEL: <http://data.europa.eu/eli/reg/2012/1025/oj>.

⁽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 (OJ L 153, 22.5.2014, p. 62, EEL: <http://data.europa.eu/eli/dir/2014/53/oj>).

⁽³⁾ Commission Implementing Decision C(2015) 5376 final of 4 August 2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

⁽⁴⁾ Commission Implementing Decision (EU) 2022/2191 of 8 November 2022 on the harmonised standards for radio equipment drafted in support of Directive 2014/53/EU of the European Parliament and of the Council (OJ L 289, 10.11.2022, p. 7, EEL: http://data.europa.eu/eli/dec_impl/2022/2191/oj).

Specific Absorption Rate

New harmonised SAR standards published



EN 50360:2017/A1:2023

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

- Main changes of A1: The inclusion of new normative document EN IEC 62209-3:2019 and associated procedures in addition to IEC 62209-1:2016.

Specific Absorption Rate

New harmonised SAR standards published



EN 50566:2017/A1:2023

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:

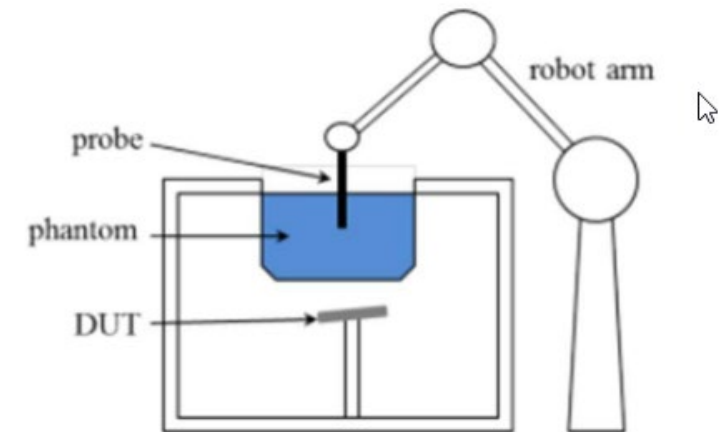
hand-held and body mounted devices in close proximity to the human body

- Main changes of A1: The inclusion of new normative document EN IEC 62209-3:2019 and associated procedures in addition to IEC 62209-2:2010

Specific Absorption Rate

Traditional SAR measurement system

- A traditional SAR measurement system consists of a phantom filled with a tissue-equivalent medium, electronic measurement instrumentation, a scanning system, an E-field probe and a DUT holder.
- The scanning system is an automatic positioning mechanism capable of placing the measurement E-field probe at specified positions.

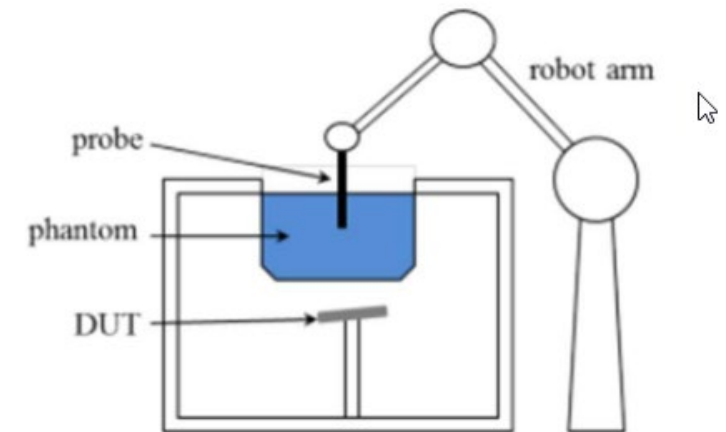


Source: Liu, Z., Allal, D., Cox, M., & Wiart, J. (2020). Discrepancies of Measured SAR between Traditional and Fast Measuring Systems. International Journal of Environmental Research and Public Health

Specific Absorption Rate

Increasing Number of Radio Interfaces

- The number of radio interfaces that need to be tested to assess SAR has increased over the last years.
- The methods included in the international standard IEC/IEEE 62209-1528 require excessively long testing times to assess compliance with SAR restrictions.
- A modern smartphone would require several weeks of continuous testing to demonstrate compliance with SAR limits using the diode probe and robot specified in IEC/IEEE 62209-1528.

