

FACT SHEET

MANAGING PRODUCT LIABILITY EXPOSURES

In today's legal climate, nearly all manufacturers, distributors, wholesalers, and retailers bear the risk of financial responsibility for the safety and reliability of the products they sell. Product liability losses have placed severe economic hardships on businesses. Simply being named in a product liability suit can be an expensive proposition. Nationally, the average cost to defend a product liability claim is \$876,000.¹ Statistically speaking, larger companies incur larger defense costs. Accordingly, the average cost to defend a products liability claim for small businesses is \$150,000.²

Consumers' increasingly expect the products that they purchase to be safe. Recent case law and legislation confirm that our courts agree and the trend shows no signs of improvement in the foreseeable future. Therefore, it is essential for businesses to proactively manage their product liability exposures, minimize the potential for claims, and provide for a strong defense in the event of litigation.

Selective's Safety Management product liability approach provides our customers with the framework to assess their organization's product liability risks, pinpoint significant exposures, and the expertise to implement effective controls to minimize this loss potential. Our three-pronged approach to controlling potential product liability losses is:

- (1) Design your product in a reasonable manner to prevent potential harm.
- (2) Warn the user about any known possible hazardous conditions that may remain in the current design. This step should include complete instructions on how the product is to be used, specifically promoting the safe use of the product.
- (3) Defend - Engage in proactive prevention strategies to lesson the impact of litigation.

Our suggested program consists of the following elements to help you implement a comprehensive



effort to cover all three phases of a good products control program.

MANAGEMENT COMMITMENT AND CONTROL

A written and published Corporate Policy Statement from top management showing the company's commitment to safety and product quality needs to be effectively communicated throughout the organization. It is imperative that this philosophy be part of the company planning and operations to ensure that all departments are working together in a coordinated program that considers loss potential at each phase of the product life cycle, from initial design through distribution and disposal.

In larger organizations or situations with more complicated product lines, management will need to establish a corporate Product liability Coordinator and a Product Quality Control Committee to manage and monitor the different department product activities. The coordinator will normally be a member of management with the authority to cut through traditional departmental lines when needed. He or she will be responsible for making sure the program works properly and measures results. The coordinator will handle the product recall and after-sale safety mechanisms. The committee should be charged with reviewing accident reports, customer complaints, test results, and design reviews for new products.

DESIGN REVIEW

The primary concern in design review is to ensure that a reliable and safe product is being brought to market. The review process should ensure that the product can be used with a reasonable degree of safety during foreseeable uses and during normal

maintenance. Obvious hazards such as nip points, sharp edges, and fire hazards will be identified along with the less obvious threats uncovered through systematic hazard analysis. Consideration needs to be given to potential mechanical, electrical, chemical, radiation, biologic, radiation, and noise hazards. The review process should change as technology improves, and be responsive to current trends in litigation and customer expectations.

This is a critically important process because problems identified at this stage can be easily corrected. This is the time to avoid the most frequent types of problems that have historically plagued manufacturers. For example, improper materials, not adhering to codes and industry standards, ignoring the state of the art, inadequate warnings, and defects in the design.

Design reviews consist of periodic evaluations of all design elements of the product. This could include prototype testing, destructive testing, reliability studies, and accelerated life cycle testing. Sophisticated analytic techniques such as Fault Tree Analysis (FTA), and Failure Modes and Effect Analysis (FMEA) can be very useful to identify critical components, how they fail, and their effects on the performance of the end product.

Whatever systematic process is used it should start with the concept of the product, consider the performance requirements of the product, and review the prototype testing and quality control criteria. A hazard checklist should then be developed that shows all primary failures, structural failures, and potential for customer misuse. Consequences of these failures need to be established for single failures and combinations of failures. The hazard analysis is then useful to help determine the probability, frequency and severity of identified hazards and help assign priority for correction.

Remember that the goal of the design review is to eliminate hazardous characteristics in the product. This is not always possible and changing technology may not allow for alternative designs, so any remaining potential problems must then be guarded in some fashion and adequate warnings provided.

