

CE Marking; ATEX, Machinery Directive, etc. – How to get it right

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The purpose of the paper is to share practical experience gained in the complexity of ensuring compliance with 'New Approach' Directives, such as the Machinery Directive, in the design, installation and commissioning of process plants. In practice, while equipment suppliers seem at this stage to be reasonably comfortable with their obligations under this legislation, in the world of 'project engineering' much confusion reigns. This ranges from doing nothing to alternatively generating CE marking conformity documentation to cover the complete scope of process plant designs. This paper describes the procedures and methodologies PM Group has developed, and is continuing to develop, for ensuring compliance with the obligations under the 'New Approach' Directives.

Background

In the past established risk assessment methodologies, such as Hazard and Operability (HAZOP) studies, sufficed to ensure the regulatory compliance of process plants. The EU's 'New Approach' to standardisation, associated conformity assessment and CE marking now runs to some 28 Directives and 5 Regulations. These 'New Approach' Directives, define "essential requirements" related to health, safety and environmental issues. Products must meet these requirements in order to be placed on the European market. As such then, the traditional process plant now has additional compliance requirements, primarily associated with the Machinery Directive, the Pressure Equipment Directive and the ATEX (Explosive Atmospheres) 'equipment' Directive.

As an international engineering design and construction management company operating in the process industry sector, PM Group had to apply a structured format to get it right, i.e. ensure compliance, but not generate unnecessary complexity and duplication of the relevant statutory provisions. Like many things in life, this was easier said than done, and while considerable progress has been made on the 'learning curve', there is 'no one size fits all solution'. For instance, some approaches tried have proved successful, but still need to be refined, not least as the commercially available 'services' with respect to CE marking, offered by the specialist 'notified bodies' and similar organisations, still continue to evolve.

As a starting point PM Group was very familiar with its obligations in relation to process safety, but was now faced with a somewhat confusing legislative structure related to CE marking, which had 'something to do with' process design and projects, but nobody was actually sure what. As a result, as often happens under such circumstances, the whole CE marking compliance would get left to the end of the project, where somebody would be left to 'pull the documentation together'. Not surprising, this resulted in what could be only described as an unsatisfactory mess, not least as it was then often found, that key documentation was missing, while other documentation existed, which never needed to be generated in the first place.

A clear and fundamental lesson had then to be learnt; first of all that a successful CE marking compliance strategy had to start right at the initial phase of the project. Secondly, one has to understand that while CE marking compliments some, but not all, aspects of process safety and plant design, its legislative origins are in the free movement of goods between EU Member States. Therefore, one has to initiate the compliance strategy at the initial phase of the design in order to identify where the CE marking obligations apply and equally as to where they don't apply. If one does this, then the necessary compliance documentation can in an orderly fashion be either delivered by the relevant equipment vendors and / or developed as required, as the design and its implementation progresses. In many respects this first question, which one has to answer, is the most critical, i.e. as to whether the item in question is a 'product' or a 'process plant'.

Product or Process Plant?

The Regulatory Scheme

Free movement of goods is the cornerstone of the EU's single market; the mechanisms in place to achieve this aim are based on mutual recognition and technical harmonisation. Standardisation has contributed significantly to the support of the Internal Market in the context of the EU's 'New Approach' legislation to product regulation and Global Approach to conformity assessment. The common thread between these complementary approaches is that they limit public intervention to what is essential and leave business and industry the greatest possible choice on how to meet their obligations. For example, the use of self-assessment or approval by 'notified bodies', which are independent organisations accredited by Member States to assess whether a product meets certain preordained standards, such as for Ex rated equipment or medical devices.

'New Approach' Directives are special in that they do not contain technical detail; they contain broad safety requirements. Manufacturers therefore need to translate these broad 'essential' requirements into technical solutions. One of the best ways that manufacturers can do this is to use specially developed European standards. These standards are called 'harmonised standards' and they are said to give a 'presumption of conformity' with the directive for which they have been written.

In other words the technical specifications of products meeting essential requirements set out in the Directives, are laid down in harmonised standards. Application of other standards remains voluntary and the manufacturer may always apply other technical specifications to meet the requirements. However, when using a harmonised standard the manufacturer is presumed in conformity with the law. On the contrary, using a standard, which is not a harmonised standard, will impose additional responsibilities. The use of anything but a harmonised standard places a burden of proof upon the manufacturer that the product meets essential requirements.

This proof may be provided by the manufacturer's 'technical file', by the employment of a third party (consultant, testing house, etc.), or by a combination of the two. The 'New Approach' Directives prescribe conformity assessment procedures, which are commensurate with the risk of injury associated with the product; essentially analogous to a traffic lights system. For low risk products the responsibility of the technical file remains solely with the manufacturer. For those of medium risk it is necessary for the technical file to be lodged with a 'notified body', but not reviewed by them. For the products identified in the relevant legislation as being of high risk, the technical file requires approval by a 'notified body'. Assessment can include inspection and examination of a product, its design and manufacture.

The Global Approach to conformity assessment therefore allows the use of the CE mark as an indication that the products comply with the essential requirements of applicable directives and that the products have been subject to a conformity assessment procedure provided for in the directives. As the UK Government's website explains about products for the European Economic Area (EEA), falling under the 'New Approach' Directives:

CE marking is required for many products and it:

- *Shows that the manufacturer has checked that these products meet EU safety, health or environmental requirements*
- *Is a key indicator of a product's compliance with EU legislation*
- *Allows the free movement of products within the European market*

By placing the CE marking on a product a manufacturer is declaring, on his sole responsibility, conformity with all of the legal requirements to achieve CE marking. The manufacturer is thus ensuring validity for that product to be sold throughout the EEA. This also applies to products made in third countries which are sold in the EEA and Turkey.

Not all products must bear the CE marking. Only those product categories subject to specific directives that provide for the CE marking are required to be CE marked.

If we take a typical process plant, this will be composed of a range of products falling under the above Directives plus other components exempt from such Directives, but is the process plant itself a 'product' with respect to above legislative and certification requirements? Clearly this would be impracticable and does not reflect that the design, construction and operation of such process plants are subject to a range of other EU safety legislation, not least related to worker protection. For instance, there are two ATEX Directives; in addition to Directive 94/9/EC on 'equipment' there is Directive 1999/92/EC on 'worker protection', which outlines the requirements for the assessment of explosion risks and the technical and organisational measures for effective mitigation of such risks. So what guidance do we use to differentiate between products covered by the CE certification process and those better described as a process plant?

