

PRODUCT

COMPLIANCE UPDATE

2020 Issue 2

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Lists of European Harmonised Standards

Update on Harmonised Standards Lists

There have been no new publications since the 2020 Issue 1 newsletter

ECHA

ECHA Newsletters

New / updated Standards – details of changes

BS EN 55011:2016 + A11:2020

BS EN 55032:2015 + A11:2020

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What happened to Preventive action

Sustainability

new EU Chemicals Legislation Finder, (EUCLEF)

BS EN ISO 11200:2014 + A1:2020

New Standards Published

March 2020

April 2020

Compliance Calendar

Headlines

New Harmonised Standards lists published in the OJEU:

None since last newsletter

Standards being withdrawn (see standards watch)

- **within 1 year**
 - European Standards 5 standards
- **within 2 years**
 - European Standards 8 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

Disclaimer:

This document is provided for information purposes only and does not replace the need to obtain further independent advice and/or to instruct/appoint a notified or competent body or person(s) to carry out further investigation and/or testing. National and International Regulations are constantly changing and evolving. Accordingly, no warranty is given, nor is any term or condition to be implied, that the information provided in this document is accurate and that it eliminates the need for seeking further advice or investigation.

November 2019

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European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking: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
22 Jun 2020	EN 61000-4-11:2004	EMC	EN 61000-4-11:04 + A1:17
17 Aug 2020	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
20 Dec 2020	EN 60950-1:2006 +A2:2013	LVD	EN 62368-1:2014 + A11:2017
	EN 60065:2014 + A2:2014		

Within 2 years

Date	Old standard	Subject	New standard
27 May 2021	EN 61010-2-201:2013	LVD	EN IEC 61010-2-201:2018
31 Aug 2021	ETSI EN 301 489-1 V2.1.1	EMC	ETSI EN 301 489-1 V2.2.3
14 Sep 2021	EN 60204-1:2006 + A1:2009	Machinery	EN 60204-1:2018
31 Oct 2021	ETSI EN 300 328 V2.1.1	Radio	ETSI EN 300 328 V2.2.2
22 Feb 2022	EN 61010-1:2010	LVD	EN 61010-1:2010 + A1:2019
	EN 61000-6-1:2007	EMC	EN IEC 61000-6-1:2019
	EN 61000-6-2:2005		EN IEC 61000-6-2:2019

European harmonised standards are regularly updated

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

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	OJEU "C" series		OJEU "L" series	
	OJEU Ref	Date	OJEU Ref	Date
EMC	2018/C 246/01	06 Aug 2019	(EU) 2019/1326	08 Aug 2019
LVD	2018/C 326/02	14 Sep 2018	(EU) 2019/1956	27 Nov 2019
RED	2018/C 326/04	14 Sep 2018	(EU) 2020/167	06 Feb 2020
Machinery Directive	2018/C 092/01	09 Mar 2018	(EU) 2019/436	19 Mar 2019
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

There have been no new publications since the 2020 Issue 1 newsletter

ECHA

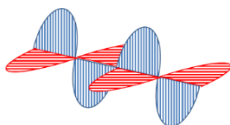


ECHA Newsletters

A quarterly newsletter from the European Chemicals Agency

- [Issue 2, May 2019](#)
- [Issue 3, September 2019](#)
- [Issue 4, November 2019](#)
- [Issue 1, February 2020](#)

New / updated Standards – details of changes



BS EN 55011:2016 + A11:2020

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

Implementation dates: (dop) 2020-11-27
(dow) 2022-11-27

This amendment introduces a completely updated Annex ZZ, which now says:

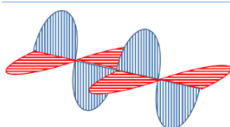
If relying on this standard to demonstrate presumption of conformity, by applying:

- Clause 6 (Limits of electromagnetic disturbances)
- Clause 7 (Measurement requirements)

then the following do not apply:

Clause	Title	Content to be ignored
3	Definitions	
3.19	Type Test	'Note 1 to entry: Recognition of a type test as type approval may depend on national or regional regulation, see H.2 in Annex H.'
7	Measurement requirements	
7.1	General	'Requirements which relate to measurements at such test sites are type test requirements. A type test may be recognized as type approval if the conditions for the statistical assessment of measurement results according to Annex H are observed.'

I'm assuming that these changes now make this standard acceptable to the European Commission, and so it could (?) be listed as a Harmonised Standard.



BS EN 55032:2015 + A11:2020

“Electromagnetic compatibility of multimedia equipment – Emission Requirements”

Implementation dates: (dop) 2020-11-27
(dow) 2022-11-27

This amendment introduces a completely updated Annex ZZ, which now says:

1. Not applicable to terrestrial and satellite broadcast receivers under Directive 2014/30/EU, and
2. If relying on this standard to demonstrate presumption of conformity, by applying:
 - Clause 5 (Requirements)
 - Clause 11 (Measurement uncertainty)

then the following does not apply:

Clause	Title	Content to be ignored
11	Measurement uncertainty	
		Refer to CISPR TR 16-4-3 for guidance on the applicability of the limits to a series produced MME.

