EMC SERVICES NEWSLETTER

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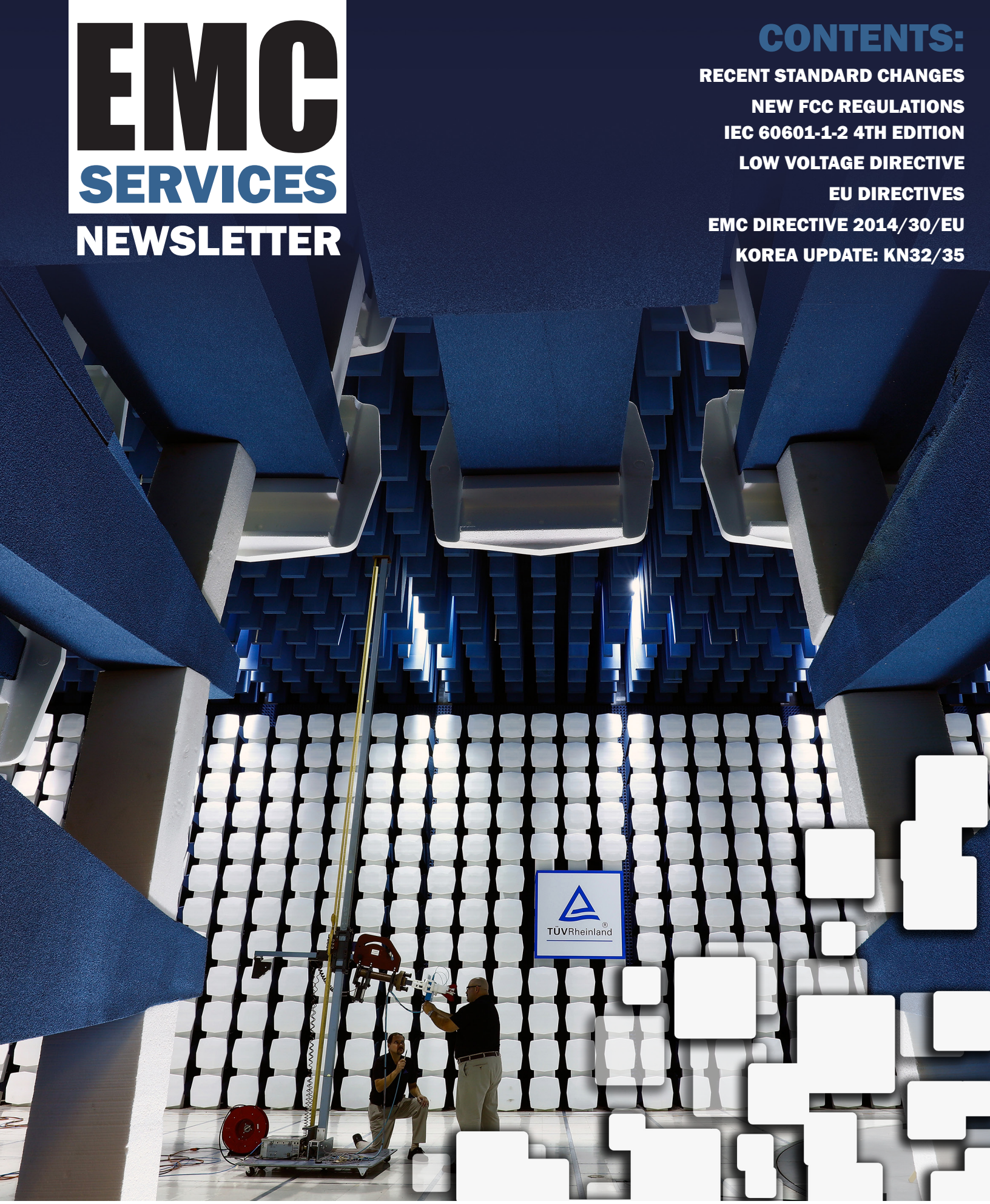


AUGUST 2016

TÜVRheinland®

RECENT STANDARD CHANGES

TUV Rheinland is committed to bringing you the latest updates and standard changes that relate to Electromagnetic compatibility testing

