

COMMENTS ON THE DRAFT EMC GUIDE 20 FEB 2006

Introduction			
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6 <sup>th</sup> pt	<ul style="list-style-type: none"> <li>The conformity assessment procedure for apparatus has been simplified to a single procedure. There is no compulsory involvement of a third party however <del>when harmonised standards are not fully used</del>, the manufacturer has the option of <del>submitting a</del> <u>presenting his</u> technical file to a Notified Body <u>for it to be assessed</u>.</li> </ul>	<ul style="list-style-type: none"> <li>The conformity assessment procedure for apparatus has been simplified to a single procedure. There is no compulsory involvement of a third party however <del>when harmonised standards are not fully used</del>, the manufacturer has the option of <del>submitting a</del> <u>presenting his</u> technical file to a Notified Body <u>for it to be assessed</u>.</li> </ul>	<ul style="list-style-type: none"> <li>The conformity assessment procedure for apparatus has been simplified to a single procedure. There is no compulsory involvement of a third party however <del>when harmonised standards are not fully used</del>, the manufacturer has the option of <del>submitting a</del> <u>presenting his</u> technical file to a Notified Body <u>for it to be assessed</u>.</li> </ul>
7 <sup>th</sup> pt	<ul style="list-style-type: none"> <li>When deviating from the harmonised standards or not applying them fully, the manufacturer has to perform a <u>detailed technical</u> EMC assessment and provide detailed documented evidence that <del>he</del> <u>the apparatus</u> respects the <del>essential</del> <u>protection</u> requirements of the EMC Directive.</li> </ul>	<ul style="list-style-type: none"> <li>When deviating from the harmonised standards or not applying them fully, the manufacturer has to perform a <u>detailed technical</u> EMC assessment and provide detailed documented evidence that <del>he</del> <u>the apparatus</u> respects the <del>essential</del> <u>protection</u> requirements of the EMC Directive.</li> </ul>	<ul style="list-style-type: none"> <li>When deviating from the harmonised standards or not applying them fully, the manufacturer has to take comment into account</li> </ul>
8 <sup>th</sup> pt	<ul style="list-style-type: none"> <li>Apparatus intended for a given fixed installation and <u>otherwise</u> not <del>intended to be</del> commercially available may be exempted from <del>the</del> <u>some</u> requirements and procedures for apparatus (e.g. declaration of conformity and CE marking), provided that <del>it</del> <u>measures are taken</u> <del>does not to</del> compromise the EMC characteristics of the fixed installation <u>and that suitable documentation is provided</u></li> </ul>	<ul style="list-style-type: none"> <li>Apparatus intended for a given fixed installation and <u>otherwise</u> not <del>intended to be</del> commercially available may be exempted from <del>the</del> <u>some</u> requirements and procedures for apparatus (e.g. declaration of conformity and CE marking), provided that <del>it</del> <u>measures are taken</u> <del>does not to</del> compromise the EMC characteristics of the fixed installation <u>and that suitable documentation is provided</u></li> </ul>	<ul style="list-style-type: none"> <li>Apparatus intended for a given fixed installation and <u>otherwise</u> not <del>intended to be</del> commercially available may be exempted from <del>the</del> <u>some</u> requirements and procedures for apparatus (e.g. declaration of conformity and CE marking), provided that <del>it</del> <u>measures are taken</u> <del>does not to</del> compromise the EMC characteristics of the fixed installation <u>and that suitable documentation is provided</u></li> </ul>
1 <sup>st</sup> § after bullet points	<p>It is important to underline that for the vast majority of applications concerning apparatus... <i>Unclear, to be reformulated</i></p>	<p>It is important to underline that for the vast majority of applications concerning apparatus... <i>Unclear, to be reformulated</i></p>	<p>Existing text seems clear</p>
3 <sup>rd</sup> § after bullet points	<p>The structure of this guide has been adapted to the practical needs of all those who need to ensure... Therefore <del>the</del> <b>The</b> Guide ... <i>Not necessary! [remark sometimes "Guide", sometimes "guide"]</i></p>	<p>The structure of this guide has been adapted to the practical needs of all those who need to ensure... Therefore <del>the</del> <b>The</b> Guide ... <i>Not necessary! [remark sometimes "Guide", sometimes "guide"]</i></p>	<p>"Guide" will be used everywhere</p>

Topic 3	<p>... used. In this case the EMC assessment has been called in this guide <u>“Detailed EMC technical assessment”</u>. This new terminology is only introduced to allow a clear distinction from the usual and preferred method of EMC assessment, which refers exclusively to the <b>use of all the relevant EMC</b> harmonised standards. <i>Wrong “” – addition</i></p>	<p>Relevant is sufficient; all the relevant could mean for example a product family standard together with the specific product standard which it is needed</p>
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### 1. Scope

