

Radio Equipment Directive RED 2014/53/EU

Questions currently raised in the application of the RED



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RED-CA

Radio Equipment Directive - Compliance Association

RED Background material



RE = Radio Equipment

- 1. Directive text RED 2014/53/EU** on COM website
- 2. Blue Guide** on the implementation of EU products rules 2016
- 3. RED Guide** (draft) + **short RED Guide** (draft)
- 4. List of NB** on NANDO website
- 5. List of EEA Authorities** on COM website
- 6. List of RED Harmonised Standards (HS)** in OJEU
- 7. Commission RED delegated acts** on COM website
- 8. REDCA material** on www.redca.eu
- 9. ETSI material** on www.etsi.org
- 10. ECC material** (EFIS + newsletters) on www.cept.org/ECO



Blue Guide (BG)

Version July 2016



Applicable to all EU product Directives.

Many questions can be answered by reading the BG.

Please make yourself aware of the BG – it is important.

Published in OJEU C272 of 26 July 2016 in all 22 EU languages

<http://ec.europa.eu/DocsRoom/documents/18027>

- The **BG** sets general requirements but individual Directives may differ!
- The RED is always leading (**has become law after being transposed by the Member State**)

RED Guide nearly ready (extra slide)



Latest draft Version March 7. Meeting March 20

Main Issue to solve was: "Combined Equipment"

Principle accepted that:

A non-radio equipment with a radio module becomes a single radio equipment under the RED if:

- The module is incorporated into the non-radio equipment, and**
- The module is permanently affixed to the non-radio equipment**

Commission indicates: The Guide will be published someday between today and June"

RED Applicability



Applies in all 28 EU Member States.

+ EFTA States (Liechtenstein, Iceland, Norway)

& in Turkey, once **Turkey's alignment** with RED is confirmed by the EU-Turkey Customs Union Agreement.

Notes:

- RED is transposed in Swiss legislation: RE has to comply with the RED to access the Swiss market. But the Swiss market is not part of the EU or EEA Market.
- Serbia plans in 2017 to transpose RED into national law.

When the terms "*European Union*", "*Union*", "*territory*" or '*Member States*' are used in the RED, they apply to all 28 EU MS + Liechtenstein, Iceland, Norway & Switzerland & Turkey (once aligned).

Detail information can be found in the **BG** section 2.8.

RED in transition period. 3 months to go.



Manufacturers have a choice!

Use RED now for RE under RED scope!

Or:

Use R&TTED until 12 June 2017 for RE under the R&TTED scope.

- **Some former R&TTED products have now moved to EMCD/LVD!**
- **Each Directive has its own unique list of HS!**

Confusion spreading around?



Some people say:

- RE “New on the EU market” must use the RED
- Only RE of a series or type already on the EU market before June 13, 2016 can still apply the R&TTED during the transition period.

Absolutely incorrect!!

Any individual RE placed on the market before 12 June 2017 can either use the *R&TTED* or *the RED*

But it may not be handy for new products to still use the R&TTED!

Overview of the applicability of 2014/53/EU (RED), 2014/35/EU (LVD), 2014/30/EU (EMCD)



1. Products in old LVD/EMCD scope and continue to be in new LVD/EMCD scope (even after applicability of the RED)

- **Products placed on the market now:**



new LVD/EMCD

2. Products within R&TTE that remain within the scope of RED

- **Products placed on the market between now & 12/06/2017:**

R&TTED or RED

- **Products placed on the market after 12/06/2017:**

RED



3. Products in old/new LVD/EMCD scope but now in RED scope

For example pure television and sound broadcasting receivers.



- **Products placed on the market between now & 12/06/2017: RED or new LVD/EMCD**

- **Products placed on the market after 12/06/2017:**

RED

4. Products within R&TTED and then outside RED

For example pure wired telecom terminal equipment - TTE.



- **Products placed on the market now:**

only the new EMCD and LVD depending on the voltage limit are applicable.

If the LVD is not applicable than the GPSD could be applicable provided that the equipment is a consumer product.

Extension transition period??

RED transition period will be extended by the EU Commission because lack of RED HS.

- **Can only be done via changing the RED!**
- **Must involve the EU Parliament & EU Council.**
- **Modifying RED would include long procedures (changing a Directive normally takes many years).**

Absolutely impossible and totally not considered by the EU Commission!!