Product – Machinery Directive

There is no doubt that defining, as to whether a process plant item is machinery or not, is where in practice the most confusion with CE marking occurs. Machinery is defined under the Machinery Directive 2006/42/EC as:

- *"An assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application".*

This definition of machinery in Article 2 of Directive 2006/42/EC includes assemblies of machinery. This is a complex area, for which the relevant guidelines on the Machinery Directive (EU Commission, 2010) provides the following guidance:

- *"The definition of assemblies of machinery does not necessarily cover a complete industrial plant consisting of a considerable number of machines, assemblies of machinery and **other equipment** originating from different manufacturers. However, for the application of the Machinery Directive, such large installations can usually be divided into sections which **may be** considered as assemblies of machinery, for example, raw material unloading and reception equipment - processing equipment - packaging and loading equipment. In that case, any risks created by the interfaces with the other sections of the plant must be covered by the installation instructions. It should also be noted that the placing on the market of equipment installed in industrial plants that is not in the scope of the Machinery Directive may be subject to other EU internal market Directives".*
- *"The person constituting an assembly of machinery is considered as the manufacturer of the assembly of machinery and is responsible for ensuring that the assembly as a whole complies with the health and safety requirements of the Machinery Directive".*
- *"Assemblies of machinery are subject to the Machinery Directive because their safety depends not just on the safe design and construction of their constituent units but also on the suitability of the units and the interfaces between them. The risk assessment to be carried out by the manufacturer of an assembly of machinery must therefore cover both the suitability of the constituent units for the safety of the assembly as a whole and the hazards resulting from the interfaces between the constituent units. It must also cover any hazards resulting from the assembly that are not covered by the EC Declaration of Conformity (for machinery) or the Declaration of Incorporation and the assembly instructions (for partly completed machinery) supplied by the manufacturers of the constituent units".*

For a company manufacturing equipment for their own use, the Machinery Directive 2006/42/EC is clear in that Article 2 states:

- *'Manufacturer' means any natural or legal person who designs and / or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer.*

So when an operating company or design company 'connects up' a number of machines together into an assembly, they are responsible for ensuring compliance for the assembly, an aspect that in practice is often overlooked. On the other hand, if it is a process plant, as opposed to an assembly of machinery, risk is controlled by application of other safety related Directives, guidelines, etc., including the adherence to the instructions provided for the machinery components being integrated into the process plant. One needs to consider this fact carefully and define the scope. For instance if we have a pump; this is clearly machinery within the context of the definition above.

If we connect it to a complex automatic filling machine, then the filling machine will undoubtedly be characterised by its own integral drive system(s). Does the integration of both results in an assembly of machinery, which requires its own CE compliance with the Machinery Directive?

The answer to this is it depends. Thankfully the circumstances which engage the requirements of the Machinery Directive to interconnected machinery are clarified in an Interpretations Paper produced by the German Authorities (BMAS, 2011). As this highlights; if when the individual machinery elements are interconnected, a production technical connection plus a safety technical connection occurs, then the result is an assembly of machinery, for which the requirements for preparing a technical file and affixing the CE mark according to the Machinery Directive apply.

One can also consider the guidelines on the Machinery Directive (EU Commission, 2010), which clarify:

The definition of assemblies of machinery indicates that assemblies are arranged and controlled so that they function as an integral whole in order to achieve the same end. For a group of units of machinery or partly completed machinery to be considered as an assembly of machinery, all of these criteria must be fulfilled:

- *The constituent units are assembled together in order to carry out a common function, for example, the production of a given product;*
- *The constituent units are functionally linked in such a way that the operation of each unit directly affects the operation of other units or of the assembly as a whole, so that a risk assessment is necessary for the whole assembly;*
- *The constituent units have a common control system*

A practical example would be the pumping of butter by a positive displacement pump to the filling machine. It is clearly obvious that if the filling machine stops and the positive displacement pump continues to run, then a dangerous pressure rise will occur; hence a safety technical connection.

On the other hand if a liquid, such as beer, was being filled by a centrifugal pump on a recirculation loop back to the filling tank, then if the filler stopped, no hazardous situation would arise. It could easily be demonstrated that there was no safety technical connection. Therefore an assembly of machinery does not arise in these circumstances and the machines can be treated as individual units, for which no additional CE compliance is engaged.

If instead of a filling machine, the same centrifugal pump is pumping fluid around a distribution loop and into a storage vessel, then neither the pipework nor the vessel fall within the definition of machinery; they are equipment. As a result an assembly of machinery with associated compliance to the Machinery Directive does not arise, as one is connecting machinery to equipment. However, other EU safety legislation related to equipment applies, which would simply engage the general obligations of EU safety legislation related to process safety or if applicable the additional specific requirements related to other 'New Approach' Directives. For instance, the pipework, depending on the hazard potential of the fluid, the pressure of the fluid and the size of pipework, could fall within the terms of the Pressure Equipment Directive. Under such circumstances the distribution pipework will require CE compliance and certification to the Pressure Equipment Directive. Equally, the pipework may not be hazardous enough to come under the terms of the Pressure Equipment Directive and there could be no other additional obligations under CE Certification for this distribution loop. However, the general safety obligations under EU legislation would still apply, which would include:

- Ensuring that the pump and motor combination has the necessary CE Certification to the Machinery Directive and Low Voltage Directive.
- Ensuring the instructions for safe use from the above has been incorporated into the design and installation of the equipment.
- Ensuring proper design and risk assessment procedures have been adhered to, including those obligations related to Directive 2009/104/EC on use of work equipment.

Note: While the English language uses the terms 'equipment' and 'machine' somewhat interchangeably, under EU legislation they have a different context. Equipment is broader in scope, such as including items of a 'process plant', which are not defined as machinery. While machinery is as strictly defined above in the Machinery Directive and is solely a subset of the broader definition of 'equipment'.

