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New Standards Published

August 2018

September 2018

October 2018

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Headlines

New Harmonised Standards lists published in the OJEU for:

Low Voltage Directive (2014/35/EU)

Latest publication, 14th September 2018: see [2018/C 326/02](#)

Radio Equipment Directive (2014/53/EU)

Latest publication, 14th September 2018: see [2018/C 326/04](#)

Standards being withdrawn (see standards watch)

- **within 1 year**
 - European Standards 1 standard

- **within 2 years**
 - European Standards 3 standards

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European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking: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
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
28 Apr 2020	EN 55014-1:06+A1:09+A2:11		EN 55014-1:2017
22 Jun 2020	EN 61000-4-11:2004		EN 61000-4-11:04 + 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Other standards being withdrawn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.

Directive	OJEU Ref	Date
EMC	2018/C 246/01	13 Jul 2018
LVD	2018/C 326/02	14 Sep 2018
<u>Radio Equipment Directive</u>	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
<u>Medical Devices Directive</u>	2017/C 389/03	17 Nov 2017
<u>Active implantable medical devices</u>	2017/C 389/02	17 Nov 2017
<u>In vitro diagnostic medical devices</u>	2017/C 389/04	17 Nov 2017

Further information:



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 4 newsletter:

- 14th September 2018 [2018/C 326/02](#) 13 standards added including:

standard	title
EN IEC 61204-7:2018	Low-voltage switch mode power supplies — Part 7: Safety requirements, (IEC 61204-7:2016)
EN 62949:2017	Particular safety requirements for equipment to be connected to information and communication networks, (IEC 62949:2017)
EN IEC 63044-3:2018	Home and Building Electronic Systems (HBES) and Building Automation and Control Systems (BACS) — Part 3: Electrical safety requirements, (IEC 63044-3:2017)



Radio Equipment Directive ([2014/53/EU](#))

There has been one publication since the 2018 Issue 4 newsletter:

- 14th September 2018 [2018/C 326/04](#) 3 standards added

None of the standards added are of obvious interest to us

New Standards – details of changes



EN ISO 50001:2018

“Energy management systems – Requirements with guidance for use”

This second edition cancels and replaces the first edition (EN ISO 50001:2011), which has been technically revised.

The main changes compared to the previous edition are as follows:

- adoption of ISO’s requirements for management system standards, including a high-level structure, identical core text, and common terms and definitions, to ensure a high level of compatibility with other management system standards;
- better integration with strategic management processes;
- clarification of language and document structure;
- stronger emphasis on the role of top management;
- adoption of context order for the terms and their definitions in Clause 3 and update of some definitions;
- inclusion of new definitions, including energy performance improvement;
- clarification on exclusions of energy types;
- clarification of “energy review”;
- introduction of the concept of normalization of energy performance indicators [EnPI(s)] and associated energy baselines [EnB(s)];
- addition of details on the energy data collection plan and related requirements (previously energy measurement plan);
- clarification of text related to energy performance indicators [EnPI(s)] and energy baselines [EnB(s)] in order to provide a better understanding of these concepts.



BS ISO 10005:2018

“Quality management — Guidelines for quality plans”

This third edition cancels and replaces the second edition (ISO 10005:2005), which has been technically revised.

The main changes compared with the previous edition are as follows.

- a) It applies the terminology from ISO 9000:2015, which includes changes to key definitions, such as:
 - 1) for the definition of "quality plan" (see 3.2), which has been modified to replace the phrase “procedures and associated resources to be applied when and by whom” by “actions, responsibilities and associated resources”;
 - 2) for the definition of “specific case” (see 3.3), which has been modified to make reference to “service”, as ISO 9001:2015 now refers to “products and services” and no longer just to “products”;
 - 3) the replacement of the terms "documentation" and "record" by the term “documented information”, which is generally used in ISO management system standards to include both “procedures” and “records” which are not necessarily distinct from each other in a digital environment (documented information needed to support process operation is “maintained”, which means that it is established and updated as required; documented information that provides evidence of conformity with requirements is “retained” which means that it is protected from unintended alterations).

<i>ISO 10005:2005</i>	<i>This document</i>
Products	Products and services
Documentation Quality manual Documented procedures Records	Documented information
Purchased product	Externally provided processes, products and services
Supplier	External provider
Monitoring and measuring equipment	Monitoring and measuring resources

- b) It is aligned to ISO 9001:2015, leading to:
 - 1) a significant revision in the clause/subclause sequence, titles and the addition of new material, e.g. the inclusion of “5.2 Context of a quality plan”, or the extension of 7.2 to also reference the monitoring of a quality plan;
 - 2) the incorporation of “risk-based thinking”.
- c) A new clause (Clause 4) on using a quality plan.



EN IEC 60812:2018

“Failure modes and effects analysis (FMEA and FMECA)”

latest date by which the national standards conflicting with this document have to be withdrawn	dow	2021-09-14
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This document supersedes EN 60812:2006, and constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) the normative text is generic and covers all applications;
- b) examples of applications for safety, automotive, software and (service) processes have been added as informative annexes;
- c) tailoring the FMEA for different applications is described;
- d) different reporting formats described, including a database information system;
- e) alternative means of calculating risk priority numbers have been added;
- f) a criticality matrix based method has been added;
- g) the relationship to other dependability analysis methods have been described

New Standards Published

National and international standards of interest published in recent months

August 2018

BS EN IEC 61010-2-201:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for control equipment
BS EN ISO 19011:2018 ISO 10005:2018	Guidelines for auditing management systems Quality management. Guidelines for quality plans

September 2018

BS 45002-1:2018	Occupational health and safety management systems. General guidelines for the application of ISO 45001. Guidance on managing occupational health
BS 45002-3:2018	Occupational health and safety management systems. General guidelines for the application of ISO 45001. Guidance on incident investigation
BS ISO 10001:2018	Quality management. Customer satisfaction. Guidelines for codes of conduct for organizations
BS ISO 10002:2018	Quality management. Customer satisfaction. Guidelines for complaints handling in organizations
BS ISO 10003:2018	Quality management. Customer satisfaction. Guidelines for dispute resolution external to organizations
BS ISO 10004:2018	Quality management. Customer satisfaction. Guidelines for monitoring and measuring
EN 50672:2017	Eco-design requirements for computers and computer servers
IEC 60812:2018	Failure modes and effects analysis (FMEA and FMECA)

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

Compliance Calendar

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

September 2018

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	29	30

A New Management System standards must be used:

- EN ISO 9001:2015, (replaces EN ISO 9001:2008)
- EN ISO 14001:2015, (replaces EN ISO 9001:2004)
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October 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 EMC Directive standards must be used:

- ETSI EN 301 489-1 V2.1.1, (replaces ETSI EN 301 489-1 V1.9.2)
- ETSI EN 301 489-17 V3.1.1, (replaces ETSI EN 301 489-17 V2.2.1)
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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						