

Product Safety: Risk Management Fundamentals For the Safety Professional

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Introduction

The role of the safety professional is ever changing with influences coming from society, business & industry as well as the government. Traditionally, safety professionals have focused on employee safety and health, including meeting or exceeding OSHA and other regulatory requirements. Within many organizations this role is increasingly being expanded to include other responsibilities including involvement with product safety. Whether this involves providing input on the selection and purchasing of products to be used in the workplace or a role in product development, the safety professional's skill sets are uniquely positioned such that they can be expanded to include product safety.

Whether your interest in product safety is more of a curiosity or you are seeking a foundation for continuing professional development in this important safety topic area, this session will provide an overview as to the risk management fundamentals impacting product safety.

Product Safety in America

The expectation in America is that products being marketed are safe. This applies to consumer products as well as products intended for use in business and industry. Fortunately, to a large extent, this expectation is being met by product manufacturers and distributors. These entities are influenced to achieve product safety by various factors some of which include consensus standards, customer expectations and regulations that apply to their products. For regulated products, the threat of violations and penalties can also motivate product manufacturers and distributors. The possibility of product liability litigation in our litigious society also influences product safety risk management initiatives.

Even with the considerable efforts focused on product safety, rarely a week goes by without the news media reporting on product safety in one form or another. These reports often involve the potential for or actual injuries, illnesses and deaths associated with products marketed in our society. The news reports may be specific to product recalls, contamination causing foodborne illness outbreaks, counterfeit products, unsafe motor vehicles, tainted pharmaceuticals, hazardous medical devices or other related topics. These reports often involve consumer products

but commercial and industrial products are not immune from media attention when safety issues arise

As an indication of societal product safety concerns, the food industry is a good example. The Center for Disease Control estimates that each year foodborne illness outbreaks result in 48 million gastrointestinal illnesses, 128,000 hospitalizations and 3,000 deaths. The CDC also estimates that each year one in six Americans will become sick with food poisoning. These numbers reflect an improvement over those reported previously but consumers, consumers' rights groups, regulators and even the food industry continue to stress the need for food safety improvements. This contributed to the implementation of the FDA Food Modernization Act.

Motor vehicles recalls are regularly issued and have both on-the-job and off-the-job safety implications. Based upon National Highway Traffic Safety Administration (NHTSA) statistics the number of recalls involving motor vehicles and related regulated products (equipment, child safety seats and tires) have increased to a level in the range from 506 – 781 per year since the year 2000. Prior to 2000 the number of recalls was less than 440 per year, with many years being substantially less than this level. During 2012 there were 664 recalls affecting 17,817,538 units. Since 1966 there have been a total of 17,042 recalls and 712,226,981 affected units.

Products, be they consumer, commercial and/or industrial products, can range from low hazard general-use items posing a negligible product safety concern up to high hazard products capable of causing serious injury or death. The ability to differentiate hazards and risk levels benefits from a multi-disciplinary approach.

Product Safety and the Safety Professional

Product safety is commonly associated with being the primary responsibility of design engineers. Engineering disciplines that may be involved include: electrical, electronic, mechanical, chemical, software, etc. These individuals commonly have a depth of knowledge specific to their engineering discipline and should be familiar with the various applicable consensus standards and industry criteria that apply to the product. The importance of the role of the design engineer is not to be understated. The education and development of these engineers in the area of product safety can, however, vary dramatically. For this reason a multi-disciplinary product design approach is promoted. The safety professional can play an important role in the product design and development process.

The safety professional can also contribute to the safety of products, machinery and equipment purchased and utilized by employees in their work environment. The importance of this role is often underestimated but can have a significant impact on injuries in the workplace. Working with industrial engineering, manufacturing and purchasing, safety input and feedback needs to be a part of the purchasing process especially for those items posing a moderate to high risk of injury.

The skill sets of the traditional safety professional that can be used to benefit product safety include knowledge and experience with:

- Hazard recognition
- Risk assessment

- Process safety
- Safety by design
- Ergonomics
- Behavioral safety
- Safety training and instruction
- Safety regulations (i.e. OSHA, FDA, USDA, NHTSA, CPSC and others)
- Consensus standards (i.e. ANSI, ISO, etc.)
- GHS – MSDS/SDS
- Incident investigation and trending
- Crisis management

Product Safety Risk Management Fundamentals

The Product

While defining what a ‘product’ is may seem overly simplistic, there can be considerable debate especially when it involves such items as software programs, electricity and natural gas. For the purposes of this discussion a product is a tangible physical item grown, manufactured and/or otherwise assembled or prepared for marketing to customers. This would include consumer goods as well as items sold for commercial, business, industrial and construction use. Products could also be referred to as: materials, merchandise, goods, food items, tools, machinery, equipment, clothing, furniture, recreational vehicles, motor vehicles, etc.