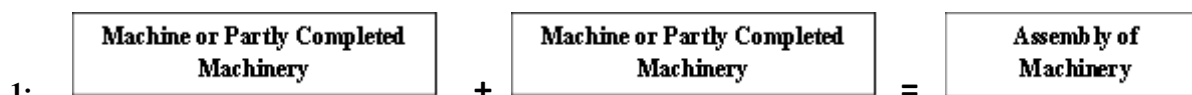
Therefore, to reiterate, the integration of a machine with equipment leads to a process plant equipment unit, which is not an assembly of machinery in the sense of the Machinery Directive. However, there is a slight twist when it comes to the definition of ‘partly completed machinery’, which was adopted in the 2006 Machinery Directive, namely:

- *‘Partly completed machinery’ means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;*

When partly completed machinery is integrated into equipment, machinery can be formed, in particular where there is a safety technical function, described previously. The classic example comprising of an agitator integrated into a vessel. For instance, if two identical vessels are bought, then clearly both are classified as equipment and depending on the size and pressure, the Pressure Equipment Directive could be engaged with its CE marking requirements. If partly completed machinery in terms of an agitator is purchased for installation in one of the vessels, then the combined vessel and agitator is a functioning unit and becomes machinery according to the above definition. Therefore additional CE marking to the Machinery Directive is required for the combined vessel and agitator. The key aspect to be addressed in the technical file is the guarding. Does the vessel and agitator combination, in its various modes of operation, provide sufficient guarding, according to the relevant sections of the essential health and safety requirements of the Machinery Directive?

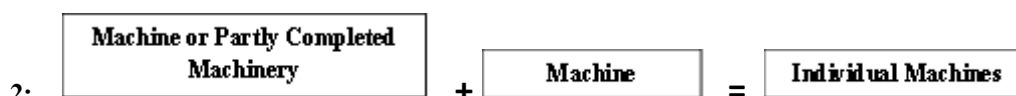
Summary – Machinery Directive

In many respects the relevant compliance scenarios can be broken down into the four shown below:



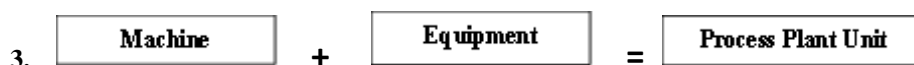
The above applies provided:

- There is a production technical connection plus;
- A safety technical connection.
- A technical file and CE marking is applicable to the assembly of machinery.



The above applies provided:

- There is a production technical connection, but no safety technical connection, or;
- Hazards at the interfaces are considered minor and controlled by simple technical and independent protective measures.
- No technical file or CE marking required; mandatory integration of safe instructions for use into design and operation.



The Machinery Directive does not apply to a process plant unit, but other ‘New Approach’ Directives engaging CE marking may apply, such as Pressure Equipment Directive. The integration of the safe instructions for use into design and operation is mandatory.



A technical file and CE marking is applicable to resulting machine / assembly of machinery when the safety technical connection applies. In other circumstances the integration of the safe instructions may suffice on its own.

Practical Examples – Machinery Directive

Example 1: A client in the food industry had integrated into a production line two distinct machinery modules, both of which were provided with the necessary CE marking and compliance to the Machinery Directive. The question then arose as to if the integrated unit was an assembly of machinery, for which its own technical file and CE conformity process was required, i.e. Scenario 1 above. The two modules did share a degree of automation integration; such that there was no doubt that a production technical connection existed. However, a simple risk assessment showed that the worst case failure led to

the product being dumped on the floor, there being no risk of injury. As such then a safety technical function did not arise. Note: The German Interpretations Paper clarifies (BMAS, 2011) clarifies:

The individual machines or partly completed machines have to function in a safety technical manner as an assembly and thereby in this regard form a unit (safety technical connection). This is the case, if the machines and / or partially completed machines are so connected which each other, such that an incident, which occurs within a component part of the plant, leads to a hazard with another component part for which the 'assembly' safety technical measures have to be activated, in order that in the hazardous situation all of the component parts are brought to a non-hazardous situation.

In Annex I Number 1.2.4.4 of the Machinery Directive it is specified for an assembly of machinery:

- *"Assembly of Machinery"*
- *In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.*

If individual machines are solely connected through a common Emergency Stop activation device, it does not correspond alone through this connection that an assembly of equipment already exists.

As such then for the integrated food production line Scenario 2 applied, as there was no safety technical function, and compliance with the legislation was obtained by integrating the safe instructions for use, provided by the suppliers of the two equipment modules, into the design and operation of the line.

Example 2: A US based client in the process of constructing their first production plant in the EU had to have fabricated a large custom made drying and curing system for a fibrous product. This was a proprietary design tailored to their product, so the fabrication company for the turnkey unit was manufacturing it for their use. The question then arose as to whether this was an assembly of machinery. The complex unit comprised of heating modules, columns, cyclones, fans, conveyors, etc. had then to be examined in terms of its constituent parts. The conclusion of this was there was one location where two conveyors interacted with each other, in both a production technical and safety technical manner. At this location therefore Scenario 1 applied and an assembly of machines applied. For the complex unit as a whole Scenario 3 applied, as it comprised modules, where for instance a fan transferred product into a series of columns and cyclones, i.e. it was a process plant unit.

Example 3: A pharmaceutical company had a production process, which required discharge and processing of a pyrophoric material through a series of conveying and processing equipment maintained in an isolator. Scenario 1 applied, as an assembly of machinery was formed when the individual machinery units were connected and controlled by a new automation system.

Product – ATEX Directive

Turning to the ATEX 'equipment' Directive 94/9/EC, then the scope of this Directive applies to "products" namely equipment, protective systems, safety devices, components and their combinations intended for use in potentially explosive atmospheres, where:

- *'Equipment' means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy and/or the processing of material and which are capable of causing an explosion through their own potential sources of ignition.*

Therefore, a process plant unit, such Example 2 above, does not fall under the ATEX certification requirements of Directive 94/9/EC, as it is not a machine or apparatus. There are components of this unit, which do fall under Directive 94/9/EC, but these would have been part of the verification process during the commissioning stage, while the ATEX basis of safety and relevant risk assessments for the process unit would be included in the Explosion Protection Document for the site. Note: From 20th April 2016 the new ATEX 'equipment' Directive 2014/34/EC will apply. While this is a change to align with the EU's 'New Legislative Framework', the differences with respect to the previous Directive 94/9/EC are quite limited and the current EU guidance documentation remains valid.