But something may be done in the OJEU on Standards applicability!

My product is a combined product (washing machine with WiFi module).

Question: Can I, just to be sure, issue a DoC that refers to EMCD, LVD and RED at the same time?



- **Art. 1.4 RED:** “RE shall not be subject to LVD, except as set out in LVD Article 3.1.a.” (= Only LVD essential requirements are copied, without voltage limitation!)
- **Art. 2.2(a) EMCD:** “EMCD shall not apply to equipment covered by the R&TTED.”
- **Art. 50 RED:** “R&TTED is repealed. References to the repealed R&TTED shall be construed as references to the RED.”

So: if RED applies, LVD & EMCD never apply!

Conclusion: You cannot issue a DOC that refers to EMCD, LVD and RED at the same time!

Compare RED with R&TTED



RED scope is different from R&TTED scope!

**RED requirements are different from R&TTED requirements.
(e.g. receivers parameters added)**

R&TTED compliant RE is not automatic compliant with the RED!

A new (or a complementary) assessment is needed for R&TTE RE to be still placed on the EU market under the RED.

Example



HS list for R&TTED indicates: EN 300 328 V1.9.1

HS list for RED indicates: EN 300 328 V2.1.1

V2.1.1 = State of the Art for RED.

If you want presumption of conformity after June 2017, V.2.1.1 has to be used. There is no need to use a NB.

You are free to use anything else after June 2017, but then it is mandatory to go to a NB.

There is no way out! If you still want to use V1.9.1 because you are not ready for V2.1.1 then you must use an NB and discuss with them if V1.9.1. is still usable.

NB's will probably not accept this, because RED standards have different requirements compared to R&TTED standards.

**EU Legislation applies to each
Individual product!!**



**Making available on the market refers to
each individual RE, not to a type, and
whether it was manufactured as an
individual unit or in series.**

***If your RE was on the market applying the
R&TTED then in June 2017 the RED applies
with different administrative/technical
requirements!***

***Any RE continued to be marketed
then must fully comply with the RED!***



RED applies to my product. I want to use standards for human exposure testing (requirement according to Art. 3.1.a), but for my product I see no HS for Human Exposure yet mentioned in the OJEU for the RED.

Question: Can I apply the R&TTED HS list?

Yes you can and you do not need to use a NB!

BUT:

You do not automatically enjoy “presumption of conformity” (because you did not use RED HS), so you need to carefully check (risk assessment!) whether all safety essential requirements correctly have been complied with and conclude that in your TD.

If in doubt ask voluntary help from an expert organisation (like one that may also be NB!)



I apply the RED to my product. I want to use EMC HS for testing (to apply Art. 3.1.b), but I see no applicable EMC HS mentioned in the OJEU for the RED.

Question: Can I then apply the EMC Harmonised Standards from the R&TTED list or the EMCD List.

Yes you can and you do not need to use a NB!

BUT:

You do not automatically enjoy ""presumption of conformity"" (because you did not use RED HS), so you need to carefully check (risk assessment!) whether all EMC essential requirements correctly have been complied with and conclude that in your technical documentation.

If in doubt ask voluntary help from an expert.

There are no RED HS yet for my product to cover the essential requirements of Article 3.2.

Question: Can I apply the previously applicable HS from the R&TTED list that are applicable to my product.



Yes you can! BUT:

- 1. Those standards do not give you “presumption of conformity” (not harmonised for the RED)**
- 2. The standards may lack receiver requirements or other requirements that are mandatory to cover under the RED.**
- 3. You must consult a RED Notified Body and ask them to perform an EU Type Examination Assessment on your product Technical Documentation. Your TD should contain a risk assessment.**
- 4. You must be able to show the Type Examination Certificate received from the NB, if asked by the Member States Market Surveillance Authorities.**

RED Notified Bodies



Can only work if they are listed on **NANDO (RED section)**! Currently there are 54 RED NB.

53 can deal with Module B/C. **1 in Japan**

22 of the 54 can deal also with Module H.

1 can deal only with Module H.

Several former “R&TTED NB” (total 75) are not RED NB or will not become RED NB!

- ◆ **There is no relation between manufacturers location and NB location!** (A Chinese manufacturer can use a Japanese NB to certify the RE to enter the EU)
- ◆ **Choice of an NB is totally free!** (no shopping around!)

