Another EMC resource
from EMC Standards

Complying with the EMC Directive, Conformity 2009 Annual Guide

Helping you solve your EMC problems

9 Bracken View, Brocton, Stafford ST17 0TF T:+44 (0) 1785 660247 E:info@emcstandards.co.uk

First published in Conformity (www.conformity.com) in March 2008
This version, written 24 Jan 09, was published in Conformity's 2009 Annual Guide

(Title) Cover Story

(Subtitle) Complying with the EMC Directive (2004/108/EC), Second Edition

(Author) Eur Ing Keith Armstrong, Cherry Clough Consultants

On July 20, 2007, the European Union's (EU's) original EMC Directive (89/336/EC) was replaced by its 2nd Edition: 2004/108/EC [1], and has an official Guide [2]. All of the 27 EU Member States now have national legislation implementing 2004/108/EC. (In the U.K., it is 'the EMC Regulations 2006, SI 2006 No.3418' [3] which also has an official guide [4].)

2004/108/EC does not cover safety issues due to EM interference, and neither does it cover human health issues caused by exposure to EM fields.

Overview of the Changes in the 2nd Edition

Here is a summary list of the changes that have been made to 2nd Edition of the EMC Directive:

- Some changes to the Protection Requirements;
- Small changes to the EC Declaration of Conformity;
- CE marking applied to products and their accompanying documents;
- New requirements for manufacturers to create EMC Technical Documentation, and to ensure products are manufactured in accordance with it;
- New requirements to provide specified EMC information with products;
- The Technical Construction File (TCF) route under the original EMC Directive (89/336/EEC) can now effectively be used without the need for a Competent Body assessment;
- Competent Bodies have been made obsolete, and replaced by 'Notified Bodies' who have no mandatory involvement;
- There are new requirements for the compliance of 'fixed installations,' and for custom equipment.

Applying 2004/108/EC

2004/108/EC applies to individual items of equipment when they are 'placed on the market' or 'put into service' in the EU for the first time. Its definition of equipment includes both 'apparatus' and 'fixed installations,' with special legal meanings for these terms. As Figure 1 shows, the new EMC Directive treats fixed installations differently from apparatus, and also has a special regime for 'apparatus intended for incorporation into a given fixed installation, and not otherwise commercially available' – what might be called custom-designed or bespoke equipment.

'Placed on the market' in the EU means [5]: the first time an item is offered for supply to end-users in the EU, and includes: selling, leasing and gifting. It is essentially the point where the end-user becomes the owner, however that occurs. It also means offering to sell, lease, gift, etc. (for example, by advertising, exhibiting, or making available via distributors, etc.) Non-compliant products may be advertised or exhibited if they are clearly marked as being non-compliant and not available to end-users.

'Put into service' in the EU means: the first time an item is used for the purpose for which it was intended, and is mostly relevant for equipment that is assembled on the user's site.

