CHAPTER 75

WHAT THE LAW REQUIRES OF THE ENGINEER

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75.1 THE ART OF THE ENGINEER

75.1.1 Modeling for the Real World

Engineers believe that they practice their craft in a world of certainty. Nothing could be further from the truth!

Because this chapter deals with the interface between law and technology, and because products liability is likely to be the legal area of concern to the engineer, our principal focus will be on the engineering (design) of products, or components of products.

Think for a moment about the usual way an engineer proceeds from a product concept to the resulting device. The engineer generally begins the design process with some type of specifications for the eventual device to meet, such as performance parameters, functional capabilities, size, weight, cost, and so on.

Implicit, if not explicit, in the specifications are assumptions about the device's ultimate interaction with the real world. If the specification concerns, for example, loading or power needs that the device is either to produce or to withstand, someone has created boundaries within which the product is to

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function. Clearly there are bound to be some uncertainties, despite the specifying of precise values for the designers to meet.

Even assuming that a given loading for a certain component is known with precision and repeatability, the design of the component more than likely will involve various assumptions: *how* the loading acts (e.g., point-load or distributed); *when* it acts (e.g., static or dynamic); *where* it acts (e.g., two or three dimensions); and *what* it acts on (e.g., how sophisticated an analysis technique to use).

The point is that even with sophisticated and powerful computational tools and techniques, the real world is always modeled into one that can be analyzed and, as a result, is truly artificial. That is, a measure of uncertainty will always exist in any result, whatever the computational power. The question that is often unanswered or ignored in the design process is: How *much* uncertainty is there about the subtleties and exigencies of the true behavior of the environment (including people) on the product and the uncertainties in our, yes, artificial modeling technique?

75.1.2 The Safety Factor

To mask the uncertainties and, frankly, to admit that, despite our avowal, the world from which we derive our design is not real but artificial, we incorporate a "safety factor." Truly, it should be viewed as a factor of ignorance. We use it in an attempt to reestablish the real world from the one we have modified and simplified by our assumptions, and to make it tractable; that is, so we can meet the product specifications. The function of the safety factor, then, is to bridge the gap between the computational world and the one in which the product must actually function.

There are, in general, three considerations to be incorporated into the safety factor:

1. Uncertainties in material properties
2. Uncertainties in quality assurance
3. Uncertainties in the interaction of persons and the product—from the legal perspective, the most important of all

To illustrate:

Example: Truck-Mounted Crane

Consider a truck-mounted crane, whose design specification is that it is to be capable of lifting 30 tons. The intent is, of course, that only under certain specific conditions, i.e., the boom angle, boom extension, rotational location of boom, etc., will the crane be able to lift 30 tons.

Inherent in the design, however, must be a safety factor cushion, not only to account for, e.g., the uncertainties in the yield stress of the steel or the possibility of some welds not being full penetration during fabrication, but also for the uncertainties of the crane operator not knowing the precise weight of the load. In the real world, it is foreseeable that there will be times when no one on the job site knows, or has ready access to sufficient data to know, with reasonable certainty the weight of the load to be lifted.

The dilemma for the engineer–designer is how much latitude to allow in the load-lifting capability of the crane to accommodate uncertainty in the load weight. That is, the third component of the safety factor must reflect a realistic assessment of real world uncertainties. The difficulty, of course, is that there are serious competing tradeoffs to be considered in deciding upon this element of the safety factor. For each percent above the 30-ton load specification that the engineer builds into the safety factor, the crane is likely to be heavier, larger, perhaps less maneuverable, etc. That is, the utility of the crane is likely to be increasingly compromised in one or more ways as the safety factor is increased.

Yet the engineer's creed requires that the product must function in its true environment of use and do so with reasonable safety and reliability. The art of the engineer, then, is to balance competing tradeoffs in design decision-making to minimize the existence of hazards, while acknowledging and accounting for human frailties, reasonably foreseeable product uses and misuses, and the true environment of product use.

And that is what the law requires of the engineer as well. We will explore some of these considerations later in this chapter. But first, let's look at the issues of professional liability.

75.2 PROFESSIONAL LIABILITY

Whether engaged in research, development, manufacturing, engineering services, or technical consulting, today's engineer must be cognizant that the law imposes substantial accountability on both individual engineers and technology-related companies. The engineer can never expect to insulate himself entirely from legal liability. However, he can limit his liability by maintaining a fundamental understanding of the legal concepts he is likely to encounter in the course of his career, such as professional negligence, agency, employment agreements, intellectual property rights, contractual obligations, and liability insurance.

75.2.1 Liability of an Employee

Negligence and the Standard of Care

A lawsuit begins when a person (corporations, as well, are considered as "persons" for legal purposes) whose body or property is injured or damaged alleges that the injury was caused by the acts of another and files a complaint. The person asserting the complaint is the *plaintiff;* the person against whom the complaint is brought is the *defendant.*

In the complaint, the plaintiff must state a *cause of action* (a legal theory or principle) that would, if proven to the satisfaction of the jury, permit the plaintiff to recover damages. If the cause of action asserted is *negligence,* then the plaintiff must prove, first, that the defendant owed the plaintiff a *duty* (i.e., had a responsibility toward the plaintiff). Then the plaintiff must show that the defendant *breached* that duty and consequently, that the breach of duty by the defendant was the *cause* of the plaintiff's injury.

