Safety and EMC

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Editorial

The European Commission's "Guide for the EMC Directive" was referenced in May 2018, Issue 158 of this newsletter and, for this issue, Alex Martin of RINA has very kindly prepared a detailed discussion of the advice provided in the Guide, looking at "inherently benign equipment", "custom built evaluation kits" and "components/sub-assemblies" as well as clarifying the use of harmonised standards. His article can be read in the EMC section.

I am grateful to Pierre Beeckman of Signify in Netherlands for pointing out to me that the ICNIRP has set up a public consultation for its draft "Guidelines on Limiting Exposure to Time-Varying Electric, Magnetic and Electromagnetic Fields (100 kHz to 300 GHz)". You may read about this in the Radiation section.

As an interesting side issue, to use sensitive words such as accreditation, accredit, accredited or accrediting in the company, Limited Liability Partnership (LLP) or business name, you would need to obtain prior approval from the Secretary of State for Business, Energy and Industrial Strategy (BEIS). Guidance from the UK government website tells you what you need to consider and what information you need to include in your application.[1]

[1] https://tinyurl.com/yabegg53

If you have any comments or enquiries regarding the content of this newsletter, please write to me at pritpal.bilkhu@rina.org

European Requirements*

General

UKAS accreditation logo and symbols

The latest version of "The National Accreditation Logo & Symbols: Conditions for use by UKAS and UKAS accredited organisations"[1] was published by the UK Department for Business, Energy & Industrial Strategy (BEIS) on 17 July 2018. It is intended for organisations working in calibration, testing, inspection and certification of systems, products and personnel. Where applicable, these conditions shall be met by UKAS and by all UKAS accredited organisations, including those outside the United Kingdom.

This document replaces the BEIS (formerly BIS) publication URN: BIS 16/25.

[1] This document can be downloaded from: https://tinyurl.com/ydcauf7s

Brexit

BSI position post-Brexit

Following the publication of the UK Government's white paper "The future relationship between the United Kingdom and the European Union" on 12 July 2018, a BSI article states that the UK Government supports the principles that the BSI had set in its position paper, "Brexit and standards: Position statement", that it published in February 2018 (reported in the *Safety and EMC* newsletter, March 2018, Issue 157). To quote the BSI article:

The Government's recently released white paper has supported our principles.

There is a specific section on standards in the white paper, which states: 'the British Standards Institution (BSI) would retain its ability to apply the "single standard model" – so that where a voluntary European standard is used to support EU rules, the BSI could not put forward any competing national standards'.

….. letter received by BSI last month from Secretary of State for Business, Energy and Industrial Strategy Greg Clark MP, in which he confirmed that the Government would not change its established approach to the use of voluntary standards to support trade. In the letter he also encouraged BSI to fulfil its mandate as the UK's national standards body and to maintain UK influence in the European standards organizations.[1]

[1] The BSI article can be read here: https://tinyurl.com/y9dkat7j

*For convenience, given the close correlation between IEC and ISO standards and those used in Europe, ***Safety and EMC*** chooses to include these within the section on **European requirements** rather than **Worldwide requirements**. Similarly, documents from other bodies which are commonly used in the EU market are also reported in this section.

Guidance for trading goods in a "no deal" Brexit scenario

The series of technical notices issued by the UK Government to set out information to allow businesses and citizens to understand what they would need to do in a 'no deal' scenario so they can make informed plans and preparations includes two notices that provide guidance on the trading of goods.

Published on 13 September 2018, "Trading goods regulated under the 'New Approach' if there's no Brexit deal"[1] explains the future arrangements for the regulation of most goods covered by the EU's New Approach, which includes those regulated under the 'New Legislative Framework' as well as machinery. In particular, it covers arrangements for conformity assessment (the testing of goods to ensure they meet relevant requirements). These goods are subject to EU-wide product specific rules. These arrangements will apply in the unlikely event that the UK exits the EU without a deal in March 2019.

The other notice, also published on 13 September 2018, "Trading under the mutual recognition principle if there's no Brexit deal"[2] provides guidance on how the importing and exporting of non-harmonised goods under the mutual recognition principle would be affected in the unlikely event that the UK exits the EU without a deal in March 2019.

[1] "Trading goods regulated under the 'New Approach' if there's no Brexit deal" can be downloaded from: https://tinyurl.com/ybeql68l

[2] "Trading under the mutual recognition principle if there's no Brexit deal" can be downloaded from: https://tinyurl.com/ydhy8p38

EMC

The European Commission's latest EMC Directive guidance

In March of this year, the European Commission published an updated "Guide for the EMC Directive"[1], as referenced in the *Safety and EMC* newsletter, May 2018, Issue 158. Although published some four years after the 2014 adoption of the recast EMC Directive, said recast was a key driver for the update – not least because the recast aligns the Directive with the New Legislative Framework and introduces obligations for importers and distributors for the first time. Interestingly enough, however, the updated Guide offers little of substance regarding these changes – it instead refers readers to the Blue Guide on more than one occasion – but offers new and salient advice on longer standing issues. These issues include what constitutes "inherently benign equipment", "custom built evaluation kits" and "components/sub-assemblies" as well as what, in practice, an EMC assessment might look like and further clarification pertaining to the use of harmonised standards. This article discusses the advice presented.

Inherently benign equipment

Recital 12 of the EMC Directive states that the Directive "should not regulate equipment which is inherently benign in terms of electromagnetic compatibility". Recital 12, therefore, provides opportunity for exclusions, something that the earlier, 2010 version of the Commission Guide discussed while also suggesting that inherent benevolence is conditional upon electrical equipment being:

- Incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunications equipment and other equipment to operate as intended
- Able to operate without unacceptable degradation in the presence of electromagnetic disturbance normally present in its intended environment.