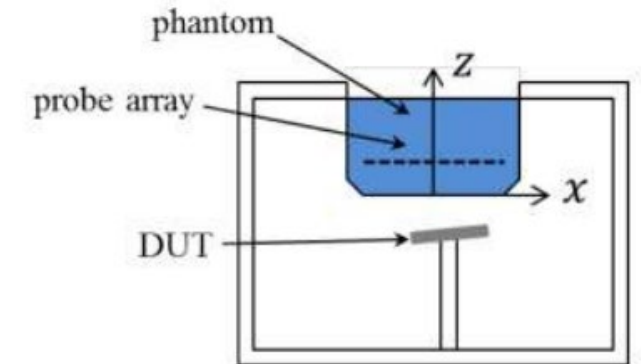


Source: Liu, Z., Allal, D., Cox, M., & Wiart, J. (2020). Discrepancies of Measured SAR between Traditional and Fast Measuring Systems. International Journal of Environmental Research and Public Health

Specific Absorption Rate Array Measurement Systems



- Array measurement systems use multiple vector or scalar probe elements that are located at fixed positions on a two-dimensional or three-dimensional grid to obtain the measurement data needed to reconstruct the field within and outside the scanned area and in the region of interest.
- The probe array measures the amplitude and phase of the electric field on a single plane.



Source: Liu, Z., Allal, D., Cox, M., & Wiart, J. (2020). Discrepancies of Measured SAR between Traditional and Fast Measuring Systems. International Journal of Environmental Research and Public Health



Content

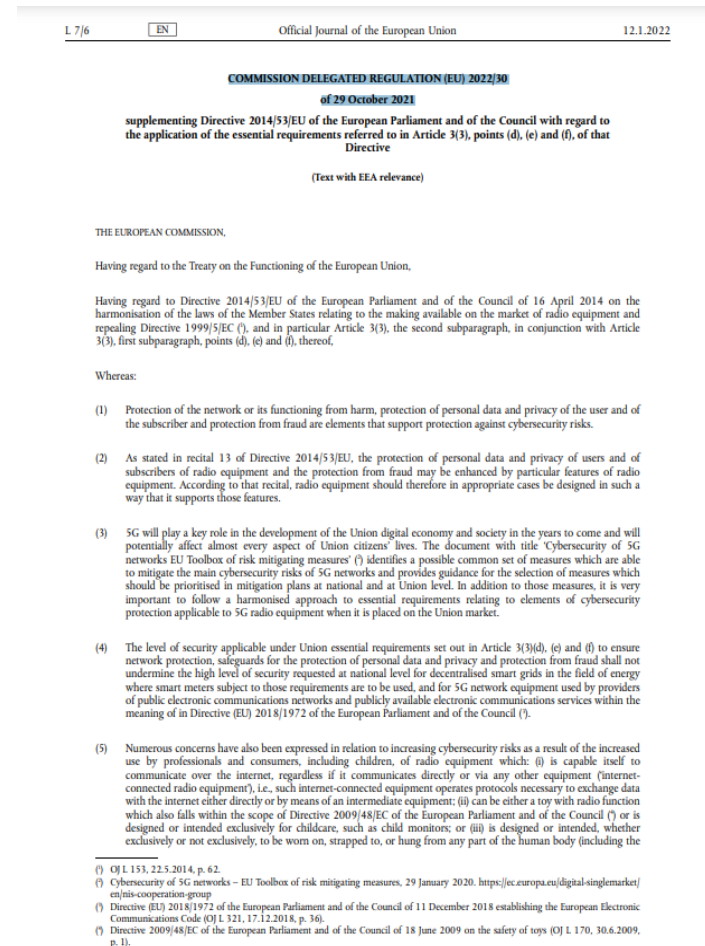
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RED Delegated Regulation EU 2022/30

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”



Development of HS

CEN/CENELEC JTC 13/WG 8 Special Working Group RED



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

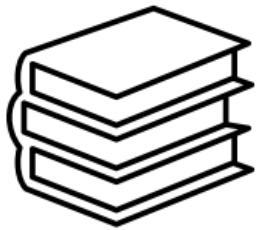
- prEN 18031-1 Common security requirements for radio equipment
– Part 1: Internet connected radio equipment
- prEN 18031-2 Common security requirements for radio equipment
– Part 2: radio equipment processing data, namely Internet connected radio equipment, childcare radio equipment, toys radio equipment and wearable radio equipment
- prEN 18031-3 Common security requirements for radio equipment
– Part 3: Internet connected radio equipment processing virtual money or monetary value

Excerpt from the presentation of JTC 13 WG 8

REDCA Meeting Lisbon, Portugal, November 2023



Family of standards



Each of the 3 standards address one of the essential requirements defined in articles 3.3.d, 3.3.e and 3.3.f of Directive 2014/53/EU and activated by the Commission Delegated Regulation (EU) 2022/30.