The doctrine of negligence rests on the duty of every person to exercise due care in his or her conduct toward others. A breach of this duty of care that results in injury to persons or property may result in a *tort* claim, which is a civil wrong (as opposed to a criminal wrong) for which the legal system compensates the successful plaintiff by awarding money damages. To make out a cause of action in negligence, it is not necessary for the plaintiff to establish that the defendant either intended harm or acted recklessly in bringing about the harm. Rather, the plaintiff must show that the defendant's actions fell below the *standard of care* established by law.

In general, the standard of care that must be exercised is that conduct that the *average reasonable person* of ordinary prudence would follow under the same or similar circumstances. The standard of care is an external and objective one and has nothing to do with individual subjective judgment, though higher duties may be imposed by specific statutory provisions or by reason of special knowledge.

Example: Negligent or Not?

Suppose a person is running down the street knocking people aside and causing injuries. Is this person breaching the duty to care to society and acting negligently? To determine this, we need to undertake a risk/utility analysis, i.e., does the utility of the action outweigh the harm caused?

If this person is running to catch the last bus to work, then the risk probably outweighs the utility. However, if the person has seen a knife-wielding assailant attacking someone and is trying to reach the policeman on the corner, then the utility (saving human life) is great. In such a case, perhaps society should allow the possible harm caused and thus not find the person negligent, even though other persons were injured in the attempt to reach the police officer.

No duty is imposed upon a person to take precautions against events that cannot reasonably be foreseen. However, the professional must utilize such superior judgment, skill, and knowledge as he actually possesses. Thus, the professional mechanical engineer might be held liable for miscalculating the load-lifting capability in the crane example, while a general engineering technician might not.

The duty to exercise reasonable care and avoid negligence does not mean that engineers guarantee the results of their professional efforts. Indeed, if an engineer can show that everything a reasonably prudent engineer might do was, in fact, done correctly, then liability cannot attach.

Example: Collapse of a Reasonably Designed Overpass

A highway overpass, when designed, utilized all of the acceptable analysis techniques and incorporated all of the features that were considered to be appropriate for earthquake resistance at that time. Years later, the overpass collapses when subjected to an earthquake of moderate intensity. At the time of the collapse, there are newer techniques and features that, in all likelihood, would have prevented the collapse had they been incorporated into the design.

It is unlikely that liability would attach to the engineers who created the original design and specifications as long as they utilized techniques that were reasonable at that time.

Additionally, liability depends on a showing that the negligence of the engineer was the direct and proximate cause of the damages. If it can be shown that there were other superseding causes responsible for the damages, the engineer may escape liability even though his actions deviated from professional standards.

Example: Collapse of a Negligently Designed Overpass

Suppose, instead, that after the collapse of the overpass in the preceding example, a review of the original analysis conducted by the engineers reveals several deficiencies in critical *specifications that reasonably prudent engineers would not have overlooked. However, the intensity of the earthquake was of such a magnitude that, with reasonable certainty, the overpass would have collapsed even if it had been designed using the appropriate specifications. The engineers, in this scenario, are likely to escape liability.*

However, the law does allow "joint and severable" liability against multiple parties who either act in concert or independently to cause injury to a plaintiff. Other defenses to an allegation of negligence include the "state of the art" argument, contributory/comparative negligence, and assumption of the risk. These are discussed in Section 75.6.

An employer is generally liable for the negligence, carelessness, errors, and omissions of its employees. However, as we will see in the next section, liability may attach to the engineer employee under the law of agency.

Agency and Authority

Agency is generally defined as the relationship that arises when one person (the principal) manifests an intention that another person (the agent) shall act on his behalf. A principal may appoint an agent to do any act except an act that, by its nature, or by contract, requires personal performance by the principal. An engineer employee may act as an agent of his employer, just as an engineering consultant may act as an agent of her client.

The agent, of course, has whatever duties are expressly stated in the contract with the principal. Additionally, in the absence of anything contrary in the agreement, the agent has three major duties implied by law:

1. The fiduciary duty of an agent to his principal is one of undivided loyalty, e.g., no self-dealing or obtaining secret profits;
2. An agent must obey all reasonable directions of the principal; and
3. An agent owes a duty to the principal to carry out his duties with reasonable care, in light of local community standards and taking into account any special skills of the agent.

Just as the agent has duties, the principal owes the agent a duty to compensate the agent reasonably for his services, indemnify the agent for all expenses or losses reasonably incurred in discharging any authorized duties, and, of course, to comply with the terms of any contract with the agent.

With regard to tort liability in the context of the employer–employee relationship, an employer can be liable only for those torts committed by a person who is considered an employee; he is not generally liable for torts committed by an agent functioning as an independent contractor. An example of an employee is one who works full-time for his employer, is compensated on a time basis, and is subject to the supervision of the principal in the details of his work. An example of an independent contractor is one who has a calling of her own, is hired to perform a particular job, is paid a given amount for that job, and followed her own discretion in carrying out the job. Engineering consultants are usually considered to be independent contractors.

Even when the employer–employee relationship is established, however, the employer is not liable for the torts of an employee unless the employee was acting within the scope of, or incidental to, the employer's business. Additionally, the employer is usually not liable for the intentional torts of an employee on the simple ground that an intentional tort (e.g., fraud) is clearly outside the scope of employment. However, where the employee intentionally chooses a wrongful means to promote the employer's business, such as fraud or misrepresentation, the employer may be held liable.

