

PRODUCT

COMPLIANCE UPDATE

2019 Issue 3

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SBD Electronics Laboratory policy and working practices

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"Standards & Certification Update":

New Standards Published

April 2019

May 2019

June 2019

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Headlines



New Harmonised Standards lists published in the OJEU for:

Machinery Directive (2006/42/EC)

Latest publication, 18th March 2018: see [\(EU\) 2019/436](#)

The New New Brexit Clock



Thu 31 October 2019

18 weeks to go (maybe)

Standards being withdrawn (see standards watch)

- **within 1 year**
 - European Standards 2 standards
- **within 2 years**
 - European Standards 2 standards

Note: Where references are made to expiry dates these are the dates published in the standards, and not necessarily the dates published in the OJEU

If you want to know more, contact us

Standards Watch

Changes to standards and EU Directives that impact on product compliance



European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking: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
21 Apr 2020	EN 55011:2016	EMC	EN 55011:2016 + A1:2017
22 Jun 2020	EN 61000-4-11:2004		EN 61000-4-11:04 + A1:17

Within 2 years

Date	Old standard	Subject	New standard
17 Aug 202	EN 62321-4:2014	RoHS	EN 62321-4:14 + A1:17
08 Sep 2020	EN 61000-4-5:2014	EMC	EN 61000-4-5:04 + A1:17

European harmonised standards are regularly updated

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

Other standards being withdrawn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.

Directive	OJEU Ref	Date
EMC	2018/C 246/01	13 Jul 2018
LVD	2018/C 326/02	14 Sep 2018
Radio Equipment Directive	2018/C 326/04	14 Sep 2018
Machinery Directive	(EU) 2019/436	18 Mar 2019
RoHS Directive	2012/C 363/05	23 Nov 2012
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

Further information:



Brexit



Product standards and safety marking

This is a House of Commons briefing on how Brexit impacts product safety, CE marking and conformity assessments. It provides a good summary of the various Technical Notices and bulletins and is a resource MPs can use when considering this issue, see

<http://researchbriefings.files.parliament.uk/documents/CBP-8583/CBP-8583.pdf>

Although not introducing anything new, it does bring together everything we currently know.

Machinery Directive



Where have all the standards gone?

There have been some very significant changes in the latest harmonised standards list for the Machinery Directive ([EU 2019/436](#)).

Many (most) standards have been removed from the list

Also the format has changed – the list now has three Annexes:

Annex	Purpose	No of standards
I	list of harmonised standards	42
II	list of harmonised standards with restrictions	2
III	previously harmonised standards to be removed from the list	37 ⁽¹⁾

Notes:

⁽¹⁾ 28 of these standards were withdrawn on 19.3.2019

There are still three types of standards:

- **A-type:** specify basic concepts, terminology and design principles applicable to all categories of machinery.
- **B-type:** deal with specific aspects of machinery safety or specific types of safeguard that can be used across a wide range of categories of machinery.
- **C-type:** provide specifications for a given category of machinery.

So how does this new list compare with the previous issue?

	OEU ref	date	pages	Standard type		
				A	B	C
Previous	2018/C 092/01	9 Mar 2018	86	1	123	675
New	(EU) 2019/436	19 Mar 2019	8	0	1 ⁽¹⁾	50 ⁽²⁾

Notes:

⁽¹⁾ 2 other B-type standards are listed but these were withdrawn on 19.3.2019

⁽²⁾ 28 other C-type standards are listed but these were withdrawn on 19.3.2019
a further 9 C-type standards on this list will be withdrawn within 18 months

One notable omission is EN ISO 12100:2010, which was removed because it “no longer satisfies the requirements which it aims to cover and which are set out in Directive 2006/42/EC”.

This leaves over 700 standards that have simply vanished – if you find them please let me know.

Environmental



RoHS Directive

22nd July 2019 is a key date in the RoHS calendar.

