

Recent Developments in the Medical Devices Directive

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Changes in the MDD

With the full implementation date of the Medical Devices Directive (MDD) fast approaching (June 14, 1998), a reevaluation of the requirements of the MDD seems warranted. One might ask why what is already known should be restated. The answer is that the number of changes that have occurred over the past few years and the colossal amount of misinformation floating about are signs that a review of the requirements might be useful.

A commonly heard rumor is that the European Commission has extended its requirements to the year 2001 for devices already shipped to, but not sold in, the EU. In other words, it applies to medical device manufacturers who have their products on the shelves in Europe before June 14, 1998. The truth of the matter is that this extension has only been *proposed* by the European Commission; the Council of Ministers has not agreed to this as of yet.

The European Commission has heavily criticized several EU member states who have not enforced other New Approach Directives, and has threatened to fine countries who do not enact these directives. Taking this into account, a medical device manufacturer would be wise to not underestimate the enforcement of the Medical Devices Directive. In fact, for many reasons, the MDD may be more heavily enforced than past New Approach Directives.

Why? For one, the Competent Authorities of each member country are in charge of regulating and enforcing the MDD. Unlike other directives that have not had the resources to actively enforce themselves, the Medical Devices Directive does. The MDD's Competent Authorities are made up of old regulatory authorities for medical devices who are used to assessing and regulating medical devices.

The UK's Competent Authority (the Medical Device Agency) has already started looking at Class I medical devices. In a recent report issued by MDA, a "large proportion" of those claiming compliance were not entitled to do so due to lack of knowledge and poor advice. What the MDA found was that many of these Class I device manufacturers did not have technical files showing compliance to the Essential Requirements of the directive, nor did they have Post Market Vigilance systems in place. Unfortunately, a common misconception is that manufacturers of Class I products only need to issue a Declaration of Conformity, a self-declaration and nothing else. This is not true. All medical device manufacturers meeting the MDD, regardless of which class their products fall into, need to:

- Meet the Essential Requirements of the Directive
- Establish a Post Market Vigilance system
- Meet the requirements of their chosen route to compliance
- Conduct risk analysis

The UK's MDA is not the only Competent Authority looking at the companies claiming compliance now and not waiting until June of 1998. Others are starting to position their review functions and processes. The only possible threat to the reasonably smooth introduction of the MDD comes from the French Government. They are threatening to amend legislation in an attempt to increase controls on high risk (Class III) medical devices. If this is an attempt by the French to raise the standard and level of control on these high risk devices, one can only applaud the objectives although not the method. On the other hand, if it is a political move to protect the French market, there is need for concern.

The point of CE Marking is to harmonize regulatory requirements throughout the EU. This harmonization also includes the levels and uniformity of assessments conducted by Notified Bodies. If the European Commission allows the French to increase their standard for assessments, other countries will follow suit and the single market for medical devices will no longer exist.

MRA

This would have serious consequences on the Mutual Recognition Agreement (MRA) between the United States and the European Union, another topic that is increasingly interesting to medical device manufacturers. The MRA was initiated on June 20, 1997 after more

than 4 years of negotiations between the EU and the U.S. The MRA is expected to be officially signed in 1998.

The MRA addresses the conformity assessment process for many business sectors—the medical device industry being one of them. This could have a big impact on a manufacturer's regulatory process. Although the MRA covers medical devices, not all medical devices are included. For instance, only Class I devices and a limited number of European Class IIa devices are covered by the MRA. However, others may be added during the 3-year transitional period.

If the MRA is signed, both the EU and the U.S. would have a group of Conformity Assessment Bodies (CABs) who will, in a sense, serve as Competent and Notified Bodies in the U.S. and the EU. What this means is that medical device manufacturers of these Class I, and some Class IIa products, who are shipping to the EU could go to a CAB in the *United States for European approval*. However, there will be a three- to four-year transition period before CABs will be able to legally assess products. In the meantime, medical device manufacturers should continue the compliance route in accordance with the EU's Medical Devices Directive and the U.S.'s FDA Quality System Requirements (QSRs).