With regard to contractual liability under the law of agency, a principal will be bound on a contract that an agent enters into on his behalf if that agent has *actual authority,* i.e., authority expressly or implicitly contained within the agency agreement. The agent cannot be held liable to the principal for breach since he acted within the scope of his authority. To ensure knowledge of actual authority, the engineer should always obtain clear, written evidence of his job description, duties, responsibilities, "sign-off" authority, and so on.

Even where employment or agency actually exists, unless it is unequivocally clear that the individual engineer is acting on behalf of an employer or other disclosed principal, an injured third party has the right to proceed against either the engineer or the employer/principal or both under the rule that an agent for an undisclosed or partially disclosed principal is liable on the transaction together with her principal. Thus, engineers acting as employees or agents should always include their title, authority, and the name of the employer/principal when signing any contract or business document.

Even if the agent lacks actual authority, the principal can still be held liable on contracts entered into on his behalf if the agent had *apparent authority,* that is, where a third party reasonably believed, based upon the circumstances, that the agent possessed actual authority to perform the acts in question. In this case, however, the agent may be held liable for losses incurred by the principal for unauthorized acts conducted outside the scope of the agent's actual authority.

Employment Agreements

Rather than relying entirely on the law of agency to control the employer–employee relationship, most employers require engineers to sign a variety of employment agreements as a condition of employment. These agreements are generally valid and legally enforceable to the extent that they are reasonable in duration and scope.

A clause typically found in an engineer's employment contract is the agreement of the employee to transfer the entire right, title, and interest in and to all ideas, innovations, and creations to the company. These generally include designs, developments, inventions, improvements, trade secrets, discoveries, writings, and other works, including software, databases, and other computer-related products and processes. As long as the work is within the scope of the company's business, research, or investigation, or the work resulted from or is suggested by any of the work performed for the company, its ownership is required to be assigned to the company.

Another common employment agreement is a non-competition provision whereby the engineer agrees not to compete during his or her employment by the company and for some period after leaving the company's employ. These are also enforceable as long as the scope of the exclusion is reasonable in time and distance, when taking the nature of the product or service into account and the relative status of the employee. For example, courts would likely find invalid a two-year, nationwide noncompetition agreement against a junior CAD/CAM engineer in a small company; however, this agreement might be found fully enforceable against the chief design engineer of a large aircraft manufacturer. In any case, engineers should inform new/prospective employers of any prior employment agreement that is still in effect.

As will be seen in the next section, however, even if an employment agreement was not executed, ex-employees are not free to disclose or utilize proprietary information gained from their previous employers.

Intellectual Property

A *patent* is a legally recognized and enforceable property right for the exclusive use, manufacture, or sale of an invention by its inventor (or heirs or assignees) for a limited period of time that is granted by the government. In the United States, exclusive control of the invention is granted for a period of 20 years from the date of filing the patent, and in consideration for which the right to free and unrestricted use passes to the general public. Patents may be granted to one or more individuals for *new* and *useful* processes, machines, manufacturing techniques, and materials, including improvements that are not obvious to one skilled in the particular art. The inventor, in turn, may license, sell, or assign patent rights to a third party. Remedies against patent infringers include monetary damages and injunctions against further infringement.

Engineers working with potentially patentable technology must follow certain formalities in the documentation and publication of information relating to the technology in order to preserve patent protection. Conversely, engineers or companies considering marketing a newly developed product or technology should have a patentability search conducted to ensure that they are not infringing existing patents.

Many companies rely on *trade secrets* to protect their technical processes and products. A trade secret is any information, design, device, process, composition, technique, or formula that is not known generally and that affords its owner a competitive business advantage. Advantages of trade secret protection include avoiding the cost and effort involved in patenting, and the possibility of perpetual protection. The main disadvantage of a trade secret is that protection vanishes when the public is able to discover the "secret," whether by inspection, analysis, or reverse engineering. Trade secret protection thus lends itself more readily to intangible "know-how" than to end products.

Trade secrets have legal status and are protected by state common law. In some states, the illegal disclosure of trade secrets is classified as fraud, and employees can be fined or even jailed for such activity. Customer lists, supplier's identities, equipment, and plant layouts cannot be patented, yet they can be important in the conduct of a business and therefore are candidates for protection as trade secrets.

75.2.2 Liability of a Business

Negligence for Services

Negligence (as defined in Section 75.2.1) and standards of care apply not only to individual engineers, but also to consulting and engineering firms. At least one State Supreme Court has defined the standard of care for engineering services as follows:

> *In performing professional services for a client, an engineer has the duty to have that degree of learning and skill ordinarily possessed by reputable engineers, practicing in the same or a similar locality and under similar circumstances. It is his further duty to use the care and skill ordinarily used in like cases by reputable members of his profession practicing in the*

*same or a similar locality, under similar circumstances, and to use reasonable diligence and his best judgment in the exercise of his professional skills and in the application of his learning, in an effort to accomplish the purpose for which he was employed.**

Occasionally, an engineer's duty to the general public may supersede the duty to her client. For example, an engineer retained to investigate the integrity of a building, and who determined the building was at imminent risk of collapse, would have a duty to warn the occupants even if the owner requested that the engineer treat the results of the investigation as confidential.†

The engineer also has a duty to adhere to applicable state and federal safety requirements. For example, the U.S. Department of Labor Occupational Safety and Health Administration has established safety and health standards for subjects ranging from the required thickness of a worker's hardhat to the maximum decibel noise level in a plant. In many jurisdictions, the violation of a safety code, standard or statute that results in injury is "negligence per se," that is, a conclusive presumption of duty and breach of duty. Engineers should be aware, however, that the reverse of this rule does not hold true: compliance with required safety standards does not necessarily establish reasonable care.

