WHITE PAPER

York EMC Services

The New Legislative Framework and EMC Directive 2014/30/EU

Untangling the Red Tape

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Untangling the Red Tape?

Six years after the New Legislative Framework (NLF) was published, a sheaf of Union acts setting out specific requirements have arrived. Among them is an updated EMC Directive, 2014/30/EU. At first glance, not much seems to have changed, particularly for manufacturers based within Europe. And although this is reinforced by the lack of a transition period (the provisions of the new EMC Directive simply come into force in April 2016), there are a number of changes that manufacturers should be aware of.

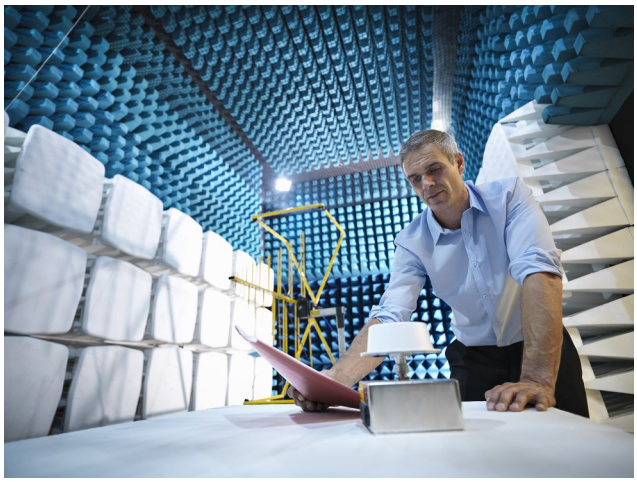
The NLF builds on the New Approach, now 29 years old, which decouples technical specifics from the legislative process. Manufacturers should all now be familiar with these decoupled directives, with their *Essential Requirements*, *Technical Documentation*, *Declarations of Conformity* and the *CE marking*, together with an ever-evolving list of *harmonised standards* that set out exactly which tests a particular piece of apparatus should be subjected to before being placed on the market. All these elements persist under the NLF.

The evolution which the NLF has engendered is largely in the supply chain. The so-called *economic operators* (including importers, distributors and authorised representatives) will have new duties, including record-keeping and an obligation to cooperate with market surveillance authorities in ensuring non-compliant apparatus is removed from the market-place as quickly as possible. This should result in an increase in the availability of evidence of compliance, which will be beneficial for all customers who use *commercial-off-the-shelf* sub-systems.

What does NLF address?

The new framework addresses the shortcomings of the New Approach implementation. In recasting several Directives at once, it improves their overall consistency and coherence. It sets out a number of conformity assessment procedures, ranging from pure self-assessment (the *internal production control*) through to third-party assessment of a product's design and audit of the manufacturer's quality system (*conformity based on full quality assurance plus design examination*). Individual Directives have chosen the modules that are most appropriate for the regulation of their selected area. The framework standardises, across the different Directives, the requirements for applying the CE marking, the documentation which must be supplied with products, and the documents which must be produced and retained by manufacturers. It also streamlines the use of notified and accredited bodies, which are of key importance to manufacturers' ability to declare conformity to the essential requirements of many Directives.

