

Kenneth Ross

Attorney at Law

Of Counsel, Bowman and Brooke LLP

447 N. Fairway Drive
Midway, UT 84049-6011
www.productliabilityprevention.com

Phone: (952) 210-2212
kenrossesq@gmail.com

Product Safety Management Literature Survey

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Summarized below are relevant comments and data from some of the main product safety sources that discuss product safety management. Some of these sources are fairly old. Despite that, I believe that they all have relevant insights into what companies have done and what the authors think companies should do to establish effective and credible product safety management programs.

Engineering Ethics and Design for Product Safety, d'Entremont, Kenneth, (McGraw Hill 2021)

This new book is written by an engineer who used to be a product safety manager at a large manufacturer and is now an engineering professor. He believes that a safety policy is insufficient to empower and encourage employees to follow the requirements of the policy. Managers need to specifically manage in a way that confirms the importance of complying with the policy. A high-ranking person must oversee safety and be willing to put pressure on those personnel who affect product safety, sometimes to the detriment of profit and loss.

This head of product safety will need to fight for the company's safety values and make tough tradeoffs before cost and safety and usability of the product. Safety cannot work through a committee. It has to be an individual who can act quickly as decisions are being made on design and manufacturing issues.

Ultimately what is the best example of a company's commitment to safety is the production of safe products and not the platitudes written in a product safety policy.

Handbook for Manufacturing Safer Consumer Products (CPSC, July 2006)

A clear, strong statement in a product safety policy from senior management should be issued by the company. It applies to internal operations and suppliers whether they are in the U.S. or international. This policy should be publicized inside the company and outside. Each policy statement is unique, but should encompass commitment, reasons for this commitment, and individual expectations.

No specific organization is suggested other than having specific individuals assigned to implementing product safety procedures and having these assignments and responsibilities in writing. The Handbook says that the worst possible situation is where authority is not delegated and there is no method for personnel to communicate critically important information to upper-level management.

The Handbook discusses training in some detail, distinguishing between training for senior executives, for purchasing personnel, and then for product designers. Training is particularly important where the

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company is just starting up a product safety program. Training should be ongoing and not just a one-time event. And all personnel who do things that can effect product safety and regulatory compliance need to receive training even if their specific function is not totally devoted to product safety.

Additional personnel are not always necessary. And additional procedures are not necessarily needed. Product safety can be integrated into existing procedures already established to provide a quality, compliant product. But it is important that specific personnel responsible for these safety-related procedures be assigned.

If a product safety manager is appointed, their functions need to be clearly described including whether they are responsible to report to the CPSC and what information they need to provide to upper management.

CPSC Recall Handbook (March 2012)

This Handbook recommends the development of an organizational policy and plan of action if a product recall becomes necessary and the designation of an employee to serve as a recall coordinator. The recall coordinator's qualifications and duties are described as well as what this recall coordinator should do at the outset.

There are suggestions about things that can be done to prepare for a recall such as establishment of a product identification and traceability system that can be used to identify the affected products and communicate with those who may have the product.

Some CPSC Required Elements of a Compliance Program as set forth in Civil Penalty Agreements

1. Written standards, policies and procedures, including those designed to ensure that information that may relate to or impact CPSA compliance is conveyed effectively to personnel responsible for CPSA compliance, whether or not an injury is referenced.
2. A mechanism for confidential employee reporting of compliance-related questions or concerns to either a compliance officer or to another senior manager with authority to act as necessary.
3. Effective communication of company compliance-related policies and procedures regarding the CPSA to all applicable employees through training programs or otherwise; Senior management responsibility for, and general board oversight, consistent with its policies and procedures of, CPSA compliance.
4. Retention of all CPSA compliance-related records for at least five (5) years, and availability of such records to CPSC staff upon request.

ISO 10377 - Consumer product safety - Guidelines for suppliers

Consumer product safety should be a key consideration in a supplier's organizational and governance structure by means of a consumer product safety compliance management program implemented and endorsed by the governing body and top management. The supplier should understand and comply with the applicable laws, regulations and standards of the product produced and the legal and

regulatory requirements of the marketplace in which the product is manufactured or sold. Responsibility for compliance outcomes should be clearly articulated and assigned and appropriate resources allocated to develop, maintain, monitor and continually improve the program.