MDD Requirements

What is required for meeting the Medical Devices Directive? Like all New Approach Directives, the MDD requires that medical devices comply with a set of essential requirements relating to performance, health and safety. Although the Directive does not specify which standards have to be met, standards are the best way of demonstrating compliance. Testing such as EMI and electrical safety testing (for active devices) is necessary.

EMC is, of course, covered by directive 89/336/EEC. This directive has been mandatory since January 1, 1996 and all products which fall within its

scope, including electro-medical devices, must comply with its provisions. However, Article 2.2 of this directive exempts those products which comply with specific directives in force by making complete provision for EMC. The MDD is such a directive, which means that up until the date of its mandatory enforcement on June 14, 1998, electro-medical devices must either comply and be certified to the MDD or to the EMC directive. After June 14, 1998, such medical devices must comply solely with the MDD. The EMC requirements expressed in the MDD are described here.

Devices must be designed and manufactured in such a way as to remove or minimize as far as possible risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge etc. and risks of reciprocal interference with other devices normally used in the investigation or treatment given.

(Annex 1, clause 9.2)

Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.

(Annex 1, clause 12.5)

Compliance with these essential requirements must be demonstrated in the Technical File. The standard EN 60601-1-2:1993 is published and available for this purpose. This standard calls up the IEC 801 basic standards for immunity to radiated fields, ESD, burst

transients and surge and CISPR 11 for emissions.

Great care must be taken if this standard is to be used, however, as there is a second edition in draft which will introduce significant changes. These involve the use of the IEC 1000 series of immunity standards and the addition of tests for conducted RF immunity, power frequency magnetic field and voltage dips, variations and interruptions. Also, harmonic emissions and fluctuations will need to be measured in line with IEC 1000-3-2 and IEC 1000-3-3.

The second edition also introduces the concept of "clinical utility" for determining failure criteria and generally requires higher levels to be applied. Anyone intending to use the current standard now for compliance must be prepared for possible retesting when the proposed second edition is published. They may also be jeopardizing the ability to earn the CE marking and supply of a device which does not in fact comply with the essential requirements by virtue of the recognized inadequacies in the standard. The way around this is to test to the draft second edition and for extra insurance, have an EMC competent body verify the results. This way, the manufacturer and the notified body assessing the device will be confident that the device meets the essential EMC requirements.

In addition to meeting the Essential Requirements found in Annex I of the Directive, a manufacturer must then choose the appropriate compliance route based on the product classification. In order to classify a product correctly, a manufacturer can look at the Classification Rules outlined in Annex IX. It is very important for the manufacturer to bear in mind that it is the *intended*

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manufacturers will no longer be able
to sell their product into Europe after
June 14, 1998.*

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purpose of the product and its potential risk to patients, users and others that determine the classification.

Once the classification has been determined, the appropriate route of conformity can then be followed. For example, manufacturers of Class IIa devices have the choice of either following Annex II, a full quality assurance audit of EN 46000 by a Notified Body *or* Annex VII, the EC Declaration of Conformity, along with either Annex V, Annex VI or Annex IV to show continuous compliance. In many cases, manufacturers have opted to follow Annex II since, for their type of company, it is more cost-effective and less time-consuming. Companies without design function are following both Annex VII and Annex V. Manufacturers who follow Annex IV, Product Verification by Notified Body (batch testing), are generally manufacturers who do not produce large quantities of devices. They may produce a couple of very large and expensive medical systems only a couple of times a year.

The last step, of course, is the CE Marking. Without this CE Marking, manufacturers will no longer be able to sell their product into Europe after June 14, 1998. This CE Marking should be placed on the device or its packet, on the instructions for use, and if applicable, on the sales packaging.

The Future

As June 14, 1998 draws near, it should be very interesting to see what happens. Will manufacturers meet the MDD in time and correctly? Will there be new medical standards that have superseded old medical standards? If so, will manufacturers test or retest to these new standards? What progress will have been made with the Mutual Recognition Agreements? Will there be alarming cases of enforcement officials pulling products off the market for noncompliance? Only time will tell. Let *none* of us wait until June 1998 to find we are not in compliance.

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