Also streamlined are the safeguard mechanisms, which



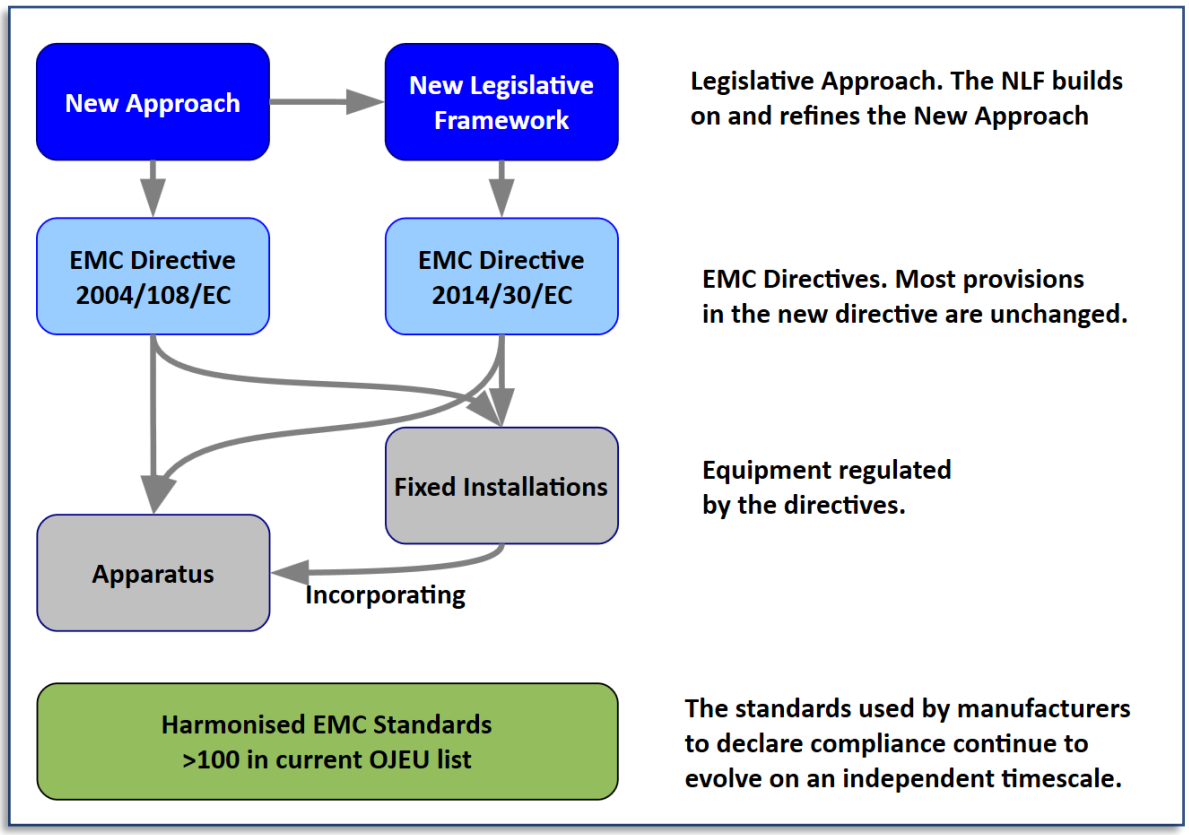
protect end users from products which are either unsafe or otherwise not meeting the essential requirements of a particular directive. The mechanisms cover both products which are non-compliant with harmonised standards, and products which comply with harmonised standards but nevertheless fail to conform to a Directive's essential requirements (indicating a failure in the standard). Other mechanisms set out procedures to deal with cases where a Notified Body has incorrectly provided a positive opinion for non-conforming apparatus.

Traceability

The new traceability requirements and explicit obligations for importers and authorised representatives present the largest change in the workings of the single European market. They have the potential to rein in unscrupulous or merely unenlightened manufacturers by ensuring that the entire supply chain recognises the need for the relevant documentation to be supplied. However, the primary reason is to allow for effective enforcement of the regulations through corrective market surveillance measures (withdrawals and recalls).

The changes to technical documentation required for apparatus under the EMC directive may surprise those who picture EMC compliance as a few days testing in a laboratory. Under the current EMC directive, compliance to appropriate harmonised standards is considered equivalent to performing the conformity assessment procedure. The technical documentation in this case can briefly list the required elements:

- Identification of the manufacturer and apparatus
- Selection of the appropriate harmonised standards
- Evidence that the apparatus complies with the standards
- Evidence of a quality system, showing that the tested apparatus is the same as the apparatus placed on the market.



Technical Documentation

The new directive removes this equivalence. The technical documentation must contain *adequate analysis and assessment of the risk(s)*; in other words, the reasoning behind the choice of standards, along with a study of the apparatus use-cases against the application of the standards. It must additionally contain relevant drawings and component schedules, and explanations sufficient to demonstrate that the apparatus will meet the essential requirements by way of the balance of evidence provided in the documentation. The diligent manufacturer will have the majority of this information already have to hand, but procedures will need to be revised.

The changing traceability requirements are potentially more disruptive to manufacturers than may be expected. Together with their name, registered trade name or registered trade mark, manufacturers must place their postal address (a single point of contact for the manufacturer) on the apparatus. Aesthetic reasons for omitting this (and instead providing the contact address on packaging or in accompanying documentation) are specifically excluded by the commission's guide on the implementation of EU product rules (the "Blue Guide", updated in April 2014). The remaining traceability requirements, regarding record keeping, will be met with minimal (or no) changes to current practices.

Fixed installations

The requirements for fixed installations are effectively unchanged. The removal of the essential requirement for documentation of fixed installations is an administrative change only, bringing the essential requirements for fixed installations into line with those for apparatus. The documentary requirements for fixed installations are now stated within the body of the directive (as they are for apparatus).

What will it mean?

So what will the new EMC directive mean for the diligent manufacturer? The essential requirements themselves are unchanged, and the harmonised standards continue on their decoupled evolution. The changes are in the traceability and documentation requirements. The documentation requirements for all aligned directives have been streamlined, so there may be a net reduction in documentation for apparatus within the scope of more than one directive. But don't forget that the company address now needs to be on the data plate.

Reduce your business risk

At Eurofins York (formerly York EMC Services), we provide training on all aspects of EMC, including the requirements of

the directive: 2014/30/EU is the third EMC directive that our courses have explained to manufacturers, regulators and installation owners. Our courses provide the means to demystify the legislative requirements and understand the tests prescribed in standards, along with both the theory and the best practice in applying EMC principles to products or to installations, from a single PCB to an entire railway. We also run courses to share our knowledge of electrical safety and of radio equipment.

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