1.1 2 <sup>nd</sup> §	<p><i>Not only the scope, but also the “aim” or “objective” of the directive should be explained (not only the placing on the market and the putting into service is regulated, but the first sentence of article 1.1 of the Directive states “This Directive regulates the electromagnetic compatibility of equipment”). So add an additional § “Aim of the Directive”</i> <i>This is important for enforcement authorities!</i> <b><u>The main objective of the EMC Directive is to regulate the compatibility of equipment.</u></b> <b><u>Its aim is to create an acceptable electromagnetic environment.</u></b> <b><u>In order to achieve this objective, provisions are put in place so that:</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>only equipment (= apparatus and fixed installations) is placed on the market and/or putted into service if it complies with the provisions of the Directive</u></b> <b><u>and</u></b></li> <li>• <b><u>good engineering practices are applied for the installation of fixed installations, with the possibility for the competent authorities to impose measures if non-compliances are established.</u></b></li> </ul>	<p><i>Accepted for adding to the introduction</i></p>
Flowchart 1	<p>The complete overall flow-chart <b>5</b> grouping flowcharts 1, 2, 3 and 4 is given in Annex <i>A flowchart 5 has been inserted (complete conformity assessment procedure for apparatus)</i> <i>I think that the correct spelling is “flowchart” or “flow chart” – I prefer “flowchart”</i></p>	<p>OK for flowchart</p>
	<p><i>Number on the right-hand side not in boxes but “(1) (2) (3) (4) (5) (6)”. This corresponds (same lay-out) with the text.</i> <i>(6) refers to “flowchart 2” and should be omitted</i></p>	<p>OK</p>

1.1.1	... generate electromagnetic disturbances and its normal operation is not affected by such disturbances. Hence, equipment without electrical and/or electronic parts is <del>excluded from</del> <b>not in</b> the scope of the EMC Directive. <i>The real exclusions as mentioned in the Directive are listed under 1.1.2!</i>	OK
1.1.2.1 2 <sup>nd</sup> §	<i>Even a better example of radio equipment covered by the EMC are normal radio's and televisions:</i> <b><u>An typical example of radio equipment not covered by Directive 1999/5/EC is receive only radio equipment intended to be used solely for the reception of sound and TV Broadcasting Services (ie normal radio's). Other typical examples of equipment not covered by the R&amp;TTE Directive are transmitters operating below 9 kHz and/or above 3000 GHz, and non-radio telecommunication network infrastructure equipment.</u></b>	<i>OK but delete normal radios</i>
1.1.2.3 2 <sup>nd</sup> §	<i>Add that such equipment is also outside de scope of the R&amp;TTE</i> ... not regarded as commercially available equipment, and therefore are outside the scope of the EMC Directive. <b><u>Such equipment is also outside de scope of the R&amp;TTE.</u></b>	<i>O K modified</i>
1.1.3 1 <sup>st</sup> – last §	Directive 89/336/EEC continues to apply for EMC phenomena not covered by this Directive and thus equipment for which such phenomena are relevant should also continue to carry a CE mark. <i>Do not understand this. The guide is for the new directive not 89/336/EEC and what is meant with "this Directive" (= automotive?).</i>	Has been modified to clarify
1.1.4 6 <sup>th</sup> -	<i>The layout of this § is out of order! OK Omit the first part and use 2 – on the same level of the others (1 = Protection eq; 2 = Manual switches)</i> <del>Also the following equipment is considered benign:-</del> Protection equipment ...	<i>Some distinction is useful</i>
1.2 3 <sup>rd</sup> §	<i>When reading art 1.1 of the directive, this statement is not exact! It regulates the electromagnetic compatibility of equipment (see also the first remark in this section. Following article 5 equipment has to fulfil the essential requirements at all time!</i> The EMC Directive <del>applies to</del> <b><u>imposes specific an precise requirements on apparatus when</u></b> placed on the market and/or put in service.	<i>OK modified</i>
1.2 § after 1 <sup>st</sup> note	One of the conditions to be considered as an apparatus in the sense of the EMC Directive is that it is intended for the end-user. In the context of this guide end-user means any consumer, business or enterprise <del>using</del> <b><u>assuming to use</u></b> the product for its intended purpose. <b><u>Apparatus placed on the market are normally intended for the end-user.</u></b>	Accepted modification for first part second addition not necessary
1.2.1 3 <sup>rd</sup> §	<i>Add that the combination has to fulfil the requirements!</i> ... it is not an apparatus in the sense of the EMC Directive and consequently the EMC Directive does not apply for such finished appliances. <b><u>It is clear the final assembled equipment has to fulfil all the applicable provisions.</u></b>	<i>Not necessary to add It would seem to add new requirements</i>

