Are You Compliant?

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It is all too easy, particularly if you are the government, to try and argue businesses are tied up in red tape and need to be given more freedom simply to get on with their own business. Indeed, some Republicans in the US would go a lot further by moving towards a completely free and unregulated market in every sense. On the other hand, one does not have to think too far to see the very severe consequences to businesses of being publicly 'named and shamed' where systems and processes have resulted in a failure to be compliant in a particular area, thus resulting in a drop in market confidence and, fundamentally, consumers or the public no longer having faith in either an organisation or one of its key brands.

How Does The Board Ensure It Is Fully Compliant With All Necessary Criminal Regulatory Requirements?

The last few years have seen the emergence of a whole range of different issues involving regulatory compliance, not just to do with product safety but also to do with regulatory obligations on the operations of a business whether by means of licensing or permitting or other formal requirements that a business must adhere to. This throws up a whole series of fundamental questions which a Board needs to get to grips with. While these apply equally to all businesses, they are particularly important to the industrial engineering and manufacturing sectors where you are ultimately producing goods which need to be of good quality and meet all necessary legal requirements.

What Do You Need To Be Compliant With?

One of the biggest challenges is the sheer breadth of requirements that are now in place. There are international standards, EU standards, individual country requirements, industry good practice: many of these will overlap but in some cases can, at least on the face of it, appear either confusing or even contradictory. One example is the EU system for

applying a CE mark to a very broad range of goods. There are a large number of different categories of goods, for example electrical or mechanical right through to medical devices, all of which require compliance with specific standards.

It is incumbent upon either the manufacturer and/or importer into the EU to ensure that these standards have been met and that appropriate CE marks have been applied. While this all sounds straightforward in theory, in practice it is often very difficult to unravel the EU directives and local regulations which apply and particularly where goods will often pass through a chain of different organisations, it is not always clear whose responsibility it is to obtain the CE mark. The specific classification of goods also has inevitable grey areas at the edges where different views can be taken by different organisations or regulators as to whether a particular product should or should not have a CE mark attached to it.

Why Is This Important?

There is also the risk that this may seem technical and bureaucratic, so why is it so important? Clearly if a product has been released onto the market and a CE mark has not been obtained properly then first and foremost this constitutes a criminal offence, certainly within Europe. Although the penalties are relatively modest, the impact of being subject to a criminal investigation followed by a prosecution, potentially followed by a conviction is a very different and difficult prospect. It could ultimately result in a company having a 'criminal record' which would then have to be disclosed in future contracts either with suppliers or customers. It also runs the risk of very severe adverse publicity – for example look at the issues that are currently facing BMW Mini after it became apparent that they needed to do a recall on certain aspects of their water pump systems. This underlines an identical problem which we have experienced in such cases namely that the impact goes way beyond the formalities of simply applying a logo to your goods or fixing a minor fault, and at least gives the suggestion that your systems and processes are weak and therefore questions whether any confidence should be placed in the broader organisation.

What Should You Do?

So how can you respond having identified which regulatory requirements are applicable to your products or services? It is clearly important to have competent and qualified individuals or teams looking at your products in very specific terms and, more importantly, being able to demonstrate compliance by having all the correct documentation in place, in date and kept under regular review.

The difficulty we often see in practice is that while all organisations will generally have someone tasked with this important exercise, it is not always given the importance or significance it deserves. Furthermore, due to the very complex nature of complying with a whole raft of detailed, potentially scientific or technical requirements, as and when an individual or a team are put in place to deal with this area, they are not always effectively managed, for the simple reason that the manager may themselves have insufficient technical knowledge (or at least believe that they do) to understand fully what should be happening and, more importantly, whether it is in fact happening. But this simply underlines the important need for appropriate processes and controls to be in place so that at Board level you can be satisfied that things are happening as they should. It is another area where good governance will ensure positive results.

We have had a number of significant cases with which we have been involved in recent weeks and months where there has been an over-reliance on a single individual: in some cases that individual does not perhaps hold the necessary competencies in all areas which have been passed to them, and as a result things have not been done properly. Even worse, when potential challenges are made to certain individuals, their responses are often accepted without question for no other reason than 'they must know what they are doing' or being told that 'this is standard across the industry', without any evidence to support that assertion.

The resulting problems which can then ensue may well result in, for example, significant product recall issues and all of the contractual and insurance obligations which that may entail. That in turn could lead to contractual issues at a much higher level in terms of whether people are prepared to continue to deal with your organisation. In some cases it can lead to regulatory investigation and criminal enforcement action resulting in criminal convictions and financial penalties. In the very worst cases, we have seen failure to ensure compliance leading to the departure (either voluntarily or forced) of a number of senior managers and potentially even directors; in other cases it has lead to question marks over the future viability of that aspect of the business.

Conclusion

The biggest problem that a Board needs to get to grips with when considering the question 'are you compliant' is the need to wrestle with Donald Rumsfeld's much maligned discourse on 'known unknowns and unknown unknowns'. Once a problem has arisen it may well be too late to do anything effective and the consequences can be very significant for the business and individual Board members whose responsibility it is to have made sure systems were in place.

The challenge is raising issues and challenges now which are not seen as questioning individuals or teams responsible for compliance but are seen in a positive light in terms of simply auditing good practice and encouraging the organisation to be open and self critical rather than defensive. Above all, it is vital to engender a far better culture that extends way beyond the issue of safety and regulatory compliance and demonstrates a positive and productive workforce and a management team working together to grow the business. ■