An overview of the EU EMC Directive 2004/108/EC
Introduction

Anyone involved in the development or quality assurance of electrical products needs to be aware of the essential requirements of the Electromagnetic Compatibility Directive (EMC) 2004/108/EC. The EMC Directive is one of the ‘New Approach Directives’; a collection of European complementary legislative measures that are intended to help facilitate free trade in line with Article 95 of the Treaty of Rome. The New Approach Directives include:

- Construction Products Directive (now evolving into the Construction Products Regulation)
- The Eco-Design & Energy Labelling Directive
- Electromagnetic Compatibility Directive
- Equipment for Explosive Atmospheres (ATEX) Directive
- Gas Appliances Directive
- The Low Voltage Directive
- The Machinery Directive
- The Measurement Instruments Directive
- The Medical Devices Directive (MDD)
- The New Legislative Framework
- Radio & Telecommunications Terminal Equipment (R&TTE) Directive
- Restriction of hazardous substances (RoHS)

The EMC Directive provides a common framework of regulation for certain types of electrical and electronic products across all EU member states - effectively
levelling the performance playing field between them. In short, if a product is placed on the market in one member state, it would have the same basic level of EMC performance as a product placed on the market in any other member state.

This paper is intended to provide an overview of the EMC Directive.

The New Approach

The EU has simplified the process of market access considerably by identifying the “essential requirements” for almost everything that is placed on the market in the region. The authorities having jurisdiction over products vary by product type and each member state has a Competent Authority for each product type or Directive.

The specific “essential requirements” for any electrical or electronic device will be listed in the Directives that apply to it. In most cases these will be “New Approach” Directives for which CE Marking and a Declaration of Conformity signify compliance. This Marking and Declaration activity is based on successful product testing to applicable harmonised Standards (testing procedures and criteria agreed upon by all member states - all be it with some local deviations in certain countries) - published in the 'Official Journal of the European Union'.

A good place to start for guidance on Directives and Standards is http://www.newapproach.org. CE Marking indicates that the equipment bearing the marking complies with all of the applicable “New Approach” Directives.

With regards to the EMC Directive, the essential requirements for electrical devices consist of generic protection requirements covering the emission and immunity characteristics of equipment; in the simplest terms, their ability to affect or be affected by other equipment in their environment.

- Emission assessment – Measuring a device to check that any unwanted radio signals emitted are below standard limits.
- Immunity assessment – Applying EMC phenomena to a device and checking its performance to standard requirements. (This could include subjecting a device to an RF field or the effect of an induced lightning strike on the mains network)
The EMC Directive

Objectives
The objective of the EMC Directive is to guarantee the free movement of electrical and electronic equipment whilst creating an acceptable electromagnetic environment within the EU. The EMC Directive first limits electromagnetic emissions of equipment in order to ensure that, when used as intended, such equipment does not disturb radio and telecommunication as well as other equipment. The Directive also governs the immunity of such equipment to interference and seeks to ensure that this equipment is not disturbed by radio emissions when used as intended.

The scope of the EMC Directive
Any electrical or electronic device falls within the scope of the EMC Directive unless their EMC obligations are covered by another Directive (Medical or Automotive products for example). Here is a list of devices that are excluded from the scope as well as some guidance with components and sub assemblies that that fall in and outside if the scope.

1) Product families excluded;
   - Radio products
   - Aeronautical products, parts and appliances

2) Products covered by other Directives
   - Automatic weighing machines (immunity only)
   - Medical equipment
   - Automotive and agricultural machinery and equipment

3) Passive devices - Devices incapable of producing interference or being interfered with e.g.
   - Cables and cabling systems, 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.
   - Headphones, loudspeakers without amplification system