Again I'm assuming that these changes now make this standard acceptable to the European Commission, and so it could (?) be listed as a Harmonised Standard.

Quality Control



What happened to Preventive action

Corrective and Preventive Action are key elements of a Quality Management System, (QMS), focussing on Continual Improvement and Customer Satisfaction. However, you may have noticed that ISO 9001:2015 does not have a separate clause or sub-clause on preventive action.

Just to remind you that Preventive Action has not gone away, it is now addressed through the use of risk-based thinking in formulating quality management system requirements.

The thing to remember is that they are two completely different things !!!

OK, first some definitions:

Preventive Action (EN ISO 9000:2015 clause 3.12.1)

“action to eliminate the cause of a potential nonconformity or other potential undesirable situation”

“Note 2 to entry: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence”

Corrective Action (EN ISO 9000:2015 clause 3.12.2)

“action to eliminate the cause of a nonconformity and to prevent recurrence”

“Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence”

So what does this mean in practice?

Corrective Action – “reactive”

Something has gone wrong and you have to put it right. You have to do two things:

1. Fix the immediate problem, **and**
2. make sure it doesn't happen again

Note: step 2 is still part of the Corrective Action it is NOT Preventive Action

Preventive Action – “proactive”

Nothing has actually gone wrong but you've identified something that could go wrong

A final thought

Remember it's “preventive” not “preventative” ☺

Sustainability

There have been two significant standards published recently supporting Sustainability and Product Eco Design



new EU Chemicals Legislation Finder, (EUCLEF)

ECHA's new online service, the EU Chemicals Legislation Finder (EUCLEF), gives companies access to a free-of-charge overview of 40 pieces of EU chemicals legislation they may need to comply with.

- [European Union Chemicals Legislation Finder](#)
- [Video tutorial: Navigating EUCLEF](#)

Companies can use EUCLEF to navigate through the EU chemicals legislative framework and find relevant information on how their substances are regulated across the EU. This will give businesses a better understanding of the obligations they might have so they can ensure they are legally on the market.

The first version of the finder covers legislation dealing with air and water quality, worker protection, pesticides, food contact materials, cosmetic products, toy safety and many more.

A further 16 pieces of legislation are planned to be added to EUCLEF in 2021.



BS EN ISO 11200:2014 + A1:2020

“Acoustics – Noise emitted by machinery and equipment – Guidelines for the use of basic standards for the determination of emission sound pressure levels at a work station and at other specified positions “

This International Standard is the frame standard introducing the basic group, ISO 11201, ISO 11202, ISO 11203, ISO 11204 and ISO 11205, on the determination of emission sound pressure levels at work stations and other specified positions.

It gives guidance for:

- facilitating the writing of noise test codes;
- providing physical explanations of this noise emission quantity compared to other noise quantities (see 4.1 to 4.3);
- comparing the different measurement methods offered by the group (see Table 1);
- facilitating the choice of the most appropriate method(s) in typical practical situations.

This International Standard is largely based on flow charts and tables. Case studies are described.

New Standards Published

National and international standards of interest published in recent months

March 2020

BS 7671:2018/A1:2020	Requirements for Electrical Installations. IET Wiring Regulations
BS 8888:2020 – TC [Tracked Changes]	Technical product documentation and specification
BS EN IEC 60812:2018 – TC [Tracked Changes]	Failure modes and effects analysis (FMEA and FMECA)
BS ISO 10005:2018 – TC [Tracked Changes]	Quality management. Guidelines for quality plans

April 2020

BS EN ISO 14006:2020	Environmental management systems. Guidelines for incorporating eco-design
BS EN 55011:2016 + A11:2020	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement
BS EN 55032:2015 + A11:2020	Electromagnetic compatibility of multimedia equipment. Emission Requirements
EN ISO 11200:2014/A1:2020	Acoustics. Noise emitted by machinery and equipment. Guidelines for the use of basic standards for the determination of emission sound pressure levels at a workstation and at other specified positions
ISO 56000:2020	Innovation management. Fundamentals and vocabulary

Compliance Calendar

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

March 2020

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					

April 2020

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 A	22	23	24	25	26
27	28	29	30			

A New EMC Directive standard must be used:

- EN 55011:2016 + A1:2017, (replaces EN 55011:2016)

May 2020

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 2020

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					

A New EMC standard must be used:

- EN 61000-4-11:2004 + A1:2017, (replaces EN 61000-4-11:2004)