Fundamentally, it is important to recognize that the expectation of society and consumers of all types is that products will be safe and suitable for the use(s) for which they are marketed. Failing to meet this expectation can have serious consequences for the manufacturer, distributor and/or retailer of the product.

Product Design & Development

The product design and development process serves as the foundation for promoting product specific safety. The attention devoted to product safety can vary considerably based upon the type of product, technology, end use application(s), the product users and other variables. A key safety concept to recognize in this category is that the product design will impact every product of this design manufactured. That is to say that a design defect would result in that defect affecting all of the products manufactured. In contrast, a manufacturing defect hopefully would impact only a batch or lot before being detected but has the potential to affect larger numbers of products if undetected or allowed to continue uncorrected.

Standards, Regulations and Requirements

As a part of applying sound engineering criteria it is important to assure that the product meets the applicable standards and other criteria that apply to it. Deviations from these criteria need to be justified and documented for possible future reference. Industry and customer specific expectations also need to be considered especially where it impacts product safety.

Risk Assessment

The risk assessment process is a critical stage in the design and development of a product. Properly conducted risk assessment takes into account a wide variety of factors such as the type of product, product use(s), product users, the use environment and other variables that can be

used to analyze potential hazards, the probability of the hazard causing or contributing to an injury or illness and establish the level of risk created. The product design and risk assessment process also needs to anticipate the opportunities for the misuse of a product. The risk assessment process, when properly utilized, will aid in determining possible design modifications or other measures that can reduce the overall risk associated with a product.

Design Reviews

During the product development process design reviews are commonly conducted to evaluate progress, to review challenges being encountered and to anticipate potential complications. These reviews provide the opportunity for the multi-disciplinary involvement mentioned earlier. Safety input at this point allows for the opportunity to eliminate or minimize risk. After the design has been completed and manufacturing has begun the ability to implement design changes becomes more problematic and less effective control measures may become necessary such as utilizing guarding and hazard warnings as opposed to eliminating the hazard.

Product Testing

Actual testing of prototype products is commonly conducted to evaluate the product performance and conformance with the applicable standards and regulations prior to manufacturing. There often are standardized testing methods that need to be applied. It is important that this testing target hazards that could be encountered during normal use, possible misuse, product failures and maintenance conditions. Hazards identified can be addressed much easier at this stage of development than after the product has been marketed. The use of third party testing organizations and possible product listing (i.e. UL) should also be considered. For some products testing is required.

Product Safety Information

The type of product safety information to be developed needs to be addressed early in the product design process. Where hazards cannot be eliminated alternate approaches to deal with them need to be identified. Specific to warning labels and other product safety information provided in user manuals, installation instructions and service/maintenance information it is important to apply ANSI Z535 and/or ISO 3864 criteria as a means of standardizing the presentation of this information. The safety symbol and signal words (CAUTION, WARNING and DANGER) are used to communicate the varying risks of injury or death. Methods are also in place for indicating the potential for property damage.

From a risk management perspective a multi-disciplinary approach to product design is encouraged with benefits often realized in conjunction with the design review process. Depending upon the product, the skill sets of the safety professional may be particularly beneficial during the design review process.

Manufacturing and Quality Management Systems

Manufacturing and related operations and processes can have a dramatic impact on product safety. As previously indicated, inconsistencies or 'nonconformances' in manufacturing and assembly can result in an inability to maintain product design specifications that affect product safety. A nonconformance has the potential to rise to the level of being a defect. Risk management initiatives need to strive to minimize this possibility.

The production equipment and machinery can impact product safety and quality as well as employee safety in the manufacturing environment. This makes these factors important to consider at the earliest possible time, namely during procurement. The ability of the materials and processes to consistently maintain the product specifications and tolerances needs to be evaluated and maximized. This evaluation also needs to address the human involvement and interaction with the process and product.

Even with manufacturing management in place and a robust quality management system the safety professional benefits from recognizing the interrelated nature of production, quality and safety. Modifications impacting one of these three areas have the potential to also impact the other areas. Consideration as to all three areas expands upon the overall business benefits that can be realized.

For subcontracted production or outsourced manufacturing, qualification and monitoring processes are often used. In some industries this entails an initial and periodic audits that include the consideration of employee safety along with variables that apply to quality and product safety.

Product Marketing and Representations

Products are marketed for intended purposes contemplated in the design. Product safety can be influenced by the marketing materials, advertising information and other product use representations, written or oral, that may directly indicate or imply product use applications going beyond that for which the product was intended. For this reason it is important to clearly define the intended use application(s) as well as to anticipate foreseeable product misuse.

Potential hazards associated with the intended product use, or possible misuse, that cannot be eliminated through the product design, need to be effectively communicated. Efforts of this type can vary considerably based upon the product and circumstances but need to consider communicating potential hazards in product safety information as well as in the form of properly configured warning labels. Assuring that this information reaches the end user also needs to be factored for products that may be purchased by other than the end user.