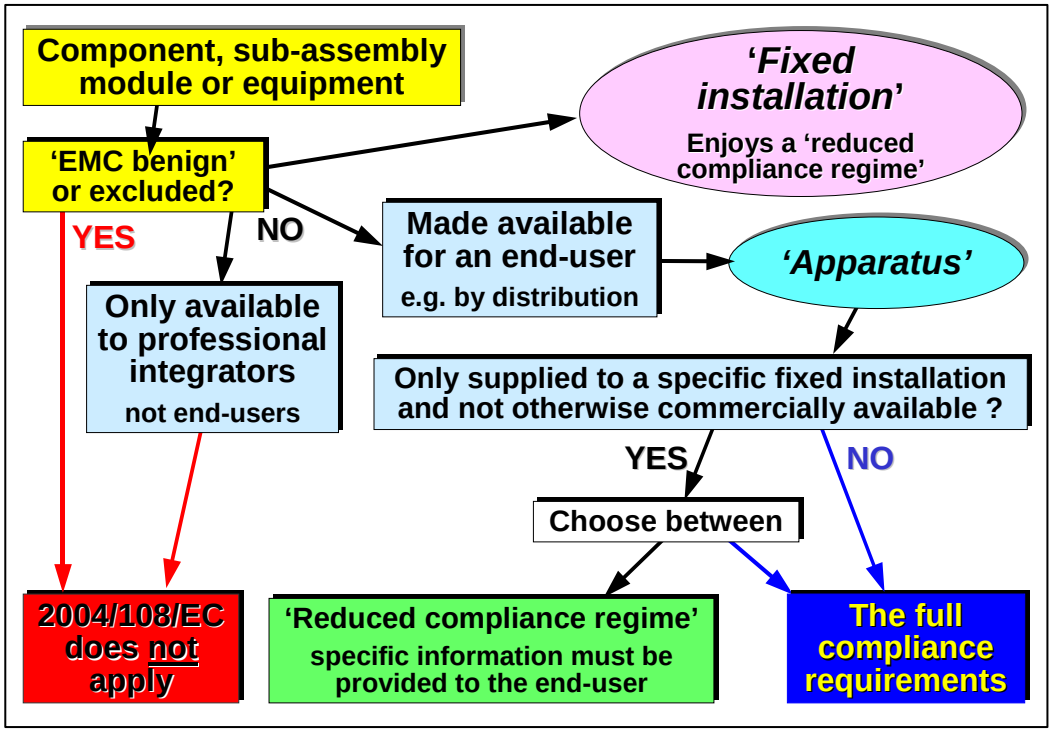

Figure 1: Applying the 2nd Edition EMC Directive

'Inherently EMC benign' equipment is excluded from the scope of 2004/108/EC, whether it is an apparatus or fixed installation. The EC Guide to 2004/108/EC [2] contains a list of what is currently considered to be inherently benign, but EMC benign equipment almost never contains any operational semiconductors (rectifiers, transistors, ICs, etc.) or thermionic valves.

Radio amateur equipment that is not commercially available; equipment covered by the R&TTE Directive (1999/5/EC), and aeronautical equipment covered by Regulation 1592/2002 are also exempt from the EMC Directive. Equipment that has EMC aspects addressed in product Directives (e.g. medical devices, automotive, etc.) is only exempt from 2004/108/EC to the extent covered by those other Directives, although this is widely misunderstood to mean they are totally exempt.

Date of Application

Models of apparatus that are first supplied to the EU market on/after July 20, 2007 must comply with 2004/108/EC.

Models that were supplied before July 20, 2007 and which comply with the original EMC Directive can continue to be supplied until July 19, 2009, after when they must comply with 2004/108/EC. If their EC EMC Declaration of Conformity is changed for any reason during this period (e.g., an update to the version number of a listed standard, a company name change, etc.), then they must comply with 2004/108/EC from that time.

All fixed installations must comply with 2004/108/EC from July 20, 2007, but [4] says it only applies to older fixed installations when they are modified on/after July 20, 2007, and then only applies to those areas whose EMC characteristics are affected by the modifications. But note that [4] is guidance, and does not change the wording of the Directive, or the UK's Regulations.

Conformity of Apparatus
As Figure 1 shows, an apparatus is anything supplied to an end-user in the EU, and the only exclusions are for apparatus that are EMC benign (see above) or 'apparatus intended for incorporation into a given fixed installation, and not otherwise commercially available' (see **Custom-Engineered One-Off Apparatus**, below).

Note that products supplied to professional integrators do not have to comply with the EMC Directive, although they might be CE marked for compliance with an EU safety directive.

2004/108/EC requires apparatus to:

a. Comply with the 'Protection Requirements;'
b. Undergo a 'conformity assessment' procedure;
c. Have technical documentation available for inspection;
d. Be supplied with specified User Information;
e. Have a signed EC Declaration of Conformity.

The above must be complete before CE marking and supply of the apparatus in the EU.

Constructing systems only from items that are CE-marked, and assuming that this takes care of the EMC compliance of the overall system or installation, is often called 'the CE + CE = CE approach.' It was very widely used under the original EMC Directive, despite havingno legal or technical justification. It is easy to show that this approach should not be relied upon, and now the EC Guide to 2004/108/EC warns against using it.

The Protection Requirements
The Protection Requirements (Clause 1 of Annex I) state the essential legal requirements for conformity of products to 2004/108/EC, in simple terms that lawyers should find it difficult to argue over:

> "Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:
>
> > (a) The electromagnetic disturbance generated does not exceed the level above which radio and telecommunication equipment or other equipment cannot operate as intended;
> >
> > (b) It has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use."

These are essentially the same as in the original EMC Directive – except for the new "having regard to the state of the art" requirement. This could have significant implications; for example, product models that complied in 2009 might not comply if supplied in 2011 because their users' EM environment(s) had changed.

Conformity Assessment

The EMC Assessment Process

Conformity assessment is specified in Annex II of 2004/108/EC, and requires an 'EMC assessment' that results in 'technical documentation' that demonstrates that the product complies with the Protection Requirements, for all of the operational modes of the product, in all of its intended configurations.

