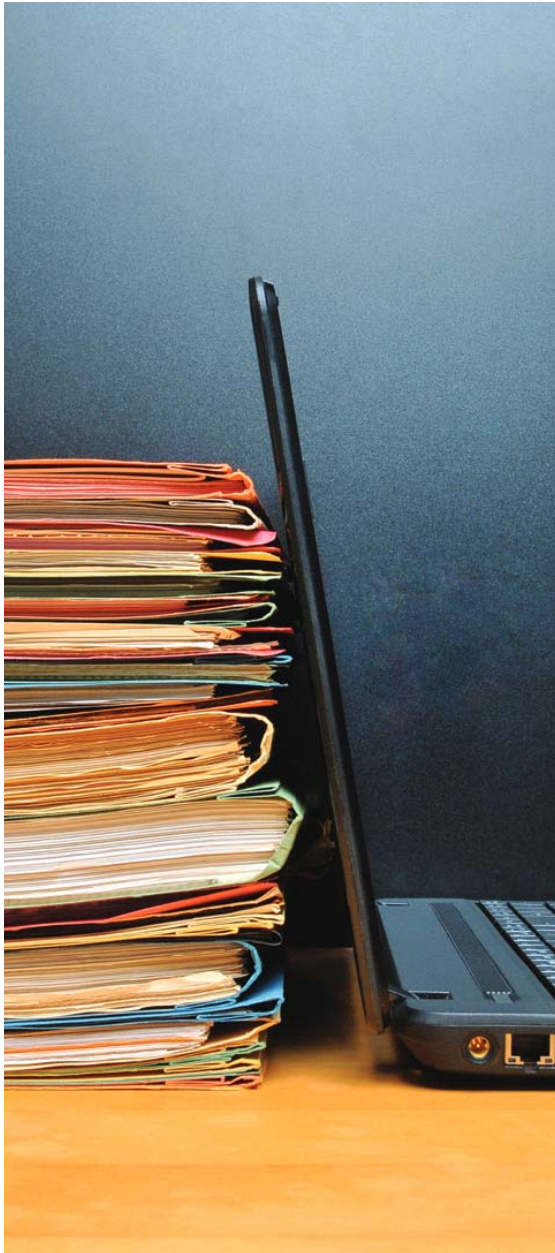


TWENTY-FIRST CENTURY DOCUMENT MANAGEMENT

Best Practices for Product Safety and Product Liability



Documents, including electronic records, are the lifeblood of any corporation. While employees come and go and change jobs within an organization, the design plans, engineering drawings, production procedures, safety memoranda, and marketing strategies that they have created represent a historical record of the safety that a manufacturer included in the product. These documents can significantly help or hurt a manufacturer or product seller, especially in the event of product liability litigation.

Unfortunately, no one knows whether the documents will help or hurt until a lawsuit is brought and the manufacturer has to respond to discovery and produce documents asked for by the plaintiffs. In addition, there may be documents that could be helpful, but which were written in a way that could possibly benefit the plaintiffs. And, perhaps even more frustrating, there may also be documents reflecting safety activities that were created but then destroyed before litigation arose.

The pervasiveness of electronic records has changed how manufacturers create, store, and destroy documents and other records. In addition, the growth in popularity of the Internet and social networking media has created more opportunities for the dissemination of potentially harmful information to the government, and to potential plaintiffs and their attorneys. Retailers and standards groups have started demanding that manufacturers employ state-of-the-art safety processes and provide documents evidencing compliance. And product liability and product safety laws have proliferated around the world, making it necessary for a manufacturer to keep track of and document everything that is going on with its products inside and outside the U.S.

Despite these changes, the main message is the same—a manufacturer must create documents to confirm its efforts to make safe products and to possibly fix unsafe products that have been sold. In doing so, a manufacturer should think about how it might need

Kenneth Ross is a Senior Contributor to *In Compliance Magazine*, and a former partner and now Of Counsel to Bowman and Brooke LLP. Ross provides legal and practical advice to manufacturers and other product sellers in all areas of product safety, regulatory compliance and product liability prevention, including document management, safety management, recalls and dealing with the CPSC. He can be reached at kenrossesq@gmail.com. Other articles by Ross can be accessed at www.productliabilityprevention.com.



