

Guide to  
**CE Marking &  
Radio Equipment Directive**  
for Low Power  
Wireless Transmitters



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Complete EMC & Environmental Stress Testing

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# 1 CE and RE Directive Overview

The CE Mark is the label placed on manufactured and imported goods in the European Union. It declares that a product meets the applicable essential health and safety requirements for European citizens.

This one label and the regulatory infrastructure behind it comprise the product conformity laws for the 28 European Union nations along with the EFTA countries of Iceland, Liechtenstein, and Norway. The CE processes are also adopted by Switzerland and Turkey through separate trade agreements. The CE Mark replaces a patchwork of individual regulatory schemes where previously every one of the separate European countries operated with their own rules, regulations, process, and conformity marks.

Many non-European nations also accept CE mark technical compliance file as evidence of conformity with their regulations without the need for further tests and evaluation. And though some nations will only accept “in-country” testing, they still follow standards aligned with the procedures and technical requirements specified in the European CE Marking regulations.

The CE regulations cover a broad range of products and set the requirements for the essential health and safety of Union citizens as well as for product operability. There are over 20 different new approach directives. Some are product and industry specific directives for categories such as medical electronics and radio transmitters and others are more general directives such as Low Voltage or EMC.

The CE mark is indeed a wide-ranging European requirement, but its acceptance and adoption by other nations plus the broad range of products that it applies to makes its reach truly global.

What is the CE Mark  
and where does it apply ?



European  
Union (EU)



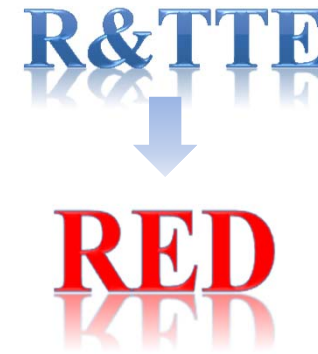
# 1 CE & RE Directive Overview

What is the RE Directive ?

The focus of this document is to describe the CE Marking conformity assessment process for low power short range wireless devices. This information will address the more common transmitters and receivers such as Bluetooth, WiFi, Zigbee, and other low power devices. These transmitters have operating frequencies harmonized for use throughout the EU.

Starting in June 2016 the Radio Equipment Directive (RED) is the new compliance requirement in Europe for wireless transmitters. The RED replaces the R&TTE Directive which previously covered radio transceivers and telephone equipment. There is a one year transition period for manufacturers who have previously issued conformity assessments for the R&TTE to transition to the RED.

Many other of the European New Approach Directives have also been updated recently including the EMC and Low Voltage Directives. The new EMC and LVD came into law in April 2016 but without any transition period.



## R&TTE Directive Transition

June 12, 2016 - Either R&TTE or RED

June 13, 2017- Only RED

### Directives Updates April 2016

Low Voltage -	2014/35/EU
EMC-	2014/30/EU
ATEX-	2014/34/EU
Lifts-	2014/33/EU
Simple Pressure Vessels-	2014/29/EU
Measuring Instruments-	2014/32/EU
Civil Explosives-	2014/28/EU
Non-automatic Weighing Instruments-	2014/31/EU

### Previously Updated Directives

Pyrotechnic Articles-	2013/29/EU
Toy Safety-	2009/48/EU
RoHS-	2011/65/EU
Recreational Craft	2013/53/EU

### Future Updates

Pressure Equipment-	2014/68/EU
Marine Equipment-	2014/90/EU

# 1 CE & RE Directive Overview

What's the reason behind the update in Directives?

The recent changes to the European CE directives are driven by initiatives for alignment with the EU's New Legislative Framework (NLF). The New Legislative Framework is a set of EU regulations that provide enhanced definitions and specific descriptions on the European conformity processes. They provide more detail for the meaning of the CE Mark so that the responsibilities of all economic operators are clear. The regulations bring better clarity and process for policies on accreditation and for recognition of notified bodies and other conformity assessment parties. In addition, the NLF establishes a more structured process for enhancing import controls and for addressing market surveillance. The objectives of the NLF is to lessen the burden on manufacturers and importers and improve trade while maintaining the safety of users.

For a few manufacturers the technical changes resulting from the alignment of directives with the NLF will be significant. However, for most manufacturers within the scope of the R&TTE or new RED the impact of the changes will be minimal. For now, manufacturers will simply update technical files and Declarations of Conformity to remain compliant with the RE Directive.

## **New Legislative Framework (NLF)**

- Regulation (EC) No 764/2008
- Regulation (EC) No 765/2008
- Regulation (EC) No 768/2008

## **Main objectives of NLF Regulations**

- Restate and detail definitions , ie
  - Manufacturers
  - Importers
  - Distributors
  - Representatives
- Structure policies for accreditation
- Refine processes for notification of CABs
- Address market surveillance
- Enhance import controls
- Clarify meaning of CE Mark

# 1 CE & RE Directive Overview

The Radio Equipment Directive, or RED is a product-specific directive that establishes the requirements for all wireless transmitters and receivers (*\*see exclusions*).

The scope of the RED includes radio devices that range from cell phone handsets and cell base stations to 2-way land mobile radios and their base stations. It covers microwave backhaul transmission systems, certain marine applications, emergency beacons, radar, radio astronomy, and many others.