Contractual Obligations

A viable contract, whether it be a simple purchase order to a vendor or a complex joint venture, requires the development of a working agreement that is mutually acceptable to both parties. An agreement (contract) binds each of the parties to do something or perhaps even refrain from doing something. As part of such an agreement, each of the parties acquires a legally enforceable right to the fulfillment of the promises made by the other. Breach of the contract may result in a court awarding damages for losses sustained by the non-breaching party, or requiring "specific performance" of the contract by the breaching party.

An oral contract can constitute just as binding a commitment as a written contract, although, by statute, some types of contracts are required to be in writing. As a practical matter, agreements of any importance should always be, and generally are, reduced to writing. However, a contract may also be created by implication based upon the conduct of one party toward another.

In general, a contract must embody certain key elements, including (a) mutual assent as consisting of an offer and its acceptance between competent parties based on (b) valid consideration for a (c) lawful purpose or object in (d) clear-cut terms. In the absence of any one of these elements, a contract will generally not exist and hence will not be enforceable in a court of law.

Mutual assent is often referred to as a "meeting of the minds." The process by which parties reach this meeting of the minds generally is some form of negotiation, during which, at some point, one party makes a proposal (offer) and the other agrees to it (acceptance). A counteroffer has the same effect as a rejection of the original offer.

In order to have a legally enforceable contract, there must generally be a bargained-for exchange of "consideration" between the parties, that is, a benefit received by the promisor or a detriment incurred by the promisee. The element of bargain assures that, at least when the contract is formed, both parties see an advantage in contracting for the anticipated performance.

If the subject matter of a contract (either the consideration or the object of a contract) is illegal, then the contract is void and unenforceable. Generally, illegal agreements are classified as such either because they are expressly prohibited by law (e.g., contracts in restraint of trade), or because they violate public policy (e.g., contracts to defraud others).

Problems with contracts can occur when the contract terms are incomplete, ambiguous, or susceptible to more than one interpretation, or where there are contemporaneous conflicting agreements. In these cases, courts may allow other oral or written evidence to vary the terms of the contract.

A party that breaches a contract may be liable to the nonbreaching party for "expectation" damages, that is, sufficient damages to buy substitute performance. The breaching party may also be liable for any reasonably foreseeable consequential damages resulting from the breach.

Contract law generally permits claims to be made under a contract only by those who are "in privity," that is, those parties among whom a contractual relationship actually exists. However, when a third party is an intended beneficiary of the contract or when contractual rights or duties have been transferred to a third party, then that third party may also have certain legally enforceable rights.

The same act can be, and very often is, both negligent and a breach of contract. In fact, negligence in the nature of malpractice alleged by a client against an engineering firm will almost invariably constitute a breach of contract as well as negligence, since the engineer, by contracting with the client, undertakes to comply with the standard of practice employed by average local engineers. If the condition is not expressed, it is generally implied by the courts.

**Clark v. City of Seward*, 659 P.2d 1227 (Alaska, 1983).

†California Attorney General's Opinion, Opinion No. 85-208 (1985).

Insurance for Engineers

It is customary for most businesses, and some individual engineers, to carry comprehensive liability insurance. The insurance industry recognizes that engineers, because of their occupation, are susceptible to special risks of liability. Therefore, when a carrier issues a comprehensive liability policy to an engineering consultant or firm, it may exclude from the insurance afforded by the policy the risk of professional negligence, malpractice, and "errors and omissions." The engineer should seek independent advice on the extent and type of the coverage being offered before accepting coverage. However, depending on the wording of the policy and the specific nature of the claim, the comprehensive liability carrier may be under a duty to defend an action against the insured and sometimes must also pay the loss. When a claim is made against an insured engineering consultant or firm, they should retain a competent attorney to review the policy prior to accepting the conclusions of the insurance agent as to the absence of coverage.

While the engineer employee of a well insured firm probably has limited liability exposure, the professional engineering consultant should be covered by professional liability (malpractice) insurance. However, many engineers decide to forgo malpractice insurance because of high premium rates. Claims may be infrequent, but can be economically devastating when incurred. The proper amount of coverage should be worked out with a competent underwriter, and will vary by engineering discipline and type of work. A policy should be chosen that not only pays damages, but also underwrites the costs of attorney's fees, expert witnesses, and so on.

Case Study

The following case serves to illustrate the importance of developing a fundamental understanding of the professional liability concepts discussed above.

S&W Engineering was retained by Chesapeake Paper Products to provide engineering services in connection with the expansion of Chesapeake's paper mill. S&W's vice president met with Chesapeake's project manager and provided him with a proposed engineering contract and price quotations. Several weeks later Chesapeake's project manager verbally authorized S&W to proceed with the work. S&W's engineering contract was never signed by Chesapeake; instead, Chesapeake sent S&W a Purchase Order (P.O.) that authorized engineering services "in accordance with the terms and conditions" of S&W's engineering contract. However, Chesapeake's P.O. also contained language in smaller print stating "This order may be accepted only upon the terms and conditions specified above and on the reverse side."

