

PRODUCT

COMPLIANCE UPDATE

2018 Issue 3

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April 2018

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Headlines

New Harmonised Standards list published in the OJEU for:

Low Voltage Directive, (2014/35/EU)

Latest publication, 15th June 2018: see [2018/C 209/04](#)

Eco-Management Audit Scheme

Latest publication, 15th June 2018: see [2018/C 209/02](#)

Changes to implementation dates

The date of withdrawal of EN 60065:2014 and EN 60950-1:2006 (+amendments) has now been confirmed as 20th December 2020.

Standards being withdrawn (see standards watch)

- **within 1 year**
 - European Standards 9 standards
 - Other Standards 1 standard
- **within 2 years**
 - European Standards 2 standards
 - Other Standards 1 standard

If you want to know more, contact us

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European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking: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
31 Jul 2018	EN 62061:2005 + A1:2013	Machinery	EN 62061:2005 + A2:15
15 Sep 2018	EN ISO 9001:2008	Quality Systems	EN ISO 9001:2015
	EN ISO 14001:2004		EN ISO 14001:2015
31 Oct 2018	ETSI EN 301 489-1 V1.9.2	EMC	ETSI EN 301 489-1 V2.1.1
	ETSI EN 301 489-17 V2.2.1		ETSI EN 301 489-17 V3.1.1
15 Feb 2019	EN 55011:2009 + A1:2010	EMC	EN 55011:2016

Note 1: the date of withdrawal of EN 60065:2014 and EN 60950-1:2006 (+amendments) has now been confirmed as 20th December 2020.

Within 2 years

Date	Old standard	Subject	New standard
21 Apr 2020	EN 55011:2016	EMC	EN 55011:16 + A1:17

Other standards being withdrawn

Within 12 months

Date	Old standard	Country	New standard

Within 2 years

Date	Old standard	Country	New standard

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.

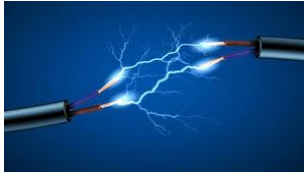
Further information:



Directive (+link)	OJEU ref (+link)	Date
EMC	2016/C 293/03	12 Aug 2016
LVD	2018/C 209/04	15 Jun 2018
Radio Equipment Directive	2018/C 092/05	09 Mar 2018
Medical Devices Directive	2017/C 389/03	17 Nov 2017
Active implantable medical devices	2017/C 389/02	17 Nov 2017
In vitro diagnostic medical devices	2017/C 389/04	17 Nov 2017
Machinery Directive	2018/C 092/01	09 Mar 2018
RoHS Directive	2012/C 363/05	23 Nov 2012

Update on Harmonised Standards Lists

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



Low Voltage Directive ([2014/35/EU](#))

There has been one publication since the 2018 Issue 2 newsletter:

- 15th June 2018 [2018/C 209/04](#)

Note the date of withdrawal of current standards EN 60065:2014 and EN 60950-1:2006 (+amendments) has now been confirmed as 20th December 2020

However, **EN 60065:2014 and EN 60950-1:2006 (+amendments) are not listed as Harmonised Standards** (under the LVD) – probably an error.

Also, neither standard is listed under the Radio Equipment Directive

Guidance



Radio Equipment Directive

The new “Guide to the Radio Equipment Directive 2014/53/EU” was published on the 5th June 2018, replacing the previous version of 19th May 2017.

This Guide brings together information previously available in several TCAM (EU *Telecommunication Conformity Assessment and Market Surveillance Committee*) documents and related Commission’s websites. Based on the RED it does not duplicate what is already contained in the Blue Guide.

Other more specific guidance or documents might be issued by the Commission services, TCAM or ADCO RED providing guidance or information on specific issues or items, for example see:

- http://ec.europa.eu/growth/sectors/electrical-engineering/ec-support_en
- http://ec.europa.eu/growth/sectors/electrical-engineering/red-directive_en
- http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en

See also “Radio Equipment Directive Compliance Association (REDCA)” website

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



How to perform a risk assessment in accordance with Directive 2014/53/EU?

The German Federal Network Agency gave a presentation to Radio Equipment Directive Compliance Association (REDCA) in May 2018

<http://redca.eu/Unrestricted%20Documents/RED%20Risk%20Assessment%20introduction.pdf>

All RED Notified Bodies (EU and MRA countries) are now working on a Technical Guidance Note for Risk Assessment, which will hopefully be published by the end of this year

Sustainability



Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The European Chemicals Agency (ECHA) has added 10 new substances of very high concern (SVHCs) to the Candidate list.