One of the common characteristics for these aforementioned devices is their transmit power levels are typically at or above 1W (*low power devices are described next*) and many are licensed service applications, meaning that in addition to the device conformity assessment the end user may need to receive a license to transmit at the particular frequency band. VHF and UHF business and professional radios are examples of licensed device applications.

Licensed devices receive exclusive rights to transmit on a particular frequency, at a specified power, and for a defined geographic location. However, unlicensed transmitters are permitted to transmit on certain licensed bands but at power levels that will not interfere with licensed users.

What types of products are covered by RE Directive ?



## \*Equipment Excluded from RED

- Police, military & state-security
- Radio amateurs
- Marine SOLAS equipment
- Cables and wiring
- Civil aviation & air traffic control

# 1 CE & RE Directive Overview

License exempt transmitters include many familiar consumer products like WiFi, Bluetooth, Zibgee, remote keyless entry, RFID, and garage door controls.

These devices typically transmit at less than 200mW and operate in designated frequency bands with specified powers, bandwidths, and duty cycles. They are primarily sold without the user having to obtain a license.

The applications of low power wireless transmitters are growing rapidly and feeding the pace of expansion for the Internet of Things. Manufactures of wireless devices that are sold into Europe must comply with all the regulations associated with the CE Mark plus any other non-CE requirements.

The European Union requirements for short range wireless transmitters are particularly unique in that the responsibility for declaring compliance is the manufacturer or importer of the device. There is typically not a third party type approval for wireless devices like that in the United States or as in nearly every other country around the world. Once the product is determined to be RED compliant by the manufacturer, importer, or distributor it can be placed on the market and sold to any buyer.

What types of low power transmitters ?



## 2 Determine CE Requirements

What is the process for RE Directive CE Marking?

The RED conformity assessment process is illustrated in the figure at the right. **Step 1** begins by determining the applicable directives, technical standards, and conformity assessment procedures. **Step 2** covers the tests and engineering assessments of the design, construction, and safety operations. In **Step 3**, the reports and findings from the evaluations are prepared, collected, and maintained to substantiate the compliance. Finally in **Step 4** the product is labeled and a Declaration of Conformity (DoC) is prepared to notify the end user and regulatory agencies that the product is ready for placement in the market.

In **Step 5**, manufacturers are required to maintain compliance throughout the life of the product. This includes evaluating continuing compliance despite component replacements, product improvements, and redesigns.

This seemingly straightforward process has proven effective for over 15 years with the R&TTE Directive and now the RED. It has helped sustain the expansive growth of wireless communications in Europe with relatively few instances of interference.

Step 1	Determine All Applicable Requirements Directives Frequency Bands Conformity Assessment Module Harmonized Standards
Step 2	Perform Testing and Analysis Effective Use of Spectrum EMC Low Voltage Directive
Step 3	Prepare Technical File
Step 4	Label Device and Issue the DoC
Step 5	Maintain Technical File and Continuing Compliance



# 2 Directives

Which Directives apply?

One of the primary objectives of European directives is to create a common set of requirements for all member states, and by doing so to eliminate trade barriers and encourage the free movement of goods. The CE Mark “New Approach” directives define essential requirements related to health, safety and environmental issues. They outline the objectives for community wide compliance with a particular aspect of technology, environment, or trade. New Approach directives establish the particular health and safety objective, but the actual technical requirements are specified in detail through harmonized “EN” standards.

Beginning at **Step 1** of the CE process, manufacturers are responsible for identifying all the directives that may apply to their products and applications. There may be a single product specific directive to cover all compliance requirements or several and it is the manufacturers obligation to conduct a comprehensive review to determine all which are applicable .

As an example, a consumer WiFi router will need to comply with the product specific RE Directive, but will likely also have to comply with the RoHS and REACH directives. In addition, the power supply for the router may need to comply separately with the EMC and Low Voltage Directives.

New Approach CE Marking Directives		
General Directives	Product or Application Specific Directives	Product or Application Specific Directives
<b>Chemical substances (REACH)</b> Ecodesign – hot-water boilers Ecodesign and energy labelling Ecodesign and energy labelling Eco-management and audit scheme (EMAS) <b>Electromagnetic compatibility (EMC)</b> Equipment for explosive atmospheres (ATEX) <b>Low Voltage (LVD)</b> Machinery (MD) New legislative framework (NLF) Packaging and packaging waste <b>Restriction of hazardous substances (RoHS)</b>	Explosives for civil uses Gas appliances (GAD) Inspection pesticide application equipment Lifts Measuring instruments (MID) Medical devices (MDD) Medical devices: active implantable Medical devices: in vitro diagnostic	Non-automatic weighing instruments (NAWI) Personal protective equipment (PPE) Pressure equipment (PED) Pyrotechnic articles <b>Radio Equipment Directive</b> Rail system: interoperability Recreational craft Simple Pressure Vessels Toys safety

## 2 Directives

Where to find information on directives & standards?

Manufacturers or importers that place their products in the European market will be required to apply due diligence in identifying and complying with the directives and harmonized standards.

The European Union website portal [www.Europa.eu](http://www.Europa.eu) provides access to the information required to determine the set of directives that apply to a product. Here, manufacturers can download the directives and examine the conformity assessment requirements.

