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Product safety – Principles and practices in a life cycle perspective

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ABSTRACT

This article describes a new product life cycle model that can be used by producers to improve safety and to prevent defective products from being placed on the market. The model has eight phases and the article describes and discusses the required safety-related issues in each phase. Analytical methods that should be used in the various phases are identified. Both consumer and industrial products are covered. The article outlines main product safety requirements with focus on European product safety legislation. The concept adequate safety is introduced as an acceptance criterion for the producer during the product development process, and factors that should be taken into account when deciding whether or not a product has adequate safety are discussed.

1. Introduction

Every day, we are in contact with a high number of products (e.g., cellular phones, computers, cars), and our lives and our perceived well-being depend on the functions and properties of these products. In developed countries, most products placed on the market generally have a high level of safety, but still some products cause harm to humans, the environment, and/or financial assets. This lack of safety is sometimes explained by (i) the increasing complexity of many products, (ii) the time- and cost pressure during product development caused by the fierce competition, (iii) new technology being put on the market before all features are known, (iv) designers and/or producers who cut corners to save time or money, or because of lack of knowledge, (v) products being used in other ways and for other purposes than anticipated, and so forth.

Most producers are striving to increase the safety of their products to enhance their competitive power, reduce warranty cost, and prevent liability claims and product recalls. In the car industry, safety is today an important marketing issue, and cars with less than four stars in the Euro NCAP tests[1] may be difficult to sell in some markets. Still, cars are launched on the market with very different safety levels, as measured by the NCAP tests.

Despite increased safety awareness among customers, producers, and authorities, there are several recent examples of accidents due to product failures. In October 2005, Ford and Bridgestone Firestone settled a dispute about whether Ford car accidents were a result of defective Bridgestone Firestone tires, or from vehicle defects. Until then, at least 271 people had been reported killed and several hundreds injured in accidents that involved such tires. Bridgestone Firestone had to recall 6.5 million tires, a €286 million company expense. The replacement of the tires cost Ford €2 billion, among the costliest in corporate history (NY Times, 2002; The Associated Press, 2005).

Product recalls are not unusual events. In 2007, Mattel had to recall more than 20 million toys (BBC, 2007), due to unacceptable levels of lead in the paint, and loose magnets which could be dangerous for children if they swallowed them (Mattel, 2007). Another example is the exploding lithium-ion batteries made by Sony. In 2006, Dell, the computer manufacturer, replaced millions of batteries in laptop computers sold between 2004 and July 2006, due to reports from customers about batteries overheating, catching fire, and even exploding. One incident was captured on film at a conference in Japan, and passed around the Internet. At that time, the cost to Dell and Sony was expected to be between €130 million and €260 million (The Economist, 2006; Blakely, 2006), but later estimates have been about €325 million for Sony (Valvik, 2007).

Viewed in light of these and several other cases, it may be relevant to ask why producers still have problems making products safe. Unfortunately, there is no simple answer to this question. Hasan et al. (2003) classify literature, studies and research work on product design into the categories; design methods, design approaches, process and models, design paradigms and reasoning, and product sizing and representation. They claim that safety is hardly included in any of these categories, and that there is no commonly used method for integrating safety into the design process. However, standards, like ISO 12100-1, ISO 14121-1, ISO/

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[1] Euro NCAPs aim is to inform drivers and the automotive industry about the safety performance of the most popular cars sold in Europe (NCAP, 2008).

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TR 14121-2 are made to give guidance on achieving the "essential requirements" to health and safety in European legislation. Product development models and methods are described in several textbooks, e.g., Roozenburg and Eekels (1995), Murthy et al. (2008), Eder and Hosnedl (2008).

Hale et al. (2007) provide a list of questions that they believe need further study to increase the knowledge about how to achieve safe design. One of the major questions they ask is if safety "is best accomplished through a structured model of decision making in design".

The main objective of this article is to address this question by describing a new model that contributes to efficient product safety performance, specification, and decision making. The model is developed to assist producers in accomplishing the desired product performance, which means that safety aspects are considered for the whole life cycle of the product; from conception to final disposal. Occupational safety issues, for example, with respect to production and operation of the industrial product are not explicitly covered. The structure of the model is proposed by Murthy et al. (2008), and the model consists of three stages (pre-development, development, and post-development), three levels (business, product, and component), and eight phases.