On this date two things must happen (unless a valid exemption applies):

- 1) Products in category 11 must comply with 2011/65/EU, (RoHS 2).
- 2) Products in all categories except 8 & 9 must also comply with amendment EU 2015/863.
(sometimes referred to as RoHS 3, but is really an amendment to RoHS 2)

			Category															
			1	2	3	4	5	6	7	8	9	10	11					
			Large household appliances	Small household appliances	IT & telecommunications	Consumer equipment	Lighting equipment	Electrical and electronic tools	Toys, leisure & sports equipment	Medical devices (non-IVD)	Medical devices (IVD)	Monitoring and control instruments (Consumer)	Monitoring and control instruments (Industrial)	Automatic dispensers	Everything else			
	Substance	Maximum Allowable concentration																
2011/65/EU	Cadmium	0.01%																
	Lead	0.1%																
	Mercury	0.1%																
	Hexavalent Chromium	0.1%																
	Polybrominated Biphenyls	0.1%	(2013-01-02)															
	Polybrominated Diphenyl Ethers	0.1%																
+ EU 2015/863	Bis (2- ethylhexyl) phthalate	0.1%																
	Butyl benzyl phthalate	0.1%																
	Dibutyl phthalate	0.1%																
	Diisobutyl phthalate	0.1%																
			2019-07-22							2016-07-22		2013-01-02		2017-07-22		2013-01-02		2019-07-22
										2021-07-22								2019-07-22

So if you aren't covered by a valid exemption to RoHS, then you will have to take action soon.

New / updated Standards – details of changes



[draft EN 303 446-1 V1.2.0](#)

“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”

[draft EN 303 446-2 V1.2.0](#)

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

Part 2: Requirements for equipment intended to be used in industrial locations”

These are high level “umbrella” standards giving a methodology for assessing EMC when a radio module is fitted into a normally non-radio product.

They are only applicable to combined and/or integrated equipment where the:

- radio function is within the scope of one or more of the standards listed in clause 2.1.2 and
- non-radio function is within the scope of one or more of the standards listed in clause 2.1.3

So when considering “what’s in scope” you have look at the scope in each of the Normative Reference standards, (ie bottom up not top down).

Take care - these standards are not intended to be harmonised under any of the EU Directives, (eg EMC Directive or Radio Equipment Directive).



BS EN 55011:2016+A1:2017

“Industrial, scientific and medical equipment — Radio-frequency disturbance characteristics — Limits and methods of measurement”

- Will become mandatory on the 12th February 2020

Key changes

This Amendment introduces the fully-anechoic room (FAR) for measurements of the disturbance field strength in the range 30 MHz to 1 GHz on equipment in the scope of CISPR 11.

It contains the complete set of requirements for measurement of radiated disturbances from equipment fitting into the validated test volume of a given FAR. It specifies a separation distance of 3m and restricts use of the FAR to measurements on table-top equipment.

At the moment the FAR can be used:

- for measurements on table-top equipment fitting into the validated test volume of the given FAR,
- for a separation distance of 3 m only, and
- if the FAR was validated according to CISPR 16-1-4.

New Standards Published

National and international standards of interest published in recent months

April 2019

BS 45002-2:2019	Occupational health and safety management systems. General guidelines for the application of ISO 45001. Risks and opportunities
BS EN IEC 61000-3-2:2019	Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current >16 A per phase)
BS EN IEC 62474:2019	Material declaration for products of and for the electrotechnical industry
BS EN 45559:2019	Methods for providing information relating to material efficiency aspects of energy-related products
BS ISO 14008:2019	Monetary valuation of environmental impacts and related environmental aspects
BS ISO 14033:2019	Environmental management. Quantitative environmental information. Guidelines and examples
PD CEN/TR 13695-2:2019	Packaging. Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging, and their release into the environment. Requirements for measuring and verifying dangerous substances present in packaging, and their release into the environment

May 2019

BS EN IEC 55016-1-4:2019	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 IEC 61000-3-2:2019 [TRACKED CHANGES]	Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current =16 A per phase)
BS EN 61010-1:2010 + A1:2019 [TRACKED CHANGES]	Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements

June 2019

Nothing to report this month

Compliance Calendar

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

May 2019

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 2019

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 2019

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 A	23	24	25	26	27	28
29	30	31				

A New RoHS requirements come into force

- Products in category 11 must comply with 2011/65/EU, (RoHS 2).
- Products in all categories except 8 & 9 must also comply with amendment EU 2015/863

August 2019

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	