In each directive is a description of the scope of applicability with the specifying details that either include or exclude the product from the directive's requirements.

The Europa portal also posts guidance documents, related regulations, decisions, as well as access to the Official Journal which lists the standards harmonized to the directive.



The screenshot shows the Europa.eu website interface. The main header includes the European Commission logo, the word 'GROWTH', and the URL 'www.Europa.eu'. Below the header, there is a navigation bar with 'Single Market and Standards' selected. The main content area is titled 'Radio equipment'. Underneath, it lists 'Directive 1999/5/EC' and 'Directive 2014/53/EU'. A table provides details for the 'Radio and telecommunications terminal equipment (RTTE)' directive.

Short name:	<b>Radio and telecommunications terminal equipment (RTTE)</b>
Base:	<a href="#">Directive 1999/5/EC</a> of the European Parliament and of the Council on Radio Equipment and Telecommunications Terminal Equipment and the mutual recognition of their conformity OJ L 91 of 7 April 1999 <a href="#">Directive 2014/53/EU</a> 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 Text with EEA relevance. <b>Applicable as of 13 June 2016.</b> OJ L 153, 22.5.2014
Modification:	
Directives repealed:	Directive 98/13/EC was repealed by Directive 1999/5/EC on 8 April 2000
Guidance for:	<ul style="list-style-type: none"><li>• <a href="#">Guidance on CE marking for professionals</a></li></ul>

## 2 Directives

In addition to the New Approach CE Marking directives, other European regulations may apply. For example, if a wireless transmitter is integrated into a passenger car, truck, bus, or agricultural tractor and that wireless device also has an immunity related function such as a CAN bus link, then the device must also carry the “E-Mark” to evaluate the performance of the device related to the safe operation of the vehicle.

The E-Marking type approval process for EMC involves testing the product with a Notified Body witness. It also includes a quality assessment to assure the conformity of production as well as other continuing compliance obligations.

Marine applications may also require type approval services. Certain on-board marine transmitters that are covered by the International Maritime Organization requirements for Safety of Life At Sea (SOLAS) are type-approved under the Marine Equipment Directive, but may also carry the CE Mark if they have other applications on shore.

The important point is that manufacturers/importers are obligated to identify and comply with all applicable requirements, CE Marking or others.

 10 R – 04 2439 UNECE Vehicle EMC Directive marking



Marine Equipment Directive (MED) “Wheel” marking

What other type-approval directives apply?



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### E-Mark

- UNECE Regulation 10.5
- Passenger Cars, Trucks, Buses, Trailers
- Ag & Forestry Tractors

### Marine Equipment Directive

- 96/98/EC
-

## 2 Harmonized Frequencies

Having identified the applicable directives and requirements, the transmitter manufacturer must also ensure the transceiver is authorized for use at the particular frequency bands of operation. There are several European website portals which provide up to date information and guidance on spectrum allocation for their particular device and they include other helpful information on guidance, standards, licensing, and other requirements.

The European Communications Office (ECO) is an organization that serves member countries and adjacent neighboring markets for collaboration on a harmonized radio spectrum. The ECO maintains a website portal [www.efis.dk](http://www.efis.dk) that includes the Frequency Information System (EFIS) where details on frequency allocation, band tables and restrictions, and other utilities that identify operations across the radio spectrum .

The ECO website portal also maintains the current revision of the primary guidance document for short range devices identified as ERC Recommendation 70-03 [www.erodocdb.dk](http://www.erodocdb.dk)

ERC 70-03 provides a helpful summary of the compliance requirements and country specific harmonized frequencies for common low power short range transmitters.

Which transmit frequency bands are permitted ?



[www.erodocdb.dk](http://www.erodocdb.dk)



[www.efis.dk](http://www.efis.dk)

## 2 Conformity Assessment

Conformity assessment is the process for evaluating a manufactured product to the European Union regulations. Because there is such a wide range of products servicing a diverse set of users and environments the RE Directive provides several options for how to conduct an assessment. The most suitable conformity procedure should be selected based on the needs of each application.

For the RE Directive there are three options for conformity assessment when a harmonized standard has been applied. These are given in the directive Annexes II, III, and IV.

The conformity assessment procedure for the majority of low power short range devices is based on internal production control and testing according to harmonized standards. Since there are many harmonized standards for low power short range devices, ie. EN 300 220, EN 300 440, and EN 300 328, Annex II is often applied and is generically called “manufacture’s self declaration”.

A more detailed description on the CE Marking process and the various conformity assessment modules is presented in the European Union “Blue Guide” on the implementation of EU product rules. It is available from the [www.europea.eu](http://www.europea.eu) web portal.

Can I self-declare compliance with the RE Directive ?



# 2 Harmonized Standards

Once the directives are identified, the next step is to determine the applicable harmonized standards to use in the evaluation for the technical requirements.