1.2.2 last §	... manufacturer of each constituent finished appliance within the system has already fully applied the Directive <b>in relation to the placing on the market</b> , and particularly taken into account the expected electromagnetic environment and the intended use. Hence, for such a so-called "system", no further conformity assessment is required. <b><u>The "system" must of course respect the protection requirements.</u></b>	Not necessary to add It would seem to add new requirement
1.2.4 2 <sup>nd</sup> §	If such installations are, however, intended to substitute for, or to extend a fixed installation ... Mobile installations are not fixed (by definition) and certainly not intended for a give fixed installation! = non legal interpretation!	Accepted in existing <b>EMC EC</b> guide Put as a note
1.3.1 last §	This sentence is misleading. All articles where "equipment" is mentioned are in theory also applicable to fixed installations. Fixed installations must comply with the essential requirements of the EMC Directive, <b>especially they have to comply with the essential requirements</b> as defined in Article 5 <b>which are referred to in</b> <del>and</del> Annex I of the EMC Directive.	<b>Existing text seems correct</b>
1.3.2 1 <sup>st</sup> §	No need to state "as defined in the EMC directive" (if something should be mentioned it should read "in the scope of the EMC directive") The general rule is that all apparatus, as defined in the EMC directive, are subject to all the relevant provisions of the EMC Directive for apparatus. This applies also fully to apparatus ...	Useful to distinguish from apparatus in the usual sense
1.4.1 3 <sup>rd</sup> §	It must be made clear that the original manufacturer is not anymore responsible for the conformity of the modified product. The manufacturer can only take responsibility for the conformity of equipment at the moment it is placed on the market (and/or put into use). Personally I think it is better to first treat "repaired apparatus and spare parts" and then "used apparatus" (may better called "refurbished apparatus sold "as new"").	Section 1.4 is deleted in accordance with WPdecision.

### 3. Conformity assessment procedure for apparatus

3.1 1 <sup>st</sup> § after bullets	... evidence that the apparatus complies with the relevant harmonised standards <b>whose references have been published in the Official Journal of the European Union</b> or, if harmonised ... It is important that HS giving presumption of conformity are used! This is the first place in the text were a clarification on what is meant with HS can be given.	OK accepted
3.1 after 1 <sup>st</sup> § after bullets	New paragraph after the paragraph "Technical documentation has to be prepared ..." to stress that the technical documentation must be the one used for production! <b>The manufacturer must take all measures necessary to ensure that the apparatus are manufactured in accordance with the technical documentation. (Annex II 8 of the directive).</b>	OK accepted
3.1 flowchart 5	As "use of harmonised standards" is to be promoted, it is better to rotate the flowchart. The use of HS on the left, detailed technical EMC assessment on the right.	At later editing stage
3.1 2 <sup>nd</sup> note	The reference to "section 3.3" is not right! This must probably be "chapter 6"	OK

3.2.1.1 1 <sup>st</sup> §	<p>The text of the directive does not mention “foreseeable”. This word is mentioned in “whereas (17)”. Annex II.2 speaks about “all normal intended operation conditions” and “confirmation in all possible configurations identified by the manufacturer as being representative of its intended use”. The directive requires that “all” apparatus comply</p> <p>Where apparatus can take different configurations, the EMC assessment should confirm that the apparatus meets the protection requirements in the <b>all possible</b> configurations <del>foreseeable</del> <b>identified</b> by the manufacturer as representative of normal use in the intended applications.</p>	Seems OK to give practical guidance that it is “limited” to foreseeable configurations
3.2.1.1 last § before note	<p>The manufacturer is responsible for identifying the possible configurations and the choice of the worst cases. <b>The use of the “worst case” approach must be documented in the technical documentation.</b></p> <p>[Remark: there is no 3.2.1.2, so why number 3.2.1.1?]</p>	OK accepted
3.2.2 2 <sup>nd</sup> §	<p><del>Unclear – to be reformulated</del></p> <p><del>When an individual apparatus is placed on the market, the compliance of that apparatus with the EMC requirements of the relevant harmonised standards, as given in the latest available consolidated list of the (OJEU), gives presumption of conformity to the essential requirements of the EMC Directive.</del></p> <p><b>An individual apparatus enjoys presumption of conformity with the protection requirements if it, at the moment it is placed on the market, fulfils the requirements laid down in all the applicable harmonised standard listed at that moment in the consolidated list published in the OJEU with reference to the EMC directive.</b></p>	Text has been modified
3.2.2 3 <sup>rd</sup> §	<p><del>Unclear – to be reformulated</del></p> <p><del>The EMC Directive refers to the moment of placing on the market for each individual apparatus. This means that for an apparatus, which is continuously placed unchanged on the market for a long period, the applicable standards may change in the course of time. The provisions given by the application of 3.2.2.3 ensure that a transition period of at least 3 years is usually foreseen between successively valid editions of the same standard.</del></p> <p><b>It is possible that in the course of the production cycle of an apparatus, a new list of harmonised standard is published in the OJEU. The provisions explained under 3.2.2.3 concerning the date of cessation of presumption of conformity should be taken into account. It is normal that a transition period of at least 3 years is foreseen between successively valid editions of the same standard. After the transition period the “old” standard can no longer be used as such to enjoy presumption of conformity for the new produced apparatus.</b></p>	Text has been modified
3.2.2.1 1 <sup>st</sup> §	<p>The list of harmonised standards <del>of</del><b>published in</b> the OJEU is regularly updated and is available on the following ...</p>	OK
3.2.2.2 2 <sup>nd</sup> §	<p>In <del>many</del> <b>practical all</b> cases it <del>may be</del> <b>is</b> necessary to apply several harmonised standards to cover the complete ...</p>	is OK accepted many kept to reflect better the situation

