Establishing an Effective Product Saf Management Program

by Kenneth Ross

An effective product safety management program can reduce accidents, reduce recalls, reduce insurance premiums, increase the safety and quality of products, and provide a more defensible product and company in the event of litigation. With all of these benefits, why do so few companies have such a program?

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Recent information on how many manufacturers have product safety programs and how they are organized is rarely available. In addition, it is difficult to find good evidence that measures the effectiveness of these programs. Much of the evidence is anecdotal and common sense. As a result, many companies struggle with the question of whether to have a formal program and how many resources to devote to such a program. What can be helpful in answering this question is to look at the "best practices" employed by manufacturers that care about selling safe products and minimizing product liability.

A few studies over the years have provided some answers. In addition, a recent survey and report confirms the conventional wisdom on product safety management and describes what the authors deem to be a "world class" corporate approach to product safety. This article will describe some of these studies and then discuss the author's ideas on how to establish a product safety management program.

The ideas in this article will hopefully help in-house counsel and other product safety personnel to implement a program in their company. They should also help defense counsel to better evaluate the defensibility of their client's management programs.

The Need for a Product Safety Audit

The first questions to be answered by the manufacturer's lawyer are does the company need a formal product safety management program, and, if so, how much effort



is appropriate. Unless the company has lots of claims and lawsuits, it is hard to know where to focus a company's efforts in developing such a program. A company that is establishing a new program or evaluating the adequacy of its current program would be wise to first do an audit of its current situation.

Establishing a new product safety and liability prevention program in a manufacturing company can be difficult if the potential hazards involved in the manufacture and sale of its products are not known. In addition, determining the scope of the prevention program is very speculative without a clear understanding of the status of the manufacturer's practices that affect safety and liability.

Before and even after a prevention program is instituted, a good way to obtain useful information is to perform a product safety and liability audit. If this audit is being done in response to claims and litigation, the company and its lawyers obviously will analyze those occurrences to determine the company's most immediate problems.

Much information can be gleaned from present and past claims and litigation. First, the company lawyer can identify the accident mode and severity of injury. Then, he or she can learn the theories of negligence and defect proposed by the plaintiff and his expert. Lastly, the lawyer can look to the results of the past litigation and claims to see how the company, the particular injured party, and possibly a judge or jury viewed the litigation.

If there have been few claims or a minimal amount of litigation, the audit phase of prevention is more difficult. The company lawyer needs to take a much broader look at the product, the users, the environment of use, and the potential for injury to determine the level and type of risks and what can be done to minimize them.

A company-wide or product line risk as-

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If the manufacturer wants to establish an attorney/client privilege over any of the audit results, it is necessary to have the audit controlled or performed by lawyers. A good argument can be made for the existence of a privilege if the attorney directly interviews the company's personnel and the company has retained the attorney to render legal advice about minimizing product liability risks. It might also be possible to argue that a privilege exists if the attorney requests that the safety professional interview employees, analyze the product's risks, and provide a report to the attorney so that the latter can provide legal advice. Where litigation is involved or anticipated, it may be possible also to invoke the work-product privilege.

Should either the attorney-client privilege or work-product privilege be established, note that either protects only the oral or written communication between the lawyer and the client, and not necessarily the information given by employees of the client. Therefore, if an engineer feels that the current safety organization of the company is deficient, the other party in the lawsuit can obtain that information during the discovery process, whether or not the information was given to the attorney doing the audit.

Product Audit Questionnaires

Audits can be performed in different ways. First, the company can employ safety professionals to come to a particular division and interview key personnel. Another approach is to have key employees fill out questionnaires; safety professionals will then interview them about their responses. In both procedures, the safety professional will follow up with recommendations based on the responses.

In a multi-divisional manufacturing concern, the audit can be a two-stage process. The inside and outside safety and legal professionals should draft a fairly simple audit questionnaire to be answered by corporate and manufacturing division personnel. This audit should elicit preliminary information so that a decision can be made as to which divisions need to perform a more comprehensive audit.

While the size and structure of a manufacturing division can change the audit procedure, generally the preliminary questionnaire should be directed to the division's management. These individuals include the general manager and heads of marketing, safety, engineering, service and manufacturing, plus any in-house or outside attorney familiar with the division's claims, litigation, and safety practices. Responses to the questionnaire should help quantify the risks and identify personnel who should be interviewed during the comprehensive audit.