By Kenneth Ross

to tell its story to a jury, customers, plaintiffs' attorneys, or the government, and to create documents that will accurately and completely describe these efforts.

IMPORTANCE OF DOCUMENTS

During the design, manufacturing, and marketing phases, a manufacturer's goal is to make a product that reasonably balances the risk of injury from use of the product against the product's functionality, utility, durability, price and other attributes. If accidents do occur and product liability claims and litigation result, a manufacturer will hopefully have evidence that it undertook sufficient measures to make a product that is reasonably safe. Thus, a manufacturer should have created and retained documents that evidence its interest in safety and regulatory compliance, and which describe the procedures that were used to evaluate a product's safety.

However, many lawyers feel that documents that analyze risk and describe design, production, and marketing processes can only hurt manufacturers and rarely help their client's case. So, they may discourage manufacturers from creating or retaining such documents, especially those that deal with safety. Invariably, those lawyers view such documents as potentially harmful and difficult to explain. Those lawyers do have a point, especially when engineers challenge and question safety during a product's development phase.

Despite that, each manufacturer must decide how to balance the risk of retaining documents that hopefully will help but could, in the wrong hands, be misconstrued, taken out of context, and used against the manufacturer in a product liability lawsuit. The goal is to create truthful documents that are helpful and not unnecessarily harmful.

DOCUMENTS THAT CAN HURT

Instances where manufacturers have suffered substantial losses because of "bad documents" are well-known. For example, juries sometimes react angrily toward manufacturers that consider the value of lives during design. What juries apparently don't like is that the documents do more than consider cost and safety

and instead associate product cost with the value of human life and the value of settling cases for presumed future incidents.

The lesson that can be drawn from such cases is not that manufacturers should avoid creating or retaining documents concerning design and manufacturing processes and procedures. Rather, the lesson is that they need to train employees on how to write defensively, as discussed below, and how to follow up on documents when someone raises safety concerns. Manufacturers should do this not only for litigation purposes, but also to document the reasons clearly and accurately supporting their design and manufacturing decisions. This is the proactive part of document management.

INSUFFICIENT DOCUMENTATION THAT CAN HURT

In addition to having documents that cause problems, a lack of documents can also hurt the defense of a case. For example, even if an engineer can remember doing safety testing, a jury may not believe that a manufacturer performed the tests if the manufacturer did not create or keep documents about those tests. In addition, in many cases, there may be no one available who remembers the reasoning. Testimony about tests that an engineer remembers conducting years ago may not sway a jury if there are no documents supporting the testimony.

In addition, one of the most significant defenses against a product liability claim is that there were no prior, similar accidents involving a product or earlier versions of that product. Without good documentation supporting the lack of similar accidents, an opponent can defeat efforts to present this defense. Therefore, getting rid of documents describing prior accidents or the lack of accidents can actually be harmful to the defense.

DOCUMENTS THAT CAN HELP

In addition to a systematic record of prior accidents or lack of accidents, documents evidencing a concern for safety and "trying to do the right thing" will go a long way toward at least defusing any thoughts by

plaintiffs of seeking punitive damages. Documents proving compliance with voluntary safety standards are particularly important. And post-sale, documents evidencing efforts undertaken in a recall can be crucial in defending the adequacy of the corrective program, especially when it can be proved that the plaintiff received a recall notice before the accident.

The reality is that if your company doesn't have any safety programs in place, has safety programs but failed to create good documents, or has thrown away the documents that were created, the plaintiff may believe that their case is much better than it really is. On the other hand, if your company has safety programs and has the documents to prove it, the plaintiff will likely obtain the documents and then will have to decide if that evidence could make the manufacturer look responsible. As an attorney, I'd rather defend a comprehensive and documented safety program any day.

POST-SALE DOCUMENTS

The potential liability of a manufacturer or product seller for negligence after sale of a product is well-known. In addition, current U.S. regulatory and common law requirements apply to information that was obtained or should reasonably have been obtained that identify an unsafe condition. The potential liability for violations of regulatory laws is growing as more foreign governments implement consumer product safety legislation. These laws contain a duty to report to the government if certain threshold safety events occur. This enhanced focus makes it even more important for a manufacturer to gather, analyze, and document safety information received from anywhere in the world.

Anything less than a "reasonable" effort to obtain and analyze post-sale information, wherever in the world it comes from, may be considered negligent by a U.S. jury in determining whether a manufacturer should have known about the problem before an accident occurred or by a government agency in deciding whether the manufacturer should have reported the safety issue to the government.

