

COMPLIANCE

2017 Issue 2

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Headlines

CE Mark DoC - NEW DIRECTIVE

Not much time left for the R&TTE => RED transition

RTTE (RED)



weeks before you MUST use

Although there are still enormous problems in getting harmonised standards published in time to meet this deadline !!!!

New Harmonised Standards list published in the OJEU for:

Two more lists have been published for the Radio Equipment Directive, (2014/53/EU).

Latest publication is: see OJEU 2017/C 118/05



Standards Watch

Changes to standards and EU Directives that impact on product compliance



European harmonised standards are regularly updated

Care should be taken to make sure product compliance is kept up to date

European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking:

Within 12 months

Date	Old standard	Subject	New standard	
13 Jun 2017 (NOTE 1)	EN 301 489-1 V1.9.2		EN 301 489-1 V2.1.1	
	EN 301 489-17 V2.2.1	I 301 489-17 V2.2.1		
	EN 300 328 V1.9.1	KED	EN 300 328 V2.2.1	
	EN 301 893 V1.8.1		(TBA)	
19 Jun 2017	EN 61000-4-5:2006	EMC	EN 61000-4-5:2014	
30 Jun 2017	EN 61000-3-2:06 + A2:09	EIVIC	EN 61000-3-2:2014	
17 Nov 2017	EN 60065:2002 + A12:11	LVD	EN 60065:2014	

NOTE 1 These old standards are not harmonised under the RED, so cannot be used after the RED becomes mandatory, (ie 13th June 2017) – even if the dow in the standard is later

Within 2 years

Date	Old standard	Subject	New standard
25 Mar 2018	EN 55014:1997 + A2:08	EMC	EN 55014:2015
05 May 2018	EN 55032:2012	EIVIC	EN 55032:2015
31 Jul 2018	EN 62061:2005 + A1:2013	Machinery	EN 62061:2005 + A2:15
15 Sep 2018	EN ISO 9001:2008	Quality	EN ISO 9001:2015
15 Sep 2018	EN ISO 14001:2004	Systems	EN ISO 14001:2015
15 Feb 2019	EN 55011:2009 + A1:2010	EMC	EN 55011:2016

EU Directives changing

One further EU Directive will change within 2017. All relevant CE Mark Declarations of Conformity will have to be re-issued for all products still being manufactured:

Within 12 months

Date	Directive	Old Number	New Number
13 Jun 2017	R&TTE	1999/5/EC	2014/53/EU (1)

⁽¹⁾ MUST use the new "Radio Equipment Directive", (RED).

Lists of European Harmonised Standards

Published in the Official Journal of the EU and giving presumption of conformity with the essential requirements of the relevant Directive.

<u>Directive</u>	OJEU Ref	Date
EMC	2016/C 293/03	12 Aug 2016
LVD	2016/C 249/03	08 Jul 2016
R&TTE Directive	2016/C 249/01	08 Jul 2016
(+ Corrigenda)	2016/C 342/15	17 Sep 2016
(+ Corrigenda)	2016/C 403/11	01 Nov 2016
Radio Equipment Directive	2017/C 118/05	12 Apr 2017
Medical Devices Directive	2016/C 173/03	13 May 2016
Active implantable medical devices	2016/C 173/02	13 May 2016
In vitro diagnostic medical devices	2016/C 173/04	13 May 2016
(+ Corrigenda)	2016/C 249/05	08 Jul 2016
Machinery Directive	2016/C 332/01	09 Sep 2016
RoHS Directive	2012/C 363/05	23 Nov 2012

Further information:





Update on Harmonised Standards Lists -

What's changed in the recent lists published in the OJEU



Radio Equipment Directive (2014/53/EU)

The OJEU publication of standards harmonised under the Radio Equipment Directive is being updated every month. There have been two publications since the 2017 Issue 1 newsletter:

10th March 2017
12th April 2017
2017/C 076/04
14 standards added
35 standards added

This brings the total number of standards harmonised under the RED to 100 (compared to over 200 standards harmonised under the R&TTE Directive)

EU Guidelines – a reminder

These guidelines have been put together by the European Commission to assist in the smooth and level application of the provisions of the Directives. They are not law and do not take away the relevant responsibilities provided for,.



Low Voltage Directive (2014/35/EU)

http://ec.europa.eu/DocsRoom/documents/20341

see also European Commission Low Voltage Directive (LVD) website

Machinery Directive (2006/42/EC)

http://ec.europa.eu/DocsRoom/documents/9483/attachments/1/translations/en/renditions/pdf

Environmental



EU Conflict Minerals Regulation adopted

The European Parliament adopted the legal text of the EU Conflict Minerals Regulation on 16th March 2017.

Implementation:

- expected to be signed into EU law by the end of May 2017.
- will take effect on 1 January 2021

Who will be effected?

