

Simpler and more transparent methods of software control needed

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Software requirements for automatic and non-automatic weighing instruments are part of the essential requirements of the NAWI and the MI Directive. To be in line with the New Legislative Framework these requirements are very generic in nature.

Further details are included in WELMEC Guides (2.3 for NAWI and 7.2 for automatic weighing instruments) and the relevant harmonised standards and normative documents. These offer technical solutions to ensuring compliance with the essential requirements of the Directives.

Current guides complicated and not futureproof

These guides have developed in a piecemeal nature with extra requirements being added to existing obligations. Adding extra requirements with every revision has, unfortunately, led to an overly technical and complicated set of requirements that are open to inconsistent interpretation in different Member States. This in turn has made it difficult for manufacturers to evaluate software to ensure that it will meet the requirements of type approval processes.

Improved methods of software control have major advantages

New innovations within weighing instruments have significant benefits for society and industry. However, the increasing divergence between the rapid technical advances and the regulatory view of different Member States hampers the further development and creates an unnecessary burden.

Therefore, CECIP is in favour of ensuring a simpler and more transparent method of software control. New methods and more alignment would have a clearly positive impact. Mainly, on the following points:

- Removing limitations on innovation and technical development
- Fostering more equal competition between notified bodies with different interpretations of WELMEC Guidance notes
- Reducing markets distortions due to more consistent interpretations of WELMEC guides
- Creating a facility for the development of procedural control of software development

Action in WELMEC WG 7 needed

CECIP is convinced that WELMEC is the best platform to improve the situation. Therefore, CECIP calls on WELMEC working group 7 to take actions to achieve the above mentioned positive effects.

This can be done by:

- Ensuring a focus on easily understandable technical solutions for weighing software developers
- Establishing transparent risk assessment methods for the assessment of software.
- Developing a quality based procedural method to ensure that the confidence in metrological software is developed
- Focussing, as WG7, on productive outputs for the weighing industry

More specifically two actions are most important for CECIP:

Incorporate guide 2.3 requirements in guide 7.2

Whilst recognising the significance of the Guide 2.3 in the development and design of Non-automatic weighing instruments CECIP also recognise that the Guide 2.3 is now anachronistic and does not reflect the rapidly changing technologies in the market place. CECIP are of the view that the improved methods of software control can most easily achieved by revoking the Guide 2.3 and incorporating requirements that relate to NAWI's in the Guide 7.2 and would encourage WELMEC WG7 to undertake this.

Further develop risk-based approach

Moreover, current WELMEC Guides only consider technical solutions to control software and do not consider procedural quality-based solutions that would enable manufacturers to demonstrate compliance via other methods. The present technical solutions can be inflexible with regard to rapidly developing new technologies and do not necessarily enable manufacturers to ensure technical compliance easily. CECIP would encourage WG7 to further develop the risk-based approach that is currently being worked on with the ultimate goal of allowing all stakeholders to use recognised risk management and quality assurance techniques in the evaluation of their software. This would enable manufacturers, notified bodies and market surveillance authorities to use mutually agreed risk management tools to ensure the full compliance with the regulatory framework

WG7 should consider further discussions on developing the risk-based quality assurance techniques to enable the comprehensive assessment of software for weighing and measuring instruments.

Make guides on software futureproof

As CECIP we believe that new software technologies can result in major improvements for the end-users and manufacturers of weighing instruments. Futureproof and consistent WELMEC guides will enable the weighing industry to reap the full benefits of these possibilities and ensure the competitiveness of the European weighing industry.

CECIP (www.cecip.eu) is the European association representing the weighing instrument industry. Founded in 1958, CECIP has currently members in 14 countries. The weighing instrument industry in Europe is world leader and consists of around 700 companies that are mostly SMEs. The total turnover is approximately 3 billion euro and the industry employ about 50.000 persons.

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