European EMC Regulations and the CE Mark

Applying the correct standards, and paying careful attention to the end environment, location and intended function of a product are necessary in order to earn the CE Mark.

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INTRODUCTION

The EMC Directive paves the way to ensuring the reliability of the sensitive electronics which now perform more powerful and critical functions in all areas of modern life. The Directive and the accompanying harmonized standards enable the free movement of goods and reduce trade barriers within the European Union.

While the importance of EMC can be justified simply in terms of technical efficiency, legal aspects also have become increasingly important. The CE Mark indicates compliance with regulatory standards and is a legal license for use by authorities inspecting those goods. It basically fulfills the function of a passport. Applying the correct standards, and paying careful attention to the end environment, location and intended function of a product are necessary in order to earn the CE Mark.

EMC DESIGN

Experience proves that addressing EMC early in the course of a project is important in order to be cost effective. Costly retrofits in the system can be avoided if the printed circuit boards are designed with due consideration to EMC. In this way, the expense of a shielded enclosure might be saved. Another fundamental consideration for any successful EMI control is the concept of prudent topology, or the zoning of EMI barriers. Any lines penetrating the shielded zones must be protected against conducted EMI by filters or surge protection devices. Additionally, the apertures of the shield should be treated with gaskets and covers. The zoning concept applies to both emission and immunity. A unit constructed accordingly will function better with many shields than with a one-layer perfect shield because of the higher safety margin in case of failure (Figure 1).

STEPS LEADING TO CE-MARKING

There are a number of frequently-used EU Directives, including the Machinery Directive 89/392/EEC, effective January 1, 1995; the EMC Directive 89/336/EEC effective January 1, 1996; and the Medical Directive 93/42/EEC, effective January 1, 1995. The Low Voltage Directive will come into force January 1, 1997, following the new approach procedure. According to officials in Brussels, the Automobile Directive is expected to be in force during the course of 1995. This article will discuss EMC regulations, known in Germany as the EMVG (November 13, 1992). Section 4 of the EMVG defines the protective requirements and hints at harmonized and nonharmonized standards (Section 5.2).

Table 1 lists harmonized standards published in the Official Journal of the EU and the Official Journal of the BMPT (German PTT Ministry). The references may be