The questionnaire to be used in the audit of a manufacturing division is divided into a number of areas. First are questions pertaining to the management of the division as it relates to safety. Next are questions relating to the performance of the division's product safety coordinator. A large section of the audit questionnaire pertains to the development of product safety standards.

In the "design and development" area are questions about preparing design specifications, risk analyses and design reviews, and engineering evaluations to verify compliance with safety requirements. This design and development section also asks about labeling specifications for warnings and documentation concerning installation, operation, and maintenance.

Other sections of the product safety questionnaire ask about purchasing, manufacturing, and quality standards. For example, in the purchasing section, there are questions about inserting "hold harmless" and indemnification clauses in purchase agreements and ensuring that there are appropriate warranties from suppliers.

Questions asked about manufacturing may include: Have standards been prepared to define handling and storage of the product as it is being manufactured? Are procedures in place to prevent the introduction of unreasonable hazards into the product? The questionnaire asks numerous questions about the quality function and whether the company ensures that appropriate product safety inspections and tests are performed and documented.

Questions are asked about marketing efforts, advertising and promotional material, and instructional literature. The audit next asks about procedures for handling product safety problems, including dealing with customer complaints. It may even ask about the more drastic steps of product withdrawal or recall.

Product stewardship includes proactive management practices that integrate regulatory compliance, and health, safety, and environmental considerations, into product development and product maintenance.

Records documenting each affected division's product safety program should be created and retained. The audit questionnaire elicits such information. The last parts of the audit pertain to education and training of division personnel, performing the product safety audit, and creating a product safety compliance manual.

Uses of the Audit

Once the comprehensive audit is finished, the auditors should be able to propose the establishment of a product safety management program, including policies, procedures, and duties of affected personnel. Or, the comprehensive audit can be used to evaluate the adequacy of a company's current program.

The audit is defined as a management tool for determining whether the division is capable of designing, producing, and delivering safe products. The audit determines whether, for instance, the manufacturing division's procedures comply with established company safety policies and directives, as well as statutes, regulations, and industry standards.

One U.S.-based multinational corporation with an extensive prevention program has a policy requiring that its internal product safety committee conduct an audit at least once per year. The committee then discusses the recommendations arising out of the audit with the management of the relevant division of the corporation. The report on the audit and a consolidated list of agreed corrective actions are then submitted to the division's attorney for review and advice. As a result of the review, the necessary improvements must be implemented within a defined time schedule.

Studies on Best Programs

Making recommendations about the elements of a product safety program can be difficult without knowing what other successful companies do in the product safety area. Thankfully, there have been some scholarly studies over the years that give some guidance on what elements to include in a program and the rationale to support them. Let's look at a few of those studies before we proceed with the practical steps of setting up a product safety program within a manufacturing company.

P ittiglio Rabin Todd McGrath, a U.S. based management-consulting firm, issued a "white paper" in 2002. In this study, PRTM surveyed 52 companies, including 15 consumer product manufacturers. The remaining companies supply raw materials (*e.g.*, chemicals) or component parts to the consumer product manufacturers or to the component part suppliers. Forty of the companies are U.S.-based and the rest are based in Europe. Some of the key findings are as follows:

- There is currently no standard approach to product safety management.
- Only a small percentage (20 percent) of consumer product companies surveyed by PRTM felt they handled safety issues successfully.
- The world-class companies (only 25 percent of 52 companies) have inserted product safety into their strategies, organization, processes, and systems. Smaller

and less successful companies have some but not all of the practices the study's authors deem important for success.

 The world-class companies spend twice as much money on product safety, have 50 percent fewer recalls, and are four times less likely to have a recall than a less successful company.

Despite the fact that the number of companies ranked as world-class manufacturers by the PRTM study was very small, the authors were able to identify the "best practices" that they believe allow these companies to successfully manage their safety issues.

The authors of the PRTM study use a broader concept than just product safety when discussing the best practices of the world-class companies. They call it "product stewardship," which includes proactive management practices that integrate regulatory compliance, and health, safety, and environmental considerations, into product development and product maintenance. The authors found that world-class companies integrate safety, regulatory, and environmental initiatives into their corporate strategies. Senior management is more involved in product stewardship issues; they have many dedicated safety professionals working in product development and in top-level decision-making. This accounts for the increased spending on safety and related issues.