3.2.2.3 last §	More complete explanations are provided together with the published OJEU list of harmonised standards and in CENELEC guide 25. <i>Do not understand the meaning of this sentence (maybe my fault!)</i>	Text modified
3.2.3 1 <sup>st</sup> §	<i>Editorial</i> ... own EMC assessment. The EMC assessment to be performed in this case has been called “Detailed technical EMC assessment” <sup>2</sup> for the purpose of this guide, in ...	<i>Use of English?</i>
3.2.3 2 <sup>nd</sup> § notes	... public enquiry or, if having passed this stage, still have to be formally adopted as EN standards and, <b>after the Commission decides so</b> , <del>then</del> have their references published in the OJEU before they can be considered giving presumption of conformity. Attention is drawn to the ...	Addition seems unnecessary
3.3	Documentation <del>for national authorities</del> required by the EMC Directive	Modified in documentation for competent authorities to distinguish <b>from ordinary documentation</b> , OK
3.3.1	As indicated in <b>Annex II.3 and Annex IV</b> of the EMC Directive ...	OK
3.3.1 last but one bullet point	... requirements – an EMC Assessment described in Annex II of the Directive- must be included. In addition to this detailed technical <u>EMC assessment</u> , <del>the manufacturer may include</del> <b>including</b> test reports, <b>results of design calculations made, examinations carried out, etc.</b> <del>and other documentation.</del> <i>The text of the directive (annex IV 1, 3<sup>rd</sup> bullet point leaves no choice!</i>	Text modified
3.3.1 new last §	<b><u>The EMC directive does not prescribe language requirements for the technical documentation. However, as stated in the Blue Guide, a national authority may request, for inspection purposes, a translation of the technical documentation into its official language. However, it should avoid doing so if the documentation is available in a language that can be understood by the national authority in question. If the authority considers a translation necessary, it must clearly define the part of the documentation to be translated and allow reasonable time for this to take place. No further conditions may be imposed on the translation, such as a requirement of a translator accredited or recognised by the public authorities.</u></b>	<b><u>The Commission will examine the legal problem of languages and translation</u></b> ***
3.3.2 after 1 <sup>st</sup> §	<i>Insert new paragraph</i> <b><u>A notified body can not sign the DoC as being empowered to bind the manufacturer. The notified body has to stick to his independence.</u></b>	<i>This part does not concern details on notified bodies</i>