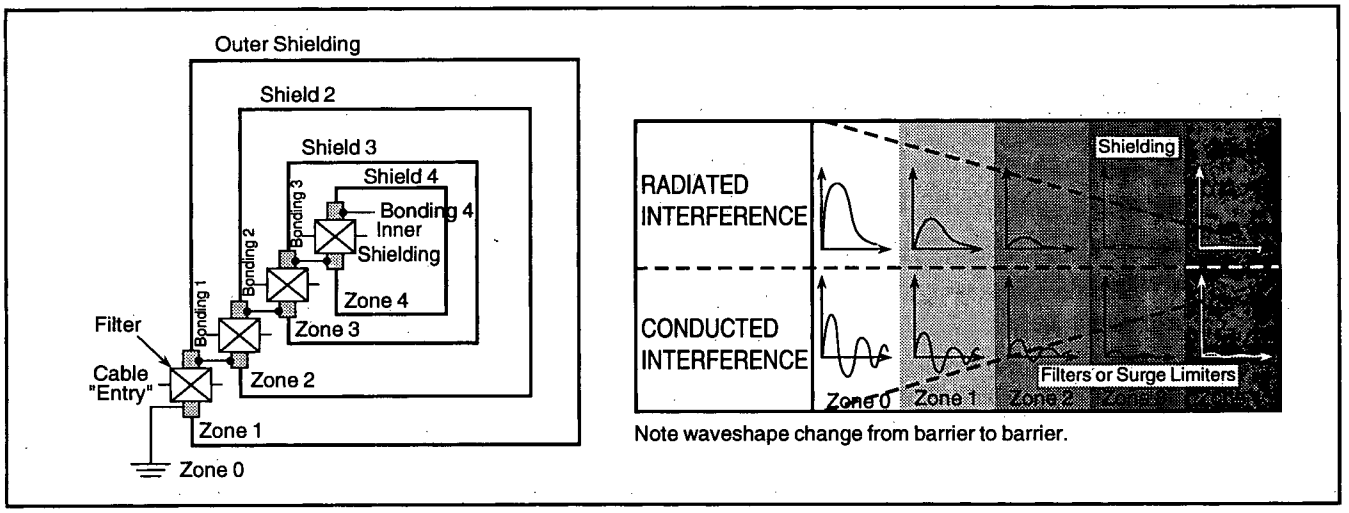

Figure 1. *The Zoning Concept.*

Families of Products under 89/336/EEC (Year of Ratification)	Emission			Immunity
	Harmonics	Voltage Fluctuations	Radio Interference	All Aspects
Household appliances and portable tools (motor-driven, such as vacuum cleaners, washing machines; heating and cooking appliances; dimmers, etc.)	EN 60 555-2 4/87	EN 60 555-3 4/87	EN 55 014 4/93	EN 50 082-1 res. 1/92
Lighting fixtures with fluorescent bulbs	EN 60 555-2 4/87		EN 55 015 2/93	EN 50 082-1 res. 1/92
TV receivers and audio equipment	EN 60 555-2 4/87		EN 55 013 6/90	EN 55 020 6/88
Information technology equipment	EN 60 555-2[1] 4/87		EN 55 022 4/87	EN 50 082[2] res. 1/92
Mains signalling equipment	EN 50 081-1 res. 1/92	EN 50 081-1 res. 1/92	EN 50 065-1 91+Amdt. 1992	EN 50 082-1[3] res. 1/92
ISM equipment	EN 50 081-2 indus. 7/93	EN 50 081-2 indus. 7/93	EN 55 011 3/91	EN 50 082-2[4] not yet harmonized indus. 1995
Industrial equipment in general			EN 50-081-2 indus. 7/93	EN 50 082-2 not yet harmonized indus. 1995
Low voltage fuses Part 1			EN 60 269-1 +Amdt. 1 1989/1993	EN 60 269-1 +Amdt. 1 1989/1993
High voltage current-limiting fuses			EN 60 282-1 1993 A1 + A2	EN 60 282-1 1993 A1 + A2
Static watt-hour meters (Cl. 1 and 2)			EN 61 036 11/92	EN 61 036 11/92
Static watt-hour meters (Cl. 0.2 and 0.5).			EN 60687 11/92	EN 60 687 11/92
Electronic ripple control receivers			EN 61 037 11/92	EN 61 037 11/92
Time switches for tariff and load control			EN 61 038 11/92	EN 61 038 11/92
Marine navigational equipment			EN 60 945 + A1 7/93 + 8/93	EN 60 945 + A1 7/83 + 8/93

1) With the new EN 61 000-3-2 in the future application to ITE.
2) EN 50 082-1 must be used till EN 55 024 is issued and harmonized.
3) A product-specific immunity standard is in preparation.
4) Generic standard immunity heavy industry not harmonized (OJ publication of the EN expected autumn '95) → CB.

***Table 1** . Harmonized EMC Standards (designated EN – European Norm; Status as of August 1995).*

found in the Official Journal of the European Union No. C44/12 (Feb. 19, 1992); the Official Journal of the European Union No. C 90/2 (April 10, 1995); the Official Journal of the European Union No. C 49/3 (Feb. 17, 1994) for ENs; the Official Journal of the BMPT/ABI, Vfg. 43/1994 (DIN VDE); and the Official Journal of the BMPT/ABI, Vfg. 99/1995 (DIN VDE).

It is advisable to always refer to the original text of the CENELEC norms in English because they normally

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represent the first draft and edition of the standard and are the basis for translation into the official languages of the EU. CENELEC is mandated to refer only to IEC and CISPR standards as long as there is no absolute need to deviate from this procedure.

Section 5 of the EMVG defines the conformity declaration and the CE-marking by the manufacturer / representative within the EU or by the importer. There are three different ways of attaining the CE Mark:

- Manufacturer's self-certification, using only harmonized standards
- Certification through a competent body and accredited test laboratory
- EC type approval, needed in Germany by the BZT for radio transmitters. Any other European notified body is also acceptable.

The third case is executed slightly differently in the EU according to different national frequency allocation. ETSI, CENELEC and CEPT are trying to further harmonize this procedure within the framework of ITU agreements.

THE COMPETENT BODY

Competent body status is basically assigned to an EMC competent person with outstanding capabilities and experience in all areas of EMC. An essential element is the profound and proven capability of the competent body to correctly perform system assessment and analysis. Normally this type of expert has 10 to 20 years of military and commercial EMC/NEMP system experience and is well-versed in computer simulation, which is sometimes the only way to assess complex systems and subdivide them into interfaces which can be tested in the EMC lab.

Section 2.8 of the EMVG defines a competent body: "The competent body issues technical construction files and conformity declarations according to Section 5.2, EMVG after positively confirming the protective requirements of the Directive." According to Annex II of the Directive (Annex I, EMVG), the minimal requirements for accreditation of a competent body are the following:

1. Availability of personnel and of the necessary means and equipment;
2. Technical competence and professional integrity of personnel;
3. Independence in carrying out the tests, preparing the reports, issuing the certificates and performing the verification function provided for in this Directive, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with the product in question;
4. Maintenance of professional secrecy by personnel;
5. Possession of civil liability insurance unless such liability is covered by the State under national law (not covered in Germany).