The PRTM study found that, organizationally, virtually all of these world-class companies have a dedicated senior level person (usually a vice president) focusing on safety, regulatory and environmental issues. And these companies provide monetary and non-monetary incentives to get company personnel to cooperate in the implementation of these programs.

In addition, world-class companies have formal processes in place to address stewardship issues. Some of these processes are: (1) full documentation; (2) milestones are defined at the start of product development efforts; (3) milestones are completed before development continues; and (4) product stewardship personnel have the power to halt or delay a development project if these milestones are not met or there is some inadequacy in compliance with safety, regulatory, or environmental requirements. The PRTM study provides some useful information. It shows that few companies have implemented a full range of processes, procedures, strategies, and personnel to effectively manage product safety during the product development and after-sale phases.

The study also estimates that it costs consumer product manufacturers, on average, \$8 million per recall for the recall and related litigation. And, the study indicates that worldclass companies have had 50 percent fewer recalls than the average manufacturer. They may spend twice as much on product safety, but the low recall rate means millions of dollars in savings.

The savings are potentially even higher, since the study made no attempt to quantify the reduction in accidents or lawsuits resulting from safer products. This of course would be difficult to calculate, unless the manufacturer had a number of accidents before a safety improvement was made.

The bottom line, which should be of no surprise to anyone, is that product safety management efforts pay for themselves, sometimes many times over. These efforts can, in part, result in fewer accidents, fewer dissatisfied customers and product users, better goodwill up and down the distribution chain, and less chance that a plaintiff's verdict will include an award of punitive damages.

The PRTM study confirms what was suspected all along. Those companies that spend more time and money during the development phase will have fewer safety problems, accidents, lawsuits, and recalls. Proactive management is the key. Reacting to product safety problems is also important, but may be too late to prevent major problems. Convincing management to try to prevent problems before they occur is a challenge. Using some of the findings of this report may make the job easier.

n 2000, the Manufacturers Alliance surveyed 30 members of the Alliance's Product Liability and Product Safety Council and issued a public report on its findings, entitled *Benchmarking Product Safety in Selected Manufacturing Companies*. The most important relevant findings are as follows:

Almost two-thirds of the companies have

a separate department or function responsible for product safety and compliance.

- In 60 percent of those companies that have a separate safety department, it is centralized in the corporate offices, and in one-third of these companies, it resides in the corporate law department.
- Well over half of these companies include safety and regulatory compliance in their general business strategic planning.
- Around 80 percent have developed or are in the process of developing a formal policy for product safety.
- Around 40 percent of the respondents have a product safety manual or procedures.
- Two-thirds of the companies integrate product safety and regulatory compliance into their existing product development processes.
- Around 75 percent of the respondents audit their programs.

The conclusions in the Manufacturers Alliance study are that centralized leadership is important, product safety is emerging as a key component of strategic planning, and formal policies and procedures are crucial to implementing a program. None of these conclusions are surprising; the literature mentioned below confirms that these beliefs about product safety programs have been around for many years.

n 1979, the Conference Board issued one of the first studies on product safety management programs. It is based on survey responses of about 300 manufacturing companies; supplemental information was obtained by interview and correspondence. There has not been an update of this study.

Despite its age, the Conference Board study does provide some good insights. It found that most manufacturers have elected to use a mixed organizational structure, establishing full or part-time product safety assignments at corporate and other levels. At the corporate level, the functions are primarily consultation and coordination. Some companies have chosen to completely decentralize the product safety function—*i.e.*, delegating the responsibility to the relevant divisions. Most, however, favor a combined approach that brings together the company's different levels to address the product safety functions. One of the most frequent arrangements is to establish a full-time product safety office at headquarters, with part-time safety assignments at operating levels. In addition, a majority of companies have a formal product safety policy.

The Conference Board study contains a chapter on the product safety audit. It reports that reliance on a formal audit has gained in popularity; its worth in establishing product safety is recognized.

The study contains recommendations from the respondent companies as to how to establish a product safety function. They are (in rank order of frequency of mention):

- Obtain full support from the company's top management.
- Centralize authority and responsibility for product safety.
- Involve all company units in product safety.
- Develop an extensive safety database.
- Construct a company-wide safety policy.
- Develop a product safety committee.
- Make operating units responsible for safety performance.
- Develop a capacity to measure and monitor safety performance.

n 1983, the Rand Institute for Civil Justice published *Designing Safer Products*: Corporate Responses to Product Liability Law and Regulation. While only nine manufacturing companies were interviewed, the authors performed further interviews and a literature search and provided some insightful conclusions on product safety management. They found that safety professionals believe that every corporation needs an organization within the firm specifically devoted to safety issues. These company people argue that without a formal organization, improved knowledge of product safety will not be appropriately used and the proper amount of safety information will not be generated.