There is also a discussion of promoting a safety culture inside and outside the company. Appendix D of this standard discusses product safety management plans. This includes management commitment to product safety, appointing a safety officer, documentation procedures, and communication systems.

Benchmarking Product Safety in Selected Manufacturing Companies (Manufacturers Alliance/MAPI, September 27, 2000)

The companies who were surveyed are members of the Alliance's Product Liability and Product Safety Council. As members of this group, it can be expected that their companies support proactive product safety efforts and that many of the Council members spend part of their time on such matters. As a result, the conclusions may not be indicative of what is going on in corporate America.

In the introduction it states that "Most companies are continually evaluating and fine-tuning their safety policies and processes to be certain that product safety considerations are factored into the design, manufacture, quality control, and marketing of all the companies' products." I assume this means companies who are members of the Alliance.

Thirty companies responded to the survey. Important relevant findings are as follows:

- Almost two-thirds of the companies have a separate department or function within the company responsible for safety and compliance.
- In three-fifths of those companies that have a separate safety function, 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% have developed or are in the process of developing a formal policy for product safety.
- Around 40 % of the respondents have a product safety manual or procedures.
- Around two-thirds of the companies integrate product safety and regulatory compliance into their existing product development processes.
- Around 75% of the respondents audit their programs.

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

The Product-SafetyFunction: Organization and Operations (Conference Board Report #754, 1979)

This book is the major work on product safety management. It is based on survey responses of about 300 manufacturing companies. Supplemental information was obtained by interview and correspondence from several other sources. There has not been an update of this survey.

Despite its age, it does provide some good insights. For a more recent discussion of product safety management guidelines, refer to the National Safety Council book that is described below.

Of the 300 companies surveyed, 251 were divisionalized, and 207 had multi-division groups. The vast majority of companies have elected to use a mixed organizational configuration, establishing full or part-time product safety assignments at corporate and other levels. Corporate level product safety functions are often relatively small and mainly perform a staff coordinating and consulting function. A minority of firms has chosen to completely decentralize the product safety function, in other words delegating the responsibility to each of the relevant divisions.

By far the largest number of companies studied favor a combined approach that brings together product safety functions at both division or group levels with those at a corporate level. One of the most frequent arrangements is to establish a full-time function at headquarters with part-time safety assignments at operating levels.

This book contains a chapter on the product safety audit. It says that occasional reliance on a formal product safety audit has gained in popularity among a number of companies studied. While still a minority practice, the procedure is judged by adherents to be of significant importance in establishing the safety-worthiness of existing and future products.

In the late 70s, 39% of the divisionalized companies had a safety committee at corporate level; 19% at the group level; 33% at the major division level. In other words, 61% had no safety committee at the corporate level and 67% had no safety committee at the major division level. These figures are too far out of date. My guess is that more committees exist now, particularly as the law department function has increased for product liability and compliance efforts have increased. A majority of companies have a formal product safety policy. This booklet 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 a firm'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.

Designing Safer Products: Corporate Responses to Product Liability Law and Regulation (Journal of Products Liability 1984)

This is an excellent insightful analysis done by the Rand Corporation's Institute for Civil Justice. All safety professionals whose works the authors read or to whom they talked conclude 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 authors interviewed corporate product safety officials in nine large manufacturing companies as well as a number of professionals involved in product safety in insurance companies and other settings. All of the manufacturing firms were among those generally recognized as leaders in the safety field.

These manufacturers thought that a separate product safety organization is appropriate due to product complexity, hazard subtlety and organizational pressures.

It is possible for product safety problems to not turn up during normal safety design reviews because of their complexity and the interaction of the product and the packaging and the environment. Hazards are very subtle, particularly given the necessity to consider reasonably foreseeable misuse. (KR Note - Another thing that divisional safety people may miss is evidence or experience from other product lines that could provide useful information for their particular product).

