BEST PRACTICES IN PRODUCT SAFETY MANAGEMENT

What Makes Sense for Your Company?

An effective product safety management program can help to reduce accidents, reduce recalls, reduce insurance premiums, increase the safety and quality of products, provide a more defensible product and company in the event of litigation, and minimize the chance of punitive damages. And the techniques have been well-developed for decades.

With that said, why are so many manufacturers being sued and fined by government safety agencies? Why are so many products being recalled, including products by well-known and respected manufacturers? Why are legislative bodies here and around the world enacting sometimes oppressive legislation to force manufacturers to do a better job of providing a safe product?

Obviously, companies must not be devoting enough resources to these efforts or are making bad decisions. Why is that?

As someone who has counseled manufacturers on product safety, regulatory compliance and product liability prevention for over 30 years, I have seen many excuses such as:

- We haven't had too many problems yet;
- Safety problems are the cost of doing business;
- Everyone's job is product safety;
- That's why I have insurance;
- My parts supplier will take care of the problem if anything happens;
- It costs too much, and I can't cover the cost in my prices;

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By Kenneth Ross

- My competitors aren't doing these things, so how can I justify the expense;
- I don't know what elements of a program are important for my company to implement; and
- This won't protect me from product liability lawsuits, so why bother.

The elements of a program to deal with pre-sale and post-sale safety issues are well-known and have been around for many decades. They generally are:

- Product safety policy;
- Product safety manager;
- Product safety committee;
- Personnel devoted to product safety;
- Training for personnel involved in product safety; and
- Procedures to confirm safety such as risk assessment, design reviews and conformity with applicable standards, adequate development of warnings and instructions, review of marketing materials, documentation guidelines, and post-sale investigation, analysis and action.

Even though these elements are well-established, the specifics of what elements should be used and how by a particular manufacturer are unknown. Therefore, the most important question that must be answered by any company manufacturing finished products or component parts is "What should my company do and how should I do it?"

Here are a few of the questions that need to be answered:

- Should the product safety manager be full-time, and should they be at corporate or in the division, or both?
- What kind of background should a product safety manager have – managerial, administrative, legal or engineering?
- To whom does the product safety manager report?
- Is there a corporate and divisional product safety committee?
- Are there product safety committees or managers for business units?
- Who is on the product safety committee?
- How often does the product safety committee meet?
- What does the committee do? Do they get involved in risk assessments for new products or just focus on post-sale issues?
- Should legal counsel be on the product safety committee? Should activities of the committee attempt to be protected by attorney-client privilege?

There are no clear answers to these questions. It depends. Fortunately, there are a variety of standards and guidelines on safety management that can be helpful.

CPSC GUIDANCE ON SAFETY PROGRAMS

The U.S. Consumer Product Safety Commission (CPSC) first published the *Handbook for Manufacturing Safer Consumer Products* in the 1970s, shortly after the agency was created. The last edition of this handbook came out in 2006 and discusses product safety policies, organization and training, as well as all aspects of design, manufacturing, quality, corrective actions, etc. In other words, it discusses safety procedures that it believes are appropriate for any company making consumer products in all aspects of design, production, sales and post-sale. Despite its focus on consumer products, this handbook can be very useful to manufacturers of industrial products.

At the beginning of the handbook, it says:

> *"Manufacturers must assure the safety of consumer products. This is achieved through the design, production and distribution of the products they manufacture. It is best accomplished by a comprehensive systems approach to product safety, which includes every step from the creation of a product design to the ultimate use of the product by the consumer. The basic concepts for a comprehensive systems approach for the design, production and distribution of consumer products are discussed in this Handbook."*

In addition, the CPSC's Recall Handbook, in existence for many years but updated in March 2012, has sections on the appointment of a Recall Coordinator, development of a company recall policy and plan, and extensive suggestions for the creation and retention of records to support a recall. Again, this information can be used by an industrial product manufacturer since these products can be recalled too.

The safety processes advocated in these handbooks are just suggestions and not legal requirements. In addition, they are similar to those procedures employed by companies who have a well-functioning safety effort. So, there is nothing particularly onerous here that a company shouldn't already be doing.

ISO 10377

ISO 10377, *Consumer product safety – Guidelines for suppliers*, was first issued in 2013. The rationale for the creation of this new standard was to assist small and medium-sized product suppliers in producing safe consumer products and in complying with safety legislation and regulations enacted by various countries. The problem perceived by the drafting committee was that many suppliers have "limited experience, few available resources, or practical reference documents to guide them through this process."

