MEDICAL DEVICES AGENCY
DIRECTIVES BULLETIN

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THE MEDICAL DEVICES, ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

INTRODUCTION

This information bulletin is the 15th in a series. It is about medical electrical devices which are liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbances. It outlines the transitional provision which apply to such devices by virtue of the Electromagnetic Compatibility (EMC) Directive and the Medical Devices (MD) Directive, and it sets out in general terms the choices available to manufacturers of such devices under these transitional provisions. The bulletin also indicates briefly the type of electrical equipment covered by the Low Voltage (LV) Directive.

THE ELECTROMAGNETIC COMPATIBILITY DIRECTIVE

The EMC Directive (89/336/EEC) is a general directive which provides for protection requirements governing electromagnetic disturbance emitted by a wide range of electrical and electronic apparatus. It came into effect in Europe on 1 January 1992. However, the EMC Directive provides that, where harmonised protection requirements are subsequently set for particular types of apparatus by product specific directives, then the EMC Directive ceases to apply to such types of apparatus when these other directives enter into force.

The EMC Directive has been implemented in the United Kingdom (UK) by The Electromagnetic Compatibility Regulations 1992 (**SI 1992 No 2372**). Whilst medical devices were excluded from the scope of these Regulations in accordance with the European Commission's Guidelines on the application of EMC Directive, *because it was expected that the Directives concerning those devices would be in place by this time,* they were brought within the scope of the EMC Regulations on 30 December 1994 by The Electromagnetic Compatibility (Amendment) Regulations 1994 (**SI 1994 No 3080**).

The EMC Directive, as amended by Directive 92/31/EEC, contains transitional provisions whereby apparatus covered by it may be placed on the market or put into service between 1 July 1992 and 31 December 1995 in accordance with national regulations in force on 30 June 1992. In the UK the national regulations which were in force on 30 June 1992 and are relevant in this case are the Wireless Telegraphy (Control of Interference from Electro-Medical Apparatus) Regulations 1963 (**SI 1963 No 1895**). These Regulations apply to a very limited range of electro-medical equipment.

THE MEDICAL DEVICES DIRECTIVE

The MD Directive (93/42/EEC) came into force on 1 January 1995. It has been implemented in the UK by The Medical Devices Regulations 1994 (**SI 1994 No 3017**). The MD Directive is a product specific directive for the purposes of the EMC Directive. Accordingly, the provisions of the EMC Directive ceased to apply to devices coming within the scope of the MD Directive as from 1 January 1995. However, the MD Directive and the MD Regulations provide that, during a transitional period from 1 January 1995 to 13 June 1998, manufacturers can choose to comply with national rules in force on 31 December 1994. By virtue of provisions in the EMC

Amendment Regulations the EMC Regulations come within the category of rules in force on 31 December 1994 for the purposes of the MD Regulations. Manufacturers may therefore choose to comply with the EMC Regulations until 13 June 1998. In addition, by virtue of provisions in the EMC Amendment Regulations, manufacturers may choose to comply with the provisions of the Wireless Telegraphy Regulations, where these apply, until 13 June 1998. In circumstances in which neither the Wireless Telegraphy Regulations nor the EMC Regulations apply to a medical electrical device, manufacturers may elect to follow the voluntary provisions of the Manufacturer Registration Scheme (**MRS**) where this applies.

Some devices, notably items of laboratory equipment such as centrifuges and analysers intended specifically for use with *in vitro* diagnostic (IVD) medical devices, are likely to fall within the scope of the EMC Directive until such time as a Directive concerning those devices comes into force.

In Summary, under UK Law

- From 1 January 1995 medical electrical devices which are active implantable devices must carry the CE marking in accordance with **SI 1992 No 3146** implementing the AIMD Directive.

- From 1 January 1995 until 14 June 1998, all medical electrical devices, other than equipment intended for use with IVDs, may;

  - be CE marked in accordance with **SI 1994 No 3017** implementing the MD Directive; **or**

  - be CE marked in accordance with **SI 1994 No 3080** implementing the EMC Directive, plus the MRS if it applies to the kind of device concerned and the manufacturer wishes to be included; **or**

  - comply with **SI 1963 No 1895** (the Wireless Telegraphy Regulations) if relevant, and otherwise only with the general provisions of Consumer Protection and Trades Description legislation, plus the MRS if it applies to the kind of device concerned and the manufacturer wishes to be included.

- From 1 January 1995 to 31 December 1995, medical electrical equipment intended for use with IVDs may;

  - be CE marked in accordance with EMC Regulations.

  Thereafter, such devices must carry the CE marking in accordance with those Regulations until such time as a product specific directive enters into force.

Where a manufacturer chooses to comply with the EMC Directive or the MD Directive during the transitional period just mentioned and he accordingly affixes the CE marking to a device, he should state clearly which Directive he has chosen to comply with in accompanying documents, notices or instructions.

THE LOW VOLTAGE DIRECTIVE

Directive 73/23/EEC concerning electrical equipment designed for use within certain voltage limits *(known as* **the low voltage (LV) Directive***)* covers equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current. It was implemented in the UK by The Electrical Equipment (Safety) Regulations 1994 (**SI 1994 No 3260**). The Regulations came into effect on 9 January 1995 and provide for a transitional period to 31 December 1996. The Regulations do **NOT** apply to equipment for radiology and medical purposes. Accordingly, the Regulations **WILL** apply to, for example, items of laboratory equipment such as centrifuges and analysers which have no specifically intended medical purpose.

FURTHER INFORMATION

Further information and copies of the earlier bulletins in the series about the Medical Devices Directives can be obtained from:-

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Further information about the EMC Directive can be obtained from:-

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151 Buckingham Palace Road
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Tel:(0171) 215 1411

Further information about the LV Directive can be obtained from:-

Mr Nick Winter
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10-18 Victoria Street
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