NANDO site:

<http://ec.europa.eu/growth/tools-databases/nando>

I have a product with 2 radio systems. Such as a Wi-Fi transmitter and Bluetooth transmitter.



Question: Can I ask NB to only do the assessment on the Bluetooth transmitter while I do the Module A assessment for the Wi-Fi part myself for which I use RED HS.

- ◆ **No you cannot !** If you go to a RED NB, the NB must assess the complete “Radio Equipment”. The RED does not allow the NB to assess only “Parts” of a “RE” product. The RED does not make a distinction between RE where parts (technologies) are covered by HS and other parts (technologies) not covered by HS.
- ◆ Therefore, where there is a mix of Article 3.2 HS and non-HS and/or a mix of technologies, the NB has as a minimum the duty to establish the conformity **of the whole “Radio Equipment” product with regard to Article 3.2.**

A Host device has no transmitters/receivers itself. With added wireless LAN USB dongles, the host can communicate.



Question: Does the host need CE marking for RED:

- 1. If the USB dongle is included in host devices**
- 2. If users buy and install the USB dongle in the host devices**
- 3. If manufacture install these USB dongles in the host devices.**

1. The product entering the market is a Host including a wireless part. The RED (CE marking + DoC, etc) is applicable to the complete Host.

2. The Host entering the market is not a wireless product and only needs CE marking (+ DoC) following the EMCD and LVD

3. This is similar to 1.

Note next slide about products packed together in one box!

Sets containing a RE (e.g. Mobile Phone) and accessoires (e.g. Charger) sold together in one box.



EU Commission recently stated:

«*Each product has to follow the Directives applicable to it.*»

Then the RE falls under the RED while the charger falls under the EMCD and LVD. **This was not the case in the past!**

To avoid any confusion COM proposed that the charger should always be under the EMCD and LVD disregarding if it is marketed together with a RE or not. **That is the final current situation for the draft RED Guide.**

COM has not yet taken final decision but very likely to happen as above. Important issue for manufacturers, it may involve several administrative complications.

Please be aware! Follow the developments! (REDCA may know them at an early stage!)

Many questions asked about **Risk assessment (RA)**



The Risks are always related to the Essential requirements.

EMCD: EMC related risks (creating interference or due to immunity not allowing a product to perform its function correctly)

LVD: Safety related risks (electrical hazards to humans, domestic animals and property)

Toys: Risks related to harming children

RED: 3 (or 4) types of risks

- RF spectrum related (Art. 3.2)
- Safety related (including SAR!) (Art. 3.1.a)
- EMC related (Art. 3.1.b)
- + maybe related to other aspects (art. 3.3).

The risks to be covered for RED are technically different for each essential requirement and may require a different approach.

We see many manufacturers only thinking about classical safety risks! That is totally insufficient!

Risk assessment: Some General rules



Manufacturers RA is not the RA as done by the MS Authorities

Administrative non-compliances are not considered to be a risk.

RA must be carried out by the manufacturer, not by a 3rd party Test Lab or NB or any other party. The manufacturer is fully responsible for the RA.

The RA has to be documented and included in the TD, unless the RA is fully included in the HS applied and cover(s) all applicable essential requirements. (CHECK THAT and if so mention it in the TD!! It is in many cases not clear or true!)

Even if HS are used, the RA has to be carried out and the manufacturer must check whether the HS covers all risks of the product. This is because it cannot be assumed that HS covers all requirements of all Directives applicable to the product or whether the product introduces also other risks not (yet) considered in the HS. The product may be using a new technology not yet covered by the HS!

Procedure for Risk Assessment



- 1. First identify all possible risks and then determine which RED essential requirements are applicable to the product. This analysis has to be documented and must be included in the TD.**
- 2. Then document the assessment of how the risks identified are going to be addressed (for example, by applying certain HS).
All risks shall be covered by the technical solutions applied (standard or other)!**

Notes:

- **State the relevant phenomena of the RE and its environment.**
- **Compare the typical and reasonably foreseeable use of the RE to the parameters in the standards: Do the standards used really cover all of the identified risks?**
- **Where the RE can take different configurations, check that the assessment confirms that the RE meets the essential requirements, “in all possible configurations”.**
- **If only part of the HS is applied or it does not cover all applicable essential requirements, then the way applicable essential requirements not covered by it are dealt with, must also be documented.**

RA applicability unclear?