The drawings supplied by S&W to Chesapeake's general contractor subsequently contained errors and omissions, resulting in delays and increased costs to Chesapeake. Chesapeake sued S&W for breach of contract, arguing that the purchase order issued by Chesapeake constituted the parties' contract and that this P.O. contained a clause requiring S&W's standard of care to be "free from defects in workmanship." Additionally, another P.O. clause required indemnification of all expenses "which might incur as a result of the agreement."

S&W agreed that its engineering drawings had contained some inconsistencies, but denied that those errors constituted a breach of contract. S&W claimed that the parties' contract consisted of the terms in its proposed Engineering Contract it had delivered to Chesapeake at the outset of the Project. S&W's Engineering Contract provided that the "Engineer shall provide detail engineering services . . . conforming with good engineering practice." S&W's proposed contract also contained a clause precluding the recovery of any consequential damages.

At a jury trial, 14 witnesses testified and the parties introduced more than 1,000 exhibits. The jury found that the parties' "operative contract" was the P.O. and that S&W's services did not meet the contractually required standard of care. Chesapeake was awarded $4,665,642 in damages.*

75.3 THE LAWS OF PRODUCT LIABILITY

75.3.1 Definition

In Section 75.1, the art of engineering was characterized as a progression from real-world product specifications to the world modified by assumptions. This assumed world permits establishing precise component design parameters. Finally, the engineer must attempt to return to the real world by using a "safety factor" to bridge the gap between the ideal, but artificial, world of precise design calculations to the real world of uncertainties in who, how, and where the product will actually function.

The laws of product liability sharpen and intensify this focus on product behavior in the real world. *Product liability* is the descriptive term for a legal action brought by an injured person (the plaintiff) against another party (the defendant) alleging that a product sold (or manufactured or assembled) by the defendant was in a substandard condition and that this substandard condition was a principal factor in causing the harm of the plaintiff.

Chesapeake Paper Products v. Stone & Webster Engineering, No. 94-1617 (4th Cir., 1995).

The key phrase for the engineer is *substandard condition.* In legal parlance, this means that the product is alleged to contain a *defect.* During litigation, the product is put on trial so that the jury can decide whether the product contained a defect and, if so, whether the defect caused the injury.

The laws of product liability take a retrospective look at the product and how it functioned as it interacted with the persons who used it within the environment surrounding the product and the persons. Three legal principles generally govern the considerations brought to this retrospective look at the engineer's art:

1. Negligence
2. Strict liability
3. Express warranty and misrepresentation

75.3.2 Negligence

This principle is based upon the conduct or fault of the parties, as discussed in Section 75.2.1. From the plaintiff's point of view, it asks two things: first, whether the defendant acted as a *reasonable person* (or company) in producing and selling the product in the condition in which it was sold, and second, if not, whether the condition of the product was a substantial factor in causing the plaintiff's injury.

The test of *reasonableness* is to ask what risks the defendant (i.e., designer, manufacturer, assembler, or seller) foresaw as reasonably occurring when the product was used by the expected population of users within the actual environment of use. Obviously, the plaintiff argues that if the defendant had acted reasonably, the product designer would have foreseen the risk actually faced by the plaintiff and would have eliminated it during the design phase and before the product was marketed. That is, the argument is that the defendant, in ignoring or not accounting for this risk in the design of the product, did not properly balance the risks to product users against the utility of the product to society.

It is the *reasonableness,* or lack thereof, of *the defendant's behavior* (in designing, manufacturing or marketing the product, or in communicating to the user through instructions and warnings) that is the question under the principle of negligence. These issues will be fully discussed in Section 75.5.

75.3.3 Strict Liability

In contrast to negligence, strict liability ignores the defendant's behavior. It is, at least in theory, of no consequence whether the manufacturer behaved reasonably in designing, manufacturing, and marketing the product. The only concern here is the quality of the product as it actually functions in society.

Essentially, the question to be resolved by the jury under strict liability is whether or not the risks associated with the real-world use of the product by the expected user population exceed the utility of the product and, if so, whether there was a reasonable alternative to the design that would have reduced the risks without seriously impairing the product's utility or making it unduly expensive.

If the jury decides that the risks outweighed the product's utility and a reasonable alternative to reducing the risk existed, then the product is judged to be in a *defective condition unreasonably dangerous.*

Under strict liability, a product is defective when it contains *unreasonable* dangers, and only unreasonable dangers in the product can trigger liability. While it is unlikely the marketing department will ever use the phrase in a promotion campaign, a product may contain *reasonable* dangers without liability. In the eyes of the law, a product whose only dangers are reasonable ones is *not* defective.

Stated positively, a product that does not contain unreasonable dangers is *reasonably safe*—and that is all the law requires. This means that any residual risks associated with the product have been transferred *appropriately* to the ultimate user of the product.

Section 75.5 discusses the methodology for uncovering unreasonable dangers associated with products.

75.3.4 Express Warranty and Misrepresentation

The third basic legal principle governing possible liability has nothing to do with either the manufacturer's conduct (negligence) or the quality of the product (strict liability). Express warranty and misrepresentation are concerned only with what is communicated to the potential buyer that becomes part of the "basis of the bargain."

An express warranty is created whenever any type of communication to the potential buyer describes some type of *objectively measurable* characteristic of the product.