The article is biased towards European law and practices, but the proposed model is generic and should be of interest for a much larger geographical audience. The first part of the article gives an overview of important concepts and regulations related to product safety, topics that constitute the framework conditions and set the scene for the model. Very few of the recent articles attempt to address such topics, but some exceptions are Kjellén (2007) and Baram (2007), even though these are more specific, as they are applied to the oil and gas industry and tort liability, respectively.

The main part of the article discusses how safe design evolves in the new product life cycle model. Regarding the term "product", we focus on physical consumer and industrial products and mainly on their consequences to human health. Food, cosmetics, and medical products are not covered. Important to have in mind, however, is that the life cycle perspective may be applied to more complex industrial systems as well, as it is one of the main characteristics of the systems engineering process (Blanchard and Fabrycky, 1998; Utne, 2006). Nevertheless, the nature of the development process will obviously depend on the complexity and hazard potential of the product.

The article concludes that meeting the objectives of safety is a trade-off decision within the constraints of cost, schedule, and performance. Maximum effectiveness is obtained by applying product safety principles early and throughout the life cycle of the product. The proposed decision making model facilitates sufficient specification of product safety requirements, decisive for succeeding in making products safe, and as such, this article suggests an answer to the question raised by Hale et al. (2007).

2. What is product safety?

The term product safety consists of two parts: *product* and *safety*. According to Roozenburg and Eekels (1995), products are "artifacts conceived, produced, transacted and used by people because of their properties and the functions they may perform". Products may be divided into tangible (physical) and intangible (e.g., software), non-durables (e. g., food) and durables (e.g., cellular phone), commercial/industrial (e.g., cranes) and specialized products (e.g., military vessels) (Murthy et al., 2008). Many products may also be considered as systems.

Safety is a term with many different definitions. MIL-STD-883D defines safety as "freedom from those conditions that can cause death, injury, occupational illness, damage to or loss of equipment or property, or damage to the environment". According to the EU general product safety directive (GPSD, 2001), absolute safety is not attainable, and safety is therefore a relative term that implies a level of risk that is both perceived and accepted.

Assembling the two parts of the term, a *safe product* may be defined as "any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risk compatible with the product's use ..." (GPSD, 2001). On the other hand, a dangerous product is defined as "any product which does not meet the definition of safe product". Product safety then is "the application of engineering and management principles, criteria, and techniques to achieve acceptable hazard risk, within the constraints of operational effectiveness, time, and cost, throughout all phases of the system life cycle (also called "system safety")" (US Air Force, 2000).

3. Product safety requirements

Producers are expected to take reasonable care regarding the safety performance of their products, which means that products have to fulfil the requirements without being too costly to produce. The product properties are addressed through the product development process, when the requirements to the product are worked out and specified. Safety requirements are dependent on the type and application of the product, and may be qualitative and/or quantitative. Product safety requirements are mainly given in laws, regulations, and standards, or stated by the customers of specialized products, or come from consumer organizations or customer interest groups (Murthy et al., 2008).

The increasing focus on a product's reliability and safety aspects has resulted in several laws, regulations, and standards. In 1985, the European product legislation was radically changed by the "new approach" method. By this approach, the "essential requirements" to health and safety of products are specified in Directives, while the European standardization bodies, CEN, CENELEC, and ETSI, are responsible for making the corresponding technical specifications to meet these essential requirements. Standards that are linked to directives in this way are referred to as "harmonized standards". They cover entire product sectors from household appliances, other electrical equipment, machinery, pressure equipment, toys, construction materials, medical devices, measuring instruments, lifts, and recreational craft, to personal protective equipment (European Commission, 2005).

Several harmonized standards have later been replaced by ISO and IEC standards that have the same role as the harmonized standards (Murthy et al., 2008). The standards are not mandatory, but the producer has an obligation to prove that the product conforms to the essential requirements.

If a product, such as a toy or a cellular phone, is found to be dangerous, the national authority takes action to eliminate risk through withdrawal of the product, product recalls, or warnings. Then the authority informs the European Commission about the product and the measures implemented. The Commission informs all other EU countries, and publishes a weekly overview of dangerous products and the means taken on the RAPEX Internet site (RAPEX, 2008). RAPEX is an acronym for Rapid Alert System and covers all consumer products, except food, pharmaceutical and medical devices, products which are covered by other mechanisms. Currently, the RAPEX guidelines are being revised (European Commission, 2008).

3.1. The general product safety directive

The EU general product safety directive (GPSD, 2001) requires producers to place only safe products on the market, and to inform