It is important to carefully consider Section 3.7 of the "ATEX Guidelines on the Application of Directive 94/9/EC" (EU Commission, 2013), which relates to 'equipment' and 'own' ignition sources, as this has a major bearing on the scope of the ATEX Directive.

- *Another defining element of equipment in the sense of the Directive is that it has to have its own potential source of ignition.*

There are thirteen different sources of ignition defined by the ATEX standards: See in particular EN 1127-1:2011 "Explosive atmospheres; Explosion prevention and protection; Basic concepts and methodology". Many of these ignition sources are directly related to the 'equipment' itself, such as mechanically generated sparks, hot surfaces, electrical apparatus, etc. However, static electricity, which is one of the thirteen sources of ignition, is ubiquitous and not solely related to what is recognised as 'equipment'. As the ATEX Guidelines therefore clarify:

- *Many common items are made from plastics (polymers) with very low electrical conductivity. These can become charged, e.g. if they are rubbed, or if dust or a liquid flows over the surface. However, in most cases this may be*

controlled by the user, and if they are used in hazardous areas it shall be assessed and controlled according to the requirements of relevant national or community legislation (e.g. Directive 1999/92/EC). In any case the user of such equipment has to consider these ignition sources when undertaking a risk assessment in the workplace.

- *Examples are plastic containers used for transporting chemicals, polyethylene pipes, buckets and chairs. If the only source of electrostatic charging comes from the process, such items are not considered to have their own source of ignition, and they are not in scope of Directive 94/9/EC. In these cases they should not be Ex or CE marked according to Directive 94/9/EC.*

If we were to take a simple cyclone or reverse jet filter housing, then in practice the only ignition source directly related to those items is static electricity, which is controlled by earthing measures according to the relevant design risk assessments and technical standards. The cyclone or reverse jet filter housing would therefore not fall under the scope of Directive 94/9/EC. There are also user related explosion risks, such that an upstream process could transfer a glowing nest as an ignition source into that cyclone or reverse jet filter housing. This would then be addressed by the design risk assessment and the chosen form of explosion protection, such as an ATEX certified explosion vent. However, this circumstance would not be an 'own' source of ignition and engage ATEX certification for the cyclone or reverse jet filter housing itself. Note: The EU Commission on its ATEX website prepared a short document on: "Application of the Directive 94/9/EC to Filter Units and Vented Silo bins - revised version". This came to the same conclusion.

Practical Examples – ATEX Directive

Example 4: A US supplier delivered an integrated dust filtration system for a project in the EU, which comprised integrated cyclones, reverse jet filter, explosion panel and fans. The question then arose as to whether the system as a whole required CE marking to the ATEX Directive. An examination of the cyclones and filter demonstrated that there were no 'own' potential ignition sources, as instrumentation comprised simple non-electronic differential pressure monitoring, while there was no moving parts inside the cyclones and filter, which could be considered as mechanical equipment with their own potential sources of ignition. The compliance requirements were therefore limited to ensuring the CE marking of the explosion panel and fans and by complying with their safe instructions for use. There was no requirement to CE mark the system as a whole.

Example 5: If we consider the situation discussed at the end of Section 2.2 in which an agitator is incorporated into a vessel and CE marking implications arose with respect to the Machinery Directive, as the agitator is classified as partially completed machinery. If processing conditions are to give rise to potentially hazardous atmospheres within the vessel, then the combination of the agitator and the vessel gives rise to potential ignition sources, such as the bearings overheating or the agitator misaligning and striking the side of the vessel. The machinery completed by integrating the agitator and vessel would then be subject to compliance with a number of 'New Approach' Directives, not just the Machinery Directive, but also the ATEX 'equipment' Directive, the Low Voltage Directive for the agitator motor and if the vessel is to be pressurised, the Pressure Equipment Directive.

Implementation Strategy

Identification

To repeat the message previously highlighted, the CE marking compliance strategy has to begin at the start of the project. Ideally by taking the initial process flow schematics and marking as to what elements fall under which relevant 'New Approach' Directives. Once this is done, the information can be tabulated in order to generate an initial list of deliverables, which will have provided by the end of the project to demonstrate the necessary compliance.

Strategize

Who provides the deliverables now listed? The obvious answer is to incorporate as much as possible into the relevant equipment specifications, which follow as the project progresses. For example if we consider Example 5 previously, then a vendor could be selected to provide the vessels with the preferred agitator units integrated and the necessary CE conformity procedures completed to the applicable 'New Approach' Directives. This can then be tracked to ensure that not only the specified equipment, but the specified documentation is delivered, in particular before final payment is issued.

There are of course limitations to what one can purchase with complete CE compliance, particularly when customised equipment occurs or where machinery components are integrated into an assembly of machinery. In such circumstances one has to manufacture for own use, which is discussed further in the Section 3.10. However, regardless of whether the CE compliance is delivered by either the chosen vendors or the project itself, a key aspect is the safe instructions for use. These are critical, if you don't have them, the downstream design cannot be finalised in a legally compliant manner, so any successful strategy for compliance has to expedite their availability for the design team.

Safe instructions for use

Their importance can be explained by the analogy that for complex products it is somewhat like a 'Russian doll'. In the centre are the smaller products at the sub-assembly level, these are placed on the market by their suppliers in a CE compliant manner, with the necessary certification and documentation, the later including the important instructions for safe use. When combining these together into a larger 'product', the manufacturer at the next level is responsible for the certification of what is usually an assembly of machinery, which requires a technical file covering the interface and the relevant documentation relating to certification, instructions for safe use, etc. This is the next layer of the 'Russian Doll'. As the product, usually a machine, becomes larger and more complex, there may well be multiple manufacturers and layers to the 'Russian Doll'.

