

## NEW REGULATORY REQUIREMENTS

Germany



The testing requirement for Polycyclic Aromatic Hydrocarbons (PAHs) became mandatory for German GS Mark certification since 2008 in accordance to ZEK 01.4-08. It has been announced already that a new requirement in accordance to PAH 20141027 (more strict PAH limits) will be enforced starting July 1, 2015.

Impact to power supplies:

- Charger or Adapters that will be applied for GS Mark Certification from July 1, 2015 onwards must be in compliance to PAH 20141027.
- Charger or Adapters already certified before July 1, 2015, must comply with PAH 20141027 before the next factory inspection for GS mark but not later than June 30, 2016.

India



The DeitY (Department of Electronics & Information Technology) has expanded the list of products subject to mandatory Registration by BIS (Bureau of Indian Standards) according to the Electronics and IT Goods (Requirement of Compulsory Registration) Order, 2012.

The added products include **power adaptors**, UPS/inverters, mobile phones and photocopiers. Target implementation date is **7 May 2015**.

## **Updated Standards under EMC Directive 2014/30/EU**



The following standards relevant to embedded power come into force in 2015 under European Commission Directive **2004/108/EC**, which was recast last year as **2014/30/EU** but whose harmonized standards continue to be in effect. These replace all older standards under the EMC directive:

Issue 10: January 2015

**EN61326-1:2013** (Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements), required by 14 Aug 2015.

**EN61326-2-x:2013** (Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-x: Particular requirements – Test configurations, operational conditions and performance criteria), some parts required by 14 Aug 2015.

**EN 300 386 V1.6.1** (Electromagnetic compatibility and Radio spectrum Matters (ERM); Telecommunication network equipment; ElectroMagnetic Compatibility (EMC) requirements), required by 30 Nov 2015.

**EN 301 489-34 V1.4.1** (Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 34: Specific conditions for External Power Supply (EPS) for mobile phones), required by 28 Feb 2015.

Design Teams will need to ensure that all applicable models meet the said requirements.

## Medical EMC Standard IEC60601-1-2:2014 adopted by EU and US



The 4<sup>th</sup> edition of the European medical EMC standard (**EN60601-1-2:2014**) was scheduled to be published on 1 JAN 2015. (The availability of the EN standard is still being confirmed, although its IEC equivalent, IEC60601-1-2:2014 was already published earlier.)

On or before 31 DEC 2018, the previous 3<sup>rd</sup> edition (**EN60601-1-2:2007**) shall no longer be valid in Europe. (The final date is subject to change until it is published in the Official Journal of the EU).

As for the corresponding IEC standard (IEC60601-1-2:2014), the US FDA shall no longer accept declarations of conformity in support of the older editions by 1 AUG 2016.



## Regulatory Compliance Engineering News

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Issue 10: January 2015

Below are the salient changes from 3<sup>rd</sup> edition to 4<sup>th</sup> edition relevant to embedded power products:

- Higher ESD requirements: 15kV air & 8kV contact discharge
- 10V/m radiated RF immunity extended to “Home Healthcare”, including applications for standard products, and maximum test frequency extended to 2.7GHz
- Higher frequency during EFT tests: 100kHz
- Higher magnetic field immunity level: 30A/m
- Additional voltage-dip test: interruption (100% dip) for 1 cycle and 0.5 cycle.