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How to do Risk Assessment (Part 1)

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How to do Risk Assessment (Part 1)

In this first instalment of a multi-part series, Keith Armstrong looks at the best ways to approach carrying out a risk assessment and details how to overcome common problems

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The previous column in this series, PSB March 2009, introduced the European Directives that are commonly relevant to panel and system builders as regards safety, and discussed the role of Risk Assessment in complying with them and in reducing a company's exposure to financial risks.

This column starts to describe how to do a risk assessment, and future columns will continue this, and will also describe how to deal with risks that are found not to be adequately controlled by the usual safety test standards.

A HAZARD is anything with potential to do HARM, and we are interested in the severity of that harm. For example, consider the hazard from something sharp: might it cause a cut that will heal in a couple of days; a cut that should eventually heal in a few weeks; amputation of a limb; amputation of two or more limbs, or amputation of the head.

A harm has a likelihood (probability) of occurrence, and what we call the RISK of a hazard is the product of the severity of the harm and its probability.

Safe design and assembly requires analysis of all reasonably foreseeable hazards and their risks, to achieve both the functionality at a reasonable cost – and the degree of safety required. It is important to understand that nothing can ever be 100% safe. Whether it was *safe enough* is determined by the courts after a safety incident, who will apply the relevant safety laws and consider arguments from lawyers acting for the plaintiff and the defendant.

But this is not very helpful, because we want to know if our product is likely to be considered safe enough *before* we deliver it to the customer! The degree of safety required depends upon Directives, their national implementing laws (and maybe some other national laws too) – but also upon the application area, the type and numbers of people exposed, and whether national media involvement is likely.

For example, people working in heavy industries are expected to be better able to take care of themselves, and to be more aware of the possibility of danger, than are children in a nursery, and this influences the way in which products intended for those applications are designed to make them safe enough. Also, the media gives more emphasis to risks to children, than to adults.

When something is safe enough, we say that its risks are tolerable. Some industries (e.g. medical [1]) use the phrase 'acceptable risk' instead, but the UK's Health & Safety Executive argue that no-one finds any risk *acceptable*, but everyone (in their right mind) is prepared to *tolerate* a degree of risk depending on the benefits that are associated with it.

If the level of TOLERABLE RISK for any hazard is unknown, there is no point in even beginning a risk assessment, because its results would be meaningless – no guide to design at all. So we can now start to create a spreadsheet for our risk assessment, with six columns on it:

a) A column for listing each of the hazards, in turn

b) The tolerable risk, for each hazard in turn

c) The actual risk, as initially assessed for each hazard in turn

d) The 'risk reduction' that is required to reduce the actual risk until it is no worse than the tolerable risk, for each hazard in turn.

e) A description of how the risk reduction was achieved

f) The final risk assessed for each hazard in turn

To make this process easier to control, 'Risk Graphs' are used to come up with a single value for the risk, to use in the spreadsheet. Figure 1 is a risk graph based on [1] that I invented just for this column, simply for the purpose of illustration.

I <u>don't recommend</u> that Fig. 1 be used – every company should find out if there is a risk graph that has been accepted (or even specified) for the particular application area they are working in, and if not they should create their own risk graph based on what they feel is a suitable model – probably one that is used in a similar application area. Many risk graphs and similar guides exist for different industries, for example: medical [1], military [2], Health & Safety at Work [3], etc.

