

PRODUCT

COMPLIANCE UPDATE

2018 Issue 6



This issue:

Headlines

Standards Watch

European standards being withdrawn

Other standards being withdrawn

Lists of European Harmonised Standards

Update on Harmonised Standards Lists

Guidance

Radio Equipment Directive

Low Voltage Directive

New Standards – details of changes

CEN/TS 17091:2018

ISO 30401:2018

New Standards Published

October 2018

November 2018

December 2018

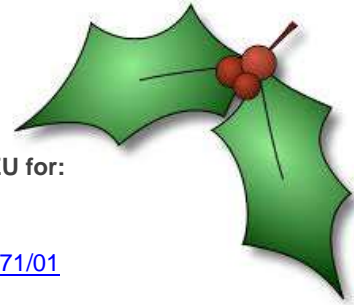
Compliance Calendar

Headlines

New Harmonised Standards lists published in the OJEU for:

ATEX Directive (2014/34/EU)

Latest publication, 12th October 2018: see [2018/C 371/01](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:2018/C_371_01)



The Brexit Clock



Fri 29 March 2019

14 weeks to go

Standards being withdrawn (see standards watch)

- **within 1 year**
 - European Standards 1 standard
 - Other Standards none identified
- **within 2 years**
 - European Standards 4 standards
 - Other Standards none identified

If you want to know more, contact us

Nadolig Llawen a Blwyddyn Newydd Dda i chi i gyd

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European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking: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
15 Feb 2019	EN 55011:2009 + A1:2010	EMC	EN 55011:2016

Within 2 years

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
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Other standards being withdrawn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

Further information:



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	2018/C 092/01	09 Mar 2018
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

Update on Harmonised Standards Lists

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

No relevant harmonised standards lists have been published in the OJEU since the last newsletter

Guidance



Radio Equipment Directive

An updated “Guide to the Radio Equipment Directive 2014/53/EU” was published on the 19th December 2018, replacing the previous versions of 19th May 2017 and 5th June 2018.

<https://ec.europa.eu/docsroom/documents/33162/attachments/1/translations/en/renditions/native>

Key change:

- Section 1.6.2.4 “Airborne equipment”, has been updated with reference to the new EU Civil Aviation Regulation (EC) No 216/2008.



Low Voltage Directive

The EC Low Voltage Directive 2014/35/EU Guidelines were updated August 2018, replacing the November 2016 version.

Changes in this version:

- New section §38 “Union market surveillance and control of electrical equipment entering the Union market”, (subsequent sections renumbered).
- New Annex added, Annex X “Additional Information”
 - Additional European Union Legislation Affecting Electrical Products
 - Industry Sectors
 - Electrical Engineering
 - Application of Directives RED 2014/53/EU, LVD 2014/35/EU and EMCD 2014/30/EU
 - Guide to the Implementation of Directives Based on New Approach and Global Approach
 - Frequently Asked Questions on LVD
- New Annex added, Annex XI “Geographical Information”
 - Application in non-EU States, countries & territories
 - Mutual Recognition Agreements (MRAs)
 - MRA with Switzerland
 - Agreements on Conformity Assessment and Acceptance (ACAAs)
- Several new footnotes added (~16)

Take care – as a result of adding new section §38, several cross-references to subsequent sections are now wrong, (they’re out by 1)

New Standards – details of changes



CEN/TS 17091:2018

“Crisis management – Guidance for developing a strategic capability”

This document provides guidance on good practice for crisis management to help the strategic decision makers of an organization to plan, implement, establish, operate, monitor, review, maintain and continually improve a crisis management capability. It is intended for any organization regardless of location, size, type, industry, structure, or sector. While it is important to be aware of human and cultural factors as they can cause stress when working as individuals and as part of groups, it is not the purpose of this document to examine aspects of these areas in detail.

This document provides guidance for:

- understanding the context and challenges of crisis management;
- developing an organization's crisis management capability through preparedness (see 5.5);
- recognizing the complexities facing a crisis team in action;
- communicating successfully during a crisis; and
- reviewing and learning.

NOTE 1 For further information on organizational resilience, see ISO 22316.

This technical specification is intended for management with strategic responsibilities for the delivery of a crisis management capability. It is for those who operate under the direction and within policy of top management in:

- implementing the crisis plans and structures; and
- maintaining and assuring the procedures associated with the capability.

It is not intended for emergency and incident response - these require the application of operational procedures whereas crisis management relies on an adaptive, agile, and flexible strategic response (see 4.3).

It does not cover interoperability or command and control or business continuity management systems.



ISO 30401:2018

“Knowledge management systems. Requirements”

The purpose of this standard is to support organizations to develop a management system that effectively promotes and enables value-creation through knowledge.

Knowledge management is a discipline focused on ways that organizations create and use knowledge. Knowledge management has no single accepted definition and no global standards predate this management system standard. There are many well-known barriers to successful knowledge management which still need to be overcome, many confusions with other disciplines such as information management, and many common misconceptions about how to do knowledge management, for example the view that simply buying a technology system will be enough for knowledge management to add value.

Each organization will craft a knowledge management approach, with respect to its own business and operational environment, reflecting their specific needs and desired outcomes.

The intent of this document is to set sound knowledge management principles and requirements:

- a) as guidance for organizations that aim to be competent in optimizing the value of organizational knowledge;
- b) as a basis for auditing, certifying, evaluating and recognizing such competent organizations by internal and external recognized auditing bodies.

New Standards Published

National and international standards of interest published in recent months

October 2018

BS EN ISO 50001:2018	Energy management systems. Requirements with guidance for use
CISPR 16-4-2:2011+A2	Specification for radio disturbance and immunity measuring apparatus and methods. Uncertainties, statistics and limit modelling. Measurement instrumentation uncertainty

November 2018

BS EN IEC 61204-3:2018	Low-voltage switch mode power supplies. Electromagnetic compatibility (EMC)
BS EN IEC 61800-3:2018	Adjustable speed electrical power drive systems. EMC requirements and specific test methods
BS EN 301549:2018	Accessibility requirements for ICT products and services
PD CEN/TS 17091:2018	Crisis management. Guidance for developing a strategic capability
PD ISO/IEC GUIDE 41:2018	Packaging. Recommendations for addressing consumer needs
EN ISO 17480:2018	Packaging. Accessible design. Ease of opening
EN 60705:2015/A2:2018	Household microwave ovens. Methods for measuring performance
IEC 62368-1:2018	Audio/video, information and communication technology equipment. Safety requirements

December 2018

BS EN IEC 60812:2018	Failure modes and effects analysis (FMEA and FMECA)
BS ISO 30401:2018	Knowledge management systems. Requirements
EN 55016-4-2:2011/A2:2018	Specification for radio disturbance and immunity measuring apparatus and methods. Uncertainties, statistics and limit modelling. Measurement instrumentation uncertainty
IEC GUIDE 116:2018	Guidelines for safety related risk assessment and risk reduction for low voltage equipment

Compliance Calendar

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

November 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		

December 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						

January 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			

February 2019

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

A New EMC Directive standards must be used:

- EN 55011:2016, (replaces EN 55011:2009 + A1:2010)