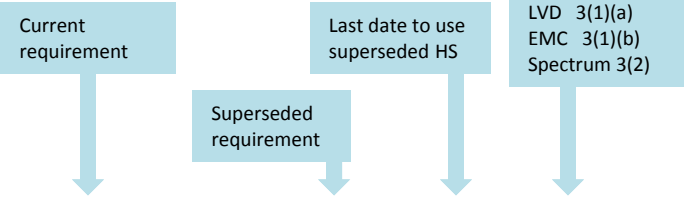
A list of harmonized standards is published in the Official Journal (OJ) of the European Union and are noted as harmonized EU standards with the prefix “EN”. Products evaluated to an EN harmonized standard means the manufacturer is given the “presumption of conformity” with the directives.

A harmonized standard is an international standard that has been developed through various standards development organizations like CEN, CENELC and ETSI. These requirements are drafted by industry experts, manufacturers, and government regulators and then through diplomatic consensus harmonized into a Euronorm “EN”.

For the RE Directive, the OJ identifies standards to apply for effective use of spectrum, EMC, and electrical safety.

Since wireless technology evolves so quickly, the standards are updated regularly to adapt to changes and new conditions. Manufacturers are responsible for monitoring the “OJ” to recognize when standards change and respond accordingly as test limits, processes, or measurement technology update with technological progress.

Which harmonized standards apply to my transmitter?



ETSI	EN 301 489-1 V1.9.2 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements	EN 301 489-1 V1.8.1 Note 2.1	Date expired (30/06/2013)	Article 3(1)(b)
ETSI	EN 301 489-10 V1.3.1 ElectroMagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 10: Specific conditions for First (CT1 and CT1+) and Second Generation Cordless Telephone (CT2) equipment	EN 301 489-10 V1.2.1 Note 2.1	Date expired (30/11/2005)	Article 3(1)(b)
ETSI	EN 301 489-11 V1.3.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 11: Specific conditions for terrestrial sound broadcasting service transmitters	EN 301 489-11 V1.2.1 Note 2.1	Date expired (30/11/2007)	Article 3(1)(b)
ETSI	EN 301 489-12 V2.2.2 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 12: Specific conditions for Very Small Aperture Terminal, Satellite Interactive Earth Stations operated in the frequency ranges between 4 GHz and 30 GHz in the Fixed Satellite Service (FSS)	EN 301 489-12 V1.2.1 Note 2.1	Date expired (30/06/2010)	Article 3(1)(b)
ETSI	EN 301 489-13 V1.2.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 13: Specific conditions for Citizens' Band (CB) radio and ancillary equipment (speech and non-speech)	EN 301 489-13 V1.1.1 Note 2.1	Date expired (30/11/2005)	Article 3(1)(b)
ETSI	EN 301 489-14 V1.2.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 14: Specific conditions for analogue and digital terrestrial TV	EN 301 489-14 V1.1.1 Note 2.1	Date expired (31/07/2006)	Article 3(1)(b)

Official Journal for the RE Directive

## 2 Harmonized Standards

For the RE Directive, the harmonized standards are organized into product specific standards and more generic application standards. Product specific standards nearly always take priority over more generic standards. An example of a common specific standard is EN 300 328 for wide band transmitters operating in the 2.4GHz band.

For short range devices, the more common generic harmonized standards include:

- EN 300 220- Garage door openers, remote keyless entry
- EN 300 330- Theft protection sensors, Near Field Communication (NFC)
- EN 300 440- RC Toys and RFID

These three generic radio transmitter standards are organized by frequency range and include both narrowband and wideband devices.

Manufacturers are encouraged to contact regulatory experts or EMC test labs that specify in RE Directive testing for guidance on the harmonized standards to apply, frequency band usage, and other requirements to consider.



Product specific vs. generic standards?



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### Product Specific Standards

#### EN 300 328- 2.4GHz wideband

- WiFi 802.11b/g/n
- Bluetooth
- Zigbee

#### EN 301 893- 5GHz wideband

- WiFi 802.11 a/n/ac
-

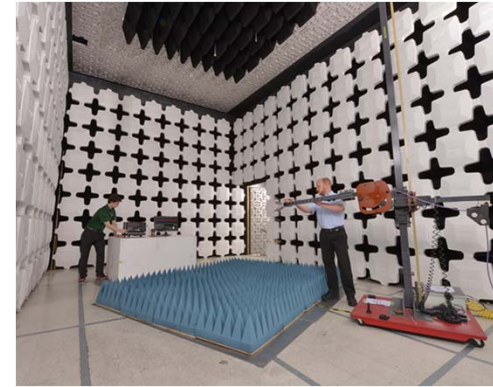
# 3 Tests for Effective Use of Spectrum

Wireless transmitter testing often takes place in an absorber lined shielded enclosure (a 3 or 10 meter ALSE chamber) as well as in open space. Some testing also occurs in a temperature controlled environmental chamber.

Two of the primary tests performed on wireless transmitters are measurements of the **output power and the spurious radiated emissions**. These test are performed by measuring at the transmitter antenna port through attenuation and directly into the measurement receiver's input. In addition, measurements are performed as a radiated test in an anechoic chamber or an open air test site (OATS).

Power and spurious emissions testing is performed with the transmitter operated at the fundamental frequency or at several channels, ie. Low, mid, high frequencies within the operating band. Radiated measurements are first recorded by the compliance receiver as a field strength then converted to power units.

Receivers are also tested for spurious emissions from the antenna port as well as by a radiated emissions test. And just as is the case with transmitters, receivers may need to be tested while tuned to low, mid, or high channels.