Organizational pressures also indicate that a product safety group 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. Can subordinate parts of an organization, operating semi-autonomously under the influence of limited financial controls, be trusted to surface and satisfactorily resolve all significant safety hazards without specific oversight to ensure that they do? If there is an attitude that safety problems are being handled by someone and that safety is not a problem as long as competent engineers are involved, there is likely to be resistance to taking the time and resources required first to surface subtle or complex hazards and then to redesign and retest to assure that they have been properly dealt with.

The prime responsibility for actively ensuring that safety factors are adequately considered rests with the division producing the product. A division may assign an individual the responsibility for overseeing its safety activities.

All commentators agree that the corporate level product safety function plays a critical role in the firm's overall safety effort even if there are divisional product safety people.

The authors believe that the corporate level product safety activity is best seen as a liaison device. Liaison devices are divided into three levels: liaison positions, task forces and standing committees, and integrating managers.

In large corporations where divisions are often geographically separated, an intra-firm diffusion of knowledge may be important. In other words, learning from other divisions' successes or failures is important within a large corporation.

Education at the corporate level is appropriate as well as auditing. Also, corporate level product safety organizations transmit and reinforce top management's commitment to product safety.

If the corporate product safety officer can introduce indicators of safety performance into the measures used to judge the performance of operating divisions so that the consequences of poor safety performance are reflected in the division's profitability, this also sends a signal. Also, the corporate level product safety officer can act as a court of appeals when a safety issue arises.

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 unit can serve as an aggregator of corporate experiences in dealing with product liability issues. These corporate units can help divisions faced with claims, but lacking experience in their handling they can tap the services of staff units to assist.

Firms that lay great stress on modifying their design procedures to assure product safety should be expected to employ audits as a tool. Some audits are defense oriented while others are more safety-related.

From the interviews, the authors initially thought that corporate size would be a determinate in the size of the corporate safety effort. However, this was not confirmed. There were three factors, which did help identify the size of the corporate safety effort. They were: inherent seriousness of the safety problems, constraints imposed by the organization of the corporation, and constraints imposed by the management and philosophy and style of the CEO.

In the first factor, the authors divided companies into three categories. First are products that are inherently dangerous, such as pharmaceuticals, automobiles and aircraft. The second category involved industrial machinery and some classes of consumer durables. The third category involved products such as home appliances.

Assigning formal responsibility for safety at some high level in a corporation might be interpreted as relieving lower level individuals of their responsibility and this might reduce overall safety.

One of the corporations interviewed hired a product safety officer from the aerospace industry who had tried to apply aerospace design assurance techniques to the firm's products. This effort was seen as overkill and abandoned. The experience left the firm suspicious about the value of formal product safety techniques and as a result the locus of corporate level product safety concerns drifted to the legal department.

The corporate level product safety effort potentially can play the most important role in firms producing moderately hazardous products. The placement of the product safety effort in the corporate hierarchy, the resources it commands, and its ability to demonstrate that the firm's CEO backs its actions are all signals that can be read and understood throughout the company.

Some firms are linking their product safety efforts to other goals such as quality in a mutually supportive way, thereby increasing the program's leverage.

The authors believe that the need for corporate product safety offices continues. The complexity of products means that corporate level efforts are still required to assure that even in large organizations there is a continued pressure to ensure that safety considerations are given due weight at all points in the process. At the corporate level, the extent of resources devoted to product safety does not appear to determine the effectiveness of the office as much as the way in which the office is structured.

What appeared to the 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 firm's products, with the need for higher level supervision or monitoring of safety related design decisions and with the interest of the CEO in the firm's safety performance.

A lean product safety organization that has the ear of the CEO and a good working relationship at various levels of the corporation is likely to be much more effective than a highly visible unit that establishes procedures, but lacks either the resources to impose them or, even more disastrous, lacks the support of the firm's top officers when such support is necessary.

National Safety Council's Product Safety Management Guidelines. 1997

This book states that a good product safety program requires a corporate policy statement, clear objectives, committed leadership, effective organizational systems, knowledgeable personnel, a specific program, employee involvement and awareness, and individual support at all levels. The chapter on product safety programs discusses leadership, organization and involvement.