An EMC Assessment should firstly assess the EM environment(s) normally expected at the user(s) location(s) [6], taking into account:

- The likely proximity to sensitive equipment that the product's emissions could interfere with;
- The likely EM threats that could interfere with the product, plus the degradation of functional performance that the user will accept when the product is interfered with.

Secondly, it should create EMC specifications for the product and design it accordingly despite component tolerances and variations in assembly and installation. Thirdly, it will verify its EMC design against the EMC specifications. 'Verification' techniques include, but are not limited to, EMC testing.

For products with many configurations and/or operational modes, the amount of verification work required can be reduced by identifying the 'worst case' combinations of configuration and operational mode – the ones that would cause the highest emissions or are the most susceptible to interference.

The 'Standards' Route to Conformity

Like the original EMC Directive, 2004/108/EC has two 'routes to conformity.' One is for the product to pass all of the relevant harmonised EMC test standards [7], and is identical to the 'self-declaration to standards' route under the original EMC Directive.

The Directive states:

> "The correct application of all the relevant harmonised standards whose references have been published in *The Official Journal of the European Union* shall be equivalent to the carrying out of the EMC assessment."

In other words, if you test to all the relevant standards, you do not need to follow the good EMC engineering process outlined above. But I do not recommend this, because the standards only cover a subset of the EM phenomena and ranges of frequencies, modulations and waveshapes that occur in the real world. For example: none of the immunity standards cover the close proximity of cellphones; and they all test over a limited frequency range.

Simply complying with the standards might not ensure compliance with the Protection Requirements (see ***The Protection Requirements***, above) in real-life operation. Article 6 of 2004/108/EC includes paragraphs that deal specifically with this possibility, although they would provide little comfort to a manufacturer who has had his products banned from the EU because of real-life interference issues. So when following the 'standards' route I recommend performing a full EMC assessment, applying all relevant harmonised standards, and then doing *whatever else it takes* to verify conformity to the Protection Requirements. This can be as quick and easy as a check with a close-field probe.

The ‘correct application’ of a standard means that the manufacturer has done enough work to have sufficient confidence that if the product were fully tested to that standard – it would pass. It does not mean that it must be tested in an independent test lab. Manufacturers are free to decide on the amount and quality of EMC testing they do, and can do it themselves if they want (many do).

The Alternative Route to Conformity

Manufacturers are under no obligation to apply any of the harmonised EMC test standards, or they might prefer to apply them but feel that some parts of them are:

- Too onerous (too costly or time-consuming);
- Not suitable for the actual EM environment(s) (often the case for vehicle mobile applications land/sea/air/space);
- Unsuitable for the product (often the case with large machines, systems constructed on the user’s premises, etc., that cannot be fitted into the standard test chambers).

So there is an alternative conformity route, essentially the ‘Technical Construction File’ (TCF) route from the original EMC Directive - but without the need for assessment by a Competent Body. For products that are too large for a test method in a harmonised standard, in-situ (on-site) EMC testing is commonly used to provide evidence of compliance. Other methods of demonstrating conformity, that can be used singly or in combination and/or with the application of parts of harmonised standards, include:

- Non-EU-harmonised EMC test methods (e.g., FCC, military, automotive, etc.);
- EMC tests developed by the manufacturer;
- Calculations;
- Computer simulations;
- Comparisons with compliant products using the same technologies and devices (but beware – technology and devices change very rapidly).

Employing Notified Bodies

2004/108/EC has replaced the ‘Competent Body’ scheme that was set up under the original EMC Directive, with a ‘Notified Body’ scheme. Notified Bodies exist only to provide advice and assistance to whatever extent a manufacturer requires. They have no mandatory involvement at all with any aspect of EMC compliance, but following their advice is a good legal defence.

Annex III of 2004/108/EC describes a procedure in which part (or all) of a Technical Documentation File (see ***The Technical Documentation File***, below) is assessed by a Notified Body, whose report is then included with that Technical Documentation. This is essentially the same as the original TCF route, but which aspects the Notified Body reports on are entirely up to the manufacturer.

Some manufacturers who are competent in EMC will be pleased with this change, because they no longer have to pay for someone else to check their work. But many manufacturers will employ Notified Bodies where they once used Competent Bodies, either because they do not feel that they have sufficient expertise, or because they want the confidence of a second opinion.

Testing Issues

The less money spent on accurate testing, the more EMC expertise is required in design and assembly to achieve a given level of confidence in EMC compliance.