However, what happens if it goes wrong and a failure occurs? Is the person involved in the final layer ultimately responsible for everything? This is of course impracticable, a manufacturer of a product has a considerable amount of intellectual property in its development, which of course he is entitled to guard and protect. While there is an obligation to prepare a detailed technical file, not least with regard to the essential safety and health requirements of the relevant 'New Approach' Directives, this does not have to be provided to the purchaser. Rather it has to be provided to the authorities on request, such as if an incident occurs, while the key safety related information is conveyed to the user through the instructions for safe use. Therefore, the user at the next level up, who could quite likely be responsible for manufacturing an assembly, has to by and large take at face value what is provided, they are not entitled to the inner design details of the product they are using. Although, as previously highlighted with 'New Approach' Directives in Section 2.1, if the product was of higher risk, the conformity assessment process would have engaged the requirements of a 'notified body'.

This situation is actually well described in the UK Government's clarification on their website in relation to Declarations of Conformity:

- *A Declaration of Conformity is not a quality certificate, nor a guarantee for safety. However, when properly drawn up along with CE marking on the product, conformity of the product with the Directive(s) quoted on the Declaration of Conformity may be presumed by suppliers in the distribution chain and by the end customer, provided there are no obvious or known defects. Additionally, market surveillance authorities, must presume that CE marked products, accompanied by a Declaration of Conformity comply with the provisions of the Directive(s) mentioned, unless they have evidence to the contrary (for example by examining or testing the product).*

If we consider the four compliance scenarios previously identified in Section 2.3, there is a common theme; none of them can be completed in a legally compliant manner, without the safe instructions for use associated with the individual components. This should be obvious, but it is often overlooked; designers have to read and incorporate the safe instructions for use. Even if it is as simple as connecting a pump and piping system to a storage tank, if you haven't read and incorporated the safe instructions for use associated with the pump, then how is the risk assessment for the design of the resulting system valid? If that risk assessment is not valid, how is the design legally compliant?

Use of check lists for risk assessment

While there is legal obligation to complete competent risk assessments, this does not necessarily mean that one has to complete a HAZOP of the relevant section of the design. HAZOP is a very popular and long established tool in the English speaking process industry sector, but far less so in the German speaking process industry, where it is designated as PAAG. Traditionally in the German speaking process industry sector, a more deterministic approach was applied, which was based around applying a specific set of rules and acceptance criteria. This was aided by their 'civil law' tradition, which unlike the 'common law' tradition of the English speaking world, requires the development of a very comprehensive set of official documentation giving legal effect; in simple terms, if it isn't prescribed, it isn't specifically allowed. On the other hand, with the 'common law' tradition, there is far less official documentation giving legal effect, so there is perceived to be a greater obligation to demonstrate compliance from first principles, such as through a HAZOP.

However, an over-reliance on the HAZOP technique has its downside. EN 31010:2010 "Risk management: Risk assessment techniques" clarifies that it "*provides guidance on selection and application of systematic techniques for risk assessment*". As it states in relation to the HAZOP technique; "*a detailed analysis can be very time-consuming and therefore expensive*".

It is important to highlight that the associated reference to 'expensive' is not just an issue of financial expenditure. While obviously there are financial implications if key design personnel on a project are tied into lengthy HAZOP schedules, these HAZOPs are also mentally tiring and over a period of time 'draining' of resources, who will lose their effectiveness. As such then HAZOPs have a major role to play, but they should be limited to process systems, which warrant them. For instance, if there is production processes and chemistry which is unique to the project, which is characterised by what would have been traditionally recognised as a chemical process system, then there is a high degree of certainty that a HAZOP is the warranted technique.

On the other hand, if one is assembling standard modules, such as a boiler and steam distribution system, then a HAZOP has more limited applicability. Not least as these follow proven design solutions codified by relevant standards and guidance documents. One does not therefore in these circumstances need to rigorously analyse from first principles, which is in essence what the HAZOP technique does, but rather ensure that one adheres to proven and established principles. For this second approach there are other techniques recognised by EN 31010, in particular the use of check-lists developed from the relevant standards and guidance.

For equipment modules, developing a check-list based on the safe instructions for use, followed by reviewing it by a number of competent technical staff, is therefore a highly applicable risk assessment technique. Indeed, such a check-list is little different than the action list from a HAZOP, which is not surprising, as it is in effect the action list having been developed by the technical team completing their risk assessment at the previous layer of the 'Russian Doll'.

So therefore does one need to go further to demonstrate compliance with the applicable safety legislation? Naturally the action items from any HAZOP or a check-list review need to be closed out, but a more in-depth risk assessment from first principles is not required. For operational reasons one might conduct a more in-depth review of a CE marked process unit, if there was a justification to educate oneself more on it, but from a legislative perspective, there is a very defined obligation in relation to adherence to the instructions for safe use, but not for further reviews.

Indeed, if we consider ‘New Approach’ Directives, such as the Machinery Directive, and their list of essential health and safety requirements, then the legislator has in effect created an appropriate check-list to be used by the manufacturer in his risk assessment. While using check-lists for risk assessment has fallen somewhat out of fashion with the process sector in the English speaking world in recent years, clearly the technique hasn’t fallen out of fashion with those, who write legislation.

In conclusion given that for legal compliance, one has to incorporate the safe instructions for use into the subsequent design, then there is clearly a lot to be said by demonstrating this fact through the development of check-lists and subsequently closing out these check-lists before project completion. Not least as this greatly facilitates with the completion of the necessary risk assessments, which will be required for design, installation and operation.

State of the Art

As Recital 14 of the Machinery Directive (2006/42/EC) clarifies:

- *The essential health and safety requirements should be satisfied in order to ensure that machinery is safe; these requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.*

Note: That while the Recitals of a Directive are not legally binding, they are an aid to the legal interpretation of the binding Articles of the Directive. The ‘essential health and safety requirements’ (EHSRs) relating to the design and construction of machinery in Annex I of the Machinery Directive also clarify in relation to ‘General Principles’ that:

- *The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.*

The relevant EU guidelines (EU Commission, 2010) for the Machinery Directive provide further guidance in that:

- *The notion of "the state of the art" is not defined in the Machinery Directive; however it is clear from Recital 14 that the notion of 'the state of the art' includes both a technical and an economic aspect. In order to correspond to the state of the art, the technical solutions adopted to fulfil the EHSRs must employ the most effective technical means that are available at the time for a cost which is reasonable taking account of the total cost of the category of machinery concerned and the risk reduction required.*
- *Manufacturers of machinery cannot be expected to use solutions that are still at the research stage or technical means that are not generally available on the market. On the other hand, they must take account of technical progress and adopt the most effective technical solutions that are appropriate to the machinery concerned when they become available for a reasonable cost.*
- *"The state of the art" is thus a dynamic concept: the state of the art evolves when more effective technical means become available or when their relative cost diminishes. Thus a technical solution that is considered to satisfy the EHSRs of the Directive at a given time may be considered inadequate at a later time, if the state of the art has evolved.*
- *A machinery manufacturer can only take account of the state of the art at the time the machinery is constructed. If an evolution of the state of the art makes it possible to approach the objectives set out in the EHSRs more closely, a manufacturer producing a series of machines according to the same design must upgrade his design accordingly (while taking account of the time necessary for the redesign and the corresponding changes in the production process).*

In a similar fashion, the ATEX ‘equipment’ Directive 94/9/EC states in its Annex II in relation to essential health and safety requirements: “*Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilized immediately*”.

Engineers completing risk assessments in the UK and Ireland are well familiar with the obligation defined in the relevant occupational safety legislation with regards to “so far as is reasonably practicable”. In the equivalent German occupational safety legislation the terminology used is “Stand der Technik” – which translates to the “State of the Art technology” which requires that the company is required to operate to the current state of technology, but not to a zero risk solution.

Therefore, despite a very comprehensive legal system relating to occupational and product safety, when it actually comes to the bottom line, i.e. how far is far enough, the legal framework is neither precise nor prescriptive; a degree of interpretation is required. Clearly two different manufacturers could derive somewhat different interpretations, as to what compliance with the above ‘state of the art’ entails. Yet at the same time a legal framework, which would be more prescriptive, would be impractical. Not least due to the myriad of complex situations which arise in practice, which cannot be individually specified for, while prescriptive requirements not only inhibit innovation, but they also promote design obsolescence.

However, there is a legal onus on those manufacturing products falling under the terms of the ‘New Approach’ Directives to demonstrate that the product complies with all the relevant essential health and safety requirements, before placing it on the EU market and / or putting it into service. This is inherently a risk based approach, as the essential health and safety requirements are broad and overarching, rather than detailed and prescriptive. As to how these essential health and safety requirements should be implemented in practice, then this is supported by the use of standards; namely regulations ‘rule’ and standards ‘support’. In Section 2.1 the role of standards was already addressed and particularly the use of harmonised standards, for which there is a presumption of conformity with the relevant essential health and safety requirements of a

specific 'New Approach' Directive. Harmonised standards are not only listed in the Official Journal of the European Union, but as the UK Health and Safety Executive's website explains:

- *Standards may help with good product design. But under the European 'New Approach' product safety regime the use of any standard by designers to meet mandatory essential requirement is completely voluntary. There is no requirement to use any standards to meet the essential requirements of product safety Directives. However, the existence of a relevant standard may effectively define the "state of the art" at the time it was originally prepared and so designers in seeking to meet essential requirements should take note of any relevant transposed harmonised standards as this sets the level of risk reduction that must at least be achieved. And in many cases standards can help designers meet essential requirements.*

This is an important point, the standards are a voluntary aid and they do not legally define the 'state of the art', as the guidelines on the Machinery Directive (EU Commission, 2010) also clarifies:

- *"Ageing" of a standard: Presumption of conformity granted to machinery complying with harmonized European standards can prove delicate if a standard becomes obsolete. If a manufacturer is clearly aware of this obsolescence, we can only encourage him to depart from the standard and be guided by the state of the art and good engineering practice in his industry.*

Specifying standards to be used for compliance

In the engineering world, it is the norm in the contractually binding specification for the equipment, to list a large number of technical standards. But how many of those engineers writing these specifications are actually familiar with the content of those standards or to be blunt about it, given their high purchase cost, have those standards actually available to read in the first place? This is not an idle issue, as where compliance with any standard, and not just harmonised standards, is declared without qualification on the Declaration of Conformity for the product; the legal person responsible for that Declaration is bound to fully meet all the requirements of those standards for his product. So what happens if technically and / or economically the manufacturer can't comply? For 'straightforward' equipment, such as pumps or reactor vessels, this situation generally doesn't arise, particularly where the production process is 'sealed', but what happens in other industry sectors, where this is not the case?

Example 6: A steel plate rolling mill is being updated with new machinery, as such then Scenario 1 applies and CE compliance requirements were identified not just in relation to the new machinery, but also with its integration into the existing rolling mill line. On such a line, steel plate weighing up to a 100 t and at temperatures approaching 1,000 °C is routinely travelling at 20 to 30 km/h. What is 'state of the art' for such a line and can the standards applicable to the Machinery Directive be successfully applied?

If we again go back to the guidelines on the Machinery Directive (EU Commission, 2010), this then clarifies:

- *Adoption of solutions proportionate to the hazard: Attempting to meet the requirements may lead to overcomplicated or excessively expensive solutions; they may even be impossible to meet. For example, how can you design a hand operated wood-saw so that the blade can cut the wood but not the operator's hand! The Directive does not allow such requirements to be ignored, but recognizes the importance of the state of the art (and let us not forget that one of the recitals refers to economic requirements). The Directive imposes only such preventive measures as are proportionate to the hazard, the cost and the technical level of the product.*

Realistically, it may well be simply impossible to comply with all the applicable standards, such as for equipment guarding, when designing such a steel plate rolling mill. Indeed, locking a machinery supplier into such a contractual requirement would simply grind the project to a halt. Therefore, the CE marking implementation strategy has to recognise, that in developing the final equipment specification for complex and hazardous equipment, the project team has to work closely with the supplier, such as specifying compliance with relevant sections of standards, rather than the whole standards in their entirety, and recognising the high degree of organisational controls, which apply in that industry sector. Engineers writing specifications also have to realise that standards come in different types, such as for Machinery Safety:

Type-A standards (basic safety standards) giving basic concepts, principles for design and general aspects that can be applied to machinery;

Type-B standards (generic safety standards) dealing with one safety aspect or one type of safeguard that can be used across a wide range of machinery:

- Type-B1 standards on particular safety aspects (for example, safety distances, surface temperature, noise);
- Type-B2 standards on safeguards (for example, two-hand controls, interlocking devices, pressure sensitive devices, guards);

Type-C standards (machine safety standards) dealing with detailed safety requirements for a particular machine or group of machines.