Standard	Description
EN55032:2012	• Any ITE/Multimedia that was previously tested under EN55013, EN55022 or EN55103-1 that is shipping into the EU after March 5, 2017 must meet the requirements. • References CISPR 16-2-3 for test method • Main technical changes for ITE products – location of EUT on test table is different than EN 55022 and LAN traffic >10% must be generated during testing. • Allows 3m OR 10m emissions testing, **Note:** Many far east countries have not agreed / adopted 3m testing. • Clarification of Display requirements during testing o Insulation of cables from the ground plane is now required for tabletop products and floor standing products. Insulation must be 150mm or less in thickness. o Loopback cables if used must be a minimum length of 2 meters.
EN 61326-1:2013	• For Laboratory equipment, process control equipment and test & measurement equipment. Compliance was required Aug 15 2015, 2006 version is no longer valid. Technical changes & retesting is required. • Your DOC's will need to revised • If your product is tested to the minimum immunity requirements of the 2006 version, you will need to re-test ESD at 4KV Contact and 8KV air discharge. • If your product uses magnetic sensitive devices, you will need to test for magnetic field immunity.
ANSI C63.4:2014	• Published on June 20th 2014. Both FCC and Industry Canada has adopted this version so it is required for products in both the US and Canada.

NEW FCC REGULATIONS

Effective July 13, 2017, Code of Federal Regulations Title 47 Part 2 Subpart J, Sections 2.948 (a) and (e) now mandate that equipment authorized under the Certification and declaration of conformity procedure be tested at an ISO/IEC 17025 accredited test laboratory recognized by the FCC.

This will require testing laboratories outside of the United States to be accredited by an organization recognized by the FCC under terms of an intergovernmental Mutual Recognition Agreement (MRA) with the USA. If a testing lab is located in a country without an MRA, it must be accredited by an organization recognized by the FCC under provisions of §2.949.

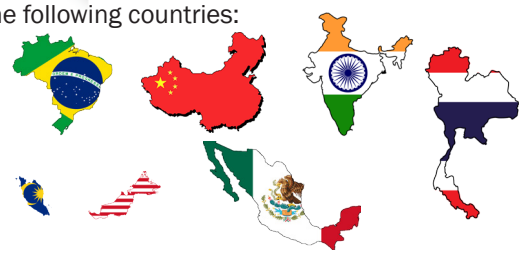
We advise due diligence when selecting a testing laboratory, as it will save headaches down the line. When timing production schedules, production managers may need to book labs further ahead to avoid bottlenecks due to the new rules.

These changes require two conditions to be met in order for a device to be fully certified for admission to the US market:

- An accredited laboratory must be used when testing products subject to the Certification and Declaration of Conformity (DoC) procedures.
- Only the accreditation bodies in those MRA countries will be recognized as having the authority to accredit testing laboratories.

This impacts the following countries:

- Brazil
- China
- India
- Malaysia
- Mexico
- Thailand



These changes have implications for the large number of equipment manufactures in China and India, the in-country test laboratories which handle their certification and DoC testing, and the responsible parties within the United States.

The FCC routinely updates their standards to reflect advances in technology. However, because changes of this scope and nature do not occur very often, it is understandable that manufacturers may require extra time to adjust their strategies or market projections.

IEC 60601-1-2 4TH EDITION INTRODUCED

The 4th edition was published in February of 2014 and will be required by the FDA for submittals after December 31, 2018. It will also be mandatory for compliance in the EU starting on December 31, 2018. The 4th edition is accepted by the FDA now and can be used in the EU now. The 4th edition will be listed as a recognized standard by Health Canada in the next recognized standards list and it is expected that the effective date will be synced with the dates from USA and EU at December 31, 2018.

The 4th edition is a risk based EMC safety standard that changes the basic EMC compliance philosophy to define tests and limits according to risk and intended use instead of device type. Tests are defined based on where the equipment is used, either in a healthcare facility or in the home use environment which includes most everything except the healthcare environment. There is also a "special" environment. The environment of intended use must be specified in the test report.

General Requirements – 4th edition:

- Risks resulting from reasonably foreseeable electromagnetic disturbances shall be taken into account in the risk management process.
- This standard requires the manufacturer to perform a number of activities with regard to electromagnetic (EM) disturbances during the design and realization of their ME equipment or ME system, and to document them in the risk management file.
- ME equipment and ME systems shall be tested in representative configurations, consistent with intended use, that are most likely to result in unacceptable risk.
- Prior to the start of formal testing, a detailed test plan shall be provided to the test laboratory by the manufacturer.
- The manufacturer must supply the test lab with the essential performance of the device.
- The manufacturer must supply the test lab with detailed, product specific performance criteria for use during the immunity testing.
- The manufacturer must provide the test lab with a specific monitoring plan for monitoring the performance of the device during immunity testing.
- According to section 6.2, an EMC test plan must be provided to the test lab by the manufacturer. The test plan must contain the items specified in table G1.
- The manufacturer must also provide the risk management file to the test lab for review that the EMC items are present in the file according to section 4.1 and annex "F".
- The manufacturer must also provide the test lab the instructions for use and accompanying documents for review against section 5 of the standard.
- There is a new requirement for immunity to RF wireless communication equipment. This requirement is found in table 9 and is a radiated immunity test at spot frequencies from 385Mhz to 5.8Ghz. The test levels are much higher at 28V/m at some frequencies.

