UKWF Technical Webinar – 24 November 2021

A Guide to additional legislation for Scale Manufacturers and Importers

Today's webinar…

Today we're discussing the additional regulations and obligations that scale manufacturers and importers should follow to ensure they are fully compliant with the Non-automatic Weighing Instrument Regulations 2016, and the Measuring Instrument Regulations 2016

In this session we will be discussing:

- The obligations of manufacturers and importers
- Regulations that manufacturers and importers of weighing instruments will need to comply with beyond the Non-automatic weighing Instruments
- Requirements for meeting the Electrical Safety Regulations 2016, the Electro-Magnetic Compatibility Regulations 2016 and the Restrictions of Hazardous Substances Regulations 2016, plus some of the harmonised standards behind these Regulations
- The principles of the Medical Devices Regulations as part of the Supply Machinery Regulations (Safety) Regulations 2008, including how they are affected by BREXIT and when you may need to consider using them
- ATEX Requirements and the Radio Equipment Regulations

Manufacturers

You are considered a manufacturer if your business…

- Manufactures a non-automatic weighing instrument
- Has a non-automatic weighing instrument designed or manufactured and markets that instrument under their name or trademark
- If you buy and sell weighing instruments from suppliers in the EU27 or the Far East
- If you place the instrument on the market in your own name or modify a weighing instrument

Remember the manufacturer does not need to be the person who assembles the instrument, it can also be the business that re-brands the product.

Your obligations as a manufacturer

As a manufacturer, you need to ensure that you…

- Have designed and manufactured the instrument in accordance with the essential requirements
- Draw up technical documentation in relation to the instrument
- Carried out (or procured the carrying out of) the relevant conformity assessment procedure which demonstrates compliance of the instrument with the applicable requirements
- Drawn up a declaration of conformity and affixed the relevant markings to the instrument

Remember the manufacturer does not need to be the person who assembles the instrument, it can also be the business that re-brands the product.

Importers

You are considered an importer if your business…

- Is placing (or putting into service) weighing instruments on the market in GB
- Your business is established in the UK and places a non-automatic weighing instrument on the market in the UK that has come from a country outside of the UK
- Many UKWF members that where previously distributors are now importers

Your obligations as an importer

As an importer, you need to ensure that you…

- Have the appropriate conformity assessment procedure, which has been carried out by the manufacturer of the regulated non-automatic weighing instrument

- The manufacturer has drawn up the technical documentation

*This will relate to all relevant regulations for that specific non-automatic weighing instrument

Other relevant Regulations

As a UKWF business, it is likely that you will be either a manufacturer or an importer for a wide range of directives, including…

- Electromagnetic Compatibility Regulations 2016 (as amended) (Different for the GB and NI)
- Electrical Equipment (Safety) Regulations 2016 (as amended) (Different for the GB and NI)
- Restrictions of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (as amended) (Different for the GB and the NI)

You may also be a manufacturer or importer for the following…

- Supply of Machinery (Safety) Regulations 2008 – will invariably apply to Automatic Weighing Instruments
- Equipment and Protective Systems Intended for use in Potentially Explosive Areas Regulations 2016 – ATEX
- Medical Devices Regulations 2002 (For GB) - This will cover weighing instruments used for medical purposes (Medical Devices Regulations 2017/745 apply in NI)

Markings from the 1 January 2023

Compliance will be demonstrated by the application of the UKCA mark for the following Regulations…

- Electromagnetic Compatibility Regulations 2016
- Low Voltage Regulations 2016
- RoHS Regulations 2012
- Machinery Regulations 2008
- Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016

*Note - Medical Devices has a separate legislative framework

How will compliance be demonstrated?

Declaration of Conformity

- A formal declaration by a manufacturer, or the manufacturers representative, that the product meets all the relevant requirements and product safety directives applicable to the products
- Must include a reference to the designated standards that have been used to show compliance

Technical File

- This represents a set of documents that demonstrate the conformity of a product with the UKCA marking legislation

What should go in the technical file?

- ✓ Your name and address, or those of any authorised representatives
- ✓ A brief description of the product
- ✓ Identification of the product, for example, the product's serial number
- ✓ The name(s) and address(es) of the facilities involved in the design and manufacture of the product
- ✓ The name and address of any approved body involved in assessing the conformity of the product
- ✓ A statement of the Conformity Assessment
- ✓ The EU declaration of conformity
- ✓ Label and instructions of use
- ✓ A statement of relevant regulations for the product
- ✓ Identification of technical standards
- ✓ List of parts
- ✓ Test results

Manufacturers - who should have the technical file?