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- Output Power
  - Spurious Emissions
  - Transmitter Functions
  - Bandwidth Usage
  - Adaptivity
  - Receiver Functions
-



# 3 Tests for Effective Use of Spectrum

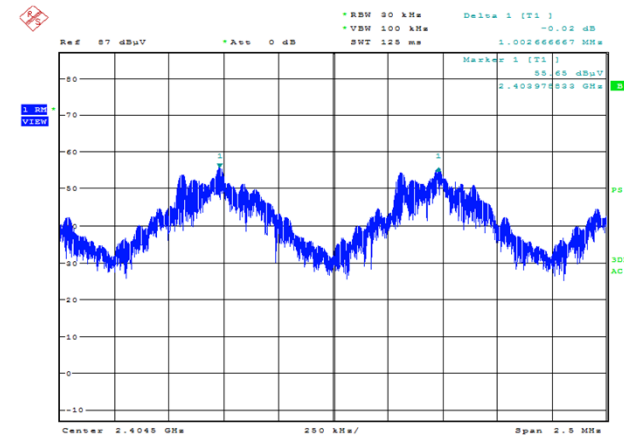
In addition to measurements of power and spurious emissions, other testing is performed to evaluate the transmitters in-band and adjacent channel performance. The nature of this testing depends on if the device communicates using narrowband or wideband techniques. For narrowband transmitters the measurements confirm that RF energy remains within a specified bandwidth and falls off at the band edges to limit adjacent channel interference. Typically the narrowband transmitters tests include:

- Permitted Range of Operating Frequencies
- Frequency Error & Drift
- Transient Power
- Adjacent Channel Power

Some of these tests may be performed while the transmitter voltage and temperature are at extremes to confirm the stability of the device performance under variable conditions.

Wideband transmitters typically disperse their RF energy by 500kHz more through the application of frequency hopping or digital modulation schemes. Measurements for wideband transmitters include:

- Dwell Time, Minimum Frequency Occupation
- Hopping Sequence, Hopping Frequency Separation
- Occupied Channel Bandwidth, Modulation Bandwidth
- Unwanted Emissions in Out-of-Band Domain



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- 
- Output Power
  - Spurious Emissions
  - Transmitter Functions
  - Bandwidth Usage
  - Adaptivity
  - Receiver Functions
-

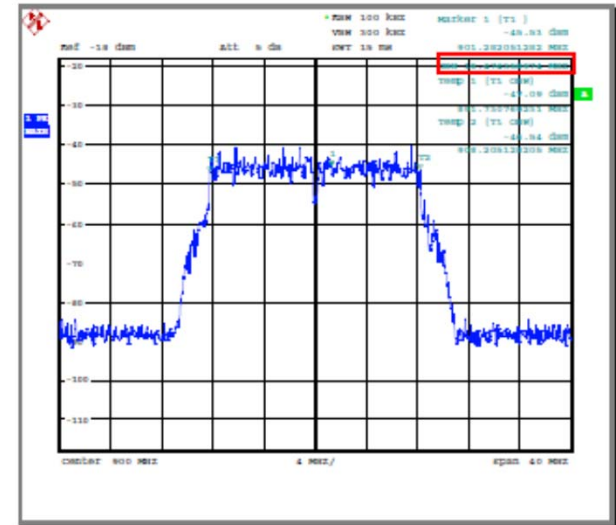
# 3 Tests for Effective Use of Spectrum

As wireless transmitters proliferate, spectrum sharing has become more important. Many regulations and standards now require that radio devices share spectrum and reduce the probability of interfering with one another. Spectrum sharing by transmitters is accomplished by either limiting the utilization of the frequency band through a transmit duty cycle or by an adaptive process. Typically wireless devices must employ some form of spectrum sharing if the transmit power exceeds 10 mW.

For >10mW transmitters, duty cycle limits restrict the device transmissions to an aggregate communication period that is a fraction of an hour and stated as a percentage. This is confirmed during the testing phase both by measurement as well as by a review of transmitter operational information.

Without duty cycle limits, transmitters need to employ an adaptive frequency agility function that “listens” to the channel before transmission and make a clear channel assessment. If the channel is open the device can proceed with transmission for a specified time then repeat the listen, assess, and transmit process. If the channel is occupied then it must either reduce power, wait, or move to a different channel.

In order for adaptive frequency agility systems to operate properly the receiver functions must also be sensitive to the intended signal and selection. Receivers are tested to determine their capability to operate as intended when presented with an unwanted signal (blocking signal) on frequencies other than those of the operating channel and the adjacent channels.



- Output Power
- Spurious Emissions
- Transmitter Functions
- Bandwidth Usage
- **Adaptivity**
- **Receiver Functions**

# 4 Tests for EMC



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## EN 301 489-1 Emissions Testing

- RF Conducted Emissions
- RF Radiated Emissions
- Low Frequency Harmonics

## EN 301 489-1 Immunity Testing

- Electrostatic Discharge
  - RF Radiated Immunity
  - Conducted RF Immunity
  - Fast Transients/Burst Surge
  - Voltage Dips & Interruptions
  - Magnetic Field Immunity
- 

As stated in Article 3.1(b) of the RE Directive, all radio equipment must comply with the requirements of the EMC directive. The harmonized standards to apply are listed in the Official Journal for the RED.

