The goal of a Product Liability Prevention Program is to produce products that are reasonably safe in normal intended and foreseeable use and to provide evidence of actions aimed at reducing the risk of an injury or damage.

BACKGROUND
The public's increasing expectations for safe and reliable products has continued the increase in liability litigation worldwide. Large monetary awards and continued legal developments in case law and statutory law have brought product liability into sharp focus. Exposure to product liability losses has placed severe economic hardships on many manufacturing, wholesale and retail businesses. In spite of the present movement for tort reform, all indications are that the challenge is not going away in the foreseeable future. It is in a business’s best interest to develop and implement an effective program to prevent potential product liability claims and to strengthen the defense position in case of product liability litigation. The degree of formality of the program will vary for each organization, depending on risks presented by the company’s products, markets served, user population, legal jurisdiction and other factors. This Risktopic provides basic guidelines for developing such a program that can be adapted to organizations’ specific situations and needs.

10-POINT PRODUCT LIABILITY PREVENTION STRATEGY
Although the emphasis may vary depending on the type of product and its use, all Product Liability Prevention Programs need following elements.

1. Management Coordination and Control: In order to control product liability exposures, it is important for the management to "walk the talk" and incorporate product safety into the company's planning, operational, and control activities. This means all company functions and resources should be working together in an effective coordinated program that encompasses all phases of the product life cycle, from the initial design through manufacturing to eventual sale and even beyond. The commitment to product safety must come from the top and be effectively communicated throughout the organization. In a formal organization, a staff coordinator or a coordinating committee may be delegated the task of integrating and coordinating product liability prevention. Management commitment is the catalyst in the overall product liability prevention program.

2. Design/Product Development: Primary concern of the design function should be to design reliable products that can be used with reasonable safety during foreseeable and unforeseeable use as well as during service and maintenance, yet five of the eight most frequent allegations in product liability litigation directly relate to design activities, such as improper material for intended use, noncompliance with standards and codes, failure to investigate the state of the art, inadequate warnings, and defective design.
Design safety review is a dynamic function requiring periodic reevaluations consistent with the state of the art, current court decisions, and public expectations that fulfill an established mission objective. Analytic hazard analysis techniques like the Fault Tree Analysis (FTA) and Failure Modes and Effect Analysis (FMEA) are used for identifying critical components, their failure modes, and their effects on the end product performance. Many companies fail to emphasize the importance of hazard analysis in the design phase and end up paying a price in increased litigation cost. Destructive and prototype testing, reliability studies, accelerated life cycle testing and safety audits are also used to ensure design safety. Emphasis on safer design is like "an ounce of prevention".

3. **Product Warnings/Instructions:** Every attempt should be made to eliminate or engineer out all known hazards during the design phase. Warnings and instructions should not be an afterthought or a substitute for a safer design and should be considered only for unavoidable dangers and hazards that cannot be eliminated or guarded against. Warnings help avoid unsafe use of a product, whereas instructions provide directions for proper and safe use of a product. Instructions should be written for easy readability for the target user profile. Warnings should be commensurate with the degree of danger and be consistent with the industry standards and practices. A multi-functional team, including design and legal, should be involved in the development of effective warnings and instruction manuals.

4. **Manufacturing/Quality Control:** The function of quality control is preventive in nature if it can quickly detect and correct deviant conditions and assist the manufacturer in controlling variances from the design specification. The degree of formality and sophistication of quality control efforts depends upon the risks and the complexity of the product but all companies do need effective quality control program to ensure that the products are being produced to actual design specifications. Quality control efforts should extend to all phases of product manufacturing from the receipt of raw materials until the finished product goes out the door and should include statistical sampling techniques to ensure acceptable quality levels. It should incorporate destructive/nondestructive testing with special attention to "critical" components, including 100 percent testing if required. Effective quality control provides an effective check against defective products leaving the plant and reaching end users. Any degradation in specifications during translation from design to production can result in defective and unsafe products.

An ISO 9000 certification does not necessarily indicate a better or a safer product but it provides an independent assurance that a Quality Management System has been implemented for a more consistent product quality. Production planning and procedures should focus on prevention of defects rather than after-the-fact inspection controls.

5. **Sales/Marketing:** Sales and advertising personnel have the greatest impact on how the products are represented to customers. They should be completely familiar with the product, its uses, and limitations. They should receive adequate legal orientation in product liability in order to help minimize potential liability exposure from undesired implied/express warranties, including statements in product brochures. Marketing is also involved in the development of product user profiles, expectations, and competitor reconnaissance. This is valuable feedback for the ongoing improvements in product design. Product liability litigation and recalls usually mean adverse publicity requiring skillful handling. Adequate training, preparation, and backup information can help minimize the adverse reaction and can demonstrate to the public the company’s efforts to design, manufacture, and sell safe and reliable products.