- The manufacturer must issue the Declaration of Conformity
- The manufacturer must draw up and maintain the technical file
- Modify an instrument such that the compliance will be affected you will be the manufacturer
- Must be maintained for 10 years and updated
- Will need to cover all relevant regulations
- If you place the instrument on the market in your own name
- This will be new for many UKWF Members who where previously distributor

Importers - who should have the technical file?

- A person established in the UK and places a non-automatic weighing instrument from a country outside of the UK on the market in the UK
- If you are not the manufacturer and are first placing it on the market, then you will be the importer
- Must mark your name and address
- Must ensure that appropriate conformity assessment procedures have taken place
- The manufacturer has drawn up the technical documentation
- The instrument bares the appropriate markings
- This will affect many UKWF members who where previously distributors

Specific Requirements - Electromagnetic Compatibility Regulations 2016

- These will relate to all electrical and electronic equipment which is likely to generate an electromagnetic disturbance
- Exempted is equipment which is incapable of generating electromagnetic interference that is harmful to radio and telecommunication equipment – likely to cover analogue load cells
- There are a range of designated standards
- https://www.gov.uk/government/publications/designated-standards-emc

Specific Requirements - Electromagnetic Compatibility Regulations 2016

- The commonly used standards are the EN61000 which are the generic EMC standards
- The manufacturer can ‘self declare’ compliance with the EMC Regulations if they have sufficient confidence in the technical files that are maintained
- These regulations will only apply to emissions requirements
- The immunity requirements are in the EN45501, which must be done by a third party

Specific Requirements – Electrical Equipment (Safety) Regulations 2016

- These will relate to all electrical equipment designed for use between 50 and 1000v AC and 75 1,500 volts DC
- This would exclude any instruments that are only battery operated
- There are a range of designated standards
- https://www.gov.uk/government/publications/designated-standards-low-voltage

Specific Requirements – Electrical Equipment (Safety) Regulations 2016

Commonly used standards are:

- EN 61010:2010 Safety Requirements for electrical equipment for measurement control and laboratory use - General Requirements
- EN 61149:2002 Protection against electric shocks - Common aspects for the installation of equipment
- The manufacturer can ‘self declare’ compliance with the Electrical Equipment (Safety) Regulations if they have sufficient confidence in the technical files that are maintained

Specific Requirements – UK Restrictions of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

- These regulations cover all Electrical and Electronic Equipment
- The list of controlled substances are regularly updated and changed –and you must keep up-to -date with these changes
- Exemption for large scale fixed installations - likely to include weighbridges and fixed platforms
- The harmonised standard is EN IEC 630000:2018
- https://www.gov.uk/government/publications/designated-standards-rohs

Specific Requirements – Machinery Regulations 2008

- Automatic Weighing Instruments
- Some differences with the other regulations
- Responsibility sits with a ‘responsible person’- this will equate to the manufacturer or the importer
- A range of different conformity assessment routes
- If the instrument is manufactured in accordance with the relevant designated standards compliance can be demonstrated with internal checks on the manufacture of machinery

Specific Requirements – Machinery Regulations 2008

- This is effectively ‘self declaration’
- Must have a UKCA mark and go on the Declaration of Conformity
- Wide range of designated standards depending upon the type of machine
- https://www.gov.uk/government/publications/designated-standards-machinery

Specific Requirements – The Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres Regulations 2016

- Generically known as ATEX
- Will require a Declaration of Conformity (or an attestation Conformity for components)
- Will need to apply UKCA marks
- Wide range of conformity assessment procedures. Contact - Geoff Botterill, who is an ATEX expert

Specific Requirements – Medical Devices Regulations 2002

There is a confusing relationship between NI and GB legislation

An instrument used for human beings for the purpose of…

- i) diagnosis, prevention, monitoring, treatment or alleviation of disease
- (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- (iii) investigation, replacement or modification of the anatomy or of a physiological process
- (iv) control of conception

Specific Requirements – Medical Devices Regulations 2002

- Weighing Instruments will be categorized as a class 1 Medical Device
- Manufacturers of Class I medical devices can self-declare their conformity against the UK MDR 2002 (as amended), before affixing a UKCA mark and placing the device on the Great Britain market
- Class I medical devices that are sterile or have a measuring function require approval from a UK Approved Body in order to be affixed with the UKCA mark and placed on the Great Britain market
- It is generally agreed that the approval for the MDR will be a type examination certificate
- Class 1 Medical Devices must be registered with the MHRA from the 1 January 2022 if they are being placed on the market in the GB

Conclusion

- We obviously spend a lot of time and resources on compliance with the NAWI Regulations and the Measuring Instruments Regulations
- Compliance with these other regulations are just as significant as compliance with the weighing regulations
- Often compliance with regulations is very expensive
- Remember - many businesses that were previously distributors are now manufacturers and distributors
- There are as many new obligations as both the status of manufacturers and importers
- There are different obligations for NI