Specifically, in the Introduction, it says that this standard:

> *"…presents what needs to be done to identify the hazards and to assess and manage the risks – from the design of the product, to the input of raw materials, to production, to distribution, to retail and to the ultimate product end-user and disposal."*

The first two sections entitled "Basic Principles and General Requirements" discuss promoting a product safety culture both within and outside the organization. In addition, it discusses the organization's commitment to provide safe products and to ensure that these products undergo continuous improvement.

Also, there are discussions concerning an organization's commitment to providing appropriate training of its employees, adequate resource allocation and appropriate records management and document control.

Lastly, the general requirements section discusses an organization's commitment to comply with all applicable laws, regulations and standards, and to undertake activities which allow the product supplier to both identify and trace that product back to its original producer.

There are also useful sections on design, production and actions in the marketplace as well as good information and samples in the standard's various Annexes.

This standard tracks the techniques that those of us in this area have been recommending for decades. However, this standard performs a useful service by identifying and assessing these techniques and best practices, and organizing and restating them in an understandable way.

Unfortunately, as one would expect, it is not as practical as companies would probably like it to be. It is impossible to create a standard or recommendations that can instruct every individual company on how they should manage safety. Therefore, in the Introduction, it says "[The standard] does not necessarily explain how it should be achieved." This means that it still requires the supplier to decide which of these best practices are appropriate and necessary for their company and how to implement them.

There are very few absolutes in product safety management and product liability prevention. Some company's products have such a low risk that many of these best practices are not necessary to undertake. In addition, some products can be reasonably safe and pose no unusual risk if they are simply designed to comply with applicable technical standards.

The ISO standard is general and somewhat vague in discussing some of these techniques. This is necessary in that there are no clear answers to certain questions. So, manufacturers should consider this standard in evaluating their own programs or in determining what programs to implement. And they should document why they have not adopted some of the procedures in this standard so that they can respond to future questions as to why they didn't do more.

STUDIES ON BEST PRACTICES

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 supporting those elements.

The PRTM Study

Pittiglio Rabin Todd McGrath (PRTM), a U.S. based management consulting firm, issued a white paper in 2002. In the study summarized in that white paper, 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 were U.S.-based and the rest were 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.

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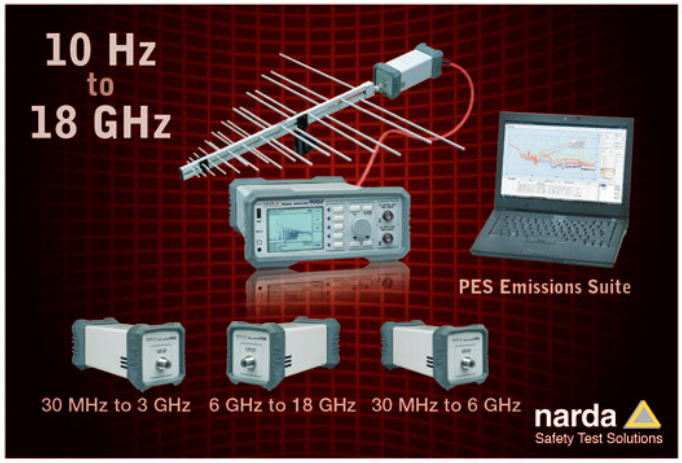

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- The world-class companies (only 25 percent of 52 companies) have inserted product safety into their strategies, organization, processes and systems. Smaller and less successful companies have some but not all of the practices the study's authors 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.

Even though 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, as well as 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 positions. 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 include:

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 very few companies have implemented a full range of processes, procedures, strategies and personnel to effectively manage product safety during the product development phase and after sale.

The study indicates that world-class 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 can mean millions of dollars in savings.

These 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 Conference Board Study

In 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 a subsequent update of this study. However, 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 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.

The Rand Institute Study

In 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.

No matter what a manufacturer does, it is always possible that its product safety program is lacking in some respect and could arguably constitute evidence of a disregard for safety.

Also, if there is an attitude that safety problems are being handled by someone else and that safety is not a problem if 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, since 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.

CONCLUSION

No matter what a manufacturer does, it is always possible that its product safety program is lacking in some respect and could arguably constitute evidence of a disregard for safety. To combat that possibility, any program must be able to show a high regard for safety, both on paper and in actions. If this showing is made, even if the jury or a government agency believes that the manufacturer could have done more, it should also believe that the manufacturer tried to do the right thing and may therefore not be subject to civil penalties or punitive damages.

The techniques and procedures are well-known; the difficult part is to analyze what is appropriate for a particular company and then incorporate them into the company's organization, culture and processes. Doing so should pay for itself, either by preventing future problems that could arise, or by providing the manufacturer with a much better defense if accidents do occur.