

The EC Directive and UK Regulations

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INTRODUCTION

In 1989 the European Community issued the EC Directive on EMC:89/336/EEC. This directive is widely regarded as the most complex and far-reaching of all the directives that are required for the establishment of the single European market. The Directive requires that all products placed on the market be shown to have an intrinsic level of immunity to enable them to operate as intended. It also requires that products be designed and constructed in such a way that the electromagnetic disturbance they generate does not exceed the level which allows other relevant apparatus to operate as intended.

Numerous conference papers, seminars and training courses have addressed the Directive. Since its announcement there has been a huge amount of speculation, misinformation and guesswork to determine exactly how the Directive affects manufacturers and suppliers of products to the EC countries. Some has been correct and some has been grossly inaccurate. This article will detail exactly how the Directive will be applied to products being supplied in the UK and to products subject to an EC declaration of conformity generated in the UK.

UK REGULATIONS - THEIR APPLICATION

It should be recognized immediately that the regulations that apply in the UK will not apply in any of the other European countries. Each has its own law and therefore its own rules and regu-

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lations for applying the Directive in accordance with those laws. The UK laws are only applicable to those manufacturers or suppliers who choose initially to import their products into the UK, manufacture in the UK, make their EC declaration of conformity in the UK, or pursue the Technical Construction File route and use the services of a UK Competent Body. However, as the Directive states, once the product is certified, free movement and sale throughout the Community is guaranteed. This means that if a company self-certifies and then issues an EC declaration of conformity in accordance with the UK Regulations, the EC declaration of conformity must be maintained in the UK. This does not preclude manufacturers from holding a copy in other EC countries in which they wish to sell the product. However, any queries concerning the compliance of the product will be investigated in the UK. A similar situation applies to a manufacturer who chooses to demonstrate compliance by the Technical Construction File route.

In this case the manufacturer must choose a UK Competent Body to confirm that the product complies. Once the technical report or certificate is issued, the manufacturer's EC declaration of conformity is again held in the UK, and the product may be sold anywhere in the Community.

The regulations for the application of the Directive were made on 5 October, 1992 and laid before Parliament on 7 October, 1992. The Directive then came into force on 28 October, 1992.

The regulations are made by the Secretary of State, a Minister designated for the purpose by Section 2(2) of the European Communities Act of 1972. In this position and in exercising the powers confirmed by the Act, he is entitled to make the regulations that implement the Directive. In doing so the Directive repeals and disallows certain sections of other UK laws. These are the Wireless and Telegraphy Act of 1949 and the Telecommunications Act of 1984.

The transitional period announced by the Commission has been incorporated into the regulations and now permits manufacturers to choose whether or not to comply with the Directive during this period. If manufacturers do not wish to comply with the Directive in the transitional period, they must comply with the existing national requirements in the EC countries in which they wish to sell their products. The implication of this is that manufacturers must comply with a range of specifications and re-

quirements instead of only one. If the EMC Directive route is chosen, then all national specifications and requirements are null and void. However, as is seen in the UK Regulations, the regulations are designed only to implement the EMC Directive where the manufacturer chooses to provide the EC declaration of conformity in accordance with the UK Regulations. If this is done, representatives from other countries cannot demand additional requirements of manufacturers. In other words, countries cannot insist that compliance is demonstrated in more than one EC country.

UK REGULATIONS - THEIR CONTENT

The manner in which the national regulations are laid out in the EC countries varies from one country to the next. Each has its own form of law making. In some cases it is very "hands off" and the implementation of the Directive into national law is simply a matter of transcribing the words in the Directive. Interpretation of the law is then a matter for the courts. In the case of UK law it is normal practice to generate detailed regulations which state how the law will be applied and the procedures for doing so. The aim is to leave very little to the imagination of those using the regulations. In this way, interpretation will be minimal and disputes will be left to the courts. It is little wonder therefore that the Directive has been expanded from 13 Articles to 8 Parts, containing 101 regulations and an additional seven schedules and some explanatory notes. This is now a very comprehensive set of regulations and there is little leeway for discussion or dispute as to how they will be applied in the UK.