EMC testing can be inaccurate, and the greatest confidence is achieved using labs that have been 'accredited' by their national accreditation bodies for each of the EMC test standards required. Some test labs also put themselves through additional assessments by international experts who set the benchmarks in world-class EMC testing.

The Technical Documentation File

2004/108/EC mandates the creation of 'technical documentation,' generally referred to as a Technical Documentation File, helping to bring the new EMC Directive into line with other EU directives.

The manufacturer, or his authorised representative in the EU, must keep this technical documentation "…at the disposal of the competent authorities for at least ten years after the date on which such apparatus was last manufactured…". This can present logistical or security difficulties, which should be able to be overcome by appropriate use of electronic file storage and the Internet.

According to Annex IV, the technical documentation must include:

a. A general description of the apparatus (should cover the range of configurations);
b. A description of the procedures used to ensure compliance with the Protection Requirements;
c. Any reports from Notified Bodies (see *Employing Notified Bodies*, above).

Documenting the procedures used to ensure EMC compliance means describing the EMC Assessment that was carried out (see *The EMC Assessment Process*, above) and will consist mainly of documents created during that work. If conformity relied on testing to all of the relevant harmonised EMC standards, this could simply be their test reports. But, when following the alternative route, more detailed documentation is required, for example:

- Technical arguments (e.g., calculations, simulations, results of tests carried out on sub-assemblies, etc.);
- Results of any EMC testing in design, manufacture, installation or operation (including non-standard methods);
- Any reasonable limitations to use agreed with the customer and/or described in the user manuals (e.g., keeping cellphones and walkie-talkies well away).

If using technical arguments based on EMC testing, include the following details (where appropriate):

- The test set-up (including similarities and deviations from harmonised standard tests);
- The instrumentation used, and its calibration state;
- The rationale for choice of parameters and limits;
- The calculated measurement uncertainties.

The Information to be Provided with Each Apparatus

Article 9 of 2004/108/EC requires the provision of specified EMC information with each apparatus. Each apparatus must be identified (e.g., by type, batch, serial number, etc.) and accompanied by its manufacturer's name and address. If an agent or importer in the EU is involved, their contact details must also be included.

The User Instructions to be provided must include any specific precautions required to ensure compliance with the Protection Requirements (e.g., EMC instructions for assembly, location, installation, commissioning, operation, maintenance, upgrade, repair, etc.), and must also describe how to operate the apparatus to achieve its intended purpose(s).

If an apparatus is not designed to meet residential/domestic emissions standards – but might be used in such environments – it must be accompanied by a clear warning that use in residential areas might cause interference. This warning may also need to be placed on the product's packaging.

The EC Declaration of Conformity

Annex IV of 2004/108/EC requires the Declaration of Conformity to:

a. Identify the manufacturer and give his address ('re-badgers' are manufacturers); also identify the authorised representative in the EU (if any) and give his address too;
b. Make reference to 2004/108/EC;
c. Identify the product(s) covered by the declaration;
d. Include two legal statements:
    - Legal statement 1 concerns conformity to the Protection Requirements, for example: "I declare under my sole authority that the relevant equipment complies with the Protection Requirements of the EMC Directive 2004/108/EC."
    - Legal statement 2 requires a list of dated references to any EMC standards (whether listed under 2004/108/EC or not) that were applied in full or in part (and which parts) during the conformity assessment (see *Conformity Assessment*, above).
e. Clearly identify, and be signed by, the Technical Vice-President (or anyone else in authority who is 'legally empowered to bind the company');
f. Give the date of its creation.

I also recommend adding a statement concerning the availability of the Technical Documentation File and the User Instructions, and their reference numbers, to help ensure that managers leave sufficient time in the project plan for this essential legal compliance documentation to be created.

The Directive states:

> "The manufacturer or his authorised representative in the Community shall hold the EC declaration of conformity at the disposal of the competent authorities for a period of at least ten years after the date on which such apparatus was last manufactured."
>
> It is important to understand that it is the *sole responsibility* of the manufacturer to assess his apparatus and declare its conformity. No Notified Body or EMC test laboratory can do this.

Affixing the CE Marking

The CE marking (Article 8 and Annex V) must be affixed to the apparatus or its data plate. Where this is impractical (e.g., the product is too small), it should be affixed to the packaging (if any). The CE mark must also be applied to any accompanying documents, which is a change from the original EMC Directive.

The drawing of the CE marking in the original EMC Directive was modified by Directive 93/68/EEC, and 2004/108/EC uses the later version, which is shown in Figure 2 with some additional details added to make it easier to follow.

