The re-cast of the NAWI and the MI Directive

There is an important review of both of these directives to bring them into line with what is known as the New Legislative Framework. More details on what this is can be found at:

http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/

The important point to note is that this review will have no practical affect on the essential requirements of both directives. The technical obligations that you must meet will remain the same.

The important differences will relate to new administrative requirements for categories of businesses that had not previously had explicit obligations under the Directives.

The new directives will create four groups of businesses.

- Manufacturers; these are any natural or legal persons who manufacture an instrument or has an instrument designed or manufactured, and markets that instrument under his name or trademark.

- Authorised representatives; means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

- Importer means any natural or legal person established within the Union who places an instrument from a third country on the Union market

- Distributor means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an instrument available on the market;

All of these together are known as “economic operators”.

The first two categories of manufacturer and authorised representative exist already, but the second two are new and you will need to prepare for the changes that the new directives will bring.

The obligations for manufacturers and authorised representatives will be largely the same as the existing obligations, except for one important change below.

Manufacturers must ensure that an instrument must be accompanied by instructions and information in a language that can be easily understood by consumers and other end users, as determined by the member state concerned.

If you supply instruments across all of the member states, this could end up being a large number of languages and a failure to do so may mean the instrument is not in compliance with the directive. This in turn would create obligations on other economic operators to supply this material

If you fall into the category of an importer or a distributor you will need to be aware of the following:

- You will need to ensure that the appropriate conformity assessment procedures have taken place, that the appropriate technical documentation has been drawn up, and the instrument is accompanied by the required documents.

  It is felt that as an importer or distributor you will have a positive obligation to ensure that these documents have been completed. It is likely that the easiest way to demonstrate this will be to have these documents on your own files. This will mean that you must get the documents form the authorised representative or manufacturer and make them available to the authorities on request.

- If you consider, or have reason to believe, that an instrument is not in conformity with the essential requirements you shall not place the instrument on the market until it has been bought back into conformity. It is clear that the directive makes this your responsibility not that of other economic operators further up the supply chain.

- If the contravention represents a risk, you must inform the manufacturer and perhaps more importantly the market surveillance authorities. It is not clear at the moment what level of contravention would represent a risk and it is hoped that guidance will be issued on this.

- If you are an importer (and not the manufacturer) you will need to mark the instrument with a name, registered trade name or registered trade- mark. This would result in the instrument having both the manufacturer and the importers name and address on the instrument. It would be important for each to be clearly distinguished.

- If you are an importer you shall carry out sample testing if deemed appropriate with regard to the performance of the instrument. This obligation has some concerns, as it is not clear who shall decide if the need to carry out tests is appropriate and it is not clear what the phrase “the performance of an the instrument” may mean. It is not clear whether this would relate just to accuracy or may include such things as EMC Immunity. It is hoped that guidance will be issued on this.

There are a number of other changes to the directives which will have a less direct effect on the operation of economic operators. The other document looks at some of these in more detail.

If you have any further questions please do not hesitate to contact me.

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