	3rd Edition	4th Edition
EN 61000-4-2	ESD immunity levels are 6Kv contact and 8Kv air discharge. Connector pins are **not tested.**	ESD immunity levels are significantly increased to 8Kv contact and 15Kv air discharge. Connector pins are tested if accessible by the standard test finger. Manufacturers should determine if these increased levels are adequate or testing should be done at higher levels.
EN61000-4-3	Radiated immunity testing to 2.5Ghz and modulation is 1Khz.	Radiated immunity is specified to 2.7Ghz instead of 2.5Ghz and modulation is now 1Khz.
EN61000-4-4	Fast transient tests done at 5Khz repetition rate.	Fast transient tests must be done at 100Khz repetition rate.
EN61000-4-5	12Vdc inputs **does not** require surge testing.	Immunity testing of DC inputs is now required. 12Vdc inputs require surge testing
EN61000-4-6	Conducted immunity levels are 3Vrms in the ISM frequency bands.	Conducted immunity levels are increased to 6Vrms in the ISM frequency bands.
EN61000-4-8	The test levels for magnetic field immunity are at 3A/m.	The test levels for magnetic field immunity are higher at 30A/m

Other Changes:

- AC line immunity tests are done at only one line voltage instead of 2 voltages in the 3rd edition.
- Patient connected tubes filled with conductive liquid are considered cables and are tested for conducted immunity.
- FDA does not accept the immunity testing exclusion for signal cables <3m long, all cables must be tested for FDA.
- Wireless functions must be active (transmitting data and functioning) during the immunity testing.
- Risk analysis must contain EMC considerations.

MORE ABOUT THE LOW VOLTAGE DIRECTIVE (LVD)

The LVD provides the important safety requirements that electrical equipment covered must adhere to, and outlines the conformity assessment procedure that manufactures must apply to ensure compliance. It applies to all electrical equipment designed for use with a voltage rating between 50 and 1000 V for alternating current or between 75 and 1500 V for direct current.

On February 26, 2014, the new LVD was issued, aligning with the new legislative framework (Decision No 768/2008/EC). The new directives entered into force on April 19, 2014, will be applicable from April 20, 2016. The measures were designed to minimize inconsistencies, improve market surveillance and to tighten the CE marking requirements.

Major Changes:

- Scope Change: Now includes protection of health of people, animals and property, covering:
   Mechanical  Electrical  Chemical
- Risk assessment and analysis is a major part of the change.
- Market Surveillance has been added.
- Manufacturer has the responsibility for the preparation of CE marking documentation, and the EU declaration of Conformity (DoC).
- There is no conformity assessment procedure in this Directive which requires the intervention of a notified body.
- Manufacturers shall keep the technical documentation referred to in Annex III and the EU declaration of conformity for 10 years after the electrical equipment has been placed on the market.
- It is necessary to ensure that electrical equipment exported from other countries entering the EU market must comply with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that electrical equipment.
- Stricter regulations and increased requirements for manufacturers, importers, representatives, and traders. In order to ensure traceability, products must now list: name, address of the manufacturer, Serial or Batch Number, Type etc. Exceptions should be provided for in cases where the nature of the electrical equipment does not allow.
- Where harmonized standards are not yet available, the appropriate IEC standard or national standard can be applied.
- End user documentation and instructions shall be in a language which can easily understood by consumers and other end-users as determined by the Member State concerned.