Document	Covers the essential requirements of	Addresses security assets and risks	Addresses network assets and risks	Addresses privacy assets and risks	Addresses financial assets and risks
prEN 18031-1 (JT013058)	3.3.(d)	✓	✓	✗	✗
prEN 18031-2 (JT013059)	3.3.(e)	✓	✗	✓	✗
prEN 18031-3 (JT013060)	3.3.(f)	✓	✗	✗	✓

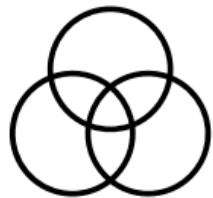
Whether one or multiple standards need to be applied to a specific radio equipment is a consideration that must be made through a risk assessment by the economic operator.

Excerpt from the presentation of JTC 13 WG 8

REDCA Meeting Lisbon, Portugal, November 2023



Main requirements in the three standards



Requirement	3.3.(d)	3.3.(e)	3.3.(f)
[ACM] Access control mechanism	✓	✓	✓
[AUM] Authentication mechanism	✓	✓	✓
[SUM] Secure update mechanism	✓	✓	✓
[SSM] Secure storage mechanism	✓	✓	✓
[SCM] Secure communication mechanism	✓	✓	✓
[LGM] Logging mechanism	-	✓	✓
[DLM] Deletion mechanism	-	✓	-
[UNM] User notification mechanism	-	✓	-
[RLM] Resilience mechanism	✓	-	-
[NMM] Network monitoring mechanism	✓	-	-
[TCM] Traffic control mechanism	✓	-	-
[CCK] Confidential cryptographic keys	✓	✓	✓
[GEC] General equipment capabilities	✓	✓	✓
[CRY] Cryptography	✓	✓	✓

!
 Note that the details of the requirements and assessment criteria and the number of sub-requirements will differ between the 3 standards.

Excerpt from the presentation of JTC 13 WG 8

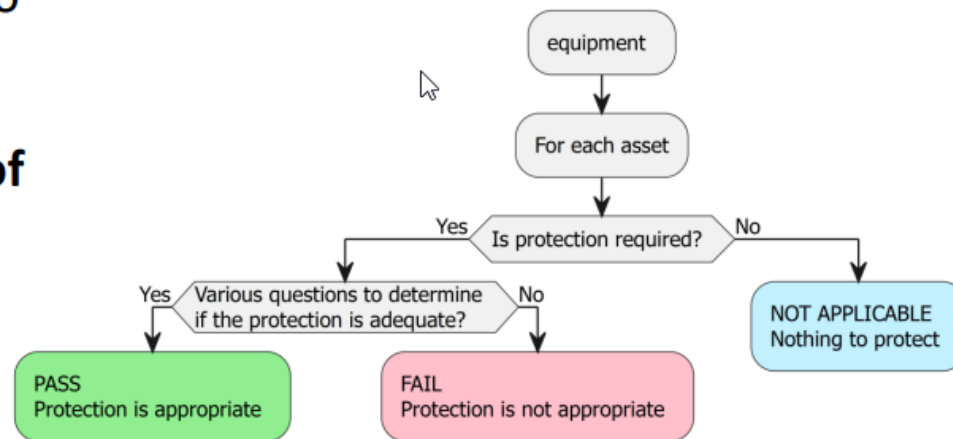
REDCA Meeting Lisbon, Portugal, November 2023



Decision trees

The standards provide **decision trees** to aid in the decision making and assessment to provide clear direction.

The decisions must be made for **each of the items specified**, for example when checking the applicability of a requirement on external interfaces, then the decision whether the appropriateness requirement and all further sub-requirements need to be fulfilled is determined for each external interface independently.



Risk Assessment



Why is the assessment of Security different?

- In general, it is not possible to “measure” security.
 - This is different from the assessment of the other aspects of the RED, where we compare physical test results against limits.
- As with the other aspects, the conformity assessment begins with a risk analysis and risk assessment.
 - This assessment results in the individual risks of a product, which must be documented.
 - These risks must be minimized, for example by carrying out appropriate assessments and tests.
 - A test plan is created from the risk assessment.

Risk Assessment



Which standards should be applied?