The EMC directive includes tests for RF emissions and low frequency harmonics and flicker. RF emissions are measured both on the AC or DC mains port as well as on telecom ports when applicable.

In addition to emissions testing, the EMC directive evaluates the susceptibility of a radio transceiver to a range of RF and electrical transient conditions. Typically immunity testing is performed on the radio transceiver integrated into host electronics. In this configuration the assembled system can be evaluated for the conditions present on the main power leads and signal leads and can be evaluated properly for the threats that are protected by the enclosure.

A series of harmonized standards are listed in the Official Journal to cover various applications of wireless transmitters. Many of the EMC harmonized standards for low power transmitters have a product specific “EN” to adapt the general EMC standard EN 301 489-1 for the particular application.

### Product Specific EMC Standards

- EN 301 489-3 Short Range Devices
- EN 301 489-17 Broadband Data Transmissions → EN 301 489-1 General Requirements
- EN 301 489-33 Ultra Wide Band
- EN 301 489-34 Mobile phone chargers

# 5 Tests/Analysis for Electrical Safety

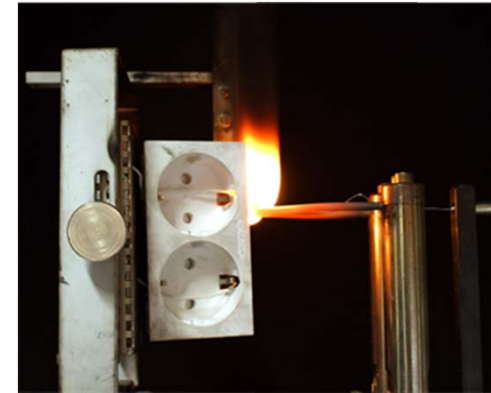
As stated in Article 3.1(a) of the RE Directive, all radio equipment must comply with the requirements of the Low Voltage Directive regardless of its voltage range. This means that even battery equipment or 12VDC powered electronics that might have fallen outside the scope of the Low Voltage Directive because the operational voltage is less than 50 VAC or 75 VDC will have to comply with the requirements of the Low Voltage to be compliant with the RE Directive.

The LVD evaluation primarily addresses the hazards of electric shock and electrical initiated fire. Other safety hazards include thermal based, ionizing radiation based, or from radio frequency transmission.

The LVD process involves an initial inspection of the test item including schematics, instruction manuals, safety labeling, and other warnings. From that review, a compliance checklist is generated to confirm those elements of the design and construction meet the objectives of the safety standards. Those items not meeting the intent of the standard must be addressed so that the hazard is mitigated.

Some typical electrical safety testing includes:

- Abnormal fault, short to ground
- Temperature rise to evaluate insulation ratings
- Dielectric withstand & ground bonding
- Safety label durability
- Impact resistance
- Creepage & clearance measurements



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## Common RE Directive LVD Safety Harmonized Standards

- EN 60950-1 Information Technology Equipment
  - EN 61010-1 Industrial measurement & control
  - EN 60065- Audio, visual
-

# 5 Tests/Analysis for Electrical Safety

Transmitters that are hand held, body worn, or operate within 20cm of a person may require an evaluation for hazards from RF exposure and Specific Absorption Rate (SAR). A SAR test report is required to be submitted as part of an electrical safety technical evaluation.

Maximum Permissible Exposure (MPE) requirements may apply for transmitters that operate at distances greater than 20cm with power levels above limits based on transmit frequency.

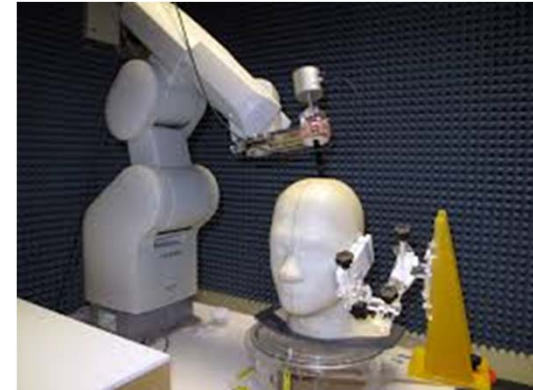
Typical standards for evaluation of RF hazards include:

EN 62479:2010- Low Power Devices RF Exposure

- Include evaluation of RF Hazards in TCF
- Review standard to evaluate exclusion vs. distance

EN 62311:2008- Generic Standard for RF Exposure

- Determine scope of hazard
- Relaxation of exclusions
- Consider impact of RF hazard due to co-located transmitters



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Note: Each wireless application has unique considerations when evaluating hazards from RF exposure, ie distance from the body, transmit power, duty cycle, type of application.

Contact Elite experts to review your specific requirements.

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# 6 Documentation

The RE Directive requires manufacturers maintain technical documentation that describes the due diligence applied for CE Mark compliance. The type of information required includes the following:

- Declaration of Conformity (DoC)
- General operational description and configuration of the product including permitted antenna types that when used will ensure compliance with the requirements.
- Design and manufacturing drawings and schematics of components, sub-assemblies, circuits, etc. for the purpose of informing how the devices meets the essential requirements.
- Test reports describing the harmonized standards that have been applied in full or in part. If harmonized standards have not been applied in full then analysis, design evaluations, related test reports, inspections and examinations are used to demonstrate compliance.
- User information to describe how the product is intended to be used and any precautions to be observed in installing, using and maintaining it, and in particular information necessary to use the device in a manner that ensures compliance.
- Software, firmware, or hardware configuration when its type or revision level may affect compliance.

