

Product Safety - Safety, Product Safety, Directives and Standards.

In this article we shall learn about some of the fundamental pitfalls that can trip and catch the unwary.

What is a 'safe product'?

When attempting to answer questions such as this it is often easier to answer the negative question of "what is an unsafe product"? Here the answer is simple:

An unsafe product is one that causes injury, or damages property.

If we look closely we see that this answer is not as straightforward as we first thought. If we consider something like water - this can kill and damage property.

We can drown in water only a few inches deep and will certainly die if we are deprived of it for many days: anyone who has suffered a burst pipe or a tap that has been left running will know the damage that water can cause.

Similarly there are no restrictions on the purchase of batteries, yet we know that the materials that they contain can be hazardous if the batteries are opened, or swallowed. These characteristics do not of themselves make the product unacceptable for use in our community provided their use is well known and accepted generally.

We take care of small children to ensure that they do not drown in the bath, burn themselves on cookers or fires and we accept that we will suffer injury if we grossly misuse certain products.

The bottom line is - nothing can be absolutely safe.

The role of standards is to provide use with guidance to the design and use of products, and to ensure an acceptable level of safety.

At this point I think it is beneficial to summarise our considerations and expectations. Most of us feel that products should not cause injury or damage and accept that we have a degree of responsibility for their safe use. These wholly reasonable views would cause us no problem if they were universally accepted and could remain in our heads - but unfortunately neither of these two conditions are true.

Firstly not all manufacturers will agree about the level of protection that they should give to the 'user', some may provide higher 'Quality' (see GKCL01) at a correspondingly higher cost: whilst others may provide a lower 'Quality' solution.

The result could be that the same type of product presenting the consumer with different levels of risk depending upon the manufacturer. This is not an ideal situation - least of all because the expectations set by the higher 'Quality' products may lull the user into a false sense of security when they used a similar product of another manufacturer.

So how does this relate to where we are now?

Many policies have shaped the path to the present but currently we have a range of ‘New Approach’ (CE Marking) directives that apply to very specific, but not all, products. Most battery powered products, and those powered from an external power supplies and mains adapters, will fall outside the scope of the Low Voltage Directive because their supply voltage is less than 60 Volts. This leads us to the first ‘rat-hole’. There is a common - and mistaken - view that “*If my product is outside the scope of the LVD then I don’t need to do anything!*” THIS IS WRONG! After all we have already deduced, in the first paragraphs, that products must be safe.

Any product outside the scope of the New Approach SAFETY directives falls, automatically, within the scope of the General Safety Directive. Thus:-

H	B	E	T	I	f	V
a	a	l	o	t	r	i
i	t	e	r	e	o	d
r	t	c	c	m	m	e
d	e	t	h	s		o
r	r	r	e		T	
i	y	i	s		P	C
e		c			o	a
r	C	C			w	m
s	h	o			e	e
	a	o			r	r
	r	k			e	a
	g	e			d	s
	e	e				
	r	r			m	
	s	s			e	
					r	
					s	

Covered By
Low Voltage Directive

Covered By
General Safety
Directive

The *Essential Requirements* contained within the General Safety directive are very similar to those of the LVD, namely:-

- ?? thou shalt not kill people
- ?? thou shalt not injure people
- ?? thou shalt not kill domestic animals
- ?? thou shalt not damage property

Therefore it is also in our interests to conduct the same safety assessments and tests for all of our products.

It is important to understand that the General Safety Directive is an 'old approach' directive and therefore one does not apply the CE Mark, does not issue a Declaration of Conformity: however we **MUST** ensure that the product is safe - within the meaning of the directive.

How do we ensure that products are 'Safe'?

The first point to note is that **we must demonstrate compliance** - good or traditional design practices are no longer good enough - if we are to place products on the market place we must be in a position to prove compliance if called upon. Hence the statement "Designed to meet" should be treated with suspicion.

The directives, generally, include a phrase similar to "...products that comply with a *relevant harmonised standard* are deemed to comply with the *Essential Requirements* of this directive...".

What this means is that if our product complies with an appropriate harmonised standard we can place the CE Marking on the product.

The important words to note here is "deemed" and "appropriate". The following are some of the implications of which we need to be aware:

1. If we can demonstrate that our product meets a relevant harmonised standard that we can legitimately apply the CE Marking.
2. If our product is found to fail compliance with a relevant harmonised standard then we 'could' be persecuted for incorrectly marking the product.
3. If our product causes an injury action may be brought against us by the Consumer - under the Product Liability Directive.
4. If our product causes an injury, or is otherwise proven not to comply with the *Essential Requirements* of the LVD, actions could be brought against us for incorrectly marking the product or other sections of criminal law.
5. If the harmonised standard is not appropriate then we may be committing an offence if we place the product on the market.