These conditions are also documented in the new Guide together with a list of examples, as follows:

- Cables and cabling, cables accessories, considered separately
- Equipment containing only resistive loads without any automatic switching device; e.g. simple domestic heaters with no controls, thermostat or fan
- Batteries and accumulators (without active electronic circuits)
- Corded headphones, loudspeakers without amplification, guitar inductive sensors without active electronic parts
- Pocket lamps (including those containing LEDs) without active electronic circuits
- Induction motors without electronic circuits
- Quartz watches (without additional functions, e.g. radio receivers)
- Home and building switches which do not contain any active electronic components
- Passive antennas

- Electromagnetic relays without active electronic parts
- Electromagnetic locks without active electronic parts
- Cathode ray tubes
- Protection equipment which only produces transitory disturbances of short duration during the clearing of a short-circuit fault or an abnormal situation in a circuit and which do not include active electronic components, such as fuses and circuit breakers without active electronic parts or active components
- High voltage types of equipment in which possible sources of disturbances are due only to localised insulation stresses which may be the result of the ageing process and are under the control of other technical measures included in non-EMC product standards, and which do not include active electronic components.

The 2018 Guide also makes a new point:
If a product under assessment is not included in the list of examples above and the EMC assessment establishes that the apparatus concerned is inherently benign in terms of electromagnetic compatibility (both for emission and immunity), the EMCD [the EMC Directive] shall not apply. However, it is recommended to document the results of the assessment and its conclusion.

Custom built evaluation kits

The new Guide offers an interpretation of what constitutes such kits for the first time. It does so by outlining criteria for determining what is "custom built" and, subsequently, an "evaluation kit". The guidance is:

Custom built

i. *A kit that has been built on the basis of a specific request from a specific customer or from a group of customers involved in a joint research and development project as for all or certain characteristics of the evaluation kit; or*
ii. *A kit that has been built for the specific requirements of a specific customer or a group of customers involved in a joint research and development project as for all or certain characteristics of the evaluation kit.*

Evaluation kits

A printed circuit board with an integrated circuit and support components to produce a working circuit for evaluation and development.

- ***Destined for professionals (customers), to be used solely at research and development facilities***

Research and development facilities meaning public or private research and development bodies.

- ***For research and development purposes***

Evaluation kits to be used in testing for further development/improvement of the function of the equipment under research and development.

A non-exhaustive list of examples of evaluation kits that do not benefit from the custom built evaluation kit exemption is presented.

Components/sub-assemblies

These are discussed in Section 1.5.3 of the new Guide. It is stated that under Article 3.2.1 of the EMC Directive:

…components/sub-assemblies are covered by the EMCD, if the following two criteria are satisfied:

(a) intended for incorporation into an apparatus by the end-user; and
(b) liable to generate electromagnetic disturbance or the performance of which is liable to be affected by such disturbance.

Based on the definitions of "placing on the market" and "making available on the market" (Article 3 of the EMCD), as interpreted by the Blue Guide, supplying a product is only considered as making available on the Union market, when the product is intended for end user on the Union market. Thus, the first criterion (paragraph (a)), which refers to the end user and hence to the end use, is satisfied once the components/sub-assemblies are considered as being "placed on the market".

The second criterion (paragraph (b)) is satisfied if the components/sub-assemblies are liable to generate electromagnetic disturbance or is liable to be affected by such disturbance. At least any of the two situations need to be satisfied. Benign components/sub-assemblies are excluded, thus not covered by the EMCD.

Performing a practical EMC assessment

The new Guide suggests that an EMC assessment is to be performed following a "defined methodology" with the Commission's advice being that:

Any conformity assessment procedure requires the manufacturer to start with an analysis of the specific risks of the product to address them in order to comply with the essential requirements because not all products present the same risks.

Once the risks are identified and the manufacturer has determined the measures to address those risks in order to comply with the essential requirements he can choose to apply the harmonised standards applicable to his product or he can choose other technical specifications.

This is interesting as it introduces commentary around risk analysis, in keeping with risk analysis being a new requirement under technical documentation in the EMC Directive.

Use of harmonised standards

The 2018 Guide offers the following as advice:

Harmonised standards are European standards that have been adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation (for example the EMC Directive).

Compliance with the applicable harmonised standards whose reference is listed in the OJEU under the EMC Directive gives presumption of conformity with the corresponding essential requirements of the EMCD.

Each harmonised standard contains information on how to achieve the presumption of conformity with the corresponding essential requirements of the EMC Directive.

In addition, the 2018 Guide offers the following clarification pertaining to product-specific, product family and generic standards:

When the manufacturer chooses to apply harmonised standards he shall select them in the following precedence order:

- *Product-specific standards (if available)*
- *Product family standards (if available)*
- *Generic standards*

Product-specific (family) standards are those written by European Standards Organisations taking into account the environment, operating and loading conditions of the equipment and are considered the best to demonstrate compliance to the Directive.

Generic standards could be used in the absence of either product-specific or product-family standards. They are divided into generic environments but do not contain specific guidance of how to operate and load equipment during the testing phase of an EMC assessment.

It may be necessary to apply several harmonised standards to cover all essential requirements of the Directive. Each harmonised standard identifies the essential requirements which it covers in an annex.

The main aspects that are generally required to be covered are:

- *Radiated disturbances*
- *Conducted disturbances at mains and telecommunication ports*
- *Immunity to continuous radiated and conducted disturbances*
- *Immunity to transient phenomena.*

Conclusion

While the updated "Guide for the EMC Directive" does not differ greatly to what was documented in the earlier, 2010 Guide, the new interpretation presented by the Commission when it comes to inherently benign equipment, custom built evaluation kits and components/sub-assemblies is noteworthy, equally the order of preference presented regarding harmonised standards. It is, however, important to remember that the guidance is not legally binding.

