European
Diagnostic
Manufacturers
Association

Place St-Lambert 1'
1200 Brussels, Belgium
+32 2 772 2225 tel
+32 2 772 2329 fax
edma@edma-ivd.eu
www.edma-ivd.eu

Position Paper

Electro-Magnetic Compatibility (EMC) Directive 2004/108/EC

September 2005

IVD Medical Devices and the EMC Directives

BACKGROUND

1. At the time that the IVD directive was being developed in the 1990s, the original EMC Directive (89 / 336 / EEC) was already on the European statute book. However, it was decided that the IVD Directive should be a self-contained Directive (i.e. a "specific directive" within the meaning of Article 2.2 of that EMC Directive) so that the EMC Directive would not be applicable to IVD medical device electrical instruments. This meant including in the IVD Directive:-

   a) appropriate essential requirements covering relevant electromagnetic (EMC) aspects of those instruments. [These requirements were in fact included in Annex I, Part B, Section 6 of the Directive.] and

   b) an appropriate exemption for CE marked IVD medical device electrical instruments from the application of the EMC Directive. This was achieved by a combination of Recital 14 of the IVD Directive which states:-

"Whereas, since electromagnetic compatibility aspects form an integral part of the essential requirements of this Directive, Council Directive 89/336/EEC of 2nd April 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility does not apply."

and by Article 1.7 which states:-

"This Directive is a specific directive within the meaning of Article 2.2 of Directive 89 / 336 / EEC which shall cease to apply to devices which have complied with this Directive."

THE NEW EMC DIRECTIVE - (Directive 2004 / 108 / EC)

A new EMC Directive (Directive 2004 / 108 / EC) was adopted by the European Parliament and the Council on 15th December, 2004, and must be applied by Member States (i.e. it comes into force) on 20th January, 2007. Article 14 of this Directive provides for the repeal of the original EMC Directive as from 20th July 2007, but it also provides that:-

"References to Directive 89/336/EEC shall be construed as references to this Directive and should be read in accordance with the correlation table set out in Annex VII."

This means that when the 1989 EMC Directive is repealed on 20th July 2007, Article 1.7 of the IVDD will have effect as if it read:-

"This Directive is a specific directive within the meaning of Article 1 (4) of Directive 2004/108/EC which shall cease to apply to devices which comply with this Directive."

Thus, the IVD Directive will continue to be a "specific directive" for the purposes of the new EMC Directive when it comes into force so that that Directive will not apply to IVD medical devices that are correctly CE marked in

accordance with the IVD Directive when they are placed on the market.

For the sake of completion, it is to be noted that, while the new EMC Directive must be applied by member states as from 20th January, 2007, there is a transitional provision whereby member states must continue to accept the placing on the market and putting into service of equipment which was placed on the market before 20th July 2009 and which was in compliance with the provisions of Directive 89/366/EEC at the time it was placed on the market. These provisions have no relevance to IVD medical device electrical instruments that were or are CE marked when they were or are placed on the market because they are exempt from the application of both the old and the new EMC directives by virtue of Article 1.7 of the IVDD.

As regards EMC matters, the position of an IVD medical device electrical instrument can be summarised as follows according to the date that when it was placed on the market. If the IVD medical device electrical instrument was placed on the market:

⇒ prior to 7th December, 1998: since the IVDD was not then in force the instrument could not have been exempt from compliance with the EMC Directive (unless, of course, it was placed on the market before even that Directive had come into force).

[Note: If such an instrument was "fully refurbished", CE marked and then placed on the market subsequent to 7th December, 1998, it would be exempt from the scope of the 1989 EMC Directive as from the date that it was placed on the market after such refurbishment.]