Of the eight parts of the UK Regulations, six parts are of particular interest. However, a brief description of all the parts follows:

Part I - Preliminary. This covers the citation and commencement of the regulations, the repeal of other legislation, interpretive definitions, and the protection requirements.

Part II - Application. The apparatus to which the regulations apply is described in this part. There are some specific exclusions as well as some transitional and general exclusions. The applicability of the regulations to products included in other directives is also covered here.

Part III - General Requirements. The general duties and requirements for the supply of relevant apparatus is described. Conformity assessment requirements are

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also covered, with the three routes to compliance being mentioned. The use of the CE mark is also included with reference to the form of the mark set out in Schedule 4. The EC declaration of conformity is described, with instructions on the retention of documents.

Part IV - The Standards Route to Compliance. This is generally known as the self-certification route to compliance and this part describes the applicable EMC standards, the publication of reference numbers of standards and if this route is used, the EC declaration of conformity.

PART V - The Technical Construction File Route to Compliance. The applicability of this

route is covered with a description of the Technical Construction Files. The appointment of the Competent Bodies is included, with details covering their eligibility and verification. In case circumstances change, the Regulations also cover the termination of appointments and transfer of functions. The power of the Competent Body to charge fees for their activities is also included in this part. Applications for technical reports and certificates is covered. The use of subcontractors to carry out tests or assessments is mentioned. The form, conditions, and withdrawal of technical reports or technical certificates is specified. The format for giving unfavorable notice to applicants is specified. Finally, the EC declaration of conformity for this route is covered.

Part VI - The EC-Type Examination Route to Compliance for Radio Communication Transmission Apparatus. This part describes the third route to compliance for apparatus requiring an EC-Type Examination certificate from a Notified Body. There are four Notified Bodies in the UK and their details are included in this part. It includes the major points that are included in Part V, but with specific reference to Notified Bodies.

Part VII - Enforcement. Enforcement authorities are specified in this part. The powers of these authorities are also detailed. These include the purchase of test items and powers of search. Seizure of apparatus, detention of apparatus and appeals against these are included in the regulations. The issuing of prohibition notices with application for appeals against these is also covered. As the regulations are law in the UK, the offenses that may be committed are also described. The defense of due diligence is also included in the regulations. Forfeiture of apparatus may be pre-

scribed and the regulations for this are included. Finally, this part describes the recovery of expenses for the activity of the enforcement authority in the event of a conviction.

Part VIII - Miscellaneous and Supplemental. This part mainly covers the disclosure of information.

Schedules. These describe the existing regulations that no longer apply. The phenomena and effects that may be described as electromagnetic disturbance are included in Schedule 2. Descriptions of the apparatus which must not be hindered are taken from the Directive. The description of the CE mark is in Schedule 4. The minimum criteria for Competent Bodies is also taken from the Directive. A very comprehensive list of apparatus for which an EC-type examination certification is required is in Schedule 6. Finally, details of prohibition notices are in the last schedule.

UK REGULATIONS - THE DETAILS

It is appropriate at this stage to look more closely into the contents of some parts of the regulations.

In Part I there is considerable emphasis on the meaning of electromagnetic disturbance as defined in the EMC Directive. In general it assumes that it is an "electromagnetic phenomenon which is liable to degrade the performance of relevant apparatus." This is extremely general and therefore is specified in Regulation 4. The only electromagnetic disturbance which is specifically excluded is a nuclear electromagnetic pulse (NEMP). The protection requirements are also extracted from the EMC Directive, but it is interesting to note that these criteria must be met:

"when it is

- (I) properly installed and maintained; and
- (II) used for the purpose for which it was intended."

This of course begs the question as to how long it must comply with the EMC Directive. There is no time stipulation. It can therefore only be assumed that it must be for as long as the equipment is used. Manufacturers should be aware of this when they consider the degradation in performance from joint corrosion, for example.

This regulation also states that the apparatus need not be designed to prevent the generation of electromagnetic disturbance, or provide for intrinsic immunity to electromagnetic disturbance generated by other relevant apparatus not generally present in the same electromagnetic environment. This essentially means that if, for example, a transmitter that is designed for use in remote locations is brought inside a building, and its antenna and the increased field strengths cause a problem, it would not be considered non-compliant with the EMC Directive.