[1] The Guide can be downloaded from: https://tinyurl.com/y8wfomhl

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CISPR 16-1-4

On 17 August 2018, the IEC pre-released the final draft of the fourth edition of CISPR 16-1-4 "Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-4: Radio disturbance and immunity measuring apparatus - Antennas and test sites for radiated disturbance measurements".[1] This standard specifies the characteristics and performance of equipment for the measurement of radiated disturbances in the frequency range 9 kHz to 18 GHz. Specifications for antennas and test sites are included.

This fourth edition cancels and replaces the third edition published in 2010, Amendment 1: 2012 and Amendment 2: 2017. In the new revised edition, provisions are added to address test site validation in the frequency range from 30 MHz to 1000 MHz using the reference site method, to take into account the receive antenna radiation pattern in the frequency range from 1 GHz to 18 GHz, and further details on test site validation using the NSA method with broadband antennas in the frequency range from 30 MHz to 1 000 MHz.

The final draft standard is available for purchase during its voting period from 17 August 2018 to 28 September 2018. If you do purchase this draft, you will automatically receive, in addition, the final publication.

[1] The final draft can be purchased from: https://tinyurl.com/ycmla8x2

Amendment 2 to CISPR 16-4-2: 2011

The IEC issued Amendment 2 to CISPR 16-4-2: 2011 "Specification for radio disturbance and immunity measuring apparatus and methods - Part 4-2: Uncertainties, statistics and limit modelling - Measurement instrumentation uncertainty" on 15 August 2018.

Amendment 2[1] can be purchased from the IEC webstore, as can the consolidated version[2] of this standard which includes the base standard, its Amendment 1: 2014 and Amendment 2: 2018.

[1] https://tinyurl.com/y7sjbn6d
[2] https://tinyurl.com/y9lph9fb

Guidance for testing portable devices near the human body

Published on 15 August 2018, the Technical Report, IEC TR 63170 "Measurement procedure for the evaluation of power density related to human exposure to radio frequency fields from wireless communication devices operating between 6 GHz and 100 GHz",[1] describes the state of the art measurement techniques and test approaches for evaluating the local and spatial-average incident power density of wireless devices operating in close proximity to the users between 6 GHz and 100 GHz. In particular, this document provides guidance for testing portable devices in applicable operating position(s) near the human body, such as mobile phones, tablets, wearable devices, etc. The methods described in this document may also apply to exposures in close proximity to base stations.

This Technical Report also gives guidance on how to assess exposure from multiple simultaneous transmitters operating below and above 6 GHz (including combined exposure of SAR and power density).

[1] IEC TR 63170: 2018 can be purchased from: https://tinyurl.com/yccsylmb

Explosive atmospheres

Correction for IEC 60079-18

The IEC issued a corrigendum for IEC 60079-18: 2014 "Explosive atmospheres - Part 18: Equipment protection by encapsulation "m"" on 25 July 2018. It replaces the final paragraph of Subclause 8.2.5.1 by the following new text:

The tensile force applied shall be derived in the following way:

- *Measure the diameter of the cable (mm), multiply this value by 20*
- *Measure the mass (kg) of the 'm' apparatus and multiply this value by 50*
- *Take the lower numerical value of these calculations and apply it (in Newtons) as tensile force for the cable pull test.*

This value may be reduced to 25 % of the required value in the case of fixed installations. The minimum tensile force shall be 1 N and the minimum duration shall be 1 h. The force shall be applied in the least favourable direction.

The corrigendum can be downloaded from the IEC webstore.[1]

[1] https://tinyurl.com/y8o9463l

Quality management systems for Ex Product manufacture

The IEC published the second edition of ISO/IEC 80079-34 "Explosive atmospheres - Part 34: Application of quality management systems for Ex Product manufacture"[1] on 30 August 2018. This standard specifies particular requirements and information for establishing and maintaining a quality management system to manufacture Ex Products in accordance with the certificates. While it does not preclude the use of other quality management systems that are compatible with the objectives of ISO 9001:2015 and which provide equivalent results, the minimum requirements are given in this document.

This second edition cancels and replaces the first edition published in 2011. The significant changes with respect to the previous edition should be considered as minor technical revisions. However, the clause numbering in regard to the previous edition has changed in order to be in line with ISO 9001:2015.

CENELEC, the European Committee for Electrotechnical Standardisation, is working on adopting this standard and its project is at the approval stage.[2] The European standard is expected to be published on 8 April 2019 and when it is published, it will supersede EN ISO/IEC 80079-34: 2011. The European standard will also be included in the harmonised standards list of the ATEX Directive 2014/34/EU.

[1] ISO/IEC 80079-34: 2018 can be purchased from: https://tinyurl.com/ydfl9arc

[2] For further information on the CENELEC project, please go to: https://tinyurl.com/yazfbz8r

Machinery

Mechanical vibration measurements on machine sets in hydraulic power generating and pump-storage plants

ISO 20816-5 "Mechanical vibration - Measurement and evaluation of machine vibration - Part 5: Machine sets in hydraulic power generating and pump-storage plants"[1] is the first edition which was published by the ISO on 20 July 2018. It provides guidelines for evaluating the vibration measurements made at the bearings, bearing pedestals or bearing housings and also for evaluating relative shaft vibration measurements made on machine sets in hydraulic power generating and pump-storage plants when the machine is operating within its normal operating range, with typical rotational speeds of 60 r/min to 1 000 r/min fitted with shell or pad (shoe) type oil-lubricated bearings. These measurements can be used to prevent damage arising from excessive vibration magnitudes and to monitor changes in vibrational behaviour in order to allow diagnosis and/or prognosis.

Machine sets covered by this standard can have the following configurations:

- Generators driven by hydraulic turbines
- Motor-generators driven by pump-turbines
- Motor-generators driven by hydraulic turbines and separate pumps
- Pumps driven by electric motors.