⇒ after 6th December, 1998 and before 7th December 2003 then:

a) if it complied with the provisions of the IVDD and was CE marked at the time it was placed on the market, it would be exempt from the scope of the EMC Directive by virtue of Article 1.7 of the IVDD, or

b) if it was not CE marked and did not comply with the requirements of the IVDD at the time it was placed on the market, it would have had to comply with the rules in force in the territory of the various Member State(s) when and where it was placed on the market – and such rules would incorporate the national laws transposing the EMC Directive [i.e. it would not have been exempt from the transposed provisions of the EMC Directive]. If such IVD electrical instrument was subsequently "fully refurbished", CE marked and then placed on the market, it would benefit from the exemption contained in Article 1.7 of the IVDD.

⇒ on or after 7th December, 2003, then it must comply with the requirements of the IVDD at that time and therefore the provisions of the 1989 EMC Directive would not be applicable (Article 1.7 of the IVDD) nor, in due course, would the provisions of the new EMC Directive be applicable because Article 1.7 of the IVDD will be appropriately amended (see above) so as to exclude the application of the new EMC Directive.

Note:

1. Some manufacturers of IVD medical device electrical instruments may also manufacture or supply electrical instruments that fall outside the scope of the IVD Directive and such instruments would not be exempt from the existing or the new EMC Directive. Examples of such non-IVD instruments would be computers, printers and uninterruptible power supplies.

2. Reference to the harmonised standard relevant to electromagnetic compatibility and IVD medical devices.[1]

DEVICES FOR PERFORMANCE EVALUATION AND THE EMC DIRECTIVES

Both the existing and the newly adopted EMC Directive apply only to electrical instruments and equipment which are CE marked when they are placed on the market or put into service. In the terminology of the Directives, devices for performance evaluation are not "placed on the market" or "put into service" - they are "made available" to those carrying out the evaluation (Article 9.4 of the IVD Directive) – and so they are not within the scope of the EMC Directive.

However, Article 9.4 of the IVD Directive states that the conformity assessment requirement for making such devices available is set out in Annex VIII of the Directive. [There is also a specific labelling requirement in Annex I, Part B, Section 8.4 (f) to use the words "For performance evaluation only".]

Annex VIII requires the manufacturer of a device for performance evaluation (or his authorised representative) to draw up a statement containing specified information and to ensure that the relevant provisions of the Directive are met.

The manufacturer's statement must include a statement:

⇒ that the device in question conforms to the requirements of the IVD Directive apart from those aspects covered by the evaluation and apart from those requirements which are specifically itemised in the statement, and

⇒ that every precaution has been taken to protect the health and safety of the patient, the user and other persons. Directive or the manufacturer must specifically say in the required statement that the device does not comply with those requirements.

Thus, in the case of an IVD electrical instrument device that is made available for the purposes of performance evaluation in accordance with the provisions of the IVD Directive, provided that the manufacturer has fully complied with the requirements of Annex VIII both as regards the specified statement and as regards the action to be taken to protect the health and safety of patients, users and others, that device will have complied with the exemption requirements of Article 1.7 of the IVD Directive and, in consequence, neither the existing nor the new EMC directive will apply. Provided that Annex VIII has been fully complied with, such a device made available for performance evaluation will not (and, indeed, must not) bear the CE marking either to indicate compliance with the IVD Directive or with the existing or the new EMC Directive.

The implicit requirement in paragraph 2 of Annex VIII of the IVD Directive that every precaution must have been taken to protect the health and safety of patients, users and other persons when a device for performance evaluation is made available extends to include aspects of electrical safety and electromagnetic compatibility. In practice, this means that the manufacturer must ensure that any electrical equipment being made available for performance evaluation does in fact comply with the EMC requirements. And,

[1] EN 61326-2-6:2006 - Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2005).

in any case, evaluating laboratories and hospitals are virtually certain to make compliance with EMC requirements mandatory in order to protect their own instruments from interference. Moreover, it is in the manufacturer's own interest to ensure EMC compliance because interference from electrical equipment in the investigating laboratory or hospital may unexpectedly affect the results obtained in the evaluation study and thereby undermine the value of those results and the whole evaluation study.