Annex V of the RED provides further detail and organization framework for the documentation.

What are the requirements for a technical file?



The technical file must be kept by the manufacturer or his authorized representative in the EU for at least 10 years after the date of manufacture.

The file must be available in at least one language of the EU (English is suitable).

# 6 Documentation

Who is responsible for the Declaration of Conformity?

Every wireless product marketed in the European Union must have a Declaration of Conformity. The “DoC” is prepared by the manufacturer, importer, or the European representative and must be signed by a person having the authority to legally support the claim of compliance.

There is not one specific required format for a DoC but as a general layout it must include the following information.

- Declaration of Conformity (DoC)**
- Name of manufacturer or importer
  - Name and address of European representative
  - Name, model number, and description of product
  - Directives and harmonized standards (with revisions noted)

in cases where several directives apply simultaneously to the apparatus, a single DoC can be issued to reference all regulations, unless the Directive specifically states it must be a separate document.

The DoC for a device that falls under the scope of the RED will need to include the operating frequency range and the maximum power. A copy of the DoC must be shipped with the wireless device otherwise a short form DoC can be sent with the product and the primary DoC can be provided by a website link.

**EC Declaration of Conformity**

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Declaring Organization: *My Company, Inc.*

1234 Smith Road  
Anytown Illinois, 60515

EU Representative: (include name, address)

XXXX,  
XXXXX,  
XXXXXX

Product Name: (Radio Transmitter ABC)  
Product Model Name: (High Performance Unit)  
Product Description: (Wireless communication link)

We, My Company, Inc. declare under our sole responsibility that the above named product conforms to the essential requirements of the European Union Directive 2014/53/EU on Radio Equipment and Restrictions of certain Hazardous Substances Directive 2011/65/EU. The following harmonized standards are those to which the product's conformance has been verified.

Directive 2014/53/EU on Radio Equipment	Harmonized Standards Granting Presumption of Conformity
Data transmission equipment at 2.4 GHz ISM band using wide band modulation techniques. Covering Article 3.2 of the RE Directive.	EN 300 328 V1.9.1
Electrical equipment for measurement, control and laboratory use - EMC requirements. Covering Article 3.1(b) of the RE Directive.	EN 61326-1:2013
Safety requirements for electrical equipment for measurement, control, and laboratory use. Covering Article 3.1(a) of the RE Directive.	EN 61010-1:2010
Reduction of Hazardous Waste	2011/65/EU
Transmitter Frequency: 2412MHz-2462MHz, Max EIRP 100mW	

Signed by: .....  
Name: ( )  
Position: ( )  
Date: ( )

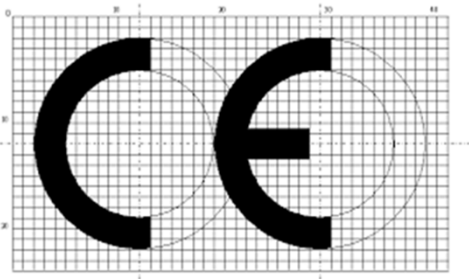
# 6 Markings

Do I need permission to place the CE Mark on my device?

Radio devices in the European Union must have the CE Mark affixed on the device in order to signify its compliance with the RE Directive. Requirements for the layout and placement of the mark include:

- Minimum height = 5 mm.
- Must be affixed permanently and indelibly
- Placement anywhere on the apparatus or in the battery compartment as long as a tool is not needed to view it.
- Placement on packaging and accompanying documents (if any).

Affixing the CE marking denotes compliance with all applicable EC “new approach” directives and this may necessitate including other markings for items like waste electrical and electronics processing or explosive environments. Refer to each applicable directive to identify the necessary labeling.





# 7 Transitioning to the RED

Many existing wireless devices are currently assessed for CE to the R&TTE Directive and these devices must conform with the new RED by June 13, 2017. Any new radio transmitter or receiver sold into the European Union on June 13, 2016 or later should be assessed for compliance with the RED 2014/53/EU.

Some of the significant differences between R&TTE and RED include:

- Telephone terminal equipment will no longer be included in the new RE Directive and will instead fall under the scope of the EMC and Low Voltage Directives. Other R&TTE products will be excluded from the RED while other devices will move from the EMC directive to the RED (see details on right).
- It will no longer be required to notify spectrum agencies of Class II equipment and Class II alert sign labeling is no longer required. Class II devices are those whose operations are restricted in Europe.
- Notified Body numbers will no longer be applied (except for full quality assurance)
- Type Examination Certificates will replace Notified Body opinions
- The RED now covers radio communication and radio determination position, velocity, or other characteristic by way of radio wave propagation including equipment below 9kHz

How will the new directive impact my compliance?