Sample Express Warranties

- This truck will last 10 years.
- This glass is shatterproof.

- This automatic grinder will produce 10,000 cutter blades per hour.
- This transmission tower will withstand the maximum wind velocities and ice loads in your area.

If such a communication is, first, at least a part of the reason that the product was purchased and then, if reasonably foreseeable circumstances ultimately prove the communication invalid, there has been misrepresentation, and the buyer is entitled to recover damages consistent with the failed promise.

It doesn't matter one whit if the product cannot possibly live up to the promise. This is not the issue. It is the failure to keep a promise that becomes part of the basis of the bargain, and that the buyer did not have sufficient expertise for not believing the promise, that can trigger the liability.

Someone with a legal bent might argue, against the misrepresentation claim, that the back of the sales form clearly and unequivocally disclaims all liability arising from any warranties not contained in the sales document (i.e., the contract). The courts, when confronted with what appears to be a conflict between the express warranty communicated to the buyer and the fine print on the back of the document disclaiming everything, inevitably side with the buyer who believed the express warranty to the extent that it became a part of the "basis of the bargain."

The communications creating the express warranty can be in any form: verbal, written, visual, or any combination of these. In the old days, courts used to view advertising as mere puffing and rarely sided with the buyer arguing about exaggerated claims made about the product. In recent years, however, the courts have acknowledged that buying is engendered in large part by media representations. Now, when such representations can be readily construed as express warranties, the buyer's claim is likely to be upheld. It should also be noted that misrepresentation claims have been upheld when both the plaintiff and the defendant are sophisticated, have staffs of engineers and lawyers, and the dealings between the parties are characterized as "arm's length."

In precarious economic times, the exuberance of salespersons, in their quest to make the sale, may oversell the product and create express warranties that the engineer cannot meet. This can then trigger liability, despite the engineer's best efforts.

Because it is so easy to create, albeit unintentionally, an express warranty, all departments that deal in any with a product must recognize this potential problem and structure methods and procedures to minimize its occurrence. The means that engineering, manufacturing, sales, marketing customer service, and upper management must create a climate in which there is agreement among the appropriate entities that what is being promised to the buyer can actually be delivered.

75.4 THE NATURE OF PRODUCT DEFECTS

The law recognizes four areas that can create a "defective condition unreasonably dangerous to the user or consumer":

1. Production or Manufacturing
2. Design
3. Instructions
4. Warnings

75.4.1 Production or Manufacturing Flaws

A production or manufacturing defect can arise when the product fails to emerge as the manufacturer intended. The totalities of the specifications, tolerances, and so on, define the product and all of the bits and pieces that make it up, and collectively they prescribe the manufacturer's intent for exactly how the product is to emerge from the production line.

If there is a deviation from any of these defining characteristics of the product (e.g., specifications, tolerances, etc.), then there exists a production or manufacturing flaw. If this flaw or deviation can cause the product to fail or malfunction under reasonably foreseeable conditions of use, and these conditions are within the expected performance requirements for the product, then the product can be defective.

What is important to note here is that the deviation from the specifications must be *serious* enough to be able to precipitate the failure or malfunction of the product within the foreseeable uses and performance envelope of the product, hence creating unreasonable dangers. To illustrate, let's return to the crane described in the first section of this chapter.

Example: Truck-Crane—Flaw or Defect?

Suppose that a critical weld is specified to be 4 in. in length and to have full penetration. After a failure, the crane is examined and the weld is full-penetration but only $3\frac{1}{2}$ in. long, which escaped the notice of the quality inspectors. There is a deviation or flaw. However, whether this flaw rises to the level of defect depends on several considerations:

First, what safety factor considerations entered into the design of the weld? It may be that the designer calculated the necessary weld length to be 3 in. and specified 4 in. to account for the uncertainties described in Section 75.1. Next, if it can be shown by the crane manufacturer that a 3½ in. weld was adequate for all reasonably foreseeable use conditions of the crane, than it could be argued that the failure was due to crane misuse and not due to the manufacturing flaw.

Alternatively, the plaintiff could argue that the engineer's assumptions as to the magnitude of the safety factor did not realistically assess the uncertainty of the weight loads to be lifted; if they had done so, the minimum acceptable length would have been the 4 in. actually specified.

While this is a hypothetical example, it illustrates the interplay of several important elements that must be considered when deciding if a production flaw can rise to the level of a defect. Foreseeable uses and misuses of the product, and its prescribed or implicit performance requirements, are two of the most important.

75.4.2 Design Flaws

The standard for measuring the existence of a production flaw is simple. One need only compare the product's attributes as it actually leaves the production line with what the manufacturer intended them to be, by examining the manufacturer's internal documents that prescribe the entire product.

To uncover a design flaw, however, requires comparing the correctly manufactured product with a standard that is not as readily prescribed as the manufacturer's own specifications and is significantly more complex. The standard is a societal one in which the risks of the product are balanced against its utility to establish whether the product contains unreasonable dangers. If there are unreasonable dangers, then the design flaw becomes a defect.

In the crane example, assume that there has been a boom failure and that the crane met all of the manufacturer's specifications, that is, no manufacturing defect is alleged. The plaintiff alleges, instead, that if the boom had been fabricated from a heavier gage as well as a stronger alloy steel, the collapse would have been avoided. The plaintiff's contention can be considered a design flaw. There is no question that the boom could have been fabricated using the plaintiff's proposed specifications and, for the sake of our discussion, we will also assume the boom would not have failed using the different material.