The growth of the Internet and social networking media have made it even easier to find post-sale information and easier for manufacturers to receive this information from those who want to communicate with them about it. Many of these documents and reports will be unverified, overstated, inaccurate, and incomplete. Consequently, manufacturers must decide how to follow up and when to investigate such reports to determine

the facts and to minimize avoidable problems that these reports could cause.

Being aware of all information—good and bad, true and untrue, complete and incomplete—can be helpful if a company can identify the important information, adequately evaluate and document it, and take any warranted corrective actions.

DOCUMENT MANAGEMENT PROGRAMS

An effective document management program includes the development of guidelines and procedures for determining which documents to create, which words to use and not use, how to deal with safety issues, how long to keep documents, when to destroy documents and how to destroy them, and in which format documents should be retained.

The pervasiveness of electronic records as the only record type that many manufacturers now create and keep makes developing a document management system difficult. And, the document management programs of many manufacturers simply address when to discard documents or delete them from the company's database. Such a narrow focus is inadequate; a document management program should consider many other elements, and without proper handling, those elements can lead to liability.

It is helpful for each manufacturing entity to establish a document management policy and guidelines. This policy should confirm that employees are encouraged to bring to management's attention, orally or in writing or both, all good and bad information about the design and manufacturing process of which they are aware. In other words, a company should encourage employees to reveal potentially damaging information and bring it to the attention of supervisors rather than ignoring it.

The policy should also contain guidance on the kinds of documents that employees should create and how to compose those documents so that they are truthful, accurate and complete and will help support a defense or are at least defensible. It should contain retention schedules for all documents, including electronic records.

Another essential part of managing a document program is educating employees about the policy and how to comply. A company's training must clearly show that the company is interested in learning about all good and bad information concerning its products,

and its documents should reflect the concern that it has for selling safe products that comply with all applicable laws, regulations, and standards.

LEGAL REQUIREMENTS

Every manufacturer doing business in the U.S. must be acquainted with the safety and quality related document creation and retention requirements imposed by U.S. and international laws and regulations. In addition, a manufacturer must consider mandatory and voluntary standards or certifications in the U.S. and elsewhere. For example, a manufacturer must develop and maintain certain documents to confirm compliance with certain European Union (EU) Directives and standards to attach a CE mark to a product sold in the EU.

Documentary evidence of compliance with such standards may strengthen a defendant's case in a product liability lawsuit. You can use that evidence to confirm that a manufacturer took steps to ensure that its products were reasonably safe and complied with all applicable laws, regulations, and standards. In other words, both the legally required and voluntary documents can be used to support claims that a manufacturer considered safety during the design and creation of a product.

Last, a manufacturer must be aware of and try to comply with any customer requirements for document creation and retention.

DEFENSIVE WRITING

Writing defensively does not mean that a manufacturer tries to hide bad information or evidence or shades the truth. On the contrary, a company's policy and educational programs must stress to employees that they should raise all issues, good or bad, during the development of the product and after sale.

In fact, the documents must portray correctly and accurately a manufacturer's rationale for designing and making its product. A record of this rationale is necessary for designing future similar products and for good historical corporate record keeping. In addition, if the content of some documents challenge or discuss safety, they must be written so that they do not create misleading impressions and allow a plaintiff to use the quotes out of context against a manufacturer in litigation.

Those employees who draft the manuals, plans, specifications, and other documents, especially those

written post-sale—the “writers”—should avoid legal terms that describe theories that a plaintiff's attorney may present to a jury in a product liability lawsuit. These include terms such as “defect,” “negligence,” “misrepresentation” and “reckless.” Use of these and related legal terms by internal writers may lead a jury to decide that a company is admitting or has admitted that its product is defective or unreasonably dangerous or legally deficient in some other way.

While a writer will have a chance to tell a jury why the word “defect” did not really mean defect in a product safety sense, the inclusion of such a loaded word in, for instance, a report on the development of a new product or an investigative report after an incident gives a plaintiff an advantage in presenting his or her case to the jury.