- 27th June 2018 [ED 61/2018](#)

<i>Substance name</i>	<i>Examples of use</i>
Octamethylcyclotetrasiloxane	Used in washing and cleaning products, polishes and waxes and cosmetics and personal care products.
Decamethylcyclopentasiloxane	Used in washing and cleaning products, polishes and waxes, cosmetics and personal care products, textile treatment products and dyes.
Dodecamethylcyclohexasiloxane	Used in washing and cleaning products, polishes and waxes, cosmetics and personal care products.
Lead	Used in metals, welding and soldering products, metal surface treatment products, and polymers.
Disodium octaborate	Used in anti-freeze products, heat transfer fluids, lubricants and greases, and washing and cleaning products.
Benzo[ghi]perylene	Not registered under REACH. Normally not produced intentionally but rather occurs as a constituent or impurity in other substances.
Terphenyl hydrogenated	Used as a plastic additive, solvent, in coatings/inks, in adhesives and sealants, and heat transfer fluids.
Ethylenediamine	Used in adhesives and sealants, coating products, fillers, putties, plasters, modelling clay, pH regulators and water treatment products.
Benzene-1,2,4-tricarboxylic acid 1,2 anhydride	Used in the manufacture of esters and polymers.
Dicyclohexyl phthalate	Used in plastisol, PVC, rubber and plastic articles. A further use is also as a phlegmatiser and dispersing agent for formulations of organic peroxides.

Note: Lead is now restricted under REACH

There are now 191 substances on the Candidate List

See [Candidate List of substances of very high concern for Authorisation](#)

New Standards

National and international standards of interest published in recent months

April 2018

BS EN 60350-2:2018	Household electric cooking appliances. Hobs. Methods for measuring performance
BS ISO 31000:2018	Risk management. Guidelines
PD IEC/PAS 63151:2018	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. Vector measurement-based systems (Frequency range of 30 MHz to 6 GHz)
PAS 7100:2018	Code of practice on consumer product safety related recalls and other corrective actions: Part I: Business Part II: Regulators
BS 1363 parts 1 to 4 (Amendment 1)	13 A plugs, socket-outlets, adaptors and connection units.
BS EN ISO 14044:2006 + A1:2018	Environmental management. Life cycle assessment. Requirements and guidelines
BS EN 55016-1-6:2015 + A1:2017	Specification for radio disturbance and immunity measuring apparatus and methods. Radio disturbance and immunity measuring apparatus. EMC antenna calibration
BS EN 61000-4-5:2014 + A1:2017	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test
BS ISO/IEC/IEEE 12207:2017	Systems and software engineering. Software life cycle processes

May 2018

BS EN ISO 9004:2018	Quality management. Quality of an organization. Guidance to achieve sustained success
PD IEC/TR 61340-5-2:2018	Electrostatics. Protection of electronic devices from electrostatic phenomena. User guide
BS EN 62321-4:2014 + A1:2017	Determination of certain substances in electrotechnical products. Mercury in polymers, metals and electronics by CV-AAS, CV-AFS, ICPOES and ICP-MS

June 2018

BS EN ISO 14024:2018	Environmental labels and declarations. Type I environmental labelling. Principles and procedures
PD CLC/TR 50674:2018	Guidelines for the verification of household appliances under energy labelling and eco design
BS EN 55016-1-4:2010 + A2:2017	Specification for radio disturbance and immunity measuring apparatus and methods. Radio disturbance and immunity measuring apparatus. Antennas and test sites for radiated disturbance measurements
BS EN 55016-2-1:2014 + A1:2017	Specification for radio disturbance and immunity measuring apparatus and methods. Methods of measurement of disturbances and immunity. Conducted disturbance measurements
BS EN IEC 61010-2-120:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular safety requirements for machinery aspects of equipment

Compliance Calendar

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

April 2018

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 2018

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 Directive standard must be used:

- EN 55032:2015, (replaces EN 55032:2012)

June 2018

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	

July 2018

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 A					

A New Machinery Directive standard must be used:

- EN 62061:2005 + A1:13 + A2:15, (replaces EN 62061:2005 + A1:13)