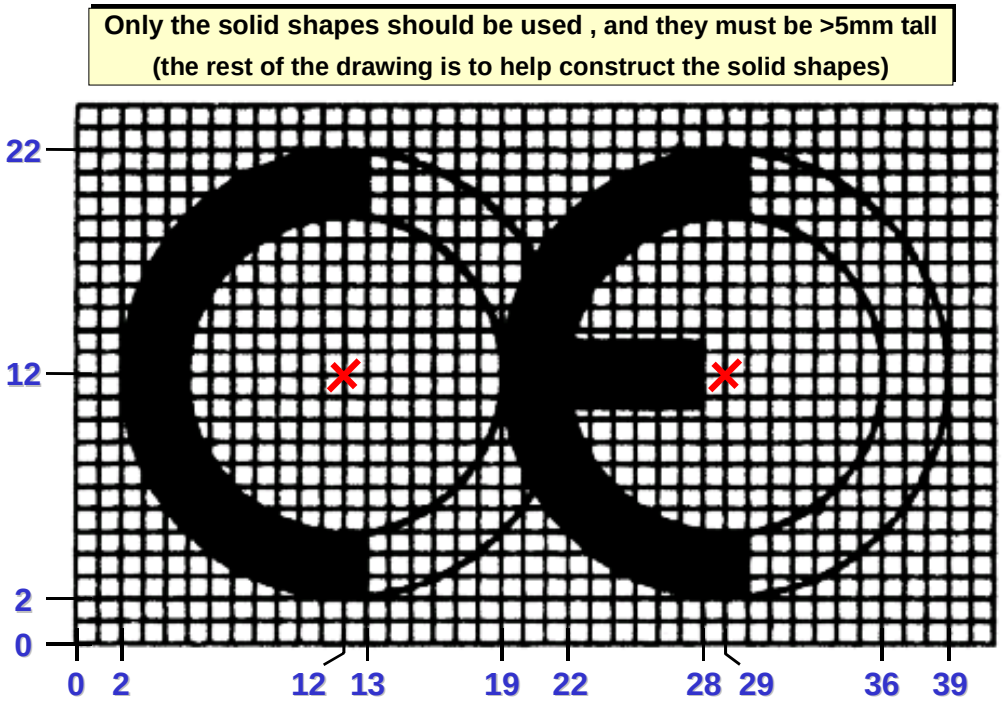

Figure 2: The rules for drawing the CE Mark

Maintaining Compliance in Serial Manufacture

Each individual item of apparatus manufactured must conform to its Technical Documentation File and comply with 2004/108/EC on the day it is supplied for distribution or to an end-user. So products in serial manufacture require appropriate quality control (QC) procedures that control, for example:

- Changes in the EMC standards listed on their EC Declarations of Conformity;
- Changes in their intended EM environment(s);
- Replacement of obsolete components, component tolerances, IC die-shrinks, variations in processes and assembly/installation methods, etc.;
- Design changes (to hardware, software, firmware).

Appropriate QC procedures include the assessment of all proposed concessions, modifications or changes for any possible EMC effects, and sample based EMC checks and/or tests in serial manufacture. I recommend that the Technical Documentation File references the relevant QC documents, and that the results of the QC activities be added on a continuing basis.

Apparatus Constructed for 'Own Use'

According to the EC Guide, if a manufacturer makes an item of equipment for use in their own business, then it is classified as 'apparatus' and all of the requirements of 2004/108 apply – depending on whether the manufacturer chooses to classify it as 'equipment intended for a fixed installation and not otherwise commercially available,' or not.

People create all sorts of fixed installations for themselves, for example, domestic multi-media installations. But if they are not doing it professionally, and if they only use apparatus that is compliant with the EMC Directive and intended by their manufacturers for the use they put it to, and follow the manufacturers' EMC instructions, then no further EMC conformity assessment is required.

Conformity of 'Fixed Installations'

A 'fixed installation' is defined as "a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location." This definition covers all installations from the smallest residential electrical installation up to national electrical and telephone networks, including all commercial and industrial installations.

The EC Guide gives a list of examples of fixed installations, which can be an entire site (e.g., an industrial plant), or any fixed installation within a site (for example, lighting installation, HVAC installation, electrical power distribution network, computer network, etc.).

The official UK Government view (expressed in November 2007, in response to a question from the author) is that a fixed installation can never be 'placed on the market.' Anything that is sold or otherwise supplied is either an 'apparatus' or an 'apparatus intended for incorporation into a given fixed installation, and not otherwise commercially available.'