The Rand Institute study found that a separate product safety organization is appropriate to deal with product complexity, hazard subtlety, and organizational pressures. Product safety problems may not be discovered during normal safety design reviews because of their complexity and the interaction of the product, its packaging, and the production/distribution environment. Hazards are very subtle, particularly given the necessity to consider reasonably foreseeable misuse.

The realities of organizational pressures within a large corporation indicate that a product safety group should be formed. The multi-divisional form of corporate organization insulates top management from minor details. These minor details, unintentionally, may work to prevent them from learning about safety problems. Subordinate parts of an organization, operating semi-autonomously under the influence of limited financial controls, may not be trusted to discover and satisfactorily resolve all significant safety hazards without specific oversight to ensure that they do. Also, if there is an attitude that safety problems are being handled by someone else and that safety is not a problem as long as competent engineers are involved, there is likely to be resistance to taking the necessary time and resources to surface subtle or complex hazards and then redesign and retest to be sure that they have been properly dealt with. For all of these reasons, a separate product safety group is an essential part of the corporate structure.

All of the companies interviewed for the Rand study agreed that a corporate level product safety department plays a critical role in the company's overall safety effort even if most of the actual safety management is done at the divisional level. The corporate office can serve as a liaison or coordinator. It can facilitate the distribution of knowledge from one division to another, especially when divisions are geographically separated; learning from other divisions' successes or failures is important within a large corporation. Also, the corporate level office can transmit and reinforce top management's commitment to product safety.

A corporate level product safety officer can introduce safety performance indicators into the performance measurement of operating divisions so that the consequences of poor—or outstanding—safety performance are reflected in the division's profitability. The corporate level officer can also act as a mediator, or even a "court of appeals," in resolving differences between divisions on safety matters. The Rand study found that an organized product safety effort may improve a firm's defensive posture in several ways. Units at the division level may be expected to know about individual products against which claims or suits have been filed. Since they will know how these products were designed, they will be better able to deal effectively with the defense of claims. Where liability suits involve many different products, a corporate level product safety officer can serve as an aggregator of corporate experiences.

What appeared to the Rand study authors to be the most effective product safety organizations were those that were sized, located, and financed at a level consistent with the safety problems inherent in the manufacturer's products. They also recognized the need for higher level supervision or monitoring of safety-related design decisions.

A lean product safety organization that has the ear of the CEO and a good working relationship at various levels of the corporation is the optimal arrangement, according to the authors of the Rand Institute study. Such an organization is likely to be much more effective than a highly visible unit that establishes procedures, but lacks either the resources to impose them. Finally, it is imperative that the safety office has the strong support of the company's top officers when such support is necessary.

Establishing the Product Safety Program

After a company has performed a risk assessment and audit of its organization, products, and procedures, it can then consider what kind of a product safety management program is appropriate. The procedures are well known, but the hard part is to decide what level of resources should be devoted to a particular company's program.

The decision is based on the perceived level of risk from the company's products and practices and the risk the company is willing to assume. The following is a discussion of specific components of a product safety management program.

Product Safety Policy

Every manufacturer should have a statement of a policy that is intended to ensure that the

products it makes are safe for consumer use. The company's lawyer can help the company draft such a statement. As an example, one large U.S.-based multinational company, which has had in effect a corporate product safety policy since the early 1970s, adopted a statement of policy, the essence of which is:

Actions shall be taken to identify and minimize potential product hazards during all phases of the product's life including development, design, manufacture, marketing, installation, service, use and disposal. Reasonable measures shall be taken to minimize the risk of injury to persons and damage to property and the environment, giving full regard to applicable federal, state, local and industry safety standards, regulatory requirements, technology, state-of-the-art and conventional standards of care and use required by society.

This safety directive also states that it is company policy to provide quality products and services that perform their intended functions safely, reliably, and with minimum effects on the environment. The policy goes on to say that each functional department in an operating unit is supposed to integrate quality, safety, and reliability into its departmental practices and procedures, and that there should not be a separate safety program set up in each operating unit.