There has been in the past some confusion on what constitutes "supply" of a product and when a product is "taken into service." These are defined in Regulation 3. "Supply" essentially means making the apparatus available for a consumer in the Community, while "taking into service" means the first use by the person who assembled it. In the case of supply the apparatus must meet the full requirements of the regulations by any of the three routes. If the product is taken into service then it need only meet the essential protection requirements of the EMC Directive as detailed in Regulation 5.

Part II is the section on relevant apparatus and has evolved to-

ward a more general position from the draft regulations that were available for comment earlier this year. There is no mention of components being excluded. However, Regulation 7 does appear to imply this by saying

"(2) For the purposes of these Regulations, electrical apparatus

(a) consists of a product with an intrinsic function intended for the end user; and

(b) is supplied or intended for supply or taken into service or intended to be taken into service as a single commercial unit,

which is

- (i) an electrical appliance;
- (ii) an electronic appliance; or
- (iii) a system."

This definition is vague in its classification of items such as PCBs. In their unfitted form they would appear to be outside the requirements as they have no "intrinsic function intended for the end user" and the apparatus in its finished form will be shown to comply with the EMC Directive.

Add-in PCBs, such as memory expansion cards, have recently been designated by all the competent bodies in the UK* as having an "intrinsic function." Therefore these boards should be shown to be compliant with the Directive. It was agreed that compliance would be demonstrated in a manner similar to that used by the FCC, i.e., the product is certified in a known host equipment and approved for use in that equipment. The use of a product in any other "unapproved" equipment would be at the risk of the user and may involve a criminal offense. An EC declaration of conformity therefore needs to be issued for all products of this type. Manufactur-

*At a meeting of the Competent Bodies in the UK Department of Trade and Industry, held in London on 4 February, 1993.

ers may use either the self-certification or Technical Construction File route to demonstrate compliance.

Apparatus supplied in kit form must also meet the full requirements of the regulations. Mention is made of the modified application for educational electronic equipment which is designed for studying electromagnetic phenomena. This type of product need not comply with the Directive if it is intended to demonstrate the effects of electromagnetic phenomena. Similarly, test apparatus is also mentioned. However, it is specifically limited to test apparatus that is designed to generate or be susceptible to electromagnetic disturbance.

The transitional arrangements for complying either with Regulations or national requirements are covered in some detail. It should be noted that the requirements are those that were in existence on 30 June 1992. In the case of Germany this was their modified HF law and in the case of Denmark it was the specifications notified in the Official Journal of European Communities, i.e., all the emission and immunity specifications plus the generic specifications that are applicable to the EMC Directive. It would appear easier therefore to comply with the Directive.

Other exclusions are apparatus:

- intended for use outside the EC countries.
- intended for an excluded installation. This applies to two or more combined items or apparatus or systems put together in a given place to fulfill a specific objective, but not designed by the manufacturer(s) for supply as a single functional unit. An example might be a metro station.
- that is a spare part — but not an apparatus in which a spare part has been fitted.

- that is a sample for a representative.
- that is secondhand — but not secondhand apparatus that has been subject to further manufacture.
- intended for use in a sealed electromagnetic environment.
- that is for amateur radio use and is not commercially available.
- that is military equipment — but not designed both for military and other use.
- that is included in other directives. In the absence of the other directives (not being applied) the EMC Directive applies.
- that is partially covered by other directives. Telecommunications Terminal Equipment is included in this list.

The General Requirements in Part III are very much a transcription from the EMC Directive. It is interesting to note that in Part III, under Regulation 35, Retention of Documentation, a responsible person shall hold the EC declaration of conformity at the disposal of the Secretary of State for a period of 10 years beginning with the date on which the latest item was supplied. This also applies to the Technical Construction File if that route is chosen. None of the parts of Regulation 35 require the documentation to be held in the UK. It might be sensible to hold the EC declaration of conformity in the UK and the Technical Construction File with the QA documentation. It is acceptable to keep the documentation on computer file or some other medium, as long as it can be reproduced in legible form.

