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# INSIGHT

# Product safety risk assessment

**Product safety legislation varies from country to country around the world. However, a single unifying requirement is that products must be designed and produced so that they are safe to use. But what is a safe product? There is no such thing as complete safety – it's not a condition that can be achieved in absolute terms.**

*There are only degrees of safety. It is a relative concept that is reliant on many factors. Therefore, in order to demonstrate compliance with the universal safety requirement manufacturers have no option but to assess risk and make judgements based on the guidance of product safety standards and other information.*

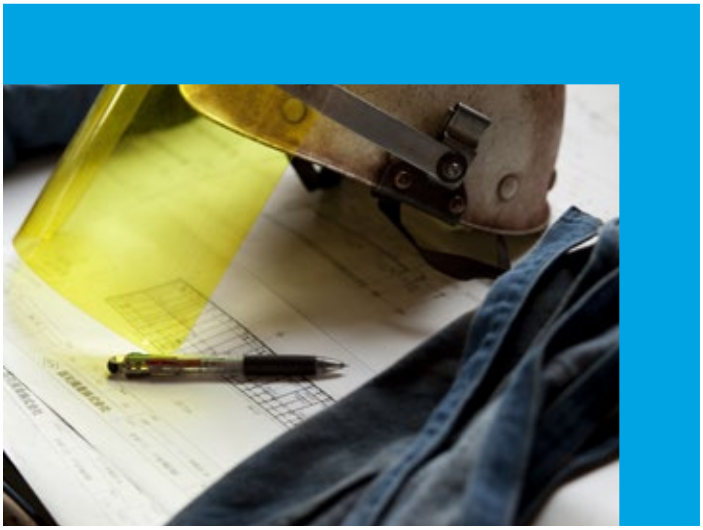
To fulfil this duty, manufacturers must undertake a product safety risk assessment, also known as a design review. Performed at the design stage, before products are produced and launched onto the market, risk assessments seek to foresee how accidents can occur. The aim is to put in place design and manufacturing controls which reduce the risk to acceptable levels.

## Risk Assessment Records

Keeping accurate records is a very important part of the risk assessment process. Their purpose is two-fold. Firstly they provide a record of the basis on which a product was assessed as being sufficiently safe for launch onto the market. Clearly, they may ultimately be used as part of a defence in the event of prosecutions or claims. However, they also provide a baseline from which to evaluate new information and decide what further adjustments or improvements might be required.

A risk assessment technical file, depending on the product, can include technical drawings, test results, a list of essential health and safety requirements, standards or other technical information which were used to make design decisions, and, a report of the hazard identification risk evaluation and improvement steps. From a practical point of view, these records must be kept for at least five years after the last product unit has been supplied. In some instances, this time-frame can be longer.

Risk assessment is a practical exercise that improves the quality of the development and manufacturing processes and helps deliver higher standards of safety and product reliability. Unfortunately, it is all too common that product safety risk assessments are either not undertaken, or are not carried out effectively.



As a result, unsafe and unreliable products are regularly launched onto the market. Safety problems are then only identified after accidents have occurred or manufacturing problems arisen. The resultant product recall costs and claims are potentially enormous. In some cases, the longer-term viability of those manufacturers involved has been threatened.

## Evaluating product risks and improvements

Evaluating what risk control improvements are required and what would be considered as suitable design controls or improvements is another critical step in the risk assessment process. Relevant product safety standards are an important source of guidance.

However, sometimes, detailed guidance is not available on every aspect of a specific product's design and intended range of use. Ultimately, the design team will need to make judgements based on risk. It is important that design teams use a formal process for evaluating risk which will include a risk matrix – a tool that assists with evaluating risk. The criteria to consider when evaluating risk is:

- When risk is assessed as high – then the risk is intolerable and improvements are required to reduce it to acceptable levels regardless of cost.
- When risk is medium – action is required to reduce risk to as low a level as reasonably possible.
- If risk is judged to be low – then it can be prioritised for action after other issues have been dealt with.

Regardless of the level of risk, the aim must be to seek to make the product as safe as reasonably possible. For example, even if the risk is low, if there is a simple or low cost means of improving safety then there have to be very good reasons for not implementing them. Improving the standard product safety must be seen as a continuous and on-going process. Manufacturers must stay up to date with new technology and any feedback that they get from users, e.g. near miss-uses, accidents etc.