THE IMPACT OF THE NEW EMC DIRECTIVE 2004/108/EC FOR THE RAILWAY INDUSTRY

[This paper was originally published in the EMC Europe Paris 2007 proceedings and is reproduced here by kind permission of the EMC Europe Paris Organising Committee; updated 02/08]

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Abstract - The new EMC Directive 2004/108/EC includes a number of changes as well as clarification and simplification when compared with the old EMC Directive, 89/336/EEC. This paper summarises the application of the new EMC Directive to the Railway Industry and identifies the changes and the new responsibilities placed on equipment manufacturers and infrastructure controllers. It raises concerns regarding: interpretation of the Directive: 'state of the art', 'good engineering practices', the fixed installation and the definition of responsible person and the role of the Notified Body.

I INTRODUCTION

The New EMC Directive (EMCD) was published in the Official Journal of the European Union on 31/12/04, 2004/108/EC [1]. It becomes effective from 20 July 2007 for new equipment and for existing equipment conformance with 89/336/EEC [2] remains valid until 20 July 2009, after this date conformance must be demonstrated to 2004/108/EC.

This paper aims to identify the main changes to 89/336/EEC. It also identifies issues raised by the new EMCD for the Railway Industry. There are implications for both manufacturers of equipment, rolling stock and infrastructure operators.

II SUMMARY OF CHANGES

TABLE I. SUMMARY OF CHANGES.

Current: 89/336/EEC	*New: 2004/108/EC*
2/3 routes to compliance	1 route to compliance
Assess to Standards	EMC Assessment (equivalent: assessment to standards)
Technical Construction file (TCF)	Technical Documentation for all equipment (old TCF)
Mandatory assessment of TCF by Competent Body (CB)	Notified Body (NoBo) opinion optional
Declaration of Conformity (DoC)	DoC and User Information
	New regulatory requirement for Fixed Installations and the 'Responsible Person'

In general terms 2004/108/EC maintains the objectives of 89/336/EEC and follows the same regulatory concept of the New Approach. It does however seek to:

- Clarify the scope by improved definitions and more clearly defined exclusions
- Treat fixed installations (FIs) under a different regulatory approach
- Enhance the clarity by more detailed essential requirements
- Clarify the role of harmonised standards
- Simplify the Conformity Assessment procedure by reducing it to a single route
- Cut "red tape" and increase manufacturer's choice by removing compulsory use of a Competent Body (CB) where harmonised standards cannot be used, but allowing manufacturers to voluntarily use a Notified Body (NB or NoBo)
- Allow better market surveillance through better traceability of the manufacturer, by defined documentation

Some of the changes reflect the practices used in more recent New Approach Directives, for example the R&TTE Directive, 1999/5/EC [3], which allows the voluntary use of Notified Bodies.

II.1 Essential requirements (Article, 5 ANNEX I)

The protection requirements remain unchanged apart from minor changes to the words and apply to 'apparatus'. They are however prefaced by the statement that 'Equipment shall be so designed and manufactured, *having regard to the state of the art*, as to ensure that……'. Specific requirements are identified for 'fixed installations' (FI), these are covered in the following sections.

III DISTINCTION BETWEEN APPARATUS AND FIXED INSTALLATIONS

III.1 Apparatus

Apparatus is defined as 'goods' which, once they comply with the EMCD can be placed on the market and/or put into service anywhere within the European Economic Area (EEA). It is the responsibility of the manufacturer to carry out a *conformity assessment* to show that the apparatus complies with the 'essential requirements' of the EMCD. Apparatus is defined as

'any finished appliance, or combination thereof [a system] made commercially available as a single functional unit, intended for the end user, and liable to generate EM disturbance, or the performance of which is liable to be affected by such disturbance.'

Apparatus also includes:
"components" or "sub-assemblies" intended for incorporation by an end user, which are 'liable to generate EM disturbance, or the performance of which is liable to be affected by such disturbance.'

Compliant apparatus must carry the CE marking.

III.2 Apparatus Conformity Assessment

Compliance with the essential requirements, the protection requirements described in Annex I, is demonstrated by the procedure described in Annex II (internal production control) or *at the manufacturer's discretion* Annex III. The only difference is that under Annex III *a manufacturer may choose to seek an opinion from a Notified Body* [the old Competent Body].

A manufacturer is required to perform an *EMC assessment*, in which all relevant EM phenomena are identified and addressed in order to meet the protection requirements. There is a presumption of conformity if all relevant harmonised EMC standards applicable to the apparatus have been met; this is equivalent to the EMC assessment.

Where apparatus can take different configurations, the EMC assessment should confirm that the apparatus meets the protection requirements in all the configurations foreseeable by the manufacturer as representative of normal use in the intended applications; in such cases it should be sufficient to perform an assessment on the basis of the configuration likely to cause the maximum disturbance and the configuration most susceptible to disturbance.