The Directive also states that "fulfilment of the conditions under points 1 and 2 shall be verified at intervals by the competent authorities of the member states."

In addition to the points mentioned above, the stringent requirements of EN 45011/CENELEC/Sept.89 — General Criteria for Certification Bodies Operating Product

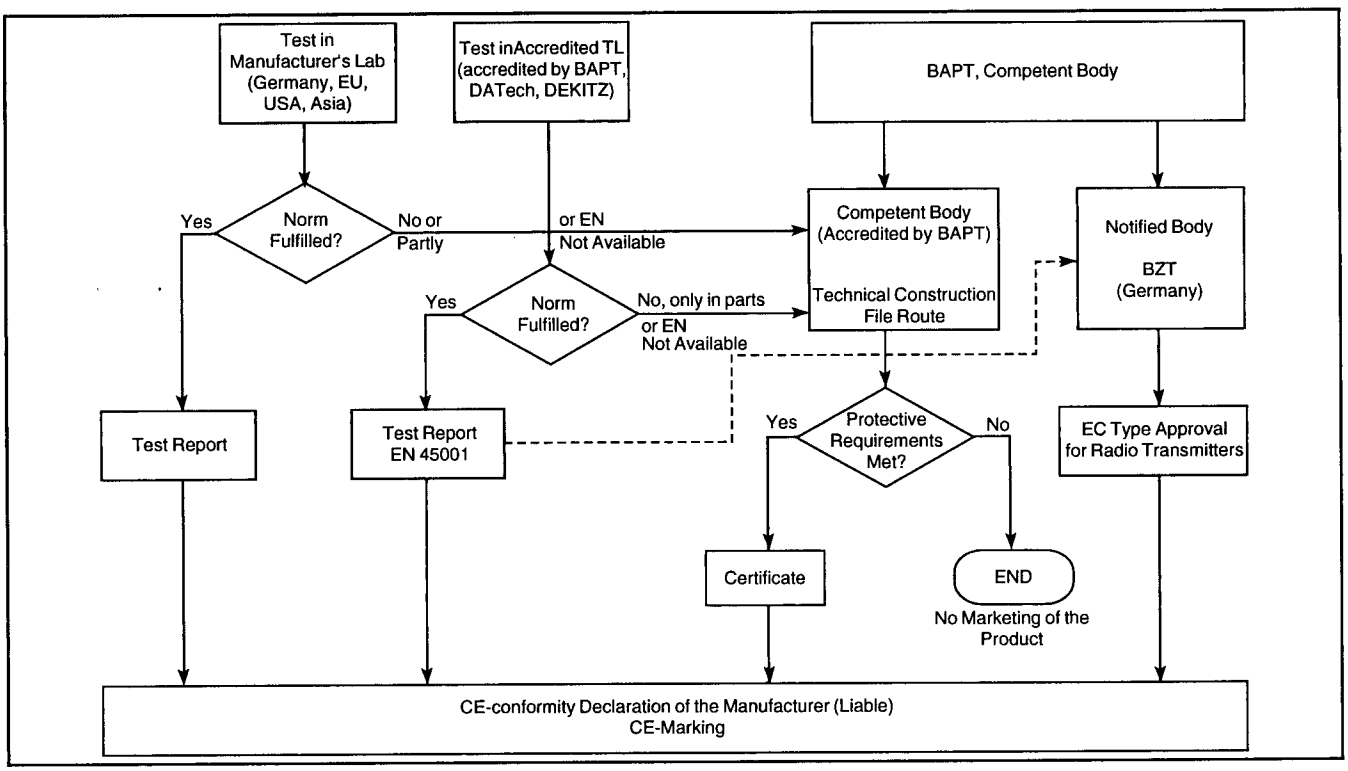

Figure 2. *Procedures for CE-marking and Subsequent EU Market Access (in Germany).*

Certification — apply to competent bodies. These requirements cover governing boards, organizational structures, certification personnel, quality manuals, confidentiality, appeals, internal audits and periodic reviews. As can easily be seen, these requirements are not simple to meet. This explains the relatively small number (18) of competent bodies in Germany. Europe has a total of about 70 competent bodies. Competent bodies can only operate in the EC; offices outside the EC are illegal.