The critical question, however, is should the boom have been designed that way? The answer is, only if the original design created unreasonable dangers. The existence of unreasonable dangers, therefore a defective condition, can be deduced from a risk/utility analysis of the interaction of crane users, users, and the environments within which the crane is expected to function.

The analysis must consider, first, the foreseeability of crane loads of uncertain magnitude that could cause the original design to fail, but not the modified design. Balanced against that consideration will be a reduction in the utility of the crane because of its increased weight and/or size if the proposed design alterations are incorporated. There will be also an increased cost. It is this analysis of competing tradeoffs that the designer must consider before deciding on the proposed design specifications. Fundamentally, though, as in the discussion of a production defect, the consideration is that of the safety factor, bridging the gap between *assumed* product function and *actual* product function.

75.4.3 Instructions and Warnings

A product can be perfectly manufactured from a design that contains no unreasonable dangers and yet be defective because of inadequate instructions. Instructions are the communications between the manufacturer and the user that describe how the product is to be used to achieve the intended function of the product.

Warnings are to communicate any residual hazards, the consequent risks of injury, and the actions the user must take to avoid injury. If the warnings are inadequate, the product can be defective even if the design, manufacturing, and instructions meet the legal tests.

While the courts have not given clear or unequivocal guidelines for assessing the adequacy of instructions and warnings, there are several basic considerations that should underlie their development:

- They must be understood by the expected user population.
- They must be effective in a multilingual population.
- There must be some reasonable and objective evidence to prove that the warnings and instructions can be understood and are likely to be effective.

Simply put, writing instructions and warnings is deceptively easy. However, gathering evidence to support the contention that they are *adequate* can be extremely difficult, costly, and time-consuming. To do this means surveying the actual user population and describing those characteristics that are likely to govern comprehension, such as age, education, reading capability, sex, cultural and ethnic background, and so on. Then a statistically selected random sample of the identified user population must be chosen to test the communication for comprehension, using the method suggested in the American National Standards Institute standard ANSI Z535.3. Finally, the whole process must be documented. Then, and only then, can a manufacturer argue that the user communications, that is, instructions and warnings, are adequate.

75.5 UNCOVERING PRODUCT DEFECTS

75.5.1 Hazard Analysis

In the preceding section, a risk/utility analysis was described as a basis for assessing whether or not the product was in a defective condition unreasonably dangerous. Now we will consider the methodology and the process of the risk/utility analysis.

We begin with a disclaimer: Neither the process nor the methodology about to be discussed is readily quantifiable. However, this fact does not lessen their importance; it only emphasizes the care that must be exercised.

The process is one of scenario-building. The first step is to characterize, as accurately as possible, the users of the product, the ways in which they will use the product, and the environment in which they will use it. These elements must be quantified as much as possible.

Example: Foreseeable Users of a Hand-Held Tool

Will the user population be comprised of younger users, female users, elderly users? If so, these populations are likely to need special ergonomic or human factors considerations in the design of handgrips, operating controls, etc. Will the tool be found in the home? If so, inadvertent use by small children is likely to be a consideration in designing the controls. Certainly the ability to read and understand instructions and warnings must be a significant element of the characterization of the users.

If the best of all worlds, the only product uses the engineer would be concerned with are the *intended* uses. Unfortunately, the law requires that the product design acknowledge and account for *reasonably foreseeable misuses* of the product. Of all the concepts the engineer must deal with, this one is perhaps the hardest to analyze and the most difficult to accept. Part of the reason, of course, is the difficulty of distinguishing between uses that are *reasonably foreseeable* and those uses that the manufacturer can argue are truly *misuse* for which no account must be taken in design.

The concept of legal unforeseeability is a difficult one. Many people might think that if they have ever talked about the possibility of misusing a product in a certain way, then they have "foreseen" that misuse and therefore must account for it in their design. This is not the case. Legally, *unforeseeable misuse* means a use so egregious, or so bizarre, or so remote that it is termed *unforeseeable,* even when such a misuse has been a topic of discussion.

A simple illustration might help.

Example: How Many Ways Can You Use a Screwdriver?

There is no question that the intended purpose and function of a screwdriver is to insert and remove screws. This means that ideally, the shank of a screwdriver is subjected only to a twisting motion, or torque.

But how do most people open paint cans? With a screwdriver, of course. In that context, however, the shank is subjected to a bending moment, not a torque. Any manufacturer who produced and marketed a screwdriver with shank material able to withstand high torque, but without sufficient bending resistance to open a paint can without shattering, would have a difficult time avoiding liability for any injuries that occurred.

The reason, of course, is that using a screwdriver to open paint cans would be considered as a reasonably foreseeable misuse, and should be accounted for in the design. On the other hand, suppose someone uses a screwdriver as a cold chisel to loosen a rusted nut and the screwdriver shatters, causing injury. The manufacturer could argue that such a use was a misuse that the manufacturer had no duty to account for in the design.