From a lawyer's standpoint, having a corporate product safety policy of any kind is similar to endorsing motherhood and apple pie. There are very few reasons why a policy is not necessary or helpful; the survey results described above confirm that most manufacturers do have a policy. Whether you are a manager or a defense attorney, it is helpful to point to a document, endorsed by the board of directors, the chief executive officer, or the president, that confirms this safety concern. In addition, the policy can be presented in court or before a government regulatory agency to confirm the company's interest in safety.

The safety policy may also clarify the safetyrelated responsibilities of each company department concerned with safety, such as General Management, Marketing, Engineering, Quality Assurance, Manufacturing, Purchasing, Field Service, Risk Management, Finance, Safety Management, and Legal, and their inter-relationships within the company. Each of the manufacturing divisions in the company may wish to have its own statement of product safety policy, in addition to the corporate policy. The division policy may differ in that it is more customized to the division's structure, product line, and culture.

Many smaller companies will scoff at the idea that a product safety policy is needed.

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But, most divisions of big companies act like small companies, especially when it comes to product safety. There are few companies with competent and adequate product safety resources at corporate headquarters that can do many of the things required by every division or product line. Therefore, having a policy or policies, especially when the company has policies in many other areas, is a helpful prelude or foundation for a product safety program.

The content of the product safety policy can be very detailed or very sketchy. There are many examples of such policies in various publications on product safety. From a legal standpoint, the main precaution is that the policy should contain goals that are generally achievable. It is not necessary for them to be achieved today or achieved to perfection. They can be aspirational, but they must be achievable at some time in the future. Don't raise the bar too high, but also don't make it look like the company's policy was created for one set of eyes—the jury's.

A well-known safety professional in Europe summarized it neatly when he said that "[a] corporate product safety policy should

be expressed in broad terms and not attempt to cover every contingency. A balance has to be achieved; it must not be so vague nor so detailed as to stifle initiative."

After the policy is created, it needs to be disseminated widely and featured in company publications, compliance manuals, and training programs.

Product Safety Manager

The company's culture, structure, risk tolerance level, and personnel policies will help dictate whether a separate employee known as the product safety manager/director is necessary. Manufacturers have said for years that it is everyone's job to make a safe product. And it really is. But, product safety is too difficult to be accomplished by people without any additional training and responsibility.

Product safety managers can be found at corporate headquarters as well as at the division level. When there is litigation regarding a product, the corporate managers are typically involved; these managers are also responsible for reporting problems to government agencies, such as the Consumer Product Safety Commission. A divisional safety manager is appropriate when a division's products can cause serious injury or when safety problems can be reported to a government regulatory agency.

At either the corporate or division level, the manager need not devote full time to product safety matters; he or she can combine this assignment with another job such as the quality or product reliability function. It is also possible to have one product safety manager for a group of divisions which make similar products.

Whether it is a full-time or part-time manager, it is an open question as to which department that person should be placed. At the division level, the conventional wisdom is that product safety pervades engineering, manufacturing, purchasing, quality, parts, sales, and field service. Yet, placing product safety personnel in one of those departments may narrow the focus of his or her responsibilities too much. It may also put that person in possible direct conflict with a supervisor who may not appreciate the safety manager's activities or the criticism they generate.

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The product safety manager could report to the engineering manager or the manufacturing manager. However, either assignment could lead to conflicts in the event of design modifications, recalls, or changes in manufacturing procedures. Reporting to the general manager of the manufacturing entity may be a better arrangement. It may serve to confirm the company's commitment to safety*i.e.*, the safety manager is representing senior management in trying to encourage all personnel to be concerned about making safe products. Of course, it is possible to have dual reporting where the manager reports to the general manager on a dotted line basis and the engineering manager on a solid line basis.

However organized, it is essential that someone is clearly in charge of product safety. In any division that makes products that can hurt people, someone should be given the product safety function, even if there is also a product safety manager at the corporate level. Working together, these two can provide adequate product safety input with a minimum of additional resources.

What sort of credentials should be sought for the product safety manager position? It is not necessary for the manager to have a degree in safety or engineering, or have worked in safety for many years, or be a member of any safety management society. Still, some safety training and experience is advisable. First, training and experience will most probably assure that person's successful performance in this important job. Second, no "on-the-job training" will be needed. Finally, in the event of claims or litigation, it is helpful to have a professionally-trained safety manager to convince the other side of the company's commitment to safety.