[1] ISO 20816-5: 2018 can be purchased from: https://tinyurl.com/y8fqhek7

Safety of electrical machinery

On 31 July 2018, the IEC published the second edition of IEC 60204-11 "Safety of machinery - Electrical equipment of machines - Part 11: Requirements for equipment for voltages above 1 000 V AC or 1 500 V DC and not exceeding 36 kV".[1] This standard applies to electrical and electronic equipment and systems to machines, including a group of machines working together in a co-ordinated manner, which operate at nominal voltages above 1 000 V AC or 1 500 V DC and not exceeding 36 kV AC or DC with nominal frequencies not exceeding 60 Hz.

This second edition cancels and replaces the first edition which was published in 2000 and the technical changes in it include the following:

- Aspects of risk assessment, which are mirrored from ISO 12100
- Equipotential bonding and earthing
- EMC and power quality
- HV switchgear and controlgear
- Creepage distances for conductors and slip-ring assemblies
- A list of machinery using HV equipment, in Annex A.

The European adoption of this standard by CENELEC has been approved and EN 60204-11 is expected to be published on 23 May 2019. The new standard will supersede EN 60204-11: 2000 and its Corrigendum published in February 2010. It will also be included in the harmonised standards list of the Machinery Directive 2006/42/EC.[2]

[1] IEC 60204-11: 2018 can be purchased from: https://tinyurl.com/y8ctn8ha

[2] For further information on the European standard, please go to: https://tinyurl.com/yddme472

Requirements for active opto-electronic protective devices

The third edition of IEC 61496-3 "Safety of machinery - Electro-sensitive protective equipment - Part 3: Particular requirements for active opto-electronic protective devices responsive to diffuse reflection (AOPDDR)" is shown as "work in progress" on the IEC website.[1] This standard specifies additional requirements for the design, construction and testing of electro-sensitive protective equipment (ESPE) designed specifically to detect persons or parts of persons as part of a safety-related system, employing AOPDDRs for the sensing function.

This third edition, which is forecast to be published on 5 October 2018, will cancel and replace the second edition published in 2008. The technical changes in it will include the following:

- Extension of the scope from AOPDDR-2D to AOPDDR-3D
- Extension of the scope from Type 3 ESPE to Type 2 ESPE
- Implementation of requirements and test procedures for AOPDDR-3D and Type 2 ESPE
- Listing of reference boundary monitoring as an optional function of the ESPE
- Implementation of instructions for positioning of AOPDDR-3D in respect of parts of the human body
- Revised requirement for combinations of single faults with conditions for no failure to danger, see for example 4.2.2.4, last paragraph.

[1] https://tinyurl.com/y8u5xhc3

Vibration limits for certain electrical machines

The fourth edition of IEC 60034-14 "Rotating electrical machines - Part 14: Mechanical vibration of certain machines with shaft heights 56 mm and higher - Measurement, evaluation and limits of vibration severity"[1] was published by the IEC on 17 August 2018. It specifies the factory acceptance vibration test procedures and vibration limits for certain electrical machines under specified conditions, when uncoupled from any load or prime mover. It is applicable to DC and three-phase AC machines, with shaft heights 56 mm and higher and a rated output up to 50 MW, at operational speeds from 120 min–1 up to and including 15 000 min–1.

This fourth edition cancels and replaces the third edition published in 2003 and its Amendment 1 published in 2007. The technical changes in the new edition include the following:

- 6.2 is significantly changed to better explain the definition "free suspension"
- 6.3: a second method of rigid mount is added since the first method is not always possible on the test floor
- 7.1: an improved option for shaft key is defined
- Clause 8: considerable effort to harmonise with NEMA MG 1 and IEEE 841 and API 541, and also to establish levels which are achievable and more in line with best practices. Table 1 is reduced to two shaft-height range sections
- 8.2: definition of twice line frequency is simplified along with the addition of Figure 7.

The CENELEC adoption of this IEC standard is at the approval stage. The European standard is expected to be published on 18 March 2019 and when it does get published, it will replace EN 60034-14:2004 and EN 60034-14:2004/A1:2007. It will also be included in the harmonised standards list for the Low Voltage Directive 2014/35/EU.[2]

[1] IEC 60034-14: 2018 can be purchased from: https://tinyurl.com/ybdl2bpo

[2] For further information on the European standard, please go to: https://tinyurl.com/ycn7sraw

National authorities responsible for market surveillance for the Machinery Directive

A list of "Contact points in charge of implementation and market surveillance for the Machinery Directive 2006/42/EC in EU Member States, EFTA/EEA, EFTA/MRA and CU countries" was published by the European Commission on 30 August 2018. The list, which can be downloaded from the European Commission's website,[1] provides the names, addresses, telephone and fax numbers and email addresses for the authorities.

[1] https://tinyurl.com/y6v3yge4

Medical devices

Transitioning to the new regulations

In order to help manufacturers transition to the new Medical Devices Regulation 2017/745/EU and the In-vitro Diagnostic Medical Devices Regulation 2017/746/EU, the European Commission published a factsheet for each of the regulations on 20 July 2018. Both of these regulations were published in May 2017 and there is a three-year transition period for the Medical Devices Regulation (MDR), ending on 26 May 2020, and a five-year transition period for the In-vitro Diagnostic Medical Devices Regulation (IVDR) which ends on 26 May 2022.

The MDR will replace the existing Medical Devices Directive 93/42/EEC and the Active Implantable Medical Devices Directive 90/385/EEC. The "Factsheet for manufacturers of medical devices"[1] states that no existing requirements have been removed but the MDR adds new requirements such as more emphasis on a life-cycle approach to safety, more stringent requirements for the designation of Notified Bodies, a new Unique Device Identification system and increased transparency. The factsheet explains the obligations of manufacturers and conformity assessment requirements and, it includes Frequently Asked Questions.

The IVDR will replace the existing In-Vitro Diagnostic Medical Devices Directive 98/79/EC. Again, no existing requirements have been removed but the IVDR adds new ones. The biggest change concerns the risk classification of in-vitro diagnostic devices and the role of Notified Bodies. The IVDR also clarifies the obligations of economic operators (manufacturers, authorised representatives, importers and distributors). "Factsheet for manufacturers of in-vitro diagnostic medical devices"[2] explains the timing of the transition, for example, some devices with certificates issued under the Directive may continue to be placed on the market until 27 May 2024 and made available until 27 May 2025. This factsheet also includes a FAQs section.