4) Benign devices - Devices deemed incapable of causing EMI
   - Capacitors (e.g. power factor correction capacitors).
   - Induction motors.
   - Quartz wrist watches (without additional functions, e.g. radio receivers).
   - Filament lamps (bulbs).
   - Passive antennas used for TV and Radio broadcast reception
   - Fuses.
5) Components of sub-assemblies not included are those
- Intended for further manufacture
- Intended for integration into an Apparatus or System, such as
  - electrical or electronic components forming part of electrical
    or electronic circuits;
  - resistors, capacitors, coils;
  - diodes, transistors, thyristors, triacs, etc.;
  - integrated circuits;
  - ‘all or nothing’ relays
  - plugs, sockets, terminal blocks, etc.;
  - LEDs,
  - simple mechanical thermostats

6) Components / Sub-assemblies included - Some examples are;
- plug-in cards for computer systems, micro-processor cards,
  central processing unit cards/mother boards, electronic mail cards,
  telecommunication cards
- programmable logic controllers
- Lift controls
- Electric motors (except for induction motors)
- computer disk drives; power supply units (PSU), where they take
  the form of autonomous equipment; electronic temperature
  controls

**Apparatus & Fixed Installation**
The Directive divides products into apparatus and fixed installations. Essentially, apparatus can be equipment that can be moved from location. This can be anything from a hair dryer to a CNC machine for example. Fixed installations are devices that are permanently installed to a predefined location; examples could be a large induction furnace or automotive production plant.

More specific requirements are given separately for apparatus and for fixed installations. In the case of apparatus the manufacturer will need to perform an electromagnetic compatibility assessment, in which all relevant phenomena are identified and addressed with a view to meeting the protection requirements. If all relevant harmonised EMC standards applicable to a given apparatus are met, it is deemed to have met the obligation for an EMC assessment. A fixed installation can require more detailed attention as it may not be practical to apply harmonised standards. In cases where the manufacturer has not applied harmonised standards or has applied them only in part, the current EMC Directive requires a construction file including a technical report or certificate issued by a notified body.
Obligations
A manufacturer is required to document the means in which the device they are placing on the market meets the essential requirements of the Directive and they must also create a ‘Declaration of Conformity’ and apply a ‘CE Marking’.

Device conformity is usually assumed by successful testing to applicable Harmonised Standards. However if testing to a complete Standard is not possible or if a device has only been assessed against sections of a Standard, the manufacturer may use an appropriately compiled technical file to support their CE Marking and Declaration of Conformity activity instead.

Testing to Harmonised Standards
Harmonised standards are generally international standards that have been adopted by the European Union – having been formally published in the Official Journal. The Official Journal has a list of standards and the date to which a revision can be used to presume conformity to the Directive.

TIP: When Declaring Conformity, you must use the current version of the applicable product Standard. Manufacturers should therefore check in the Official Journal that the version of the Standard that they are using to assess their device is the latest one; so keep an eye on the ‘date of withdrawal’.

The first step to choosing the correct Harmonised Standards for a device is to check whether it has a product specific Standard. An example of a product specific Standard could be ‘EN61326 equipment for measurement, control and laboratory use for example’; this standard contains both Emission and Immunity requirements.

Care should be taken to ensure all relevant Standards are complied with; for example, Information Technology devices must comply with EN55022 for emissions and EN55024 for immunity.

For devices that do not fall within the scope of a product specific standard, generic Standards may be used; these are:

- EN61000-6-1: Immunity for residential, commercial and light-industrial environments
- EN61000-6-2: Immunity for industrial environments
- EN61000-6-3: Emission standard for residential, commercial and light-industrial environments
- EN61000-6-4: Emission standard for industrial environments

Note: The Emissions limits for the residential, commercial and light-industrial
Standard are tighter than those in the industrial Standard; however the industrial Standard has a higher immunity requirement. Often manufacturers who have a device that can be used in multiple environments work to the residential emissions Standard and the industrial immunity Standard to ensure that the 'worst case' EMC performance has been considered.

Both product specific and generic Standards reference 'Basic Standards' for their test methods. Commonly used basic Standards are the EN55016 range for emissions and the EN61000-4 range for immunity. Basic standards will include test levels but the level applied to a device will be defined in Generic Standard.