Product Safety Committee

A manufacturing company may wish to set up a product safety committee comprised of individuals from various departments of the company. This committee, like the product safety manager, may be at both the corporate and division level. The responsibilities of such a committee could include the following responsibilities:

- Establish guidelines and criteria for the identification and quantification of product hazards.
- Perform design reviews and other analyses to minimize product risk to an acceptable level.

- Establish guidelines and criteria for creating warning labels and instruction manuals.
- Establish guidelines for creating advertising, promotional brochures, and other printed sales material.
- Establish guidelines for the creation of product warranties, exculpatory clauses, and contractual disclaimers in contracts and purchase orders.
- Analyze product problems and determine a need to notify government agencies and/or the need to recall products, retrofit products or issue safety warnings.
- Create a document retention policy and procedure as it relates to safety and reliability.

Individual members of the product safety committee can develop and administer audits of the product safety program, and set up training sessions for company personnel. They can develop an accident or incident reporting system with guidelines for follow-up by appropriate personnel. They can assist attorneys in the investigation and defense of product liability claims and litigation, and administer recall/ retrofit/warning letter programs. Members of the committee can also represent the company in industrywide or governmental groups related to product safety.

A product safety manager should chair the committee, whether the manager is part-time or full-time. Lawyers can have an integral role in the running of this committee. They can provide legal input on design, manufacturing, and marketing questions, review minutes of the committee meetings, and try to ensure that proper documentation concerning progress made in solving safety problems is being created and retained.

Since lawyers are trained to be good communicators, their legal role can be expanded to assist product safety committee members to express themselves more clearly about safety problems, about the ways in which these problems are managed and solved, and about ways to improve communications throughout the design, manufacturing, and marketing process.

Product Safety Procedures

When the risk assessment and audit is completed, the manufacturer is ready to institute the prevention and safety program. The company should be sure that it follows through seriously and carefully to establish and implement its policies and procedures, and that it informs all affected employees that it believes are necessary to ensure reasonable safety in its products. If a company establishes a policy, and then does nothing to implement it, an injured claimant can argue that it does not seriously care about safety and only created the "paper policy" to impress a jury.

It is beyond the scope of this article to discuss in detail the procedures to be employed by manufacturers in implementing a product safety program. The author has written extensively on some aspects of this subject in For The Defense. For more information, see: Ross & Adams, "Legally Adequate Warning Labels: A Conundrum for Every Manufacturer," October 1998 For The Defense 7; Ross,"The Importance of a Proactive Document Management System," October 1999 For The Defense 24; Ross & Main, "Foreseeable Hazards and Misuse: Risk Assessment and Product Liability," April 2001 For The Defense 34; and Ross, "The Increased Duty to Take Post-Sale Remedial Action," April 2002 For The Defense 37.

As a general matter, product safety processes recommended by safety experts and by companies experienced in product safety all include extensive research and analysis at the front end, before the product's design specifications are even drafted. The company should have a very good idea of the risks it is assuming with a particular product when it is still in its conceptual stage.

Then, a product safety analysis should be performed as the product makes its way through the development of specifications, making a prototype, and final production. Various wellknown analytical techniques can be used to assist throughout the process: risk assessment, hazard analysis, FMEA, fault tree analysis, and design review will assist the manufacturer in identifying and evaluating risk before the product is approved for production. Applying these techniques, management will have a chance to decide for itself how much risk it is willing to assume.

Conclusion

No matter what a manufacturer does, it is always possible that the elements of the product safety program and its implementation are lacking and could arguably constitute evidence of a disregard for safety. To combat that chance, any program must be able to show a high regard for safety. If this showing is made, even if the jury believes that the manufacturer could have done more, it should also believe that the manufacturer tried to do the right thing and will not be inclined to award punitive damages. One manufacturer of heavy equipment justifies its extensive and costly safety program on the belief that no jury will ever make an award of punitive damages against it.

As companies better organize themselves for the world-wide challenges of providing safe

products, the bar will be raised. Companies who do not follow the lead will be at great risk of further product safety, product liability, and regulatory problems, in the United States, in Europe, and in other foreign countries. The techniques are well-known; the difficult part is to analyze what is appropriate and then incorporate it into the company's organization, culture, and processes. Doing so should pay for itself, either by preventing future problems that could arise or giving the manufacturer a much better defense if accidents do occur. FD