Mobile installations are defined as: "…a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations" and the EC Guide gives the example of an outside broadcast truck. Mobile installations are treated as apparatus, because like products that are placed on the market, they can be used anywhere in the EU.

Where a 'system,' 'large machine' or 'moveable installations' meets the definition of a fixed installation, then it is treated as such. In all other cases, they are treated either as apparatus, or as 'apparatus intended for incorporation into a specified fixed installation and not otherwise commercially available.'

As Figure 1 shows, a fixed installation enjoys a 'reduced compliance regime', which means it is <u>not</u> required to have:

- An EMC assessment;
- A conformity assessment;
- An EC Declaration of Conformity;
- The CE marking affixed.

However, <u>all</u> fixed installations must comply with both parts of the Essential Requirements in Annex I, specifically:

a. The Protection Requirements (same as for apparatus);
b. The Specific Requirements for Fixed Installations.

The specific requirements for fixed installations include:

1. The appointment of a named 'Responsible Person', responsible for the following;
2. The application of good EMC engineering practices 'having regard to the state of the art.' This does *not* mean using state-of-the-art EMC engineering, but good EMC engineering practices appropriate for the fixed installation in question, applied by someone who understands the state of the art.
3. Following the EMC instructions provided with supplied equipment;
4. Documenting the good EMC engineering practices that have been employed. No details are

given on how to create this, but it must be kept ready for inspection for as long as the fixed installation is in operation.

Despite having had at least two years to prepare for 2004/108/EC, with a few notable exceptions very few owners or operators of fixed installations in the EU, or their mechanical and electrical contractors, have any clue about modern good EMC engineering practices. For example, most of them think that single-point grounding is essential, and that any cable shields must only be connected at one end. Very few sites appear to have appointed any Responsible Persons.

Constructing installations only from items that are CE-marked and assuming that this takes care of their EMC compliance is often called 'the CE + CE = CE approach.' As noted above, this approach was very widely used under the original EMC Directive, but the EC Guide [2] now warns against it.

Custom-Engineered Apparatus
2004/108/EC calls this category of apparatus 'Apparatus intended for incorporation into a given fixed installation, and not otherwise commercially available.' It applies to products designed and/or assembled specifically for an individual (named) fixed installation. Such products need not:

- Be CE marked to the EMC Directive (although they might need CE marking under a safety directive);
- Have an EC EMC Declaration of Conformity;
- Comply with the Protection Requirements;
- Follow any conformity assessment route.

But, if the above relaxations are to be enjoyed, the products must be supplied to their end-users with:

a. The physical location (e.g., street address) of the fixed installation the product is intended for;
b. A description of the fixed installation's EM environment;
c. Information showing that the manufacturer has taken item b into account;
d. Instructions on how to assemble/install the product so as not to cause the fixed installation to fail to comply with the Essential Requirements.

2004/108/EC does not provide any further details on the above requirements, but the EC Guide [2] and the UK Guide [4] include some useful information on the level of detail required.

Keith Armstrong *is a principal with Cherry Clough Consultants (www.cherryclough.com) and a frequent contributor to* Conformity. *He can be reached at keith.armstrong@cherryclough.com.*

References
[1] 2004/108/EC in English:
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_390/l_39020041231en00240037.pdf,
or in any EC language:
http://ec.europa.eu/enterprise/electr_equipment/emc/directiv/dir2004_108.htm
[2] The EC's official guide on 2004/108/EC:

http://ec.europa.eu/enterprise/electr_equipment/emc/guides/emcguide_may2007.pdf[3] The UK's EMC Regulations 2006, SI 2006 No.3418:
http://www.opsi.gov.uk/si/si2006/uksi_20063418_en.pdf
[4] The UK's official guide to the 2006 EMC Regulations:
http://www.berr.gov.uk/sectors/sustainability/regulations/ecdirect/page12469.html
http://www.berr.gov.uk/files/file47539.pdf[5] The EU's 'Blue Guide', "Guide to the Implementation of Directives Based on the New Approach and the Global Approach", 2000:
http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm,
also (in English only) from:
http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf
[6] A great deal of useful EMC information is available from the 'Publications & Downloads' page at www.cherryclough.com, including: 'How to Assess an EM Environment' and 'An In-Situ EMC Testing Procedure'
[7] The EMC Directive's official homepage and list of harmonised test standards is:
http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/emc.html