In addition to the above, the European Commission has published step-by-step implementation guides for the new regulations,[3, 4] and a document entitled "New EU rules to ensure safety of medical devices" which describes the background to the new regulations and their benefits for the patients and the consumers. [5]

[1] The factsheet on medical devices can be downloaded from: https://tinyurl.com/ycjkvz96

[2] The factsheet on in-vitro diagnostic medical devices can be downloaded from: https://tinyurl.com/yb6refdt

[3] The guide for the medical devices can be downloaded from: https://tinyurl.com/yauhdbek

[4] The guide for in-vitro diagnostic medical devices can be downloaded from: https://tinyurl.com/ya575u6k

[5] "New EU rules to ensure safety of medical devices" can be downloaded from: https://tinyurl.com/y9z3cohw

Power systems

Selection and erection of electrical equipment for safety services

The pre-release version of IEC 60364-5-56 "Low-voltage electrical installations - Part 5-56: Selection and erection of electrical equipment - Safety services" can be found on the IEC website.[1] This standard covers general requirements for safety services, selection and erection of electrical supply systems for safety services and electrical safety sources. Standby electrical supply systems are outside the scope of this part and it does not apply to installations in hazardous areas.

This third edition cancels and replaces the second edition which was published in 2009 and the technical changes in it include the following:

- Modifications to normative references and terms and definitions
- Under electrical circuits for safety services, addition of requirements concerning circuit and overcurrent protection in order to maintain reliability of safety service power supplies under fire conditions
- Addition of requirements stating that electrical circuits for safety services are not to be protected by RCDs or AFDDs
- Addition of requirements to prevent emergency lighting systems being adversely affected by any control system
- Addition of Annex D: Fire switch, Annex E: Example of installation methods of safety services with cable management system, Annex F: Wiring systems and Annex G: Guidance on suitable locations for electrical sources for safety services.

[1] Pre-release IEC 60364-5-56: 2018 can be purchased from: https://tinyurl.com/ycaaclmk

Guidelines for the LVD Directive

The European Commission published "Low Voltage Directive 2014/35/EU Guidelines: Electrical equipment designed for use within certain voltage limits"[1] on 19 August 2018. Prepared by the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (GROW) of the European Commission in cooperation with Member States, European standardisation bodies, European industry, European consumer organisations and other relevant sectoral stakeholders, this document updates and replaces the first version of the "guidelines on the application of Directive 2014/35/EU" of November 2016.

This guide is intended not only for the use of Member States' competent authorities but also by the main economic operators concerned, such as manufacturers, importers and distributors and their trade associations; bodies in charge of the preparation of standards as well as those involved in the conformity assessment procedures. Readers' attention is drawn to the fact that this guide is intended only to facilitate the application of the LVD and it is the text of the LVD and the national laws transposing the LVD that are legally binding. This document does, however, represent a reference for ensuring consistent and harmonised application of the LVD by all stakeholders.

[1] The guide can be downloaded from: https://tinyurl.com/y9vf7wtg

Product safety

SCHEER opinion on human risk from LEDs

SCHEER, the Scientific Committee on Health, Environmental and Emerging Risks, published its final "Opinion on Potential risks to human health of Light Emitting Diodes (LEDs)"[1] on 6 June 2018.

After reviewing recent evidence, as requested by the European Commission, SCHEER has concluded that there is no evidence of direct adverse health effects from LEDs emission in normal use (lamps and displays) by the general healthy population. There is some evidence that exposure to light in the late evening, including that from LED lighting and/or screens, may have an impact on the circadian rhythm. It goes on to say that at present it is not yet clear if this disturbance of the circadian system leads to adverse health effects.

SCHEER is, however, cautious about the effect that blue LEDs may have on children and the older people. It also states that as this technology is evolving, it is important to monitor the risk of adverse health effects from long-term LED use by the general population.

[1] The Opinion can be downloaded from: https://tinyurl.com/yamshbed

IECEE work

An article by Antoinette Price in the IEC e-tech magazine, Issue 4, 2018 explains the work of IECEE, the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components, an international conformity assessment system based on IEC International Standards. The different schemes test the safety, quality, efficiency and overall performance of electrical and electronic components, devices and equipment to ensure they comply with IEC standards. IECEE covers 23 categories of electrical equipment and testing services.

The article describes the new proposed functional safety programme as being limited to a scope of three standards: IEC 60947-5-3 and IEC 60947-5-5 (related to discrete hardware only) and IEC 61800-5-2 (safe torque off function related to discreet hardware only), with the focus on IEC 61508 and other derived functional safety standards as a future state.

Based on the need to have qualified personnel conducting the evaluations of the functional safety of industrial installations and equipment, IECEE is developing a programme for the Certification of Personnel Competency (CoPC) in the areas of cyber security and functional safety, among others.[1]

[1] The article can be read here: https://tinyurl.com/y9wwvmh4

Public consultation on drones

On 26 July 2018, the UK government set up a public consultation for policies proposing safer use of drones and the powers of enforcement. The proposed policies include:

- The minimum age requirement for operators of small unmanned aircraft
- Whether the 1km flight restriction around protected aerodromes is sufficient
- A proposal to mandate and regulate a Flight Information and Notification System (FINS) or just regulate the FINS
- The powers required by enforcement bodies in order to properly police drone use and penalise incorrect use, including the possible use of fixed penalty notices
- Counter drone technology system proposals.