RED text seems to suggest that only for Module B/C and only for Article 3.2 essential requirements, the product TD shall contain a RA, which needs to be checked by the NB.

This is not true!!

For all Modules (including Module A and H!) and for all essential requirements, (Art. 3.1.a & 3.1.b & 3.2 & 3.3) the product TD shall always contain the RA!!

(similar for EMCDD and LVD! In all cases to apply risk assessment)

Good background documents on risk assessment



CENELEC Guide 32: Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment

Download free of charge from:

<https://www.cenelec.eu/membersandexperts/referencematerial/cenelecguides.html>

Blue Guide Section 2.7 and 4.1.1 and 4.3

RED Harmonised Standards (HS)

A HS is a European standard = EN (so not an IEC Standard or similar!) adopted by CEN, CENELEC or ETSI, on the basis of a request made by the Commission.

Only after the reference is published in the OJEU the "presumption of conformity" exists!!

HS published under R&TTED, LVD or EMCDD cannot be considered as HS under the RED!!!

RED HS published in the OJEU = State of the Art



Manufacturers will often use the method of applying all HS, which provides presumption of conformity with the RED essential requirements. EU Commission tries to give “approximately” monthly OJEU updates. The list is not complete as ETSI is still working on several standards.

ETSI RED Standards work programme

251 Work Items for Harmonised Standards (as per 24.1.2017)

51 Harmonised Standards in the OJEU (10.2.2017)

79 Harmonised Standards awaiting OJEU listing.

48 in Public Approval/Resolution of comments

8 Approved by TB – awaiting start of ENAP

97 Scheduled for delivery to EC after June 2017

Guides & EMC Standards for “Combined Equipment”

- ❖ **ETSI Guide EG 203 367: Published June 2016**
- ❖ **Dedicated HS (EN 303 446-1) for combined equipment in the domestic environment**
Approved by ETSI October 2016
(Not yet in OJEU)
- ❖ **Standard for Industrial environment (EN 303 446-2) under development**

No exemption of the RED based on:

- Transmit or Receive Frequency
- Level of transmit output power or receiver sensitivity
- Input Power Voltage or Current
- Size of the product, Mass produced or single product, etc.

Specific Exemptions of the RED

- custom built evaluation kits destined for professionals to be used solely at R&D facilities (**COM is preparing detailed guidance, will be in RED Guide**)
- Products and applications that use EM waves for other purposes than radio communication and/or radio determination (generally known as ISM equipment) for example:
 - inductive warming and heating appliances;
 - pure wireless power transfer (without any communication or radio determination on the same frequency of the power transfer or any other frequency). **If the WPT product detects/senses the position of the device/object, this is radio determination and thus covered by the RED.**
 - RF surgical equipment and systems, cookware suitable for inductive heating appliances and Inductive and capacitive proximity switches and sensors

Exemptions of the RED



Airborne equipment

Airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 **are excluded from the RED.**

But: Still to be decided the following: !!

Radar for helicopters flying in confined spaces and wing-tip radar for aircraft taxiing on the ground will be covered by the RED.

“Small” UAV (Unmanned Aerial vehicle) covered by Machinery Directive & RED, and not EASA

GSM/LTE on Board will not be covered by EASA as they are not involved in the direct control of the aircraft in flight

Specific example: **Drone (UAV)**

Drones < 150 kg are excluded from the scope of Regulation 216/2008 and are subject to the RED, while drones > 150 kg are not subject to the RED.

In future this may change because of the discussions about the new EASA regulation .

Please follow developments

RED Delegated acts for Article 3.3 essential requirements



Article 3.3 has additional requirements but is only effective if a delegated act is adopted

There are currently no delegated acts yet for RED Article 3.3

BUT: Art. 50 RED: References to the repealed R&TTED shall be construed as references to the RED.”

So: Commission Decisions adopted under the R&TTED according to Article 3.3 continue to be valid for the RED.

- 2000/637/EC: to radio equipment covered by the regional arrangement concerning the radiotelephone service on inland waterways
- 2001/148/EC: to avalanche beacons
- 2004/71/EC: on essential requirements relating to marine radio communication equipment which is intended to be used on non-SOLAS vessels and to participate in the Global Maritime Distress and Safety System (GMDSS)
- 2005/53/EC: to radio equipment intended to participate in the Automatic Identification System (AIS)
- 2005/631/EC: concerning ensuring access of Cospas-Sarsat locator beacons to emergency services

Make sure to take account of them, if relevant!