The conformity has to be demonstrated through *'technical documentation'* (TD) as described in Annex IV (this is in effect the old Technical Construction File used under 89/336/EEC), regardless of whether or not products are manufactured in compliance with harmonised standards, and a Declaration of Conformity (DoC) issued. The technical documentation may include a report from a Notified Body (Annex III) confirming the compliance of the apparatus with the essential requirements. The TD and DoC should be available upon request to the Competent authorities for up to 10 years after the last date of manufacture of the product.

Compliance with a harmonised standard is clarified, it means conformity with its provisions e.g. limits and using the methods the standard describes, e.g. the use of receivers meeting CISPR 16 requirements. Presumption of conformity is limited to the scope of the standard(s) applied and the relevant essential requirements covered by the standard(s).

Equipment must now be accompanied by information clearly identifying the product (e.g. type number, batch code, etc), and the name and address of the manufacturer or his EU authorised representative. Where the manufacturer or authorised representative is outside the EU then the person responsible for placing the apparatus on the EU market must be identified. These provisions are to strengthen the means available to the market surveillance (enforcement) authorities to verify conformance of apparatus and take enforcement measures considered necessary.

The manufacturer will also need to provide information on any *specific precautions to be taken at installation*, assembly, maintenance or use of the apparatus to ensure that it complies with the protection requirements.

A specific restriction must be explicitly stated where apparatus is not suitable for use in residential areas (similar to the FCC requirement). This requirement is already in place for ITE complying with EN 55022 ie Class A, but is in effect now extended to all industrial and railway equipment.

For railway equipment manufacturers this means little change since the railway EMC standards, the EN 50121 series [8], were not published in the OJ and therefore manufacturers had to follow the TCF route under 89/336/EEC. Now under 2004/108/EC they will do the same but the TCF will now be called *Technical Documentation (TD)*. EN 50121-X:2006 was published in the OJ in September 2007 and can now be used by manufacturers to give a presumption of conformity. The TD will confirm that the apparatus complies with the protection requirements. This will include the technical justification for not using a standard or how a test method has been adapted, etc.

The new EMCD allows the manufacturer to decide whether to involve a third-party and if so to what extent. The CBs are to be renamed as Notified Bodies (NBs or NoBos) to align them with recent new approach directives and remove anomalies. Requirements for NoBos are largely as for existing CBs; Article 12 and Annex VI.

Since use of the CB/NoBo is optional and no longer mandatory for railway equipment, then additional measures may be needed under contractual requirements since the train operator (TOC) or owner (ROSCO) or the infrastructure controller (NR) may need the reassurance of an independent third party assessment.

It should be noted that testing to the EN 50121 standards will be obligatory under the TSIs for conformance with the Interoperability Directives [10].

Testing to EN50121 is also a requirement of the UK's railway group standard GE/RT8015 as part of the safety case for rolling stock to be taken into service on Network Rail [9].

Rolling stock reconditioning must be considered as for example under the UK EMC regulations, reconditioning is considered as manufacture. New equipment fitted will either be: 'components for further manufacture', not requiring the CE marking but will require EMC control under contract, or equipment carrying the CE marking, however the 'system integrator'/prime contractor will be responsible for EMC conformance and the CE marking of the 'system'. Again the third party report on the TD will be optional and if for example a ROSCO needs this assurance, then it must be in the design contract [11].

III.3 Fixed Installations and the regulatory regime

Fixed installations (FIs) are identical to the 'excluded installation' defined in the 1991 Guidelines [4] and the old UK EMC Regulations [5]. FIs are assemblies of various apparatus and other devices, carrying the CE Marking, installed and/or constructed *'applying good engineering practices'* (Annex I specific requirements) and intended to be used permanently at a pre-defined location within the EU (e.g. electricity distribution networks, telecoms networks, large machinery and assemblies of machinery on manufacturing sites). A FI is not subject to conformity assessment, it must, however, meet the protection requirements. The 'good engineering practices' shall be documented and the documentation held by *'person(s) responsible'* for inspection by the national authorities for as long as the FI is in operation.

Clearly a Railway is a FI.

The Competent Authority may request evidence of compliance of the FI with the protection requirements and when appropriate initiate an assessment. Member States are required to set out the provisions for the identification of the *person(s) responsible* for the compliance of a FI; this is simply reinforced by the Commission's guide to the directive [7]. Under the UK regulations a 'responsible person' means '…in relation to a fixed installation, the person who, by virtue of their control of the fixed installation is able to determine that the configuration of the installation is such that when used it complies with the essential requirements' [6]. If a FI is identified as an unacceptable source of emissions, a Competent Authority can request that the responsible person brings it into compliance with the protection requirements.

Since the constituent apparatus of the fixed installation will conform to the EMCD and this conformance is likely to have been demonstrated by compliance with harmonised standards, then, the Commission argue, the EM environment of the fixed installation is defined allowing for addition of apparatus employing *'rapidly changing technologies'* itself conforming to harmonised standards. This is consistent with the EN50121 standards [8], which cover all the constituent parts of the Railway.