The consultation closed on 17 September 2018.[1]

[1] Further information on this consultation can be obtained from: https://tinyurl.com/ybh5tex7

Revised British standard for household switches

Published on 31 July 2018, BS EN 60669-1 "Switches for household and similar fixed-electrical installations. Part 1: General requirements"[1] has been derived from IEC 60669-1: 2017. This standard applies to manually operated general purpose functional switches, for alternating current only with a rated voltage not exceeding 440 V with a rated current not exceeding 63 A, intended for household and similar fixed electrical installations, either indoors or outdoors.

BS EN 60669-1: 2018 supersedes BS EN 60669-1: 1999+A2: 2008 which will be withdrawn on 15 February 2019.

[1] BS EN 60669-1: 2018 can be purchased from: https://tinyurl.com/yacnr3r5

OPSS to strengthen the UK's world-leading product safety regime

On 10 August 2018, the UK Office for Product Safety and Standards (OPSS) (the setting up of which was reported in *Safety and EMC* newsletter, No. 157, March 2018) launched its strategy and delivery plan ("Strengthening national capacity for product safety: Strategy 2018- 2020" and "Strengthening national capacity for product safety: Delivery plan 2018-2019")[1] which set out a bold programme of action to enhance the UK's ability to identify risks, protect consumers and co-ordinate large scale product recalls and repairs. Included in the plan are ambitious new measures such as:

- A new national incident management team for product safety incidents capable of coordinating large scale product recall and repair programmes
- Establishing a new website to support consumers with reliable information and advice about recalled products
- Increased support for local authority enforcement teams at ports, borders and points of entry to ensure the safety of goods that are entering the UK
- Close working with manufacturers to ensure they are compliant with safety regulations from an earlier stage of the production process
- Developing tools and guidance to assist local authorities in improving risk assessments and identifying mistakes before they happen.

The delivery plan also sets out a number of additional commitments for the OPSS including:

- Working with white goods manufacturers, gaining assurance that their compliance systems are robust and that they are implementing the Product Recalls Code of Practice
- Publishing a Strategic Research Programme, setting out priorities for scientific research into potential product safety risks
- Preparing the first national Strategic Assessment to prioritise product safety actions, based on scientific evidence
- Working with the Royal Society for the Prevention of Accidents (RoSPA) and public health bodies to further improve injury data collection
- Working with the government's Behavioural Insights Unit to understand how to most effectively reach consumers in product recall scenarios and with wider product safety messages
- Encouraging greater diversity in standards committee membership
- Supporting consumer awareness campaigns about specific hazards.

[1] Both the strategy and the delivery plan can be downloaded from: https://tinyurl.com/ybmolfkq

EESC's opinion on the Goods Package, Union harmonisation legislation and mutual recognition of goods

On 10 August 2018, the Official Journal of the European Union published the opinion of the European Economic and Social Committee (EESC) on "The Goods Package: Reinforcing trust in the single market", "Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council" and "Proposal for a Regulation of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State".

The above package includes the EMC Directive 2014/30/EU, the Low Voltage Directive 2014/35/EU, the Radio Equipment directive 2014/53/EU and the ATEX Directive 2014/28/EU.

Overall, the EESC welcomes the work done by the European Commission in producing this package but it regrets that it has failed to take more control by the excessive "flexibility" of some of the provisions which give the Member States too much leeway. Apart from listing 15 conclusions and recommendations, the opinion of the EESC includes specific comments about amending some of the articles of the proposals.[1]

[1] The EESC opinion can be read here: https://tinyurl.com/ydcn3ynw

IMCO votes on legislative proposals for better checks and safety of goods sold in the EU

According to a press release[1] issued by the European Parliament on 3 September 2018, rules to ensure better checks and safety of goods sold in the EU were approved by the Internal Market Committee (IMCO) on that day.

The "Goods package" contains two legislative proposals: one on compliance and enforcement and the other on mutual recognition. Together they aim to strengthen checks made by national authorities and customs officers to prevent unsafe products from being sold to EU consumers and to make it easier for companies, especially SMEs, to sell their products across Europe. These measures should also prevent rogue traders from gaining an unfair competitive advantage over companies that respect the rules.

The proposed regulation on compliance and enforcement provides for the 500 different authorities responsible for market surveillance in the EU member states to cooperate and coordinate better, based on an increased exchange of information on faulty products and ongoing investigations, and through the creation of an EU Network, to which MEPs give new tasks and powers. Market surveillance, including of products sold online, and national authorities' powers to investigate and enforce rules are also strengthened and clarified in MEPs' amendments.

The proposed regulation on mutual recognition aims to reduce trade barriers within the single market, simplify procedures for companies and national authorities, enhance cross-border cooperation and improve problem solving.

The committee's votes gives the rapporteurs a mandate (still to be green-lighted by plenary) to start talks with the Council of the EU in order to reach an agreement on the final laws. The mandate on the compliance and enforcement rules was approved by 24 votes to 10 and the one on mutual recognition by 28 votes to five.

[1] The press release can be read here: https://tinyurl.com/y92vajx4

Safety of household and similar electrical appliances

Four parts of IEC 60335-2 have been changed as follows:

- The IEC issued Corrigendum 1 to IEC 60335-2-5: 2012 + Amendment 1: 2018 "Household and similar electrical appliances - Safety - Part 2-5: Particular requirements for dishwashers" on 29 August 2018. The Corrigendum, which can be downloaded from the IEC webstore, replaces some text in Clause 15 Moisture Resistance.[1]
- On 24 August 2018, the IEC published the final draft of Amendment 2 to IEC 60335-2-8 "Household and similar electrical appliances - Safety - Part 2-8: Particular requirements for shavers, hair clippers and similar appliances". It is available for sale until the end of the voting period on 5 October 2018. By purchasing this final draft, you will automatically receive, in addition, the final publication.[2]
- Amendment 2 to IEC 60335-2-31: 2012 "Household and similar electrical appliances - Safety - Part 2-31: Particular requirements for range hoods and other cooking fume extractors" was issued by the IEC on 17 August 2018. It can be purchased from the IEC webstore.[3]
- Also on 17 August 2018, the IEC issued Amendment 1 to IEC 60335-2-21: 2012 "Household and similar electrical appliances - Safety - Part 2-21: Particular requirements for storage water heaters".[4]