EUROPEAN UNION DIRECTIVES

On March 29, 2014, the European Commission published the recasts of eight CE marking directives. These directives have new reference numbers and are aligned with the rules and responsibilities for CE marking that were published earlier in Decision 768/2008/EU. These include:

Directive	Description
Low Voltage Directive Directive 2014/35/EU	Relating to the making available on the market of electrical equipment designed for use within certain voltage limit
Electromagnetic Compatibility Directive Directive 2014/30/EU	Relating to electromagnetic compatibility (recast).
ATEX Directive Directive 2014/34/EU	Relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast).
Lifts Directive Directive 2014/33/EU	Relating to lifts and safety components for lifts.
Simple Pressure Vessels Directive Directive 2014/29/EU	Relating to the making available on the market of simple pressure vessels.
Measuring Instruments Directive Directive 2014/32/EU	Relating to the making available on the market of measuring instruments (recast).
Non-automatic Weighing Instruments Directive Directive 2014/31/EU	Relating to the making available on the market of non-automatic weighing instruments.
Civil Explosives Directive Directive 2014/28/EU	Relating to the making available on the market and supervision of explosives for civil uses (recast).
Radio Equipment Directive Directive 2014/53/EU	Relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

NEW EMC DIRECTIVE 2014/30/EU

As of April 2016, the new directive is required for all applicable products being sold in the European Union. Requirements listed in Annex I of the directive remain the same.

Key Changes:

- The directive now applies to distributors and importers, not just manufacturers
- Additional information is required in the technical file
- DoCs now need to be translated into the language or languages required by the Member State in which the apparatus is placed or made available on the market.
- Notified Body requirements have been updated, significant changes made.

Manufacturers Requirements:

For manufacturers the changes are relatively minor. The current method of using harmonized standards remains, and no new testing is required to show compliance with the new directive.

When possible manufacturers shall indicate the following: name, registered trade name or registered trade mark and the postal address at which they can be contacted, otherwise it should be included on the packaging or in the accompanying documentation.

Equipment must be accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users.

Manufactures have a responsibility to immediately take corrective measure withdraw or recall any equipment they believe is not in conformity with 2014/30/EU.

Additionally, the Directive now specifies and includes the following:

- Importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer.
- Ensure that the manufacturer has provided the technical documentation
- Bears the CE marking and is accompanied by the required documents.

Importers' Notice:

Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the apparatus. This is additional to the Manufacturer's details.

Importers shall ensure that:

Apparatus has instructions and safety information in an appropriate language.

Storage or transport conditions do not jeopardize its compliance with the safety objectives.

Keep a copy of the EU declaration of conformity for 10 years

Technical File Requirements:

It is now stated that the Technical Documentation shall make it possible to assess the apparatus' conformity with the applicable requirements of this Directive and shall include an analysis and assessment of the risk(s). The technical documentation shall cover, the design, manufacturer and operation of the apparatus. The technical documentation shall include at least the following-

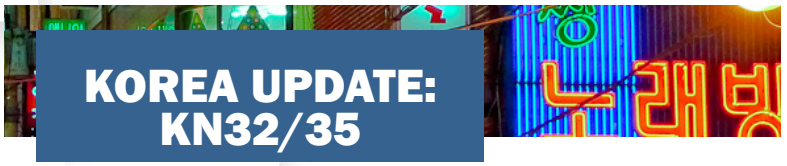
- A general description
- Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., and the descriptions and explanations necessary for their understanding
- A list of the harmonized standards applied in full or in part, and, where those harmonized standards have not been applied as well as descriptions of the solutions adopted to meet the essential requirements. (Where applied, parts of partly applied harmonized standards should be specified.)
- Results of design calculations made, examinations carried out, etc.
- Test reports.

Declaration:

The Declaration of Conformity must have the model structure set out in Annex IV (a template is now provided), must contain the items specified in the modules of Annexes II and III as appropriate, and must be continuously updated as required. It must also be translated into the language or languages required by the member state in which the apparatus is placed or made available on the market. The new contents include;

- Title: 'EU Declaration of Conformity'
- The Declaration can be numbered (optional).
- Includes: This declaration is issued under the sole responsibility of the manufacturer.
- States: The object of the declaration is in conformity with the relevant Union harmonization Legislation.
- Suitable identification of the product should be included, sufficient to allow product traceability.
- The new EMC Directive number should be specified: 2014/30/EU.

CLICK TO READ FULL DIRECTIVE



KOREA UPDATE: KN32/35

Please be advised that Korea EMC rule KN22/24 and KN13/20 will be changed to KN32/35 from Jan 1st, 2016. KN22/24 (ITE device) and KN13/20 (Audio, Video device) will be combined as "KN32/35" which is for Multi Media device.
TUV Rheinland N.A has received A2LA accreditation & Korea RRA Recognition for KN 32 and KN 35 (the new standards for multi-media equipment). It is mandatory to use the new KN 32 and KN 35 standards starting Jan 1st 2016 in all Korea submittals. The old standards KN 22 / KN 24 / KN 13 / KN 20 are no longer valid.