## Equipment now within the RED

- Broadcast sound and TV receivers
- Transceivers below 9 kHz
- Radio-determination devices (radar, RFID)

## R&TTE equipment now excluded from RED

- Telecom terminal equipment (now covered by EMC and LVD)
- Custom built evaluation kits destined for professional R&D facilities

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A Declaration of Conformity should reference the RED after June 13, 2016.

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# 7 Transitioning to the RED

What is a summary of the steps to take for continued compliance with the RED?

Other differences between R&TTE and RED include having the Declaration of Conformity (DoC) shipped with product or have a short form DoC with website link to full text DoC. The DoC must now include transmit frequency and maximum power.

Future updates include more emphasis on receiver performance and spectrum sharing. In addition starting in June 2018, manufacturers may need to register low level compliance radios and assign a registration number.

Several other additional requirements will be phased into RED compliance through the compliance requirements in harmonized standards and other separately published regulations and decisions (*see box at right side of page*).

Manufacturers should act now to update their compliance with the new RE Directive.

Action Items include:

- Review new directive(s) and comply with changes (especially for broadcast receivers, TTE, Kits)
- Confirm harmonized standards applied for testing are still current and update the DoC to reference the new directive and other compliance details
- Label the product with the CE Mark, manufacturers name/address, product trade name, and batch or serial number
- Include safety Information in a language easily understood by end-users.
- Be familiar with responsibilities of Manufacturer, Importer, Distributor and Authorized Representative

## Additional new RED requirements:

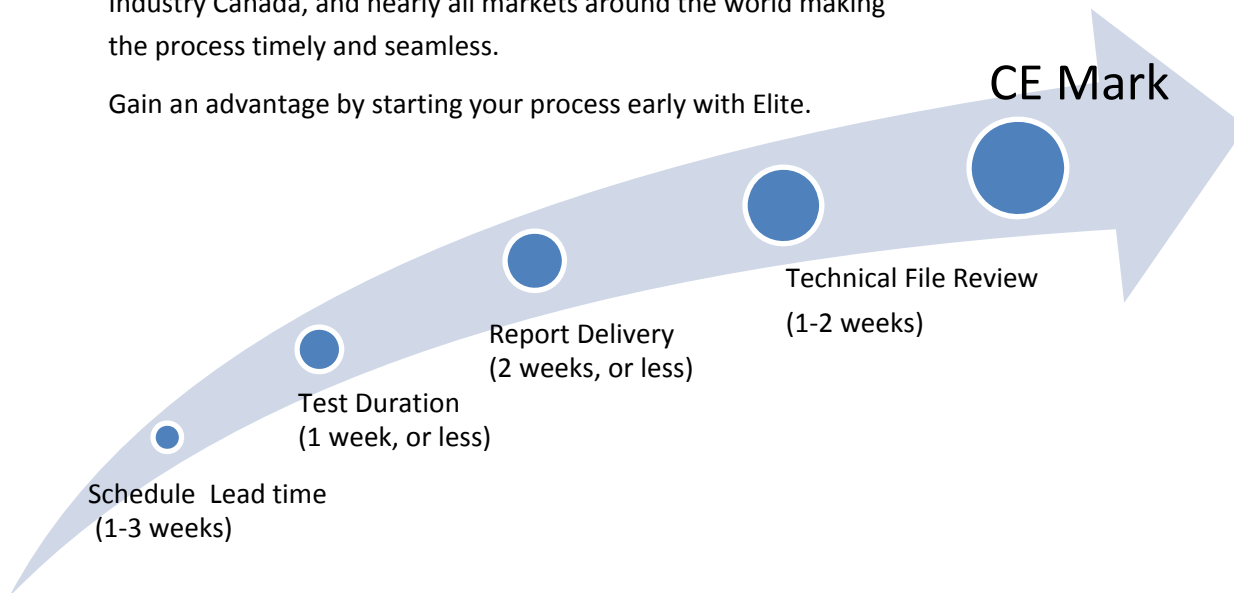
- Common chargers, especially for mobile phones
- Ensure network compatibility
- Have appropriate telecom interfaces
- Cause no harm, misuse, or unacceptable degradation of network services
- Protect personal data and privacy of user subscriber
- Protect from fraud
- Ensure access to emergency services
- Support users with a disability
- Ensure software updates/revisions to radio maintain compliance

# 8 Time Line

So with this simple guide a wireless transmitter manufacturer will have a general idea on how to complete an RED conformity assessment.

At Elite, our business is to help clients throughout the process and successfully deploy transmitters and receivers to their destination markets in the shortest time possible. Our assistance extends beyond this guide with Elite sales and application engineers ready to answer compliance questions and provide the guidance to quickly process a CE Mark. We also provide services for FCC, Industry Canada, and nearly all markets around the world making the process timely and seamless.

Gain an advantage by starting your process early with Elite.



# 8 Final Comments

Contact Elite today to get moving quickly on your path to obtaining the CE Mark for your wireless transmitter. Keep in mind that we regularly complete CE Marking tests along with FCC and Canadian test and certifications. This complete service saves time, cost, and adds convenience. We can help speed your effort from start to finish in all areas of regulatory and compliance tests and certification.

For more information on this topic contact the following Elite staff:

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Dan Crowder, FCC/CE Mark Team Leader, 630-495-9770 x 101, [decrowder@elitetest.com](mailto:decrowder@elitetest.com)

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