[1] Corrigendum 1 to IEC 60335-2-5: 2012 + Amendment 1: 2018 can be downloaded from: https://tinyurl.com/y93t5cnq

[2] The final draft of Amendment 2 to IEC 60335-2-8 can be purchased from: https://tinyurl.com/y9nbrbqw

[3] Amendment 2 to IEC 60335-2-31: 2012 can be purchased from: https://tinyurl.com/y854j5s6

[4] Amendment 1 to IEC 60335-2-21: 2012 can be purchased from: https://tinyurl.com/yb985wph

Safety requirements for laboratory electrical equipment

The IEC issued Corrigendum 1 to IEC 61010-031: 2015 + Amendment 1: 2018 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 031: Safety requirements for hand-held and hand-manipulated probe assemblies for electrical test and measurement" on 6 August 2018.

This Corrigendum, which can be downloaded from the IEC webstore[1], adds the following values after the 3rd paragraph in Clause 9 *Temperature limits and protection against the spread of fire and Sub-Clause 9.1 General:*

Metal: 55 °C

Non-metallic materials: 70 °C

PROBE WIRES: 75 °C

[1] https://tinyurl.com/y7y5o7vx

Failure modes and effects analysis

The third edition of IEC 60812 "Failure modes and effects analysis (FMEA and FMECA)",[1] published by the IEC on 10 August 2018, explains how failure modes and effects analysis (FMEA), including the failure modes, effects and criticality analysis (FMECA) variant, is planned, performed, documented and maintained. The purpose of FMEA is to establish how items or processes might fail to perform their function so that any required treatments could be identified. An FMEA provides a systematic method for identifying modes of failure together with their effects on the item or process, both locally and globally. It may also include identifying the causes of failure modes. Failure modes can be prioritised to support decisions about treatment. Where the ranking of criticality involves at least the severity of consequences, and often other measures of importance, the analysis is known as FMECA. This document is applicable to hardware, software, processes including human action, and their interfaces, in any combination. An FMEA can be used in a safety analysis, for regulatory and other purposes, but this being a generic standard, it does not give specific guidance for safety applications.

This third edition cancels and replaces the second edition published in 2006. The following are some of the changes in the new edition:

- The normative text is generic and covers all applications
- Examples of applications for safety, automotive, software and (service) processes have been added as informative annexes
- Tailoring the FMEA for different applications is described
- Different reporting formats are described, including a database information system
- A criticality matrix based method has been added.

FprEN 60812: 2018[2] is the number of the European project for the adoption of IEC 60812: 2018. The European standard is at the approval stage and the standard is expected to be published on 14 May 2019. It will then supersede EN 60812: 2006.

[1] IEC 60812: 2018 can be purchased from: https://tinyurl.com/y7gprbz3

[2] For further information on the European project, please go to: https://tinyurl.com/y7y2o2ta

Radiation

Draft ICNIRP guidelines

On 11 July 2018, ICNIRP (International Commission on Non-Ionizing Radiation Protection) set up a public consultation for its draft "Guidelines on Limiting Exposure to Time-Varying Electric, Magnetic and Electromagnetic Fields (100 kHz to 300 GHz)" which ends on 9 October 2018. The draft is comprised of the main guidelines document and two appendices. These, along with the consultation template, can be downloaded from the ICNIRP website.[1]

After the 90 days consultation period, all comments will be reviewed by the ICNIRP members for finalisation of the draft. Information regarding the publication date will be displayed on the ICNIRP website in due course.

[1] https://tinyurl.com/yapmp2he

Worldwide requirements

Canada

Release of ICES-006, Issue 3

Innovation, Science and Economic Development Canada (ISED) published Interference-Causing Equipment Standard ICES-006, Issue 3, "AC Wire Carrier Current Devices (Unintentional Radiators)" on 24 July 2018. This standard sets out limits and methods of measurement of radiated and conducted radio frequency emissions produced by AC wire carrier current devices classified as interference-causing equipment, according to section 2.5a of this document. AC wire carrier current device is a device that transmits radio frequency signals by conduction, over electric power lines, which is used in commercial, business, light industrial or residential buildings.

The new standard will come into force upon publication on the Spectrum Management and Telecommunications website. Issue 3 replaces ICES-006, Issue 2, published in June 2009 and, it has:

- Removed requirements that are common to various ICES standards and instead added a normative reference to ICES-Gen
- Updated the other normative references with corresponding latest editions
- Removed the output voltage test method and limits
- Clarified the radiated emissions (both on the test site and in-situ) test methods and limits.

A transition period, within which compliance with ICES-006, Issue 2 or ICES-006, Issue 3 is accepted, ends in July 2019. After the expiry of this transition period, all products subject to this standard that continue to be manufactured, imported, distributed, leased, offered for sale, or sold in Canada shall comply with ICES-006 Issue 3.[1]

[1] ICES-006, issue 3 can obtained from: https://tinyurl.com/ybjtycq9

India

Electrical transformers

On 16 August 2018, India notified the WTO Technical Barriers to Trade Committee of its Electrical Transformers (Quality Control) Order 2018, the objective of which is to reduce the failure of distribution transformers, to increase the standard and quality of transformers and to prevent manufacturing and sale of substandard transformers.

This Order covers indoor and outdoor type oil-immersed distribution transformers up to and including 33 kV as per the following ratings:

- Three phase ratings up to and including 200 kVA, both non-sealed and sealed type
- Three phase ratings higher than 200 kVA up to and including 2500 kVA, both non-sealed and sealed type
- Single phase ratings up to and including 100 kVA sealed type.