Part IV is an amplification of the EMC Directive standards route to compliance. In detailing the applicable standards, the regulations recognize the source of the standards as being the CENELEC or ETSI standards. The latter are used for telecommunication ap-

paratus. In addition to their publication in the Official Journal of the European Communities they are also published in the London, Edinburgh and Belfast Gazettes. These are the official UK government newspapers. The format for an EC declaration of conformity is given at the end of Part IV under Regulation 40 for cases where the standards route is used. It is interesting to note that the name and address of the responsible person has to be included, as do the standards that have been applied. No doubt volunteers for the first function will be sought.

The Technical Construction File route outlined in Part V consists of 18 regulations. This part is extremely detailed and describes the general content of the Technical Construction File and other aspects of compliance by this route. It was considered that, as this approach is complex and industry in general will not understand the route, another explanatory document was required. The Department of Trade and Industry (DTI) therefore published a "Guidance Document on the Preparation of a Technical Construction File as Required by EC Directive 89/336." If all the rules are followed, a manufacturer should be able to complete the file to the satisfaction of the Competent Body. However, the DTI does recommend that a manufacturer discusses with, or seeks assistance from the Competent Body, at least in the first instance, to ensure that it is prepared correctly. It can prevent a lot of wasted resources.

COMPETENT BODIES

The DTI in the UK has now appointed 26 Competent Bodies. This is far more than any other EC country. The reason for this is simple. Authorities are cognizant that as awareness of the Directive increases, there will be a shortage

of resources to handle the certification work. This is particularly so if manufacturers choose to use the Technical Construction File because of the absence of complete specifications. To minimize this anticipated backlog, a large number of Competent Bodies have been appointed. By definition a Competent Body is one that has been appointed in the UK or is a Competent Body in one of the other member countries. The same rules will apply in all other EC countries. Therefore a UK Competent Body may act in that role in Germany or elsewhere in the EC countries.

The appointment of the Competent Bodies took place on 28 October 1992. In doing so, DTI specified the relevant apparatus that each Competent Body is authorized to examine. The scope of the bodies varies considerably and is based on the criteria in Annex II of the EMC Directive. Although the Competent Body is a company, the appointment effectively applies to people in the company. Therefore the DTI has to be satisfied that the persons performing the examination of the Technical Construction Files have the necessary experience to do the work. This judgement has been based on the production of Curriculum Vitae for all staff considered qualified. Unqualified personnel may not perform this work. Regulation 46(6) states that the Secretary of State "shall from time to time publish lists of UK Competent Bodies indicating the descriptions of relevant apparatus in respect of which body is authorised." This information is now available.

In appointing the UK Competent Bodies the DTI has appointed some companies that are manufacturers as opposed to independent companies. This has been done on the proviso that the work of the Competent Body is independent of the manufacturing function. In a company having

ISO 9000 approval this will be so. However, the Competent Body has to be willing to accept outside work as long as it is within the authorized capability of the body. The Competent Body can refuse work where it is not capable of performing the work within a period of three months from the date of the application.

In exercising its function, the Competent Body issues a technical report or certificate. Needless to say, it is not required to do so if the apparatus does not conform to the protection requirements. It will also not accept, in accordance with Regulation 51, an application for a technical report or certificate unless the application:

- is in writing
- is accompanied by a draft technical construction file
- includes particulars of which applicable EMC standards the manufacturer has applied, and
- contains a declaration by the applicant that no application to another Competent Body for a technical report or certificate regarding that apparatus is outstanding.

It should be remembered that Technical Construction File for a UK Competent Body should be in English. Other official community languages may be used where the application is made to a Competent Body in another member country. It is presumed that national languages will apply in all other member countries although this is not yet confirmed.

Regulation 49 covers the power of the Competent Body to charge fees. It should be recognized that Regulation 49(2) assigns the power to require that fees be paid with the application.

A further interesting point is that Regulation 52 permits the Competent Body to subcontract testing, assessment or inspection to

some other person. There is no notification that the person should be based in the UK or be of UK citizenship. This raises the question as to whether or not the function could be carried out by a U.S. citizen. The answer must be yes, but of course the technical report or certificate cannot be issued by that person. Therefore the Competent Body must be convinced as to the quality of that person's work and their capability to perform the work. This situation also applies to the other routes to compliance and it is envisioned that many companies will wish to use their own facilities or those of a test laboratory in their own countries to perform assessment work. These need not be accredited facilities, but it is in the manufacturer's interest to ensure that the testing or assessment is performed correctly.