Additional phrases and words to keep out of documents include overstated expressions, characterizations or opinions. They can cause problems for a company. For example, writers should not use phrases such as “occurs often” or “occurs frequently” when an engineer has only noticed two or three occurrences. Don't use the word “catastrophic” in connection with a product failure unless it truly was catastrophic. “Catastrophic” may be a commonly understood term among engineers, but it may be unnecessarily strong and inflammatory when heard by a jury.

Another term to avoid is “crisis.” Writers trying to get the attention of their supervisors may want to call every problem a crisis. This is unnecessary overstatement; it suggests that a company is having huge problems all the time. Similar terms are “smoking gun,” “ticking time bomb,” and “sitting on a powder keg.” They are inflammatory, maybe overstated, and definitely unnecessary.

In addition to choosing words and phrases carefully, a company must organize its flow of documents to ensure that supervisors read and analyze such information, and then respond to bad reports or criticisms written by a company's lower-level employee. This is called “closing the loop.”

THE DANGER OF NOT RETAINING DOCUMENTS

Documents that describe a manufacturer's concern for and incorporation of safety into the design of its product are of little litigation value if they are not retained long enough to be introduced in a future lawsuit. In fact, if a manufacturer lacks documents,

a plaintiff's attorney might use that fact against the manufacturer by raising a rebuttable presumption that the documents were incriminating and were destroyed for that reason.

Some companies might destroy such reports shortly after a product launch because they do not reflect the final design. This would make it more difficult for a plaintiff to argue that the manufacturer should have adopted one of the rejected alternative designs. However, with no documents on which to rely, witnesses testifying on behalf of the company will have to describe from memory which alternative designs were considered and rejected, which safety tests were performed during the design of the product to select the final design, and how the company incorporated safety into the final product. Moreover, the company's liability may well rest on the company witness' credibility in front of a jury rather than on the facts of the design process. In some situations, it might be better to retain the documents pertaining to the alternative designs that were ultimately rejected.

PRODUCT HISTORY FILE

A comprehensive retention program should contain a history of the life of a product, from creation through end of life. Having a core history, initially assembled after the development of each product or product line, will allow a manufacturer to prove that it complied with all safety and other requirements on a routine basis. The project manager could gather all documents from all sources within a company pertaining to the project and organize them into a comprehensive, coherent file that describe the history of the development of the product. Drafts and duplicates of documents should be destroyed. Documents should be organized so that an email and its response are grouped together.

Developing this product history file does not mean that potentially harmful documents, such as an internal memo that questions whether a company's current design is reasonably safe, should be destroyed. In fact, attorneys can usually determine if documents have been destroyed and will try to argue that the manufacturer had something to hide.

Juries and judges understand that there may be internal differences of opinion during the development of a product. All a manufacturer will need to explain is how the manufacturer handled this dissenting opinion—that it was fully considered and then accepted or rejected – and the basis of the final decision. Disclosure

of dissension within a company can be beneficial; it confirms that a manufacturer encourages varying opinions and does not try to hide bad or potentially damaging information. Of course, it can also be harmful if a jury believes that a rejected opinion was correct.

There are no specific or universal guidelines on how long a company should keep such documents. A company does need to comply with certain legal requirements and any customer requirements. And companies will have an overriding sense of how long to keep documents to support their business purposes. Otherwise, documents that are necessary to explain a product's design should be kept if they might be needed to defend the manufacturer. A company will need to make decisions about retention time on a case-by-case basis, first considering the life expectancy of a product, applicable statutes of limitation and repose, and how long after the product's expected life that the company might anticipate claims or lawsuits, to name a few.

A manufacturer should also consider keeping some documents forever, especially if they represent an old design. Subsequent designs and redesigns are often based on earlier designs. Products evolve over time, and therefore a manufacturer may need the earliest product development documents to explain later designs.

As a result, if such a file were developed, a company should keep the product history file permanently in electronic form which would allow specific files to be easily located.

CONCLUSION

In the history of product liability litigation, documents have proven both helpful and harmful to plaintiffs and defendants. Even though some documents may ultimately turn out to be harmful, a manufacturer must proactively establish a document management system that ensures compliance with legal requirements and results in the creation of a story of the development and life of a product. The system should also include procedures, education and training that will minimize the creation of misleading and unnecessarily harmful documents.

Although this system can be difficult to organize and implement, it will clearly confirm a manufacturer's efforts to produce a reasonably safe product and be potentially helpful in defending its conduct and its products in the future. 