WHITE PAPER

York EMC Services

# The Importance of Ensuring On-Going Compliance for Products

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## Introduction

A raft of new CE Marking Directives was implemented in 2016. Amongst the nine new pieces of legislation was the third edition of the EMC Directive and new Low Voltage and ATEX Directives.

Rather unusually, the changes to eight of the nine directives were identical and furthermore the ninth contains the same changes as part of a wider overhaul. So why new directives and what are the implications for manufacturers?

## The Need for New Directives

Some years ago, the European Commission published the New Legislative Framework (NLF), a separate piece of legislation intended to act upon all CE Marking directives. The 2014 directives represent the first tranche to incorporate these new provisions.

The Commission periodically reviews its legislation to check, amongst other things, that it is being effective. One measure is the feedback from market surveillance campaigns which measures individual directives' effectiveness at delivering compliant products onto the market.

Market surveillance campaigns consistently show that more needs to be done. The most recent market surveillance campaign for the EMC Directive, for example, sampled 55 solar panel inverters with the result that just 9% met both the technical and administrative requirements of the directive. Delving into the data reveals that the samples were only tested for emissions, so the 9% compliance rate assumes that all samples would have met the requirements of all the immunity tests – an unlikely scenario. It also assumes that the two-thirds of samples that did not have their Technical Documentation assessed would have all met the requirements – again, an unlikely scenario.

The real compliance level will be lower, but how much lower? No-one knows as the data isn't available. What is certain is that this particular market sector is close to being entirely non-compliant.

This is not an isolated example, market surveillance from other CE Marking directives shows an unacceptably large number of non-compliant products reaching the market – at least in the sectors chosen.

For manufacturers who take their compliance responsibilities seriously, there is an associated cost; whether this is from third-party testing or providing the resources necessary to generate the required documents. Other manufacturers don't incur these costs and the Commission is cognisant of the fact that producing compliant products could be seen as a competitive disadvantage.

The new Directives contain some important changes introduced by the NLF. The manufacturer remains responsible for product compliance but now everyone in the supply chain, from the importer to the distributor, has responsibilities, all designed to make sure that the manufacturer has met the necessary regulatory obligations and that only compliant products reach the end user. The message is clear; the whole supply chain is now effectively policing the correct application of the new directives.

## Placing on the Market – An Often Misunderstood Concept

CE Marking Directives make reference to *placing on the market,* defined as "the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community."

This wording is often only partially understood; ask a typical manufacturer what this means in practice and their common interpretation is that placing on the market is the equivalent of launching a new product; it is something that happens once; that is then the end of the matter.

The directives' definition is that each product is individually placed on the market and therefore should be compliant; hence the need to ensure on-going compliance beyond that initial product launch.

Non-compliant products on the market fall into one of two categories; those that were never compliant in the first place and those that were compliant when they were initially placed on the market as a new product, but have subsequently ceased to be compliant.

## The Challenge of Remaining Compliant

A product's on-going compliance is affected by several factors and only one of these is within the manufacturer's control.

Firstly, compliance with harmonised European standards is the basis on which a Declaration of Conformity (DoC) is made for CE Marking Directives. They provide a clear set of requirements to be met in order to satisfy a directive's technical requirements. The issue is that all standards change over time; periodically amendments are issued followed by complete revisions every few years.

New and revised standards are accompanied by a *transition period* of typically two or three years. During this time the manufacturer can choose whether to continue to use the old version or move across to the new one but beyond the end of the transition period only the new version applies. Therefore the manufacturer needs to be assured that the product is actually compliant with the new requirements and reflect this in the Technical Documentation and DoC.

Secondly, whilst standards change relatively frequently, directives do not normally change from one year to the next, but 2016 was an exception. The nine updated directives were all new pieces of legislation with new numbers which need to be reflected on the DoC. For example, the new EMC Directive came into force on 20th April 2016 with no transition period, so from this date DoCs for current products should refer to 2014/30/EU. Any 'current' DoCs still referring to 2004/108/EC are invalid as this directive has been superseded.

Lastly, the product itself, something that the manufacturer does have control over. During a product's life cycle it is likely to be subjected to a number of changes; necessary design changes, obsolete components, cheaper components and additional functionality, all of which will result in a product that is different in some way than the one which was *initially placed on the market*. Just like for changes to standards, the manufacturer needs to be assured that the updated product is actually compliant and reflect this in the Technical Documentation and DoC.

Ensuring that these three aspects (harmonised standards, directives and product evolution) are reviewed regularly should result in on-going compliance.

## Protecting Brand Reputation

What can take many years to build can be tainted very quickly through adverse publicity. Mention of the Samsung Galaxy Note 7 is more likely to conjure up images of melted phones rather than a device at the forefront of the latest mobile technology. Even for a company of Samsung's size and resources, this will take some time to shake off.


Meeting the requirements of the relevant CE Marking Directives is also a form of brand protection. The directives are in place not only to allow the free movement of goods within the EU, but to ensure that products are safe and reliable; an inherent consumer expectation. Products that are not compliant, or those where the manufacturer cannot adequately demonstrate that they are, may be hindered within the supply chain through the additional responsibilities on importers, authorised representatives and distributors.

Moreover, the new directives seek to ensure that market surveillance is more robust and that the identification of products, particularly where they have been rebranded, can be more easily established so that their path through the supply chain can be established. Non-compliant products detected in one country can lead to the removal from the market in all European Member States.

## Conclusion

With the stated aim of the new Directives firmly focussed on ensuring that only compliant products reach the market, manufacturers need to be aware of their responsibilities, now more than ever. Not only to ensure that a product is compliant at launch but it is on-going throughout its entire production lifecycle.

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