The proposed date of adoption and the proposed date of entry into force are yet to be determined. The final date for comments is 60 days from the date of the notification.[1]

[1] The WTO notification can be downloaded from: https://tinyurl.com/yb64mlcv

Israel

Safety requirements of audio visual equipment

On 27 August 2018, Israel notified the WTO Technical Barriers to Trade Committee of its intention to revise and replace mandatory standards SI 60065: 2012 (and its Amendment 1: 2015) and SI 60950 Part 1: 2015 by a new standard SI 62368 Part 1 "Audio/video, information and communication technology equipment. Part 1: Safety requirements". This draft standard adopts IEC 62368-1: 2014. This draft revision is based on the principles of hazard-based safety engineering and is, therefore, significantly different from the current practice.

Both the old standards and this new revised standard will apply from entry into force of this new revision until 20 June 2019. During this time, products may be tested according to the old or the new revised standard.[1]

[1] The WTO TBT notification can be downloaded from: https://tinyurl.com/ycosnykv

Mexico

Mobile terminal equipment

On 20 July 2018, Mexico notified the WTO Technical Barriers to Trade Committee about its Draft Official Standard PROY-NOM-221/2-SCFI-2018, "Technical specifications for mobile terminal equipment that can use the radio spectrum or connect to a public communications network. Part 2. Mobile terminal equipment operating on the following wavebands: 700 MHZ, 800 MHZ, 850 MHZ, 1900 MHZ, 1700 MHZ/2100 MHZ and/or 2500 MHZ". It establishes that, when such equipment is in operation, it shall not cause interference that is harmful to other authorised equipment or telecommunications networks and services authorised by the Federal Telecommunications Institute. It does not apply to mobile terminal equipment that uses international roaming within the national territory.

The proposed date of adoption is given as to be determined. The proposed date of entry into force is stated as 60 calendar days after its publication in the Official Journal as a final standard.[1]

[1] The WTO TBT notification can be downloaded from: https://tinyurl.com/y8dr4oof

Republic of Korea

Safety of electrical appliances

On 2 August 2018, the Republic of Korea notified the WTO Technical Barriers to Trade Committee of its intention to amend the Electrical Appliances Safety Control Regulation. The amendment includes the following changes:

- Secondary lithium cells with more than 700 Wh/L volumetric energy density and 4.4V charging voltage that are used in smart phones, laptops and tablet PCs will become subject to safety certification
- Electric heaters, electric warmers/heating cabinets, fluid pumps and electric bathtubs which are currently subject to safety certification will be downgraded to being subject to safety confirmation
- Electronic musical instruments and binding machines which are currently subject to safety confirmation will be downgraded to being subject to the supplier's assurance of conformity
- The scope of electric vehicle chargers which are subject to the safety confirmation will be expanded from 100kVA to 200kVA.
- The LED illumination systems will be added to the detailed items for lighting equipment subject to safety certification
- PCB LED modules are included in the detailed items for lighting equipment subject to safety confirmation.

The proposed date of adoption is October 2018 and the proposed date of entry into force is given as October 2019 for chargers for electric vehicles, LED illumination systems, PCB LED modules and October 2020 for cells.[1]

[1] The WTO TBT notification can be downloaded from: https://tinyurl.com/y79xyrn8

Saudi Arabia

Draft technical regulation for PPE

On 24 July 2018, Saudi Arabia notified the WTO Technical Barriers to Trade Committee of its Draft Technical Regulation on Personal Protective Clothing and Equipment (42 page(s), in Arabic). This regulation specifies terms and definitions, scope, objectives, supplier obligations, labelling requirements, conformity assessment procedures, responsibilities of regulatory authorities and market surveillance authorities, violations and penalties, general rules and transitional rules.

The proposed date of adoption is one year from the date of publication in the Official Gazette as is the date of proposed date of entry into force.[1]

[1] The WTO TBT notification can be downloaded from: https://tinyurl.com/ybdsnrev

Singapore

Changes to the SAFETY Mark

Circular 2018-03[1], published by Enterprise Singapore on 20 July 2018, explains the changes that will be made to the requirements on usage and affixing of the updated SAFETY Mark for controlled goods, replacing Circular 2018-02 of 6 April 2018.

There will be a grace period until 1 April 2019 for Registered Suppliers to get used to the changes in usage of the updated SAFETY Mark for new registrations of Controlled Goods. From 2 April 2019, all newly registered Controlled Goods must be affixed with the updated SAFETY Mark.

There will be a grace period until 1 April 2022 for Registered Suppliers with Controlled Goods registered prior to 2 April 2019 to strictly comply with the changes in the usage of the updated SAFETY Mark. From 2 April 2022, all Controlled Goods, including any existing stock bearing the old/former SAFETY Mark, must be affixed with the updated SAFETY Mark.

[1] Circular 2018-03 can be read here: https://tinyurl.com/yc26xt9h

Thailand

Telecommunications terminal equipment

On 9 August 2018, Thailand notified the WTO Technical Barriers to Trade Committee of its intention to amend two standards, NTC TS 3001-2555: 2012, which specifies minimum technical requirements for electromagnetic compatibility of telecommunication terminal equipment and NTC TS 4001-2550: 2007, which specifies minimum technical requirements for electrical safety of telecommunication terminal equipment. The new standards, NBTC TS 3001-25xx: 20xx "Electromagnetic Compatibility" and NBTC TS 4001-25xx: 20xx "Electrical Safety" will be amending the previous versions by adding optional electromagnetic compatibility and electrical safety requirements of TISI 1561-2556: 2013 and IEC 62368-1. On publication of the new standards, the previous versions (NTC TS 3001-2555: 2012 and NTC TS 4001-2550: 2007) will be superseded.

The proposed date of adoption and the proposed date of entry for both the standards have not been given. The final date for comments is 60 days from the date of the notifications.[1, 2]

[1] The WTO TBT notification for electromagnetic compatibility can be downloaded from: https://tinyurl.com/ybqesa6c
[2] The WTO TBT notification for electrical safety can be downloaded from: https://tinyurl.com/y73r2gvl

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