It should also be noted that the following standards will need to be considered in compliance activity: EN61000-3-2 and EN61000-3-3 for devices below 16A per phase and EN61000-3-11 and EN61000-3-12 for devices between 16A and 75A per phase. These are emission standards which apply to almost all ac mains powered devices (excluding some devices within the Standards) and they are used to measure the harmonic emission signature that a device puts back on to the mains supply and how much 'Flicker' a device causes to the mains supply with the switching of loads.

**Assessment without Harmonised Standards**

If it is not possible to test to harmonised Standards or it is only possible to test to them in part; a technical file documenting how and why the manufacturer believes that the device meets the essential requirements of the Directive needs to be created.

If the manufacturer believes that they are technically competent to compile a technical file correctly and base their conformity on it they may do so. However not all manufacturers have the engineering resource to do this and in these circumstances they may compile their construction file and have it checked by a Notified Body of the European Union. The Notified Body can then issue an opinion that they believe the device meets the essential requirements of the Directive. Also, if more than one model has been tested to cover a range, a Construction File can be used to identify and justify the worst case scenario.
Contents of a Technical File

Declaration of Sole Application (DoSA)
This is a document which states whether the applicant (manufacturer or his agent) has submitted the Construction File to any another Notified Body. The DoSA should give the following information:

1. Name and model number of product
2. A Construction File reference number
3. Name and address of manufacturer
4. Name and address of agent if different to the manufacturer
5. The Notified Body to whom the Construction File has been reviewed by
6. The DoSA should be on company headed paper and signed by a person in authority e.g. manager

Product Identification
The product needs to be easily identified, particularly by a third party and should contain the following information:

- Manufacturer’s name and address and the agents name and address if applicable
- Manufacturer’s information – this should be in the form of a user manual and contain external and internal photographs to clearly identify the product and provide a short description of how the product works.
- A technical specification including all operating frequencies, bandwidths, power levels, power requirements etc
- The intended function of the product
- Intended location – this should include any limitations on the intended electromagnetic environment.
- A list of all model numbers covered by the file – where the TCF is based on the testing of a single model but covers several variants a manufacturer’s letter is required stating that the variants are electronically similar.

Technical Rationale
The testing of one or more units can be shown to be representative of any variants included in the Construction File.

Testing should be performed on a worst case configuration as identified by the manufacturer. Any aspects of EMC performance inherent in the design should be included e.g. nothing in circuitry to generate interference.
Technical Description
This will enable the product to be identified fully in case of dispute, modification etc down to component level.

- Block /schematic diagrams
- Circuit diagrams
- PCB layouts
- Bill of materials identifying individual components
- All the above diagrams should be titled with drawing numbers to reference the product; this is particularly important where the circuit boards are being provided by another manufacturer.
- Any interconnections to auxiliary equipment.
- Details of any product variants (this will be covered more in depth in the technical rationale).

Quality Assurance
This should provide details of any internally or externally audited quality procedures followed by the manufacturer, in order to demonstrate manufacturing process continuity - with a view to the ongoing conformance of the product with the unit(s) tested

Significant Design Features
This should include any measures to enhance EMC performance, including the use of filters or screening etc

Test Data
This should include the relevant signed EMC test reports which need to clearly identify which units have been tested and to what Standards.

Technical documentation

The Directive requires that the technical documentation must cover the design and manufacture of the apparatus, in particular:

- a general description of the apparatus;
- evidence of compliance with the harmonised standards, if any, applied in full or in part
- where the manufacturer has not applied harmonised standards, or has applied them only in part, a description and explanation of the steps taken to meet the essential requirements of the Directive, must be included in the technical file
EC Declaration of Conformity

The EC Declaration of Conformity must contain, at least, the following:

- a reference to this Directive
- an identification of the apparatus
- the name and address of the manufacturer and, where applicable, the name and address of his authorised representative in the Community
- a dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of this Directive
- the date of that declaration
- the identity and signature of the person empowered to bind the manufacturer or his authorised representative

Non-conformity and Penalties

It is the responsibility of the member states to individually check that the devices available in their country are compliant with the Directive and take action when in the event of non-conformity. Enforcement activities his can be random product surveillance (i.e. the authorities taking products ‘off the shelf’ and retesting them independently) or be initiated due to a complaint by a consumer, retailer, distributor and even from a manufacturer’s competitor. The authorities will then have the product assessed and if necessary request ‘corrective action’ to bring about compliance.