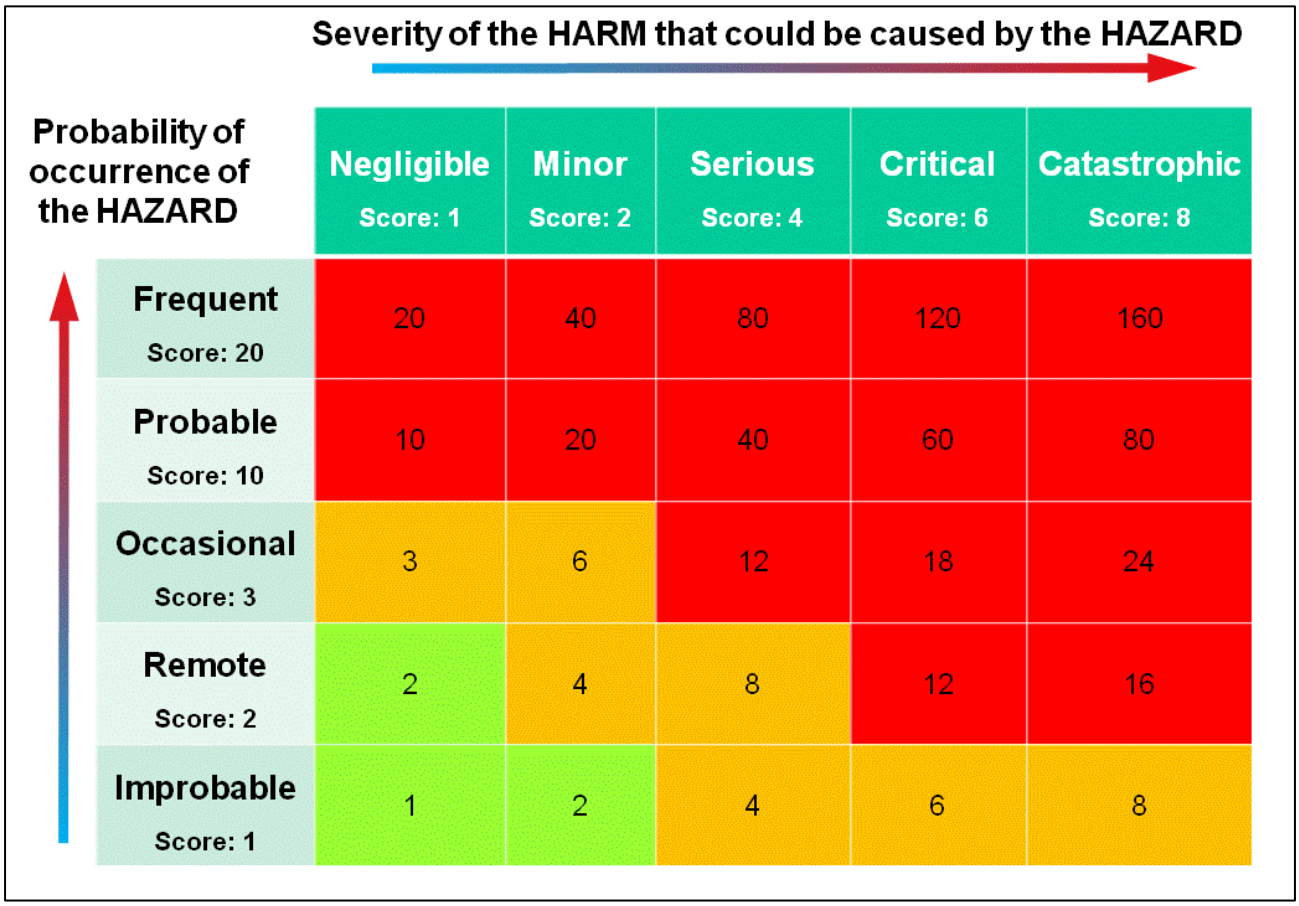

Figure 1 Example of a risk graph

The numbers I have allocated to the 'probabilities' and 'severities' are arbitrary, and the multiplication that appears in the individual cells represents the overall risk. In Figure 1, risk numbers of 10 or more are considered intolerable, and must be reduced regardless of cost, so they have a red background to their cells. Risk numbers between 3 and 9 represent tolerable risks that should be reduced where cost-effective (cell background in gold). Numbers of 2 or less can be ignored (green background).

Of course, calculating whether a risk-reduction measure is cost-effective requires placing a value on a life, and on various kinds of lesser harm. But beware – someone under 30 whose injuries will require 24-hour nursing for the rest of their life could 'cost' more than someone who is over 60 but dies.

In some applications it can be useful to add extra multiplying factors, for example depending on how able the person exposed to each hazard is supposed to be able to look after themselves, and/or how the media would view the risk.

Figure 2 shows some examples of how the categories for Severity and Probability in Fig. 1 could be allocated. Depending on the application, different measures of probability will be appropriate. For example: "probability of harm per use"; "probability of harm per hour of use"; probability of harm per year", etc.

References:

[1] ISO 14971 "Medical devices -- Application of risk management to medical devices"

[2] "Practical experiences in Upgrading and Standardising the Safety & Environment Systems (SEMS) for the RN Marine Power & Propulsion Systems Division", J P Oliver and Chris Blake, 2nd IET International Conference on System Safety, 23-24 October 2007, Savoy Place, London

[3] "Reducing risks, protecting people – HSE's decision-making process", Health and Safety Executive, ISBN 0-7176-2151-0, cost £5.00, www.hsebooks.com. Also, the HSE information Sheet "Guidance on Risk Assessment for Offshore Installations", HSE Offshore Information Sheet No. 3/2006, describes the use of a risk graph.

Examples of five severity levels

Common terms	Possible description of the result of the HARM
Catastrophic	Death
Critical	Permanent impairment or life-threatening injury
Serious	Injury or impairment requiring professional medical intervention
Minor	Temporary injury or impairment not requiring professional medical intervention
Negligible	Inconvenience or temporary discomfort

Examples of five probability levels

Common terms	Examples of probability range
Frequent	$\geq 10^{-3}$
Probable	$< 10^{-3}$ and $\geq 10^{-4}$
Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
Remote	$< 10^{-5}$ and $\geq 10^{-6}$
Improbable	$< 10^{-6}$

Figure 2 Examples of assigning categories

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.emcacademy.org/books.asp.