3.3.2 after 1 <sup>st</sup> § after notes	Insert new §: <b><u>The identification of the apparatus should allow unambiguously linking between the EC Declaration of Conformity and the product.</u></b>	OK accepted
3.3.2 2 <sup>nd</sup> § after notes	In most case the dated reference to the specifications under which conformity is declared, will be the <b><u>dated</u></b> harmonised standards that are applicable to the apparatus in question as listed in the <i>OJEU</i> :-	Dated reference is sufficient dated standard is not a correct expression
3.3.2 3 <sup>rd</sup> § after notes	When harmonised standards are used partially only, the reference to the <b><u>dated</u></b> standards should be indicating which relevant sections/paragraphs of these standard have ...	Dated reference is sufficient dated standard is not a correct expression
3.3.2 new § after 3 <sup>rd</sup> § after notes	<b><u>It is possible that in the course of the production cycle of a product, revisions of the EC DoC have to be issued. This can e.g. be the case if a newer version of a harmonised standard is (to be) used (after the date of cessation of conformity of a superseded standard) or when the basic technical information for a product changes. This stresses the importance of dated references and of a dated EC DoC.</u></b>	<b><u>Accepted in principle for insertion into section for EC declaration of conformity</u></b>
3.3.2 last but one §	All information regarding the concept of making the DoC available for the authorities, as well as where to keep the DoC is given in <b><u>3.3.3.</u></b>	OK
3.3.2 last sentence of last but one §	<i>I can not find legal justification to request a DoC in one of the official languages of the Community – although the same text can be found in the Blue Guide. However the following is also mentioned in the Blue Guide “A national authority may request a translation of the technical documentation and the EC declaration of conformity into its official language.”</i> <del>The EC declaration of conformity must be drawn up in one of the official languages ...</del> <b><u>The EMC directive does not prescribe language requirements for the EC declaration of Conformity. As the EMC Directive does not require the apparatus to be accompanied by the DoC, a member state can not request it to be into one of his official languages However, as stated in the Blue Guide, a national authority may request, for inspection purposes, a translation of the EC declaration of conformity into its official language.</u></b>	<b><u>The Commission will examine the legal problem of languages and translation ***</u></b>
3.3.2 last §	<i>Annex 6 is not the correct reference</i>	<i>OK</i>

3.3.3 item 3	A failure to present the information within a reasonable period, in response to a <del>duly substantiated</del> request by the authority, constitutes an infringement of one of the administrative requirements of the Directive. <i>There is no provision in the directive that such a request should be “duly substantiated”, so this can not be imposed!</i>	OK
3.3.3 item 3, addition	... constitutes an infringement of one of the administrative requirements of the Directive. <u>This failure also causes serious doubt that a conformity procedure has been performed and especially if the electromagnetic compatibility assessment has been made. This can even lead to a decision to withdraw, prohibit or restrict the free movement of the apparatus.</u>	Existing text seems sufficient
3.3.3 add an item 6	<u>The manufacturer has to provide the documentation and can not use the argument that it contains confidential information (eg IPR’s). The manufacturer can directly send the information to the competent authority concerned. The authority must observe secrecy when treating the information.</u>	<u>Addition does not seem necessary</u>
3.4 3 <sup>rd</sup> §	... marks that are likely to mislead third parties in relation to the meaning of the CE mark, e.g. by giving the impression that they are needed in order to have free access to a Member State’s market or to fully meet the public interest objectives covered by the EMC Directive. However, for equipment under ... <i>I can not agree with the examples given – The CE-mark is required to have free access</i>	Seems clear enough
3.4.2 2 <sup>nd</sup> §	Although not explicitly mentioned this information needs to be on the apparatus (or its data plate). This will establish a link to the accompanying documentation where more information is given. <i>See no (direct) obligation in the directive to give more information on “type, batch, serial number, ...”</i>	OK
3.4.2 3 <sup>rd</sup> §	Specific apparatus intended for incorporated into a given fixed installations and otherwise not commercially available shall have this identification information in the accompanying documentation and need not have it on the apparatus. <u>For this specific apparatus the accompanying documentation must however provide additional information (see 4.4).</u> <i>The addition is necessary to make it clear that other documentation requirements apply for such apparatus.</i>	Not relevant in 3.4.2 for identifying marks
3.4.5 title and text	Title: ... compliance is not ensured with the protection requirements of <u>in</u> residential areas Text: ... for which compliance with the protection requirements of <u>in</u> residential areas is not wording of the directive	OK
3.4.5	... The EMC Directive requires that, where appropriate, the indication of restriction of use be also provided on the packaging. <i>Does “where appropriate” mean that if there is a packaging, the indications must be on this packaging?</i>	?????