It’s worth noting that non-compliance doesn’t necessarily mean ‘dangerous’. Something as simple as incorrect documentation presented with a device can lead to a non-conformity, and in most cases these can be easily resolved when identified. Some non-conformities are serious though, and may require for the product to be recalled, which will have a significant financial implication for the company involved.
Depending on the seriousness of the non-compliance, penalties can include:

- 3 months imprisonment, £5k fine or both
- Remedial action – being forced to pay for a full recall of all sold items, this has further implications of costs:
  - Logistics of Recall
  - Bad press
  - Loss of contracts with retailer’s exporters etc
- Forfeiture – the courts can take non compliant stock and destroy
- Court Expenses – this can be significant if there is a defence experts would be required spiralling costs incurred

**Summary**

- Compliance with the EMC Directive is mandatory in Europe for the devices covered by the Directive
- When considering compliance to the EMC Directive, it is important to remember that it is part of a suite of Directives that form the infrastructure of the CE Marking regulations – so shouldn’t be undertaken in isolation. You will still need to consider device characteristics such as electrical safety under the Low Voltage Directive, the material safety under the Restriction of Hazardous Substances (RoHS) Directive and even perhaps the energy efficiency of the product under the EcoDesign Directive – so check which Directives apply
- Manufacturers can either used testing to harmonised Standards as a basis of their CE Marking and Declaration of Conformity activity, or an appropriately constructed technical file
- Getting the associated paperwork right is key, as incorrect or incomplete documentation can lead to a non-conformity that requires corrective action
- Compliance with the Directive is policed and serious non-conformity carries serious penalty.
How Intertek can help

EMC Testing Compliance with the EMC Directive is a mandatory requirement for CE marking within Europe and is fast becoming mandatory for an increasing range of products for countries outside the EU, such as Japan, USA and the Middle East.

Nearly 50% of all products fail to fulfil the EMC requirements at the first attempt of EMC testing. This is why Intertek’s experienced engineers are on hand to assist you with the investigation and resolution of EMC problems that can occur during the testing phase. Our engineering experts provide support and guidance at every point during the design process to ensure products comply with market requirements - through design review and pre-compliance testing, full testing to Standards and stringent professional assessment.

Whether you need advice on factory production control, building a technical file or even how CE Marking should be applied, we can help. From evidence to support your CE Marking and Declaration of Conformity activities or for a full product certification and Marking - or even working towards international market access via the IECEE CB scheme, Intertek have a compliance route to meet your needs and budget.

We are an EU Notified Body under the EMC Directive and a member of the IECEE CB scheme as well as being accredited by a number of other international authorities such as the US FCC, Industry Canada, A2LA, the Australian Communications Authority (ACMA), Japan’s Voluntary Control Council for Interference (VCCI) for IT & telecom Equipment, the HOKLAS scheme in Hong Kong, the Swedish Board for Accreditation and Conformity Assessment (SWEDAC) and Taiwan’s Bureau of Standards, Metrology and Inspection (BSMI) to name a few. So get in touch to see how we can help you with your next EMC assessment project.

Contact us

Intertek House  
Cleeve Road  
Leatherhead  
Surrey  
KT22 7SB

Tel: 01372370900  
Fax: 01372370999  
Email: electrical.uk@intertek.com

For more information on specific testing and certification information, please contact Intertek at 1-800-WORLDLAB, email icenter@intertek.com, or visit our website at www.intertek.com.

This publication is copyright Intertek and may not be reproduced or transmitted in any form in whole or in part without the prior written permission of Intertek. While due care has been taken during the preparation of this document, Intertek cannot be held responsible for the accuracy of the information herein or for any consequence arising from it. Clients are encouraged to seek Intertek’s current advice on their specific needs before acting upon any of the content.

www.intertek.com