Only applies directly to EU-based importers of tin, tantalum, tungsten and gold, whether these are in the form of mineral ores, concentrates or processed metals, eg

- Upstream companies (ie mines / traders / smelters & refiners)
 - Have to comply with mandatory rules on due diligence when they import
- Downstream companies (ie component producers / manufacturers / end-users)
 - those importing metal-stage products also have to meet mandatory due diligence rules
 - those operating beyond the metal stage do not have obligations under the regulation; but they are expected to use reporting and other tools to make their due diligence more transparent

Official information

- Press release:
- Draft regulation:



New Standards

ETSI are working on two new standards for integrated radio and non-radio equipment that will support of EMC compliance under the Radio Equipment Directive, (article 3.1(b) of 2014/53/EU).



Draft ETSI EN 303 446-1 V1.1.0 (2017-03)

ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment;

Part 1: Requirements for equipment intended to be used in residential, commercial and light industry locations

Available free of charge from ETSI:

http://www.etsi.org/deliver/etsi_en/303400_303499/30344601/01.01.00_20/en_30344601v010100a.pdf Some key points:

General

- test parameters are referenced from other published standards.
- "At least one configuration of typical intended use shall be tested with both non-radio and radio functions operating at the same time."
- "The configuration of the EUT should be established in order to:
 - maximize the emissions of the EUT;
 - ensure the EUT is most susceptible;
 - be typical of the intended use".

Emissions

- Radiated emissions are tested up to a maximum of 6 GHz
- Exclusion band(s) defined in the applicable radio EMC standard(s) are applied.

Immunity

- The radio function of the EUT shall be tested against the requirements of the applicable radio EMC standard(s)
- the non-radio function of the EUT shall be tested against the applicable nonradio EMC standard(s)
- it is recommended to select one or more configuration that exercise these functions simultaneously during the application of each test
- radiated immunity is tested from 80 MHz to 6 GHz

expected publication date: 18th December 2017 expected citation of the OJEU 31st March 2018



Draft ETSI EN 303 446-2 V1.1.0 (2017-03)

ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment;

Part 2: Specific conditions for equipment intended to be used in industrial locations

Available free of charge from ETSI:

http://www.etsi.org/deliver/etsi_en/303400_303499/30344602/01.01.00_20/en_30344602v010100a.pdf

This is basically the same as Draft ETSI EN 303 446-1 V1.1.0, but now references out to industrial standards.

> expected publication date: 18th December 2017 expected citation of the OJEU 31st March 2018





New Standards

National and international standards of interest published in recent months

February	2017
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IEC 61010-1:— (Amendment 1)

Safety requirements for electrical equipment for measurement, control, and laboratory use. General

requirements

IEC 61010-2-030:2017

(Edition 2)

Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for equipment having testing or measuring

circuits

BS EN 62209-1:2016

Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices. Devices used next to the ear

(Frequency range of 300 MHz to 6 GHz)

March 2017

BS 8888:2017

Technical product documentation and specification

PD IEC/TR 61000-2-5:2017

Electromagnetic compatibility (EMC). Environment. Description and classification of electromagnetic

environments.

April 2017

BS EN 50332-3:2017

Sound system equipment: headphones and earphones associated with personal music players. Maximum sound pressure level measurement methodology. Measurement

method for sound dose management

PD ISO/IEC GUIDE 46:2017

Comparative testing of consumer products and related

services. General principles



Compliance Calendar

What's happening in the Compliance world in the next few months March 2017

MON	TUE	WED	THU	FRI	SAT	SUN
		1	2	3	4	5 A
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

- A New EMC standard must be used:
 - EN55022:2012, (replaces EN55022:2010)

April 2017

MON	TUE	WED	THU	FRI	SAT	SUN
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

May 2017

MON	TUE	WED	THU	FRI	SAT	SUN
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

June 2017

MON	TUE	WED	THU	FRI	SAT	SUN
			1	2	3	4
5	6	7	8	9	10	11
12	13 A	14	15	16	17	18
19 B	20	21	22	23	24	25
26	27	28	29	30 C		

- A New Radio Equipment Directive must be used:
 - 2014/53/EU, (replaces 1999/5/EC)

New Radio standards must be used:

- EN 300 328 V2.2.1, (replaces EN 300 328 V1.9.1)
- EN 301 893 V?.?.?, (replaces EN 301 893 V1.8.1)

New EMC standards must be used:

- EN 301 489-1 V2.1.1, (replaces EN 301 489-1 V1.9.2)
- EN 301 489-17 V3.1.1, (replaces EN 301 489-17 V2.2.1)
- ^B New EMC standard must be used:
 - EN 61000-4-5:2014, (replaces EN 61000-4-5:2006)
- ^C New EMC standard must be used:
 - EN 61000-3-2:2014, (replaces EN 61000-3-2:2006 + A2:2009)