- The use of harmonised standards is not mandatory.
 - From today's perspective, it is to be expected that the harmonized standards will not contain detailed test cases.
 - The reason is the horizontal scope with a huge variety of products included.
 - Furthermore, it is currently difficult to estimate whether they can be completed on schedule.
- It therefore makes sense to look at other standards.
 - Examples include the application of ETSI EN 303 645 or IEC 62443-4-2, both of which provide valuable information in their area of application.
 - It should be noted that none of these standards fully covers the essential requirements of the RED 3.3d/e/f. This has to be addressed in the Risk Assessment.

Risk Assessment and Technical Documentation

Example Access Control



- Manufactures would have to document all external interfaces that the equipment has.
 - For all the external interfaces, the manufacturer has to document whether access control is required.
 - If access control is required:
 - What access controls were implemented?
- This gives a detailed output of what has been designed into the product to mitigate the risks arising from access controls.

Notified Bodies in NANDO

New Approach Notified and Designated Organisations Information System



- 63 RED-Notified Bodies are listed in NANDO.
- 15 RED-Notified Bodies are listed with the scope „Article 3.3.d“ in NANDO currently (2024-01-24).
- This figure will continue to rise in the future.

The screenshot shows the 'Single Market Compliance Space' interface for 'Notified Bodies'. It includes search filters for Country, Body type, Notification status, Legislation, Procedure/article or annex, and Products. The search results table lists 15 notified bodies.

Body type	Body Name	Country
NB 0063 ex:620,956,560	Kiwa Nederland B.V.	Netherlands
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 0366	VDE Prüf- und Zertifizierungsinstitut GmbH	Germany
NB 0370	LGAI TECHNOLOGICAL CENTER, S. A.(Applus+)	Spain
NB 0413	INTERTEK SEMKO AB	Sweden
NB 0470	NEMKO Group AS	Norway
NB 0598 ex:403	SGS FIMKO OY	Finland
NB 0681	Eurofins Product Service GmbH	Germany
NB 0682	cectecom advanced GmbH (formerly CTC advanced GmbH, merged with CETECOM GmbH (NB 0680))	Germany
NB 0700	PHOENIX TESTLAB GMBH	Germany
NB 1008	TÜV Rheinland InterCert Muszaki Felügyeleti és Tanúsító Korlátolt Felelősségű Társaság	Hungary
NB 1413	MATRIX TESTING, INSPECTION AND CERTIFICATION LTD.	Hungary
NB 2784	KL-Certification GmbH	Germany
NB 2806	CerTrust Kft.	Hungary
NB 2957	Intercert Global Sp. z o.o.	Poland



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Radio Equipment in Vehicles

Type Approval Regulations for Vehicles



- Vehicles, equipment and parts are regulated under type approval regulations, e.g. UN/ECE Regulation No. 10 in EMC.
- There are currently no UN/ECE regulations on radio equipment.
- In the sense of the European Low Voltage-, EMC- and Radio Equipment Directive vehicles are defined as „non electrical products“.

Radio Equipment in Vehicles

Responsibility of Vehicle Manufactures



- The main responsibility of the vehicle manufacturer is to ensure that the installation of the radio equipment in the vehicle does not compromise the compliance with the RED.
- The vehicle manufacturer has to perform a risk assessment, including additional testing, if necessary.
- It is a verification that the radio equipment, when it is installed in the vehicle and it operates in combination with systems, parts or components of the vehicle, remains compliant with the RED.
- The European Commission has drafted a position paper to clarify the responsibilities of the radio manufacturer and the vehicle manufacturer.



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REDCA Technical Guidance Notes

TGNs on Development



- TGN 33 on Radio Equipment installed into Vehicles
 - It is still a work in progress.
- TGN 29 on Guidance related to NB EU-TEC updates
 - A new version is expected in 2024
- TGN 30 Risk analysis/assessment guide
 - ETSI is working on a risk assessment guide for manufacturers. *“ETSI TR 103 879 Guidance on risk assessment and risk reduction for radio equipment according the Radio Equipment Directive 2014/53/EU”*
 - It will be limited to the requirements of article 3.1b) (EMC) and article 3.2 (radio)



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REDCA Information

Last and next Meeting



- The 46th REDCA meeting was held hybrid in Lisbon, Portugal with more than 200 participants in November 2023.
- 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 a European City **in the week commencing 13 May 2024.**
- Depending on the venue, a hybrid meeting is foreseen.



Thank you for your attention.

Any Questions?

chairperson@redca.eu

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, CEN/CENELEC, 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 in a European city in the week beginning May 13, 2024.**
- 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.