6. **Vendor Management:** In many companies, purchasing has evolved from purchasing raw materials and components to highly sophisticated supply chains managing vendors spanning the globe. Vendor management is responsible for sourcing of qualified vendors and procuring quality raw materials and components at a competitive cost. Vendor management must work closely with design, manufacturing and quality control to ensure consistent compliance with design specifications and requirements for delivery schedules. Vendor management and quality assurance should jointly evaluate the capabilities and reliability of suppliers through vendor selection/rating plans. Suppliers of critical components/services must have their own written contracts and adequate liability insurance protection to cover liability resulting from defective products/services supplied by them, too.

7. **Legal:** Whether an in-house legal staff or an outside legal counsel, the Legal Department can play a key role in orientation and education on various legal aspects within the organization. They serve as legal advisers in specific matters, such as review of all marketing materials to help reduce undesired implied/express warranties, document retention policy, and assistance in defense of products claims. They help interpret the laws and regulations as they apply to product safety, including recalls.

8. **Field Service:** Field service is involved in after-sales activities like installation and repairs and often maintains close contact with the customers and end users of products. Due to their unique position, they are most likely to hear customer complaints and reactions to their products. They have an opportunity to observe misuses and unsafe uses of the product. They are often the first to hear of undesired incidents/accidents. It is important that service personnel be
adequately trained in technical aspects of the product and its operation. They should be instructed to report any feedback that can be useful in improving product safety.

9. **Document control:** Effective documentation is useful in demonstrating to the courts and juries the extreme care the company takes to design, manufacture, and sell safe products. A document control system should be based on company policy, management analysis, regulatory requirements for traceability and appropriate legal counsel. Many records and documents are generated during various stages of product life cycle. Examples are design, manufacturing, quality control, sales, shipping, and service records. Documents pertinent to product liability loss control should be retained for at least the expected life of the product (or its design) plus the longest statute of limitation. Electronic records present confidentiality and other challenges. A document control program should address storage, protection, achieving and retrieval of all critical records. Adequate documentation will help identify and locate the products that might reach customers in a defective condition. If a product recall or field modification ever becomes necessary, only accurate and detailed records will make it possible.

10. **Post-Sale Management:** Field monitoring systems provide a central source to receive and review post-sale user experience, including customer complaints, incidents, accidents, claims, and service and warranty reports. Review and analysis of feedback can help detect developing trends and identify potential hazards in design, manufacturing, quality control, packaging, service, and inadequate warnings and instructions. This information is valuable to management to coordinate corrective actions in design, manufacturing, quality control, or to identify the need for a field modification retrofit, or a recall. Product recalls are expensive but it can be much more expensive to not be able to recall a product when it is necessary.

The analysis of post-sale feedback should be an ongoing process and should be a joint effort by all departments. Subsequent to the initial sale of a product, if a manufacturer becomes aware of new and additional dangers associated with their product, the manufacturer has a duty to warn its customers and product users of the potential risk of injury. Monitoring of news sources and competitor product performance also could be a source of valuable information. If the severity and likelihood of this potential risk is high, the manufacturer may consider additional measures, such as field modification, retrofit, or a product recall. In addition to help reduce product accidents and liability litigation, an effective field monitoring program can assist in the continual task of improving customer satisfaction.

Some products may have a regulatory mandate for post-sale monitoring and reporting requirements. In addition to reporting requirements of products presenting unreasonable risk of serious injury or death, the Consumer Products Safety Commission voted in 2010 to establish and maintain a publically available, searchable, and Internet accessible Safe Products database for safety of consumer products and allows the general public to report potential defective or hazardous consumer products via Internet accessible on www.saferproducts.gov.

**CONCLUSION**

Consumers use the courts and the legal systems to establish their rights and expectation of safety. Tort reforms in recent years have attempted to address the continued threat of expensive liability claims. Although the legal theories affecting product liability have been liberalized over the years, it is still not a “no fault” absolute liability system. You can still defend a product liability suit if you have an effective strategy in place for managing this risk. An effective risk management strategy that considers product safety and risk benefits over the entire life of the product can help in reducing product liability claims and strengthen the manufacturer’s defense position in the event of litigation.

**RESOURCES**

- James Thorpe and William H. Middenhorf: "What Every Engineer Should Know About Product Liability."
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