Installation, Service and Maintenance

For some manufacturers their products require installation as well as periodic service and maintenance activities. From a product safety perspective these activities need to be considered with attention directed as to who will be doing the product installation, service and maintenance work.

A product manufacturer performing installation, service and maintenance work needs to have detailed policies and procedures that anticipate not only the hazards that may encounter but also the impact of the field activities on the overall safety and performance of the product. Unsafe characteristics need to be corrected. When this is not possible measures need to be taken to communicate the type and severity of the hazard to the customer. Documentation needs to be standardized and be maintained to verify the work and the communication with the customer.

The use of a third party installer hired by the product manufacturer has similar implications to utilizing their own employees along with possible limitations or shortcomings in the ability to control work practices and generate the necessary documentation.

Business and industry needs to pay attention to the installation, service and maintenance work being performed on equipment and machinery because of the potential adverse impact on these items, their employees and the facilities.

Post Marketing Activities, Incident Investigation and Case Management

Product manufacturers need to monitor the use and performance of their products including feedback from their customers. Customer service, warranty activity and other mechanisms can be used to track and trend problems with their products. Social media Internet sites are a relatively new means through which product related feedback can be obtained. Feedback indicating product safety concerns need to be escalated to the appropriate management representatives for follow-up.

For those occasions when an incident occurs that involves a manufactured or distributed product there is a need to investigate the incident in an effort to determine fundamental and root causes. In the product safety area these investigations are often completed by engineering with the possible involvement of quality assurance but may benefit from the skills of a safety professional. The results of such investigations may bring about the need for modifications to the product design, manufacturing methods, quality control measures and/or marketing methods.

Depending on the circumstances there may be the need for a corrective action or a recall. As a part of the product safety risk management program initiatives of this type need to be contemplated with response plans in place.

Financial, Legal and Liability Implications

Unsafe products can have significant financial and legal implications for the product manufacturer as well as other businesses involved with the manufacturing or marketing of the product(s). This can include the suppliers of raw materials and component parts as well as contract manufacturers, subcontractors, distributors, installers and servicing companies. There have been companies that have gone out of business due to the ramifications of marketing an unsafe product. Still others have survived such situations but have had to deal with large settlements and verdicts against them. The top ten jury verdicts awarded in cases involving an individual plaintiff averaged \$203 million during 2012. The same averages from 2011 and 2010 were 184 million and \$157 million respectively.

Product liability, according to the Black's Law Dictionary, "Refers to the legal liability of manufacturers and sellers to compensate buyers, users, and even bystanders for damages or injuries suffered because of defects in goods purchased." Even though the vast majority of product liability cases are settled prior to going to trial many cases do go to trial. The media often reports on huge verdicts against product manufacturers, distributors or retailers involved. Beyond being aware of the potential for product liability claims and litigation, product safety initiatives benefit from knowing about the factors that can influence such cases.

Legal Theories of Recovery

There are three commonly pursued theories of recovery in product liability. The application of these theories varies on a state-by-state basis. They include:

- Negligence
- Breach of Warranty
- Strict Liability

In general negligence has to do with failing to meet a responsibility of exercising 'reasonable care'. This can apply to the product design, manufacturing or the product safety information.

Breach of Warranty can either be expressed or implied, but in either case involves allegations that the product did not perform consistent with the representations made. These can include representations made by the manufacturer, sales representatives, distributors and related parties.

Strict Liability may create responsibility on the part of a product manufacturer, and entities related to the design, manufacturing and marketing of the product, for the consequences caused by product defects without the need to prove negligence. Typically, one must establish that the product is defective, that it is 'unreasonably dangerous,' and that the defect caused or contributed to the bodily injury and/or property damage.

Product Defects

The product defects pursued under strict liability commonly include:

- Design defects
- Manufacturing defects
- Defects in Marketing also referred to as a Failure To Warn

As was mentioned earlier, design defects affect all of the products having that design as opposed to manufacturing defects that more commonly impact a sub-group of the total products produced, namely those having the defect. Defects in marketing, or failure to warn defects, typically entail a lack of or inadequate information as to possible hazards that can be encountered in conjunction with the use of the product. Warning labels, product user manuals, installation instructions and similar documents are representative of those items used to communicate product safety information. Once again, ANSI and ISO standards provide information on the standardized methods that have been established for the presentation, format and communication of this information.

Summary

The information provided on product safety risk management fundamentals offers the safety professional the opportunity to expand their knowledge base in this topic area. With this information he or she can expand their safety and health role so as to factor for product safety considerations when selecting products, equipment and machinery to be purchased. There also is the potential to broaden their range of influence within the organization where they work by getting involved in new product design and development that capitalizes on the knowledge, skills and experience already in place. For those individuals having a higher level of interest in this topic area, this training could serve as the foundation for pursuing a career in product safety risk management.

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