Expected RED implementation acts



- Clarify definition of radio equipment (RED Article 2.2)
 - Operational rules for the information on the compliance of combinations of RE and software (RED Article 4)
 - Operational rules for Product Registration (RED Article 5)
 - Establish the equivalence between notified radio interfaces and assigning a RE class: (RED Article 8.2)
 - Information on restrictions on putting into service or requirements for authorisation of use exist (RED Article 10.10)
 - Withdrawal of a NB (RED Article 33.4)
 - Determining whether the national measure to prohibit or restrict the RE is justified or not (RED Article 41.1)
 - Compliant equipment which presents a risk (RED Article 42.4)
- = Has Priority and are currently being prepared.*

Be aware!

Draft Implementation Act RED Art. 10.10

If RE has restrictions on putting into service or to requirements for authorisation of use, the packaging of the RE shall indicate visibly and legibly:

- (a) a pictogram, or
- (b) the words 'Restrictions or Requirements in', in a language easily understood by end-users as determined by the MS concerned, followed by the abbreviations of the MS, where such restrictions or requirements exist.

The pictogram shall be in the form of a table.

Its contents may take different variations (e.g. colour, solid or hollow, line thickness), provided they remain visible and legible

Requirement: list MS where restrictions exist.



AT	BE	BG	CZ	DK
EE	FR	DE	IS	IE
IT	EL	ES	CY	LV
LI	LT	LU	HU	MT
NL	NO	PL	PT	RO
SI	SK	TR	FI	SE
CH	UK	HR		

Example for 5 GHz WiFi products that can operate in 5150 – 5350 MHz.

Need to have this pictogram containing the symbols of all EEA countries. (Switzerland & Turkey included)

The User instructions must contain all the details about the restriction.

This relevant information shall be translated only into the language(s) of the MS where the RE is marketed

Latest Market surveillance campaign on Radio Controlled Toys



4 groups of toys:

- **RC vehicle** – design to ride on wheels,
- **RPAS** – design to fly,
- **RC boat** – design to float,
- **other RC toy which cannot be part of above mentioned groups.**

RC Toys characteristics



Operating frequency ranges:

27 MHz, 35 MHz, 40 MHz, 2,4 GHz

Numbers checked:

Overall RC vehicle	56	1	20	7
RPAS				12
RC boat	3		1	
Other RC toy	6		2	3
Overall	65	1	23	22

Majority of RC toys manufactured in PR China (97%), remotely controlled on the 27 MHz (59%) and designed as a RC vehicle (76%)

Results



> 70% administrative non-compliances

81% of RC toys had at least one non-compliance.

41% of assessed RC toys were found to be non-compliant in relation to the effective use of spectrum.

Spurious emissions (98% of technically non compliant products) is the main reasons for non-compliance against art. 3.2.

These low compliance figures could lead to applying in future the RED product registration procedure to this product category!

Example of recent Rapex action against Radio (RED) product



Rapid Alert System for dangerous non-food products



Alert number	A12/1399/16
Category	Hobby/sports equipment
Risk level	Serious risk
Product user	Consumer
Product	Fitness watch
Brand	BASIS
Name	PEAK
Type/number of model	Unknown
Batch number/Barcode	The recall affects all Peak watches (sold until June 2016).
OECD Portal Category	77000000 - Automotive
Description	Wristwatch-type fitness and sleep tracker device with a USB charging cradle.
Country of origin	China
Notifying country	Spain
Risk type	Burns, Fire
Risk description	The charging cradle can overheat leading to a fire. In addition, the watch can overheat causing burns to the skin on the wrist underneath the watch. The product does not comply with the requirements of the Radio Equipment Directive.
Measures adopted by notifying country	Measures taken by economic operators: Recall of the product from end users (By: Importer)
Products were found and measures were taken also in	Denmark, France
Images	

Is REDCA of interest to you?



- 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, etc.
 - Possibility to get answers from fellow experts on specific RED (technical) questions.
 - Special Workshops
- 205 members (many also from outside EU such as Japan, China, USA, etc.)

Interested? Go for information to: www.redca.eu
or talk to me!!

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Thank you for your attention

Any QUESTIONS ??