Thus using a harmonised standard will allow us to apply the CE Marking but does not guarantee that the product will meet the *Essential Requirements* of the relevant directive - failure to comply may, however, be used as evidence for the prosecution.

So in this way the harmonised standards can be compared to the Highway Code in that both give guidance but do not guarantee that we will not have an accident.

Demonstrating compliance, and producing a '*Data File*' are within the capability of most competent engineers but are specialist tasks that require expert knowledge of the standards, their interpretation, the application of the product, and how compliance will be maintained during manufacture. We shall consider this task in future articles.

Choosing an Appropriate Standard

Choosing the correct standard is the most significant task - it **MUST** be selected at the start of the project before any detailed design or specification of components is considered as it may (and probably will) affect all of these activities.

The choice of standard must be yours: but it is important to understand how the product functionality and interfaces affect the standards that may be appropriate.

Example:- I manufacture electrical test equipment and read the “SCOPE” of EN 61010 and decide to use it.

Some of my products have RS 232 interfaces and connect to Personal Computers PC's): these products are covered by EN 60950.

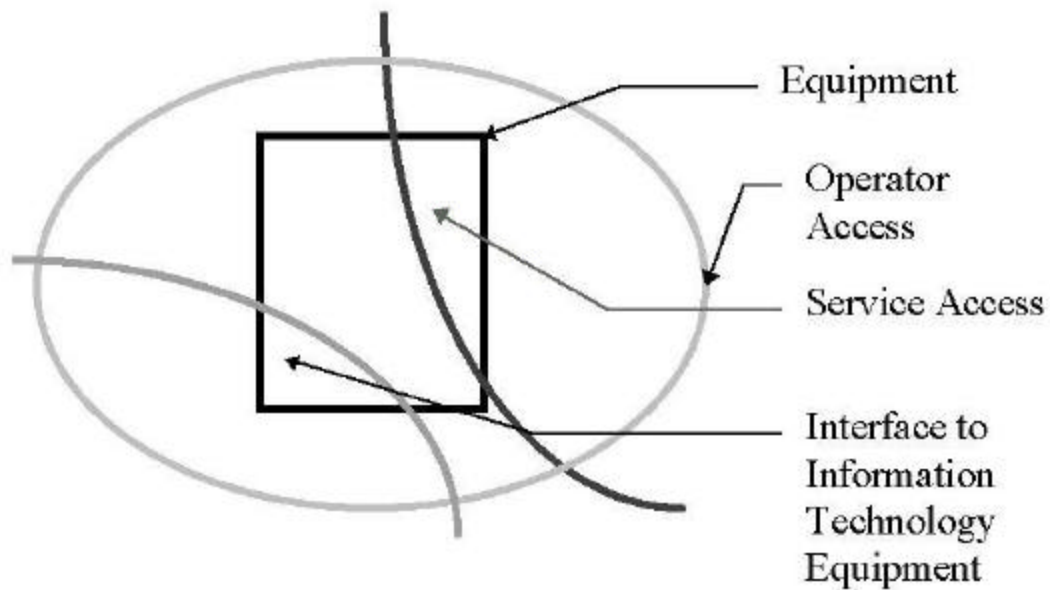
When I compare EN61010 and EN60950 I discover significant differences between them. In the case of electrical insulation of a safety barrier I discover that the (EN61010) “Creepage” and “Clearance” distances I have used between “Hazardous Voltage” and the “Operator Accessible” RS232 outputs do not comply with those of EN60950 (which requires a greater distance for my particular application).

In this situation we must consider the risk to which the operator is exposed. The operator of my test equipment is limited by an appropriate standard. The risk to which the PC operator is exposed is limited by EN60950: but my connecting my equipment to the PC I may be exposing the “Operator” to a higher degree of risk.

“Am I committing an offence?” “Could I be prosecuted?” - Frankly I do not know - that decision would be up to the Enforcement Authorities and the Courts - but if I was to be prosecuted I personally would feel more certain of victory if I was acting for the prosecution.

Mapping Functionality and Interfaces

Just as our choice of standard will be affected by the application of the product, our design will be affected by other interfaces.



This mapping exercise will:

1. Force us to consider aspects we might otherwise forget
2. Provide a formal record of our “due Diligence”
3. Act as a focus for remedial actions
4. Provide a Design Record to allow designers to follow our methodology at a future date.

We should complete this mapping exercise during the concept phase: if we fail to do it then there is a risk not only to the PCB’s layout but to the mechanical design; our labelling and instructions may also be non-compliant. Hence we may be forced to undertake expensive re-design before we can well the product or even supply prototypes for evaluation.

Mapping of electrical interfaces and components that require special consideration (e.g. need a Fire Enclosure) should also be carried out and the result added to our “*data file*”.

In the next article we shall some of the physical and mechanical consideration of the design. This is because it is these items that will define the overall shape, size and construction of our new product.