Where apparatus is designed and built for incorporation into a specific FI and is *not otherwise commercially available*, it is not required to undergo formal conformity assessment procedures. The manufacturer may choose to either follow conformity assessment procedures or to provide accompanying documentation detailing the name and site of the FI and the EMC precautions to be taken for the incorporation of the apparatus in order to maintain the conformity of the installation. The manufacturer must also provide identification of the apparatus and his name and address, or the name and address of his authorised representative (if the manufacturer is outside the EEA) or the person within the Community responsible for placing the equipment on the market.

III.4 How in practice will the FI requirements impact the railway?

Railway infrastructure controllers will need to appreciate the implications and implement policy.

In the case of new build the 'responsible person' will be the Prime Contractor and will oversee and co-ordinate all collaborators/suppliers, EMC installation and approvals documentation; similar to RLE's role in the construction of the CTRL [12]. After commissioning and handover, the infrastructure controller will become the responsible person e.g. Chief Engineer/ Technical Director, who will arrange to hold all the EMC documentation.

This documentation will be 'living' documentation; as upgrades occur information will be added.

For existing build the new EMC Directive is not retrospective. So the EMC documentation will be built up over time by upgrade project documentation, plus any extant data/documentation.

So the questions remaining are:

- How will it be put into practice?
- Will there be enforcement?
- Are there benefits?

Suggested scenarios for possible implementations have been outlined in the paper.

Enforcement seems unlikely, since Competent Authorities have shown little appetite to enforce the EMC requirements for products. This latter should actually be easier under the new requirement for TD retention as authorities can demand to see the TD not just a DoC! We shall await with interest!

There are benefits. The FI requirements lend weight to the need for a structured approach to EMC encompassing: safety aspects, interoperability and EMC Directive conformance [10].

IV TRANSITIONAL PROVISIONS AND TIMESCALES

Member States are required to implement the new EMCD into regulations by 20 January 2007 and these are *to be applied from 20 July 2007* (Article 16).

Directive 89/336/EEC will be repealed as from 20 July 2007 (Article 14).

A transition period of 2 years is allowed for the introduction of the new requirements. *Equipment compliant with 89/336/EEC can continue to be placed on the market until 20 July 2009* (Article 15), but equipment new after 20 July 2007 must meet the` requirements of 2004/108/EC.

V CONCLUSIONS

- Manufacturers are required to perform an EMC assessment; application of harmonised standards is deemed to be equivalent to performing the assessment.
- Manufacturers are required to produce Technical Documentation (TD) to demonstrate conformity. In effect this is the same as the current Technical Construction File (TCF), but without the mandatory requirement for a third party Competent Body Report.
- Manufacturers may choose to obtain an independent conformity statement from a Notified Body (NoBo) (new name for the CB); the manufacturer specifies to the NoBo the parts of the essential requirements/protection requirements that the NoBo is to assess.
- Manufacturers are required to make a DoC
- Manufacturers are required to supply information on any specific EMC precautions to be taken when the apparatus is assembled, installed, maintained or used.
- A Fixed Installation (FI) at a pre-defined location is required to conform to the essential requirements but does not have to follow the conformity assessment procedure and therefore does not have to carry the CE marking. The FI will usually consist of: equipment carrying the CE marking installed as specified by the manufacturer(s) and specific equipment not otherwise commercially available can be incorporated, accompanied by documentation which indicates precautions to be taken for incorporation into the FI; the installation shall follow 'good engineering practices' which must be documented. A railway is a FI.
- The new EMCD 2004/108/EC will have an accompanying Guidance Document, which like the previous 1997 guidelines, will have no legal status but is expected to provide some guidance on the interpretation of terms such as 'state of the art', 'good engineering practices' and perhaps when a large machine can be judged a fixed installation or equipment.

Of concern is:

- Whilst it is apparent that for *'presumption of conformity'* a standard should be applied in full, a manufacturer can actually do what he chooses under the EMC assessment and there is no mandatory requirement for his decisions to be assessed by a NoBo.
- The role of the NoBo. This is well defined and the requirements to be a NoBo are stringent, but the use of the NoBo will be entirely at a manufacturer's discretion unless otherwise contractually obliged to perform the third party assessment.
- The interpretation, which might be applied to FIs e.g. there is reference to large machines in the Directive preamble, so the question is when does apparatus become a FI? Some other key definitions remain open to interpretation including "benign equipment", and "good engineering practice".
- There is no clear definition of the 'responsible person' in respect to FIs, This may well be a contractual issue with the ownership of responsibility being transferred to the user.

Acknowledgment

The author gratefully acknowledges the permission from York EMC Services Ltd (www.yorkemc.co.uk) to write and publish this paper.

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