Directive 2014/31/EU on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments

Introduction

The "New legislative framework"(The NLF) was adopted in 2008 and was intended to help the internal market for goods work better and to strengthen and modernise the conditions for placing a wide range of industrial products on the EU market.

The Directive 2014/31/EU (The NAWI Directive) is part of a package of 8 Directives that have been recast to meet the requirements of the NLF. The changes are of an administrative nature and the technical requirements remain the same.

The Directive contains requirements for economic operators, conformity assessment bodies and market surveillance authorities. These notes only look at the changes that businesses will need to consider.

There are four categories of economic operator created by the Directive and each type of operator will have new and clearer obligations depending upon their position in the supply chain.

Manufacturer - Importer

A manufacturer is any legal or natural person who manufactures an instrument or has an instrument designed or manufactured, and markets that instrument under his name or trademark. Importers are those businesses that are first making an instrument available on the market or putting it into service within the EU.The definition of manufacturer is now much clearer and it does not need to be the owner of the type approval

There are a number of new obligations that both the manufacturer must have positive process in place to ensure compliance with the requirements.

Markings –name and address

The instrument must now be marked with the name, registered trade name or registered trademark **and** the postal address. The requirement for the postal address is new. The address must be single point at which the manufacturer or importer can be contacted, so the name and address of national agents in other member states will not be acceptable.

The other extra burden with these requirements is that end users must in a language easily understand it, so it is very likely that different languages will be required for this information.

The obligation for importers is slightly different in that the information can be given on packaging **and** accompanying documents if the only reason that the importer has to open the packaging will be to apply the information.

Markings- CE Mark and supplementary metrology marks

The requirements for the CE mark are not changed and these can be found in the Regulation 765/2008.

The M mark is no longer the same as the existing NAWI Directive. The green M will go and it will become a letter M and the last two digits of the year in which it was affixed, surrounded by a rectangle at least 5 mm high.

It is the rectangle that must be 5mm high and there are no requirements for the size of the M or the last two digits of the year in which it was affixed, which can be any size as long as they are visible, legible and indelible

It is also important that the last two digits of the year in which it was affixed relate to the affixing of the M mark and not the date when the instrument was made available or put into service.

The CE and the other supplementary metrology marks must be placed on the instrument before it is placed on the market, the supplementary marks must immediately follow the CE mark and identification number (the notified body number) must follow these marks.

The Declaration of Conformity

The format for the Declaration of Conformity can be found in Annex VI and this should be followed. There should only be one Declaration of Conformity for all relevant directives.

This requirement will clearly create some problems when an instrument is made available or placed on the market at the different times; i.e. it is finished for the purposes of the Low Voltage or the EMC Directive, but is calibrated for gravity or verified at a later date. The requirements of the directive recognise this and allow for the single EU Declaration of Conformity to be a dossier made up of relevant individual declarations

This is an important point, as it will allow for flexibility for the businesses that must maintain this documentation, but are not responsible for drawing it up.

As with all of the other requirements, the declaration of conformity must be in a language of the member state where the instrument is made available or placed on the market. This will probably mean that you will need to have these declarations translated into the language where your instruments are made available or placed on the market

Instructions, information and technical files

The manufacturer or importer must ensure that the instrument is accompanied by instructions and information in a language which can be easily understood by end users in the member state in which it is made available or placed on the market.

If a manufacturer or importer receives a **reasoned** request from an enforcement authority, they must provide **all** of the information necessary to demonstrate conformity with the instrument in a language, which can be easily understood by that authority

This requirement may turn out to be very onerous, as the entire technical file may need to be provided in the language of the member state making the request.

Language requirements

As we have seen from above. The following information must be in a language that can be easily understood by end users as decided by the member state in which the instrument is made available or placed on the market.

- The name and postal address of the manufacturer and importer.
- The Declaration of Conformity
- The instructions and information
- If required from a reasoned request by a competent authority, the technical files

Other requirements-Manufacturers

Manufacturers must have procedures to ensure that production remains in conformity with the requirements of the Directive.

When **deemed appropriate** with **regard to the risks** presented by the instrument they shall carry out sample testing of the instrument and if necessary keep a register of complaints, of non-conforming instruments **and keep distributors informed of any such monitoring**. It is assumed that the majority of manufacturers will be carrying out appropriate testing but the obligation to keep distributors informed is a new one.

Depending upon how this obligation is interpreted this could be an onerous obligation and manufacturers should be putting procedures in place to ensure that distributors can be informed of any such monitoring. Although the obligation only applies to distributors it is felt that the same information should be supplied to importers where relevant

If the instrument has already been placed on the market and the manufacturer believes that it may not be in conformity with the Directive they shall ***immediately*** take corrective measures to bring the instrument back into conformity. This could have far reaching implications for the control of software. If, for example, a manufacturer believes that security patches are necessary it appears they should supply these immediately.

If the manufacture believes the non-conforming instrument presents a risk they must also notify the competent national authority.

Other requirements –Importers

The other requirements for importers are slightly different from those of manufacturers.

An importer must ensure that the correct conformity procedures have been followed and that the manufacturer has drawn up the appropriate technical files and applied the correct markings. This will involve a process or procedure to demonstrate that these checks have been made.

If the importer considers or has reason to believe that an instrument may not comply with essential requirements they shall not place the instrument on the market until it has been bough back into compliance and shall inform the manufacturer **and the market surveillance authorities.**

The obligation to tell the market surveillance authorities is significant and may be onerous depending on how this is implemented in practice.

If the instrument has already been placed on the market, the obligations with regard to potentially non-complaint instrument are the same as the manufacturer above.

Obligations of distributors

A distributor is any person who is not the importer or manufacturer who makes an instrument available on the market. This will create specific obligations for many businesses that were not specifically included previously

The distributor must undertake the following actions and have procedures and evidence to support that they have completed them.

- They must take due care in relation to the requirements of the

Directive

- Before making an instrument available on the market they must verify that all of the markings and all the required documentation is with the instrument
- They must confirm that the manufacturer or importer have met their obligations
- If distributor has reason to believe that an instrument that they intend to supply is not in conformity with the Directive they shall not make it available on the market until it has been bought back into conformity
- If the instrument presents a risk they shall inform the manufacturer, importer **and the market surveillance authorities. This is a new and potentially onerous obligations**
- If the distributor believes it is not in conformity and it has already been supplied, they shall take corrective measures to bring it into conformity. **If it presents as risk they shall inform the competent national authority**

If an importer or distributor places the instrument on the market under his own name or modifies an instrument already placed on the market they will be considered to be the manufacturer.