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Risk Assessment is good safety engineering, and
reduces financial risks

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This December sees the implementation of several important safety directives.
Keith Armstrong reviews those of relevance to the panel building industry,
and looks at their consequences

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The two main Safety directives of concern to PSB readers are the Machinery Directive, and what is usually referred to as the Low Voltage Directive, or LVD.

At present there are two Machinery Directives: 98/37/EC and 2006/42/EC, with the latter being mandatory from 29th December 2009. 98/37/EC has been repealed by 2006/42/EC, which makes no *official* provision for a transition period from the old to the new Directives.

However, it has been legal to declare a machine as being in conformity to 2006/42 since it was published in the Official Journal of the EU on the 9th June 2006. So, in practice, until 29th December this year, a machine can be supplied with an EU Declaration of Conformity that lists either directive (or both!).

For new types of machines, it is almost certainly best to declare conformity to 2006/42/EC right from the start. The general advice for machines that are already declared as being in conformity with 98/37/EC, is to assess them for conformity with 2006/42/EC (and create the necessary documentation) at a convenient time between 9th June 2006 and 29th December 2009. This would usually be when their designs were being modified, and some conformity assessment work would have been necessary in any case. At the time of writing (January 2009) there are only 11 months left to do this.

The current version of the LVD is 2006/95/EC, and it is simply a consolidation of the original LVD (73/23/EEC, as amended by 93/68/EEC and other Directives over the years). Its requirements are no different, but – where the LVD applies to a product – 2006/95/EC should now be listed on its EU Declaration of Conformity, regardless of whenever that model was first placed on the market.

2006/42/EC can be downloaded from:

http://ec.europa.eu/enterprise/mechan_equipment/machinery/revdir.htm,

and 2006/95/EC can be downloaded from:

http://ec.europa.eu/enterprise/electr_equipment/lv/direct/text.htm.

Both Machinery and LVD Directives require a risk assessment to be carried out, and for it to be used to guide the design and manufacture of the product. This is an explicit requirement in both machinery directives, for example 2006/42/EC states: "*The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.*"

However, in the LVD the requirement to carry out a risk assessment and take its results into account during design/manufacture is implicit. 72/23/EEC says: "*The Member States shall take all appropriate measures to ensure that electrical equipment may be placed on the market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Community, it does not endanger the safety of persons, domestic animals or property when properly installed and maintained and used in applications for which it was made.*"

The key phrase here is: "*...having been constructed in accordance with good engineering practice in safety matters....*". Risk assessment has for decades been recognised as a good safety engineering practice, so should be applied as part of LVD compliance. Unfortunately, it appears that many manufacturers are unaware of what constitutes good safety engineering practices, and so have not been applying risk assessment when complying with the LVD.

There are a number of other safety engineering issues that are implicit in the LVD, which was one of the first EC directives and only has a few brief paragraphs setting out its 'essential requirements'. Since the LVD was originally published in 1972, the European Commission has discovered that manufacturers tend to ignore implicit requirements, and only bother to comply with explicit requirements. Having had the benefit of 26

years experience with the LVD, 98/37/EC includes a 12 page list of explicit requirements, and 2006/42/EC increases this to 29 pages.

There has been a draft second edition LVD in the works for several years (2006/95/EC is not a second edition, merely a consolidation of the first edition and its various amendments). This draft would replace the existing few paragraphs of *implicit* requirements, with several pages of *explicit* requirements, including the mandatory requirement to conduct a risk assessment.

Many manufacturers believe that complying with a directive is just a matter of passing tests to all of the relevant standards that listed under that directive in the Official Journal of the EU. But when we read the directives we discover that complying with listed test standards only provides a 'presumption of conformity' – which allows a product to have the CE marking affixed and be offered for supply to customers in the EU. The word 'presumption' means exactly that – if the product is found to be unsafe, it does not comply with the directive and the full weight of legal enforcement can come down its manufacturer – *even if the product passes all the relevant tests!*

The range of technologies and applications available to products is so large that it is impossible to cover them all by performing a few standardised tests at an affordable cost. Added to this is that the process of creating or updating safety standards, and getting them listed in the Official Journal, is so slow that they are always several years behind the times. Whole new technologies or application areas can arise, that were never considered by the people who wrote the standards that provide the 'presumption of conformity'.

So we can see that simply relying on a product passing tests to published safety standards, means that they could still be unsafe in some way that was not addressed by the tests, making the product non-compliant. Whilst no responsible manufacturer wants to supply products illegally, a much more pressing concern – and one on which the very existence of the manufacturer might depend – is that *relying on safety standards alone does not ensure that financial risks are controlled.*

Good safety engineering that ensures legal compliance whilst also helping control financial risks, proceeds as follows:

- a) Perform a thorough risk assessment, which outputs a list of all of the reasonably foreseeable safety hazards that are so risky that they need to be controlled in some way.
- b) Compare this list with the risk control achieved by applying the usual safety test standards.
- c) Where there are some risks that are not adequately controlled by applying those safety standards,, they should be controlled by other means.

Doing a thorough risk assessment requires much more work than, for example, performing an FMEA (Failure Modes and Effects Analysis). Future columns in this series will discuss how to do risk assessments, and how to deal with any risks they discover that are not adequately controlled by passing the usual safety test standards.

The EMC Directive and UK Regulations, and their official guides, plus a great deal of useful and practical information on EMC and EMI, are available as described in the document: '*Some Useful References on EMI and EMC*' posted on this site.

EMI and EMC is often ignored (incorrectly) in risk assessments. People believe that as long as they ensure that the equipment passes the relevant EMC tests under the EMC Directive, maybe with the immunity test levels increased, this is sufficient. **But this approach is quite wrong**, and it is trivially easy to show why. Instead, read and apply the IET's new Guide on EMC for Functional Safety, 180 pages, August 2008, (which replaces the IEE's 2000 Guide). Free download from: www.theiet.org/factfiles/emc/index.cfm, and available as a reasonably-priced (£27) colour-printed-book from www.emcademy.org/books.asp.