In summary it can be stated that the competent body can or must take action in the following cases:

- in spite of the existence of harmonized standards (manufacturer's choice)
- where there is a lack of harmonized standards
- if standards are impractical
- where product variants exist
- where foreign certificates exist

The first case is sometimes chosen due to legal reasons.

ACCREDITED TEST LABORATORIES

EN 45001/May, 1990, "General Criteria for Operation of Testing Laboratories," is the basis for the accreditation and control of: purpose, definitions, legal identity, impartiality, independence and integrity, technical competence, administration, personnel, premises and equipment, working procedures, test methods and procedures, instructions, quality management systems, test reports, subcontracting, confidentiality and security, cooperation with clients, bodies granting accreditation, and other laboratories including bodies producing standards and regulations. The list also includes responsibilities resulting from the use of accreditation, criteria prescribed, claims, fees, and misleading use of accreditation.

The normative definition of testing is: "a technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure." This means that to operate an accredited test laboratory, one must have a fairly high level of knowledge in standards, measurement technology and the application of quality management procedures. *Testing by an accredited laboratory becomes mandatory if the competent body requires proof of conformity to standards.* This is stated in EN 45011, Point 11.1. In exceptional cases, however, the competent body can deviate from this path if it is convinced that EN 45001 is positively fulfilled. (This is known as private subaccreditation).

Point 6.3 requires the absolute ability to prove traceability for the test results back to national and international standards. This includes an obligation to participate in round robin tests. These ensure and improve the accuracy of the test results. Because the competent body relies on the test results from EN 450001 accredited test laboratories, there is a strong legal aspect to testing. These high-quality services are not inexpensive. Furthermore, ongoing training of the personnel and regular calibrations can prohibit the laboratory from operating at 100-percent efficiency. Most difficulties confronted by accredited test laboratories in Germany involve interpretation of standards and measurement accuracy for EM fields.

The accreditation regulations of test laboratories specify scope and sometimes limits. Before laboratories are commissioned, they should be researched to ensure that they can adequately perform the work. Advertising has to be fair and correct. Accreditation is only granted to a particular laboratory and never to the entire company. Not following these rules will automatically revoke the accreditation.

Setting up a test laboratory calls for a minimum of one-man year for the accreditation alone. After the first accreditation there is usually an annual re-evaluation which increases costs. In addition to the formal aspects, considerable effort is needed to maintain the calibration status. The manager of the test laboratory and his crew are responsible for the correct testing. The capability and the potential to perform tests are assessed, as well as the equipment.

After the testing is completed, one critical and time-consuming task specified by EN 45001 is the test report. The test report calls for a precise product description, operational mode and the failure criteria of the EUT. Any consulting or advice to the customer in this report is strictly forbidden. In many cases, it is necessary to have the development engineer assist in the EMC test. Additionally, the definition of the proper use of the equipment as intended by the manufacturer in its foreseen EMC environment has to be considered. Product documentation must be completed correctly, sometimes requiring system aspects to be taken into account. One mistake sometimes made by test laboratories is issuing "certificates." This responsibility is reserved to the competent body. If the test laboratory uses prEN standards, there is the absolute need to get the competent body involved for the final certificate, based on a technical construction file (TCF).

INTERACTION BETWEEN THE TEST LAB AND THE COMPETENT BODY

From the previous discussion, it should be clear that knowledge of the current status of each standard is of utmost importance. It is therefore mandatory for the test laboratory and competent body to keep abreast of the national and international standardization efforts, including maintaining personal contact with the standard committee chairmen. Participation in the national group of German competent bodies and attendance at their regular meetings is obligatory. The recently formed association of European competent bodies in Brussels should further aid in gathering information. The Internet presently does not offer any real help. For the non-expert, particularly from outside Europe, this sometimes results in total confusion. The search for reliable information can be

likened to detective work. However, CEN/CENELEC follows clear mandates and rules to arrive at a harmonized standard. There are three well-defined procedures:

- doa — latest date of announcement of a new standard on national level
- dop — latest date of publication of an identical/harmonized norm
- dow — latest date of withdrawal of opposing standards

A word of caution should be given here with respect to the German Vfg. decrees. Most of them are intended to bridge the transitional period, ending December 31, 1995.

In principle, a manufacturer could freely declare conformity with the EMC directive (EMVG) or any other nationally harmonized EMC law under this umbrella without actually measuring field levels. However, this is close to committing economic suicide, because no court would accept this procedure in breach of contract cases or liability lawsuits.

In the real world, nobody gets around the competent body for nonharmonized standards. The preferred European conformity procedure is to apply a manufacturer's self-declaration using harmonized standards. The problem is that presently there is a lack of existing standards for many product areas.