Once the technical report or certificate is issued, that manufacturer makes an EC declaration of conformity. If the Competent Body believes the product does not comply with the protection requirements, Regulation 55 states that it can withdraw the technical report or certificate. In this case the Technical Construction File is not complete and the manufacturer must cancel the EC declaration of conformity. This might occur when a manufacturer produces a product which complied when tested, but in the manufacturing process was modified and then was found on investigation by the enforcement authority not to comply. The lesson here is that the Competent Body should be contacted to authorize any changes that have an EMC impact.

For EC-type examinations a Notified Body is required, as specified in Part VI. In reality the regulations are very similar to those for the Competent Body. The main difference is that Regulation 62 specifies the Notified Bodies. They are:

- Defence Research Agency of the Ministry of Defence — for marine equipment
- Civil Aviation Authority — for aerospace applications
- British Approvals Board for Telecommunications — for equipment connected to the telecommunications network
- Radiocommunications Agency for the Department of Trade and Industry — for ground-based equipment

The application for the EC-type examination is similar to that for the Technical Construction File. However, no file is required and the manufacturer simply submits the equipment for examination. The certificate may relate to a single item, an item representative of a number of items presented, or a number of items which are variants of the same basic design.

The question as to where or how this activity is to be carried out has raised some interest, but because subcontracting is feasible under Regulation 66 there is no reason why this work could not be carried out in the U.S. or elsewhere. Once more, quality of test and other resources becomes of interest and the Notified Body must have confidence that the assessment or test is being performed correctly.

The last major part, Part VII, concerns enforcement. Where enforcement authorities wish to ascertain whether or not an apparatus complies with the Regulations, they may purchase the apparatus. If the product fails to comply and a suspension notice is served, then the person from whom the apparatus was purchased may have it tested. In this way there is a double-check carried out on the same product.

If the product fails to comply then a prohibition notice is served in accordance with Regulation 78.

In this case the manufacturer is prohibited from manufacturing, supplying, taking into service or using the apparatus, except with the consent of the Secretary of State. A similar regulation applies where the enforcement authority has reasonable grounds for suspecting that the regulations have been contravened. This sounds fairly draconian, but in reality a warning will almost certainly be given first. If the problem is not addressed action will be taken. Of course this assumes that the enforcement authority has the authority to do this. This authority does not apply to U.S. manufacturers. It may therefore be presumed that the manufacturer may still make the product, but cannot legally market it in the Community. In the case of a UK manufacturer who is also supplying the product for export outside the Community it is the opinion of the DTI that as Regulation 12 excludes exports outside the Community from these regulations, the manufacturer may still manufacture and supply the product for export only.

Part VIII is also concerned with the punishment that may be levied on persons contravening the regulations. There are two levels available. The first level applies to a contravention of the general requirements, and carries a fine of up to £5000. If a prohibition or suspension notice is served and that is contravened, a fine of up to £5000 and 3 months imprisonment may be imposed. There are other offenses that may also result in a similar punishment. Regulation 96 also allows the court to order costs and the recovery of the enforcement expenses. These may be considerably higher than any fine. The fines may seem small in comparison with the financial advantages to be gained in selling a product. However, since the product may be forfeited and there will be considerable loss of respect for a com-

pany in this situation, the government considers this level of punishment adequate.

It is worth noting that as the UK operates by the laws of reasonableness, Regulation 88 allows a defense of due diligence. Basically this means that a manufacturer who sincerely tried to comply with the regulations will not be convicted of an offense.

CONCLUSIONS

There is no doubt that this is a very comprehensive set of regulations. It will be difficult in the early days for many manufacturers to understand exactly what is required of them. The DTI is not staffed to provide an answering service to the UK, let alone any other countries, and therefore their recommendation is that manufacturers obtain the services of a Competent Body, even if a manufacturer intends to use the standards route to compliance. The Competent Body will know the correct way to conform to the regulations. It will also prevent waste of resources and repeated returns to the authorities when things go wrong. Most Competent Bodies will provide simple advice free of charge, but it may be worth contracting for support while learning these regulations.

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