The book contains information on establishing a product safety policy, a product safety department and product safety policies. In addition, it states that every good program needs a system to evaluate its continuing effectiveness, such as a product safety audit.

Concerning a product safety professional, it says that the organizational assignment depends on the personnel available, the nature of the organization, and the types of products made. This function is usually a staff rather than a line position, and is many times part-time.

It states that there is no consensus about the best way to organize a company for product safety and that it is heavily related to risk and management style.

The rest of the book provides guidelines on product safety management in various areas. The authors generally describe what companies and personnel can do and they offer no recommendations as others have done in some of the other books.

Products Liability. Frumer & Friedman (1993)

There are two volumes of the Frumer & Friedman treatise related to product safety. These are Volumes 3A and 3B.

Chapter 70 pertains to product safety management: policy, systems and elements. This chapter is written by three safety engineers. The material in this and other safety chapters was updated as of 1991 or 1992.

In Chapter 70, the authors state that a sufficiently large number of American and foreign companies have now included in their corporate organizational operating policies and procedures for the control and assurance of product safety to the point that a state-of-the-art standard has now been established. While product safety management techniques are becoming increasingly common among larger multi-divisional concerns, their use by smaller companies (under \$100M in sales) is the exception rather than the rule.

The authors feel that there should be a written policy issued by top management. The documents should be numbered for identification and retrieval, and should be dated and coded for revision status.

In most cases, the company does not actually establish a new function or unit, but rather assigns the responsibility to the manager of an existing organizational section already having another primary function or responsibility. Many policies leave vague the subject of who has what authority. Then, the specific person filling that job can determine whether they should be weak or strong or merely perform an advisory function.

The product safety philosophy relies heavily on the use of pre-designated formal safety reviews at critical stages in the design and manufacture of new or modified products.

A management audit is the technique normally employed to assure that safety system objectives and methods are still valid, the procedures are implemented without exceptions, and that all safety and documentation control data is recorded.

Chapter 71 relates to reviews. This chapter describes a management review to investigate or confirm the merits of a product safety system. This might be the kind of review necessary for a company to determine what to do and how to do it. The next review described is an operation review. Presumably this is just like an audit.

Chapter 72 deals with organizational structure. The product safety concept has found its greatest acceptance in companies that are large, have sales volume of over \$500M, are multi-divisional, and are considered by the public as the ultimate source of recovery in a lawsuit.

The authors show a typical organization chart for a fictitious divisionalized company engaged in the manufacture of a variety of products. The products range from aircraft to food to automotive to consumer products.

For this fictitious company, they show a full-time corporate quality and safety director who reports to the president of the corporation. It is a one-man staff position, and his major responsibilities are to provide corporate level guidance to the corporate staff and the non-autonomous divisions and to assist the major divisions when requested. The corporate product safety position is a staff assignment. All divisional product safety assignments are line functions. The choice of line as opposed to staff product liability assignments appears to depend on the philosophy of the management group involved; performance results in existing programs indicate no special advantage for either choice.

The product safety concept coordinates a selective group of tasks that are the functional responsibility of independent operating units. For this reason, many companies have seen the need to organize the product safety function under the control of a senior management committee or counsel. This could be the corporate product safety committee or product integrity committee.

The division product safety committee customarily reports to the division president or COO, with an informal tie to the corporate committee.

A product safety program's design purpose is to collectively manage a wide variety of functions in the manner best suited to realize the safest possible product. The well-managed product safety program is primarily an overview. In no known case does the formal product safety program, managed by a specifically chartered product safety organization, have the responsibility for the performance of all tasks. The product safety organization reviews and approves operating requirements, audits compliance, and provides a continuing assessment of the adequacy of product safety activities.

Companies organized for the product safety management function have generally found the procedural systems alone will not yield the desired product safety results. This has prompted several companies to implement formal training programs. This training creates awareness in the product safety objectives as well as the reinforcement of basic professional and workmanship skills.