Case Study 1: Machinery Directive (MD)

A large paper-sorting machine, 30 m long and including several drives, was to be certified according to EN 60204-1. This system falls under the MD 89/392/EEC, transposed into German Law 9, Deutsche GSGV, dated May 12, 1993. The commissioning of the machine was intended to take place in various EU member states. End-use environments would be offices, light industry or government premises. It was the intention of the manufacturer to positively declare, fulfilling all legal, protective requirements.

According to the manufacturer's specifications, EMC is defined according to:

- Emissions - EN 55011, EN 55022 and EN 55014
- Immunity - IEC 801-2 (1984) ESD, IEC 801-3 (1984) Fields, IEC 801-4 (1988) Burst
- Commissioning on public premises

The problems encountered included expected measurement problems with EM fields, the manufacturer's references to obsolete standards, missing standards, manufacturer inexperience with EMC, and problems in evaluating subsystems according to EMC.

The correct procedure and conformity assessment is as follows:

- The manufacturer contracts with a competent body in a member state. A hardware evaluation of the machine is conducted according to technical documentation regarding EMC aspects: zoning concept, filtering, cable routing, shielding of boxes and systems. The client and/or the competent body prepares a test plan and subcontracts with an accredited test laboratory to perform EMC tests on a subsystem level. The competent body is required to consider further EMI phenomena to fulfill the protective requirements:
- ESD according to latest norm: IEC 801-2 (1991/0.7 ns rise time)
- IEC 1000-4-2 1/95
- EM fields according to ENV 50140 (AM and PM)
- IEC 1000-4-3 2/95
- Surge protection requirements according to ENV 50142 due to the draft status of IEC 801-5
- Low frequency harmonics, flicker requirements according to EN 60000-3-2 and 3-3 (because of disturbances in supply systems caused by the power electronics of the drives). This procedure can be necessary as a result of the competent body's assessment, e.g., finding important system-specific deviations (EN 60555-2/1986).

Case Study 2:
Medical Device Directive — Electrocardiogram (EKG)

A manufacturer of an ECG-PC system wished to declare, fulfilling the protective requirements according to EN 60601-1-2. The applicable EMC requirements for emissions are EN 55011 and for immunity are IEC 801-2 (1991), ENV 50140, IEC 801-4 (1988), ENV 50142. The unit was intended for use in a hospital.

The problems encountered were that the EKG amplifier is mounted on a plug-in PCB (the supplier was from Switzerland, not an EC member), the listing of the standards was incomplete, and a medical doctor was expected to assemble the system. This is illegal, because the doctor was not an EMC specialist (Section 5.5 EMVG is violated).

The correct conformity procedure is that the manufacturer subcontracts a competent body according to Section 5.2, EMVG to do a conformity assessment. A hardware evaluation of the medical device is done based on technical documentation (zoning concept, EMC-measures, etc.). The competent body subcontracts with an accredited test laboratory to test the subsystem and, because of this particular EMC-environment, the competent body fulfills additional protective measures:

- ENV 50140 including AM and PM modulation
- ENV 50141
- EN 61000-4-8 (50 Hz), Magnetic field immunity

The plug-in PCB was tested in three different brands of PCs; these configurations will later be included in the product documentation. The ECG manufacturer of the PCBs produced, with the help of the competent body, an EMC-system installation guideline for the correct assembly of the system in the hospital. This documentation mentioned the probability of 80 % of all equipment to be within spec with an 80 % confidence level.

As demonstrated in the previous examples, statistics and quality control in the production process play important roles in EMC.

Product Family Certification

In the case of technically similar products, such as switched mode power supplies produced in large quantity, the competent body can certify the complete number of product variants. This does not necessarily call for individualized testing. A test laboratory of the competent body's choice performs selected testing, after which time the competent body globally certifies the rest of the product family. This represents an enormous savings for the customer. In addition to Section 5.2, EMVG (Art. 10.2 of 89/336/EEC) this is also possible in principle under Section 5.1, EMVG. It is the manufacturer's choice and is available even in the case of the existence of harmonized standards.

SUMMARY

An attempt has been made to elucidate the operation of a competent body and a test laboratory for the EMC CE-marking requirements. Practical case studies demonstrate the technical and managerial skills involved. Marketing and legal implications are also highlighted. In order to successfully set up a competent body and test laboratory, a multimillion-dollar investment is needed. Independence, impartiality, and technical competence must be assured. Testing and certification of products manufactured by the same organization, without clear separation and independence of a competent body and test laboratory from the rest of the company, are not permissible.

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