MANUFACTURING

The manufacturing operation needs to be held accountable for turning the design specifications

into a finished product without altering specifications significantly. Any degradation in this process can introduce defects that lead to an unsafe product. Manufacturing managers need to recognize product liability issues and be aware of product safety goals as well as production goals. They should also be involved with the planning and design phase in addition to their normal inspection and production control efforts.

QUALITY CONTROL

All manufacturing efforts need to have some type of quality control standards to assure that products are being produced to actual design specifications. A quality control process will provide an effective check against defective products leaving the plant and reaching the end user. The quality control process should extend to all phases of the manufacturing system from receipt of raw materials through packaging and shipping of the finished product. The quality control function needs to have knowledge of appropriate testing processes for specific components as well as statistical sampling methods that will allow the committee to achieve high quality standards.

MANUALS/INSTRUCTIONS/LABELING

Courts have demonstrated to manufacturers that they have a "Duty to Warn" users about their product when it presents a danger beyond what is contemplated by the average user possessing ordinary knowledge common to the community. Negligence in marketing has been attributed to inadequate warnings and instructions. Product manuals generally include assembly, operation, maintenance, and service instructions along with a parts list. It must be written in clear, easily understood language. The product manual should:

- Highlight correct and safe methods for assembly and maintenance
- Warn about improper assembly
- Warn against modifying the product or using unauthorized parts
- Describe the product's limitations
- Warn of any existing hazards
- Specify maintenance procedures and frequencies
- Clearly show the consequences of misuse

Labels must warn the user of the product's hazardous characteristics. Any governmental requirements for labeling must be met, but these are only minimal standards. The manufacturer is responsible for making sure that the labels also include complete and conspicuous warnings and antidotes if chemicals are involved.

Key elements of a warning can be found in the American National Standards Institute (ANSI) standards Z-535.1-.5 and Z-129.1. These describe specific ways to effectively use a signal word like DANGER or CAUTION, how to state the hazard clearly, the need to give an avoidance instruction, show consequences, and use colors.

All sales and marketing literature should be subjected to a critical review by legal counsel. They should be used to review all printed material to find undesired implied or express warranties and help determine document retention policies. These legal specialists should have experience with product liability litigation. They can help interpret laws relating to product safety and can be quite valuable as members of the product liability committee.

Sales and service personnel can have a great impact on how the product is marketed to the customer and influence how the product is used after the sale. They need to be trained in how the product is represented to the end user and make sure its proper use and limitations are presented. Known hazards need to be warned against in discussions with the customers. They will need to strongly promote the safe use of the product and avoid any exaggerated claims that can lead to misuse.

DOCUMENTATION/RECORD KEEPING

Documents pertinent to product liability should be retained for at least the expected lifetime of the product plus the longest current statute of limitation that applies. Types of records needed to be retained can be quite diverse depending on the product, but should include significant items from the entire life cycle of the product. This would include key documents from the design, manufacturing, quality control, sales, shipping, and service phases of the product life. This should also include enough information to locate a product that may

have reached a customer in defective condition. The company will need to monitor the performance of the product in the marketplace. A customer complaint log should be maintained with documented follow through for each entry.

PRODUCT RECALL

Even with an effective product liability control program in place, it may be necessary to recall a product at some point in time. Recalls may be needed due to the discovery of defects in design, manufacturing shortcomings, subsequent test results, customer complaints, or governmental intervention.

The recall process needs to happen quickly in order to mitigate further problems and should consist of these elements:

- An internal system of documentation that allows the company to identify its product and trace the customers who purchased the defective products. This process may use model numbers, serial numbers, and batch or date codes
- Suspension of production and distribution of the effected product
- Inform the appropriate regulatory agencies.
- Provide written instructions to company sales, service personnel
- Notify dealers and distributors about the problem and what to do
- Publicize the recall after legal counsel has approved

Recall plans should be tested periodically to make sure they work.

By implementing a comprehensive product liability management program and employing our DESIGN, WARN, and DEFEND approach you will be able to protect your organizations financial health by minimizing your exposure to loss. Specialists in our Safety Management department are available to assist you in evaluating the effectiveness of your current product liability loss prevention strategies and able to guide you through the process of strengthening your defenses.