#### 4. Procedures for fixed installations

4.1 2 <sup>nd</sup> §	<p><i>There is no need to explain why certain provisions of the directive are not applicable. Normally New Approach directive applies to “placing on the market and putting into use” (see Blue Guide 2.1 and 2.3.2). As fixed installations are at some time taken into use, all principles of such a directive could be applied. The EMC directive is an exception.</i></p> <p><i>The EMC directive does not mention “placing on the market or putting into service” in its scope (art 1.1). The aim is to “regulate the electromagnetic environment of equipment” .</i></p> <p><i>It is very important in the beginning of this chapter that fixed installation has to comply with the protection requirements!</i></p> <p><i>By their nature fixed installations will not be subject to the need for free movement within the European Community. Therefore they are not subject to the requirements for CE marking or the need for a declaration of conformity or for a formal EMC assessment before installation.</i></p> <p><b><u>It was considered appropriate not to apply all (administrative) requirements regarding apparatus to fixed installations. There is no requirement to CE mark a fixed installation, neither is there a requirement to draw up a EC Declaration of Conformity for a fixed installation.</u></b></p> <p><b><u>Fixed installations have however to respect the protection requirements and other specific requirements are applicable.</u></b></p> <p><b><u>Special measures are foreseen in the Directive to handle complaints about disturbances being generated by a fixed installation.</u></b></p>	Accepted (delete administrative)
4.1 4 <sup>th</sup> §	<p>.... The <b><u>specific</u></b> essential requirements described in Annex I of the EMC Directive specify that ... is in view of respecting the <b><u>essential</u></b> protection requirements which are expressed in an identical way for fixed installations as for apparatus.</p> <p><i>Also the protection requirements apply!</i></p>	OK
4.1 1 <sup>st</sup> § after notes	<p>Good engineering practice, particularly in the field of EMC, is in constant evolution. Therefore there is a need to ensure that ‘state of the art’ practices are used to meet the EMC Directive when a fixed installation is <b><u>being put into service-installed and operated.</u></b></p> <p><i>The directive mentions only “installed”, however article 13.2 has also to do with problems of the installation during operation, thus during the lifetime of the fixed installation. To avoid this, good engineering practices should be used on a continuous basis.</i></p>	Text modified
4.2	<p><i>Text incomplete!</i></p>	Completed in new <i>proposal</i>

4.4 after 3 <sup>rd</sup> §, new §	<p><u>An apparatus can only be considered as “specific apparatus” in the sense of article 13.1 of the directive if there is a direct link between the provider of that specific apparatus and the owner, installer, designer or responsible of the given fixed installation the specific apparatus is intended for. A relation provider – customer is required.</u></p> <p><i>As the directive speaks of “intended for incorporation into a given fixed installation”, there must be a predefined relation between the persons involved (provider – customer). If this is not taken into account, the notion “otherwise not commercial available” is lost. It must be clear beforehand were the specific apparatus is going to.</i></p>	<u>Accepted for addition</u>
4.4.4 <sup>th</sup> §	<p>... into a fixed installation. However some other additional information requirements apply (see 4.4.1). <del>This apparatus does not need to CE marked</del> <u>It is not allowed to appose the CE mark to this kind of apparatus to attest compliance with the EMC directive.</u></p> <p><i>In my view it is forbidden to CE mark such equipment based on the EMC directive.</i></p>	Accepted and reformulated
4.4.1 1 <sup>st</sup> §	<p><del>The manufacturer of the concerned specific apparatus shall indicate in the</del> <u>The accompanying</u> documentation <u>accompanying the specific apparatus shall indicate</u> the type, the batch, the serial number and any other identifying information as well as the name and address of the manufacturer and, if he is not established within the Community, the name and address of his authorised ...</p> <p><i>It is not stated in the directive that this is an obligation laid on the manufacturer.</i></p>	<u>Accepted</u>
4.4.1 after 1 <sup>st</sup> §, new §	<p><u>The accompanying documentation shall list the fixed installation for which the specific apparatus is intended and the electromagnetic compatibility characteristics of that fixed installation.</u></p> <p><i>This is a requirement stated in article 13.1, 2<sup>nd</sup> § of the directive.</i></p>	<u>accepted but ‘listing’ seems to go further than identifying (identifying is kept)</u>
4.4.1 2 <sup>nd</sup> §	<p><del>He shall f</del><u>Furthermore indicate</u> the precautions to be taken for the incorporation of the apparatus in order not to compromise the conformity of the given fixed installation <u>shall be indicated.</u></p> <p><i>It is not stated in the directive that this is an obligation laid on the manufacturer.</i></p>	accepted
4.4.2 2 <sup>nd</sup> §	<p>Apparatus designed according to a specific specification given by a potential client <del>for its own purposes;</del> intended for a fixed installation.</p> <p><i>“own purpose” does not directly mean fixed installation. This could open the door for improper use of this “exemption clause”</i></p>	accepted
4.4.2 3 <sup>rd</sup> §	<p>Apparatus derived from a generic apparatus adapted to the specific need of the client <del>for its own purpose</del> or to the specificity of any particular location, in a fixed installation.</p> <p><i>“own purpose” does not directly mean fixed installation. This could open the door for improper use of this “exemption clause”</i></p>	accepted

4.4.2 4 <sup>th</sup> §	Apparatus made in small series <u>for a client</u> and which need a special adaptation by the manufacturer for each specific fixed installation for which they are intended. <i>It is not mentioned in the directive that the adaptations should be made by the manufacturer. In my view it is probably the installer of the fixed installation who will make the specific adaptations. The direct link between the provider of the specific apparatus and the user is important.</i>	accepted
4.4.2 last §	Apparatus made in small series and delivered by the manufacturer for incorporation into a well defined type of fixed installations, each of them at the final location necessitating appropriate EMC adjustments by the user of the installer according to the instructions <u>accompanying the specific apparatus</u> of the manufacturer of the apparatus. <i>See above</i>	accepted

