

// MINIMIZE RISKS FOR USERS, PATIENTS OR OTHER TO AN ACCEPTABLE DEGREE

Risk analysis and/or product standard?

The manufacturer, meticulous to details, might question whether a risk analysis is obligatory in the case of an existing product standard. The answer is: In principle yes, because the product standards also aim to define the necessary measurements, in order to reduce the risk to an acceptable degree. But the standards are often not state-of-the-art. Thus the manufacturer should verify if the current technology is still covered by the standard.

Moreover the product standards assume standard realizations. »Exotic« concepts are often not considered. In these cases the more basic EN 1441, describing the risk analysis, is a lot more helpful. Furthermore the product standards (partly implicitly) are based on the assumption that certain application fields and principles are present. Thus it must be verified if the product is covered by it. Finally the product standards do not consider the optional components. Therefore it should be checked if all functions/components of the product are covered by the standard.

A challenge

Even if the revised standard IEC 60601-1 has not been submitted as a final draft: Its implementation will be a challenge for the manufacturers. steute has prepared for it early and profits from the know-how of other application fields (safety switchgear for industrial applications, switchgear for explosive-endangered areas) concerning the application of relevant standards and methods (e. g. risk analysis, risk assessment).

Fig. 2

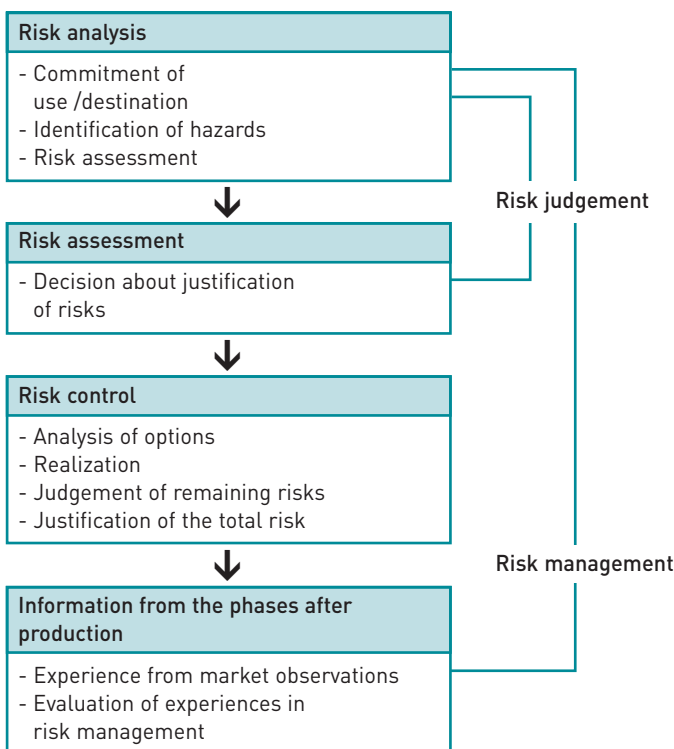


Fig. 3