A safety standard shall not contradict the basic concepts and general principles for design stated in a type-A standard, but can deviate from specific requirements. The overall purpose of the type-A standard is to provide manufacturers, designers, etc. with the strategy or framework necessary to achieve adequate risk reduction. When a type-C standard deviates from one or more technical provisions dealt with by a type-A or a type-B standard, the type-C standard takes precedence.

For many straightforward equipment items, such as air compressors, an applicable type-C harmonised standard exists. In this case, EN 1012-1:2010 “Compressors and vacuum pumps - Safety requirements - Part 1: Air compressors”; so equipment specification is relatively simple. However, for more complex items, there is unlikely to a directly applicable type-C standard, so a considerable amount of investigative and preparatory work has to be done by the specification engineers to ensure the optimum CE marking implementation strategy. The days of ‘cut and paste’ from previous projects are gone.

Involvement in the Risk Assessment

The type-A standard for machinery safety is EN ISO 12100:2010 “Safety of machinery - General principles for design – Risk assessment and risk reduction”. This supports the implementation of the “Principles of safety integration”, which are the initial essential health and safety requirements of the Machinery Directive. This risk assessment begins with identification of the limits of the machinery, such as the characteristics and performances of the machine or a series of machines in an integrated process, and the related people environment and products, over the different phases of its life. For a relatively straightforward equipment item, this is something a manufacturer could do on his own, but for a complex machine, such as Example 6, this requires additional input from the project team and potentially also from plant operations.

For example, with respect to determining the limits of use; what are the anticipated levels of training, experience or ability of the users, which include the operators and maintenance personnel? Then there is the ‘danger zone’, defined as any zone within and / or around machinery in which a person is subject to a risk to his health or safety. With regard to Example 6, there are clearly going to be danger zones associated with the new machinery, which will impact on the existing line. While clearly also the existing line will have additional danger zones, which will impact on the new machinery. So if these issues are not properly co-ordinated with the machinery supplier, how are they going to be got right? So for complex machinery, a successful implementation strategy requires active involvement at the risk assessment phase.

Indeed, the same can be said of the ATEX ‘equipment’ Directive. The supplier can make assumptions about the internals of his equipment, such as a mill or a dryer, but he does not control the external environment, which is impacted by adjoining equipment, production methods, etc. All too often over conservative assumptions are made by the supplier, such as Ex rating all the external components compliant with a dust explosion Zone 22 area, when in reality for a modern hygienic facility, no persistent dust layers occur external to equipment and this Ex rating and associated cost is unnecessary.

There are also occupational safety obligations relating to use of work equipment, which arise under the Directive 2009/104/EC. The Provision and Use of Work Equipment Regulations (PUWER) are the UK implementation of this Directive, which require that any new equipment complies with the relevant Community Directives which are applicable, plus that it is subject to an initial inspection to ensure that the work equipment has been installed correctly and is operating properly. Naturally for complex equipment, the engagement of the project team, at the early risk assessment stage, has benefits when it comes to the final project phase and demonstrating compliance with the use of work equipment legislation.

Technical File

EU harmonisation legislation obliges the manufacturer to draw up technical documentation containing information to demonstrate the conformity of the product to the applicable requirements. In Annex VII of the Machinery Directive the contents of the technical file are specified, such as the risk assessment used to comply with the essential health and safety requirements, the design details, the safe instructions for use and the Declaration(s) of Conformity. The technical documentation must be kept for 10 years from the date of placing the product on the market, unless the applicable Union harmonisation legislation expressly provides for any other duration. As the Machinery Directive clarifies:

- *The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.*
- *The technical file does not have to include detailed plans or any other specific information as regards the subassemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.*

Note: As previously highlighted, only the authorities given statutory powers of enforcement for the ‘New Approach’ Directives have a right to see the technical file. It does not need to be published or given to the end users. As the EU Commission’s “Draft Guidance Document on the Low Voltage Directive Transition for 2006/95/E to 2014/35/EU” states:

- *There is not specific time limit in the Directive for a "reasonable period". This period has to be assessed by the authorities on a case-by-case basis, taking into account the level of urgency / seriousness of risk and the efforts for the economic operator to follow-up the request. A default period could be e.g. 10 working days, but giving the possibility to shorten it or extend depending of the case.*

The CE marking implementation strategy has then to not only focus not only on ensuring the provision of the correct documentation, but also in some cases arranging for its correct storage for potential retrieval if the circumstances should ever arise. For instance is we consider Scenario 1 in Section 2.3, a technical file would be required for the assembly of machinery. However, it would not be necessary for this file to duplicate various technical documentation obtained with the two individual machines forming the assembly, if these could be retrieved if required, such as from the operating site’s system for maintenance documentation. Indeed, the use of ‘document processing platforms’ on large projects has facilitated this, particularly where multiple parties are involved in ensuring the necessary compliance.

Manufacturing for own use

A successful CE implementation strategy will seek to place, as much as possible, the burden of compliance on the equipment suppliers. However, there are some exceptions where this will not work, such as where bespoke equipment for a unique production process is required or where sometimes the project team is required to integrate equipment items from different manufacturers, such as the assembly of machinery in Scenario 1 in Section 2.3. In this case it will be necessary to 'manufacture for own use' and complete the necessary technical file and Declaration of Conformity. Given good competent technical resources, this is in general not a difficult task, in particular if there is prior experience of having operated similar equipment in the past. However, there are legal implications, which are inherently related to the 'risk / reward' concept.

The 'Blue Guide' on the implementation of EU product rules (EU Commissions, 2014) explains in its Section 1.4 the legislation on product liability. Legal or administrative action may take place against any person in the supply or distribution chain, who can be considered responsible for a non-compliant product. The producer must compensate damages caused by the defective product to individuals (death, personal injury) and private property (goods for private use). Ten years after the product is placed on the market, the producer ceases to be liable, unless legal action is pending.