### 5. Enforcement of the directive

5 5 <sup>th</sup> §	.... The legal and administrative surveillance infrastructures can thus differ from one Member State to another. <u>However administrative cooperation between national authorities assures an equal approach and information exchange.</u>	Not necessary for the user
5.6 <sup>th</sup> §	No pieces of equipment will be excluded from surveillance operations, even if they have been subject to any voluntary certification scheme or other voluntary initiatives, or have been assessed involving <u>if the technical documentation has been reviewed</u> by a notified body. <i>The task of a NB is not to assess products, but to review the technical documentation.</i>	Text slightly modified
5 note	... checking if and how conformity with the essential protection requirements was achieved. <i>“protection requirements” is enough</i>	agreed
5.1 last § and Annex 6	<del>Some examples of special measures are detailed in Annex 6 To be deleted. It is not a good idea to give examples if similar provisions have never been used in the previous directive. These examples give the impression that the article should be used in these cases.</del>	OK annex 6 has been deleted
5.1 1 <sup>st</sup> §	<del>To be reformulated – propose to delete – no added value, second § explains the same thing! An exception to the principle that market surveillance can only take place after the manufacturer has taken formal responsibility for the equipment is the case of equipment being displayed and/or demonstrated at trade fairs, exhibitions and demonstrations.</del>	Seems useful explanation
5.2 2 <sup>nd</sup> §	... until it has been made to comply, and that adequate measures are taken during demonstrations, where appropriate, to ensure that <u>electromagnetic disturbances are avoided</u> radio communications, electrical supply and telecommunications networks, as well as equipment connected thereto, are protected against electromagnetic disturbances. <i>Stick to the text of the directive!</i>	Explanation given seems correct and useful (see whereas)

5.2 last §	<u>Market surveillance Competent</u> authorities will monitor that this obligation is respected and can take appropriate measures when this obligation is not followed by the persons responsible for the display and/or demonstration. This may include stopping any demonstration or having ... <i>It is not always the market surveillance authority who treats interference cases.</i>	OK
<b>6. Notified Bodies</b>		
6.1 3 <sup>rd</sup> §	... will verify the competence of the NB based on the <u>minimum criteria</u> given in Annex <del>IV</del> <u>VI</u> of the EMC Directive.: <i>Not Annex IV but Annex VI</i>	Ok
6.1 3 <sup>rd</sup> §	... at regular intervals by the Authority. The NB does not need to have any EMC testing capabilities, facilities or equipment but can be for example an engineering firm only operating with qualified consultants and without equipment. <i>I fully agree with the last statement. The task of a NB under this directive is to review the technical documentation provided by the manufacturer. The task of the NB is not to test equipment, neither to be involved with consultancy. It task is only to judge if the technical documentation properly demonstrates that the requirements of the directive have been met (see Annex III 3).</i>	OK
6.2 3 <sup>rd</sup> §	Only accept requests for <u>help assessment of the technical documentation</u> from manufacturers (in or outside the Community) or the manufacturer's ... <i>Help is suggestive (consultancy) and it is better to use the wording of Annex II 2</i>	OK
6.2 § 5 & 6	If the compliance of the apparatus is confirmed, issue a Notified Body statement (make link to example of NB statement) to the manufacturer <u>or the authorised representative. If the compliance of the apparatus is not confirmed, the NB will usually provide a negative response describing on what grounds the technical documentation of the apparatus fails to demonstrate compliance to the Directive. The manufacturer has thus the possibility to correct any failures.</u> The NB should only give a statement on those aspects of the essential requirements of the apparatus that have been assessed by the NB. The manufacturer shall add the statement of the NB to the technical documentation of the apparatus. <del>If the compliance of the apparatus is not confirmed, the NB will usually provide a negative response describing on what grounds the technical documentation of the apparatus fails to demonstrate compliance to the Directive. The manufacturer has thus the possibility to correct any failures.</del> <i>More logical structure. The last sentence is an obligation for the manufacturer, not for the NB. It does not fit in "The NB shall: "</i>	Modified to take into account
6.2 new § before note	<u>The role of the NB is limited. The ultimate responsibility for the compliance of an apparatus remains with the manufacturer even if a NB has been involved.</u> <i>To make it clear that the involvement and responsibility of a NB is limited.</i>	<u>Not necessary to insist</u>
6.3 1 <sup>st</sup> §	The EU Commission maintains a website list of all NB's <u>including the CAB's</u> , ...	OK

