



National
Measurement &
Regulation Office

Technical Briefing Note

**For the Introduction of new weighing and measuring instruments
European Directives on 20th April 2016**

(Version 2)

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1 Introduction of new weighing and measuring instruments European Directives on 20th April 2016

The current European Directives [2009/23/EC](#) for non-automatic weighing instruments (NAWI) and [2004/22/EC](#) for measuring instruments (MID) will be replaced on 20 April 2016 by European Directives [2014/31/EU](#) and [2014/32/EU](#) respectively, as part of the "[New legislative framework](#)".

These new Directives implement the text of EU Decision No [768/2008/EC](#) and make reference to Regulation (EC) No [765/2008](#) on accreditation and market surveillance.

The current UK regulations relating to NAWI and MID instruments will be replaced by two new regulations on 20th April 2016. The existing regulations relating to MID instruments will be consolidated into one omnibus regulation. Access further information, including the draft legislation, on [European Union \(EU\) measuring instruments framework](#).

All instruments placed on the market after 20th April 2016 will have to comply with the requirements in the new Directives and Regulations.

No changes have been made to the scope or the essential requirements and therefore this alignment measure does not affect the presumption of conformity on which harmonised standards and normative documents are based.

The permitted choice of conformity assessment modules are unchanged, however the language may differ in some ways to the current Directives (the NAWI Directive now uses the Global Approach B, D/D1, F/F1 and G).

2 The main changes and implications

- clearer definition of Economic Operators (manufacturers, authorised representatives, importers and distributors) and their obligations
- introduction of analysis and assessment of the risk(s)
- accredited in-house bodies may be used for conformity assessment modules A2 and C2
- improved traceability and co-operation with Market Surveillance authorities
- structure and content of the Declaration of Conformity now described in specific Articles and Annexes
- NAWI conformity markings now in line with the current MID markings: Green M replaced by M followed by the last two digits of the year of affixing, surrounded by a rectangle
- NAWI Directive harmonised standard will become EN45501:2015 (with EN45501:1994 withdrawn on 20th April 2016) – EC Type Approval Certificates will remain valid, but additional testing and examination may be required when the certificates are renewed or revised
- manufacturer's (and importer's when applicable) full address must appear on the instrument
- importers and distributors can become the manufacturer if they place an instrument on the market under their name or modify an instrument already placed on the market
- under the requirements of the new Directives all Notified Bodies are required to be re-notified

NMRO, operating as the Member State, will be contacting the UK Notified Bodies. The re-notification process will be taking place prior to the legislation being implemented – with the re-notification becoming effective on 20th April 2016.

3 Required actions for organisations with Type Examination certificates issued by NMRO

Note: This section has been revised since first publication

The EU Commission have confirmed that all type examination certificates issued under Directive 2004/22/EC (MID) and 2009/23/EC (NAWI) will remain valid.

No action is needed by manufacturers.

There have been some questions posed around this issue. NMRO will address these in the next Technical Briefing note.

Should you have any questions please contact [Grégory Glas](#).

4 Required actions for organisations certified to conformity assessment modules D, D1, E, E1, H and H1 issued by NMRO

Organisations certified to conformity assessment modules D, D1, E, E1, H and H1 will be required to submit a written confirmation to NMRO that their Quality System has been transitioned to the new requirements.

Please include with this correspondence the following information;

- a description of any changes made to the Quality System
- supporting evidence

Please use the gap analysis documents for [NAWI](#) and [MID](#), to assist you in identifying the relevant requirements and determine the changes involved to ensure compliance to the new Directives.

The submission should be made electronically, by the 18th April 2016 to [NMRO ACB](#) with the title: "**Confirmation of transition**".

We strongly advise you to submit your confirmation to us **by 25th March 2016**, so that there is time remaining to resolve any issues identified at the review.

There will be a charge of £95 for the review of the submission. This will be invoiced after the review is completed. There may be additional charges for additional review time should any significant issues be identified.

Should you have any questions please contact [Max Linnemann](#).

5 The following Gap Analysis documents provide a detailed analysis of the changes and implications for Economic Operators and Notified Bodies:

[NAWI gap analysis](#)

[MID gap analysis](#)



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