Admittedly this is very unlikely to happen if the 'state of the art' is ensured in the design, installation and operation of the equipment, while the producer is not liable if the state of scientific and technical knowledge, at the time when the product was put on the market, could not as such enable the existence of the defect to be discovered (the development risks defence). However, if consider the risk / reward equation; if a product, such as a machine, is mass produced and put on the general market, then the risks are appreciably higher, due to the number of people as a result exposed. However, with 'one-off' equipment in an industrial plant with good organisational controls, this risk is inherently reduced.

As regards reward, an equipment supplier invariably has a 'margin', while the company operating bespoke equipment benefits from the 'margin' obtained on the products produced by that equipment. However, a process design and project delivery company, such as PM Group, which completes such technical files and associated 'Declarations of Conformity', obtains a reward, which is limited to the profit margin on the manhours involved on the technical assistance. This creates a dilemma, in that the legal liabilities, i.e. the risk, are inherently greater than the reward. One could argue that in some cases completing simple integration of machinery and ensuring the compliance of resulting assemblies, is essentially within the service remit of a process design and project delivery company. However, this is not the same as manufacturing for own use complex bespoke equipment for a client and taking responsibility thereof.

Example 7: A US client in the consumer product sector was constructing through its European subsidiary its first production facility in the EU. It had developed in its US facility unique bespoke equipment with a US supplier, which was integral to the processing of the raw material. However, that supplier was not interested in developing capabilities with respect to CE marking, as the equipment order for the new European plant was for it a 'one off'. The solution was that PM Group specialists worked with the client's engineering team to develop a technical file and Declaration of Conformity. As far as the experienced US Professional Engineers (PE) on the client team were concerned, they and their company had an ethical responsibility to ensure this level of equipment safety regardless of the fact that in 'Europe' there was very defined documentation and legal requirements. As the 'New Approach' legislation defines an 'Authorised Representative', as any natural or legal person established in the Community, who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with the relevant Directive, the client was then able, as an authorised representative, to sign the Declaration of Conformity and take ownership of the technical file.

While the example above is very relevant where the client is already very familiar with the machinery, it cannot be applied in every case, particularly where the hazards are considered to be high. At the same time, the Machinery Directive only requires that approval of a 'notified body' be obtained for the 'high risk' machinery specifically listed in Annex IV of the Directive, such as sawing machinery with blades. However, could the experience of the 'notified bodies' be brought to bear with respect to machinery, which was not listed in this Annex IV, i.e. what services do these companies provide outside of those legislatively prescribed? This avenue was explored with a number of 'notified bodies', where it was found that while they could review designs, they had a conflict of interest with signing the Declaration of Conformities, as this was not compatible with their role as an official 'notified body' for product approval.

Currently a 'solution' has been found for such complex machinery and is being used by PM Group, where the services of TUV Nord as a 'notified body' are used to audit the design of the relevant machinery, while one of their subcontractors takes the role of the authorised representative as required, signs the 'Declaration of Conformity' and takes ownership of the technical file. For instance, for Example 3, where the hazards were considered both unique and high, while a manufacturer provided the integrated assembly of machinery as a package, his design and CE compliance was audited by TUV Nord to ensure compliance with the Machinery Directive and the Provision and Use of Work Equipment Regulations.

Modified equipment

Process plants will always be subject to modification and as the Guidelines on the Machinery Directive (EU Commission, 2010) clarifies:

- *"Thus machinery that was subject to the provisions of the Machinery Directive when it was first made available must be maintained in a state of conformity with the essential health and safety requirements of the Machinery Directive that were applied when it was first placed on the market or put into service".*

- *“This also applies whenever machinery is modified by the user during the course of its lifetime, unless the modifications are so substantial that the modified machinery must be considered as new machinery and be subject to a new conformity assessment according to the Machinery Directive”.*

In any project incorporating modifications to existing machinery / machinery designs, the project team must consider if any proposed upgrade to the machinery is so substantial that the machinery should be considered subject to a new conformity assessment. Unfortunately the EU Guidelines on the Machinery Directive (EU Commission, 2010) do not provide any further information in this regard, leaving it to the National Authorities. There is limited guidance in this matter, but given the importance of machinery to the German export economy, it is not unsurprising that specific guidance has been issued there by the German authorities, which is available as an English translation (BMAS, 2015).

- *In each individual case it must be determined whether new hazards have resulted from the modification of the (used) machinery or whether an existing risk has increased. Here we can distinguish three types of cases:*
 1. *There is no new hazard or no increase of an existing risk, so that the machinery can still be considered safe.*
 2. *Although there is a new hazard or an increase in an existing risk, the existing protective measures of the machinery before the modification are still sufficient so that the machinery can still be considered safe.*
 3. *There is a new hazard or an increase in an existing risk and the existing protective measures are not sufficient or suitable.*
- *Additional protective measures are not needed for modified machinery in the case type 1 and 2. Modified machinery of case type 3, however, must be examined further systematically through a risk assessment concerning the question of whether a substantial modification has been made. It must be determined whether it is possible to bring the modified machinery back to a safe state with simple safeguards. A review must be undertaken to determine whether the simple safeguard eliminates or at least sufficiently minimizes the risk. If this is the case, the modification may usually be considered as non-substantial.*

Example 8: A pharmaceutical company purchased a standard filter dryer package, but because of the unique characteristics of the production process installed its own automation system, which differed to that specified with the standard supply. As such the equipment was modified and the approach taken was to utilise the services of TUV Nord to audit the new design and its subcontractor to issue the ‘Declaration of Conformity’ as the authorised representative.

As regards the ATEX Directive, the ATEX Guidelines (EU Commission, 2013) confirm the same position above, in that a substantial modification; *“is any modification affecting one or more of the health and safety characteristics covered by EHSRs (e.g. temperature) or the integrity of a type protection. In this case Directive 94/9/EC has to be applied. This does not preclude the application of other relevant directives”.*

Conclusion

CE compliance can be successfully implemented into a project delivery strategy, but this requires planning and that planning has to start at the initial phase of the project. Key to the successful implementation of this strategy is the identification of which ‘New Approach’ Directives apply to the various elements of the project and equally so the identification of where they do not apply. Once this has been completed additional attention to detail has to be given to such as the safe instructions for use, the standards used for specifying equipment, the risk assessment used for the design of complex equipment and ensuring that while manufacturing for own use is minimised, where it is completed, it is legally compliant.

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