6.4	<p><del>Coordination between Notified Bodies.</del>  <i>This is not relevant for the Guide, propose to delete this item. The text refers also to “approved TGN’s”. These TGN’s have no legal binding value and are approved by who?</i></p>	Seems useful information
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### Annex 3 – Guidance on the application of harmonised standards in practice

	<p><i>The annex is not only on harmonised standards, but about the application of standards in general So the title should be changed:</i>  Guidance on the application of <del>harmonised</del> standards in practice</p>	<i>Put harmonised in brackets</i>
1 <sup>st</sup> §	<p>In declaring compliance to a given harmonised standard; the manufacturer takes full responsibility that all the EMC requirements <u>and limits</u> of the harmonised standard are fully respected. Requirements are expected <u>to</u> be met when the apparatus is tested to the standard <del>by market surveillance authorities.</del>  <i>Especially the respect of the limits imposed by the HS is of importance. No need to mention market surveillance authorities.</i>  <i>Maybe it is better to use the (slightly modified) wording of whereas 13 to replace this paragraph.:</i>  <b><u>Compliance with a given standard means that the manufacturer guarantees conformity of his product with the provisions of that standards and that this can be demonstrated by applying the methods (tests, measurements methods, ...) this standard describes or refers to.</u></b>  <b><u>If a harmonised standard whose reference has been published in the OJEU is used, the manufacturer enjoys presumption of conformity for the elements covered by that harmonised standard.</u></b>  <b><u>The use of harmonised standard should be the preferred way to demonstrate compliance.</u></b>  <i>This last sentences are necessary to stress the importance of the use HS.</i></p>	Text has been modified to take into account
2 <sup>nd</sup> §	<p><i>Reformulate:</i>  The most secure way for the manufacturer is to apply strictly, <b><u>without any deviation</u></b>, the <del>declared</del> standards <b><u>referred to</u></b>, relevant to its apparatus <del>without any deviation</del>. As most EMC standards include a series of tests with associated measurement methods, that implies in particular that all normative tests indicated should be done exactly as required by the standard with regard to test and measurement methods</p>	Text has been modified to take into account
a) b) c)	<p><i>No need to use this kind of numbering</i></p>	

New § to be added after c) eventually to be numbered d)	<p><u>In practice not all products of a series are tested against the harmonised standard. In most cases the manufacturer use a statistical method to verify the compliance with the harmonised standard or he opts to apply it as a type test on one item. The directive requires that each equipment fulfils the requirements.</u></p> <p><u>It must be clear that the manufacturer takes also a risk in doing so. If the manufacturer declares compliance against a harmonised standard, then each individual item placed on the market should fulfil the requirements of that harmonised standard. The manufacturer should take this into account when using measurement uncertainties. He should always put himself on the safe side.</u></p>	<p><u>Not accepted as sometimes standards include a statistical evaluation and this statement would contradict those standards</u></p>
Note	<p>The reassessment may in practice be limited to the modifications if any directly affecting the apparatus concerned. <u>This reassessment should be documented in the technical documentation.</u> Modifications or revisions in standards often concern only a small range of the apparatus ...</p>	<p>Section related to used and modified apparatus has been deleted in accordance with WP decision.</p>

#### Annex 4 – Detailed technical EMC assessment

	<p><i>In some parts of the text (“d”) under Immunity – Conducted low frequency phenomena and “a”) under Immunity – Radiated low-frequency field phenomena) it is stipulated that “this has to be indicated in the user documentation” .</i></p> <p><i>Is there a legal basis to require this?</i></p>	<p><i>It seems normal to request that</i></p>
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#### Annex 6 – Special Measures used in EMC enforcement

	<p><i>To be deleted: it is not a good idea to give examples if similar provisions have never been used in the previous directive. The examples give the impression that the article should be used in these cases (waking up sleeping dogs!). The explanation in 5.1 is enough.</i></p>	<p><i>This annex is deleted</i></p>
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#### Others

Article 14	<p><i>It could be helpful to foresee an explanation on the transitional provisions (article 14).</i></p>	<p><b>The Commission considers the matter ***</b></p>
Anex II 4	<p><i>Something should be said about the obligation to keep the technical documentation and DoC for at least 10</i></p>	<p><b>OK</b></p>

<p>&amp; 6 Annex II 8</p>	<p><i>years after the date on which the apparatus was last manufactured</i> <i>This requirement is, for the moment not mentioned in the Guide – see my proposal to insert an additional § in 3.1 after 1<sup>st</sup> § after bullets</i></p>	<p><i>OK added in section on documentation</i></p>
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