

# Risk Control Bulletin

## Element of a Product Liability Program

### Manufacturing

RISK CONTROL



#### Background

Over the years, product liability lawsuits against manufacturers and sellers of products have been steadily increasing. Recent legal development in the areas of asbestos, cumulative trauma disorders, and cigarettes has put the product liability issue in the newspaper headlines. One study concluded that 40% of surveyed CEOs felt that the threat of product liability litigation has a major impact on their firms. The debate continues to rage in Congress and various legislatures over product liability tort reform. With this in mind, businesses should develop and implement a Product Liability Risk Control Program to minimize Product Liability claims and strengthen their defense position in case a claim does occur.

#### Program Elements

##### Corporate Policy Statement

The Corporate Policy Statement should direct top management's attention to product safety and provide for a conscious decision to build safety into the product life cycle (from initial design through manufacturing to eventual safe and final disposal of the product).

Management should identify a person of sufficient authority to be responsible for product safety. A large organization may choose to have a product safety committee (representing all departments) for this function.

##### Design and Product Development

The design and product development process is the single most effective and important aspect of product safety. Product safety starts in the mind of the product designer (s). It affects subsequent decisions and practices related to materials, productions, testing, processes, labeling advertising, packaging and distribution.

The primary concern of the designer(s) should be to develop "reasonably safe" products that are reliable and maintainable. A product is considered "reasonably safe" if the potential risks of using it are judged to be acceptable by society.

A product should be designed with its entire life cycle and total use environment in mind (from the moment it leaves the factory until it no longer exists). One must remember that the manufacturer can be held responsible, not only

for accidents caused by intended use of the product, but also for those caused by reasonably foreseeable misuse. In essence, good product design means designing the product so as to minimize the risk assumed by the product user.

Liabilities stemming from the design and product development process are usually based on one or more of the following premises:

- A concealed danger has been created
- Safety devices have not been incorporated
- Materials are of inadequate strength
- Failure to comply with accepted standards
- Failure to consider possible misuses of the product which were reasonably foreseeable
- Warnings and instructions are inadequate

##### Warnings/Instructions

Products should be accompanied by adequate warnings and safety instructions for all dangers related to the intended users, and reasonably foreseeable misuses. The purpose for a product warning is to positively affect the user's behavior. However, an adequate warning will not prevent the product from being held as defective by a court if the hazard could have been reasonably removed by a safer alternative design.

Instructions and manuals should provide directions for product assembly, installation, use, service and disposal. Warnings and instructions should be easy to read and understand, and should be aimed at all reasonably foreseeable users.

##### Quality Control

Most companies need some type of quality control program to ensure that the products produced do indeed conform to design specifications. Failure to control conformance to design specifications will mean excessive product violations resulting in possible manufacturing flaws, product failure, or product liability litigation.

The quality control function should be independent of engineering and manufacturing departments and should report to management in order to remain impartial and unbiased. Depending upon the complexity of the product,



quality control programs will vary in formality and sophistication. A good quality control program will have:

- A written manual with policy, responsibility, and authority established
- Vendor/supplier monitoring
- Control of special processes
- Incoming inspection and testing, especially for critical components
- In process inspection and testing
- Finished products tested and samples retained for batch produced or bulk material
- Product preservation, packaging and shipping procedures
- Segregation, disposal, and/or repairs of nonconforming raw material, work in process, or finished goods
- An error analysis and corrective action system
- Periodic calibration for all test equipment
- Record retention for all quality control test results, batch and lot data, customer complaints, etc.

Of course, a good quality control program is not an “end all” to solving the product liability problem, as it may only ensure the best “poor product” if you have a “poor design and product development” process.

### **Sales/Advertising**

Liability for an injury associated with the use of a product can result from inaccurate written statements regarding product capabilities or performance made in advertisements, sales brochures, sales presentations and catalogs.

Sales literature and advertising should be coordinated with engineering department, legal staff and product safety committee to ensure that all material clearly represents the use and capabilities of the product. Terms such as “absolutely safe”, “shockproof”, and “fireproof”, etc., should be avoided. Sales personnel should be trained to accurately describe the capabilities of the products they are selling or distributing.

### **Purchasing**

Purchased materials can have a major impact upon the safety of the company’s product. The purchasing function is responsible for obtaining quality raw materials and components from reputable suppliers at a competitive cost.

Purchasing should work with the product safety committee as well as with design, engineering, manufacturing

and quality control departments to develop a list of components and/or raw material critical to product safety. Prospective vendors of critical components should be informed of the concern. Purchasing should also compile a list of approved suppliers and utilize a vendor rating system developed in conjunction with quality control to rate the capabilities and reliability of suppliers.

### **Legal/Contractual**

A firm may choose to have legal counsel on a retainer basis or provide for their own in-house legal department. Legal counsel provides consultation and guidance for compliance with laws and regulations.

All contracts, warranties and disclaimers, purchase orders, warnings/labeling, instructions and manuals, and advertising should be reviewed by legal counsel versed in Product Liability law.

### **Field Operations**

Sales, service, installations and repair personnel are always in contact with end users of the company’s products. This provides a communication channel from the users and customers back to the company.

Field operations personnel should be trained to recognize problems and report any malfunctions, accidents, misuses or customer complaints to the product safety committee and/or the design and engineering department.

### **Recordkeeping/Documentation**

Without proper recordkeeping and documentation, a Product Liability claim is difficult to defend. The following items should be maintained for the life of each product plus any applicable statute of limitation:

- Product designs, design reviews, design changes
- Materials and component purchase records (with specifications)
- Quality control procedures and test results
- Sales and shipping records
- Warranty and product service records
- Complaint files

Recordkeeping demonstrates to the courts and juries that the company took another needed step in developing a “reasonably safe” product. It may also help prove that a defect was caused by mishandling after leaving the control of the manufacturer.

### **Field Monitoring**

Product malfunctions, accidents, misuses, customer com-



plaints, claims, service reports and warranty reports should be reviewed by the product safety committee and management as end user experience can identify flaws in design, manufacture or warnings for a particular product. If appropriate, corrective action can be taken to prevent future loss.

Depending on the nature of the problem, an organized system of field modification or recall may be necessary. The following elements are generally needed for a recall of a product:

- Recall policy with established responsibilities
- Product traceability system
- Recordkeeping system to monitor for effectiveness

### **Conclusion**

An organization's vulnerability to product liability in today's litigious society is predicated upon the above Elements of a Product Liability Risk Control Program. However, neither society nor the courts expect all manufacturers to conduct their product liability risk control program in the same way or the same degree of sophistication. The elements and their degree of formality should be commensurate with the product exposure/hazard presented to the user.

For help in strengthening your product liability risk control program, contact your CNA Risk Control Representative.