Finding the line that separates the misuses the engineer must account for from the misuses that are legally unforeseeable is not easy, nor is the line a precise one. All that is required, however, is for the engineer to show the reasonableness of the process of how the line was ultimately decided, while attempting to meet competing tradeoffs in selecting the product's specifications. Unquestionably, we can always imagine all types of bizarre situations in which a product is misused and someone is injured. Does this mean that all such situations must somehow be accounted for in design? Of course not. But what is required is to make a reasonable attempt to separate user behavior into two categories: that which can reasonably be accounted for in design and that which is beyond reasonable considerations.

The third element in the risk/utility process is the environment within which the user and product interact. If it is cold, how cold? If it is hot, how hot? Will it be dark, making warnings and instructions difficult to read? Will the product be used near water. If so, both fresh and salt? How long will the product last? Will it be repainted, scraped, worn, and so on? These, too, would be considerations in warning adequately.

The scenario building must integrate the three elements of the hazard analysis: the users, the uses, and the environment. By asking "What if . . . ?," a series of hazards can be postulated from integrating the users with the uses within an environment.

Example: "What if an Air-Operated Sander . . . ?"

What if an air-operated sander is used in a marine environment? What if the user inadvertently drops it overboard and then continues to use it without having it disassembled and cleaned? What hazards could arise? Could corrosion ultimately freeze the control valve continually open, leading to loss of control at some future time, long after the event in question?

75.5.2 Hazard Index

After completion of the hazard analyses, the hazards should be rank-ordered from the most serious to the least serious. One way to do this is to assign a numerical probability of the event occurring and then to assess, also using a numerical scale, the seriousness of the harm. The product of these two numbers is the *Hazard Index* and permits a relative ranking of the hazards. The scales chosen to provide some measure of probability and seriousness should be limited; the scale may run, for example, from 0 to 4. A 0 implies that the event is so unlikely to occur, or that the resulting harm is so minimal, as to be negligible. Correspondingly, a 4 would mean that an event was almost certain to occur, or that the result would be death or serious irreparable injury. With this scale, the hazard index could range from 0 to 16.

Once this is done, attention is then focused on the most serious hazards, eventually working down to the least serious one.

75.5.3 Design Hierarchy

Ideally, for each such event, the objective would be, first, to "design out" the hazard. If a hazard can be designed out, it can never return to cause harm.

Failing the ability to design out the hazard, the next consideration must be guarding. Can an unobtrusive barrier be placed between the user and the hazard? It must be noted that if a guarding configuration greatly impairs the utility of the product, or greatly increases the time needed to carry out the product's intended function, it is likely to be removed. In such a case, the user is not protected from the hazard, nor is the manufacturer likely to be protected from liability if an injury results, because removing an obtrusive guard may be considered a foreseeable misuse.

If the hazard cannot be designed out, nor can an effective guard be devised, then *and only then* should the last element of the design hierarchy be considered: a warning.

A warning must be viewed as an element of the design process, not as an afterthought. To be perfectly candid, if the engineer has to resort to a warning to minimize or eliminate a risk of injury from that hazard, it may be an admission of a failure in the design process.

Yet there are innumerable instances where a warning must be given. Section 75.4 described the considerations necessary to develop an adequate warning, the legal standard. What was not described there are the three necessary elements that must be included before the process of establishing adequacy begins:

1. The nature of the hazard
2. The potential magnitude of the injury
3. The action to be taken to avoid the injury

A warning paraphrased from an aerosol can of hair spray provides an exercise for the reader:

⚠ WARNING

- **Harmful vapors**
- **Inhalation may cause death or blindness**
- **Use in a well-ventilated area**

The reader should analyze these three phrases carefully and critically, then describe the user populations to which the warning might apply, then answer the question of whether or not it is likely that injury could be avoided by that user population. Suppose that a foreseeable portion of the population using this aerosol can are people whose English reading ability is at the 3rd or 4th grade level. (It is estimated that about half of English-speaking Americans cannot read beyond the 4th grade level.) What can you conclude about comprehension and the ability to avoid injury?

Warnings are, in fact, the most difficult way to minimize or eliminate hazards to users.

75.6 DEFENSES TO PRODUCT LIABILITY

Up to now, we have only looked at the factors that permit an analysis of whether or not the product contains a defect, i.e., an unreasonable danger. Certainly the ultimate defense to an allegation that the product was defective is to show through a risk/utility analysis that, on balance, the product's utility outweighs its risks and, in addition, that there were no feasible alternatives to the present design.

It may be, however, that the plaintiff's suggested design alternative is, in fact, viable as of the time the incident occurred. Is there any analysis that could offer a defense? There may be, by considering a *state-of-the-art* argument.

75.6.1 State of the Art

Decades ago, the phrase *state of the art* meant, simply, what the custom and practice was of the particular industry in question. Because of the concern that an entire industry could delay introduction of newer, safer designs by relying on the "custom and practice" argument to defeat a claim of negligence, the courts have adopted a broader definition of the term.

The definition today is "what is both technologically and economically feasible." The time at which this analysis is performed is, in general, the date the product in question was manufactured.

Thus, while a plaintiff's suggested alternative design may have been technologically and economically feasible at the time the incident occurred, their argument may not be viable if the product was manufactured 10 years before the incident occurred.

To make that argument convincing, however, means that engineers must always be actively seeking new and emerging technology, looking to its potential applicability to their industry and products. It is expected, too, that technological advances are sought, not only in the engineer's own industry, but in related and allied fields as well. Keeping current has an added dimension, that of being alert to broader vistas of technological change outside one's own industry.

The second element of today's state-of-the-art principle is that innovative advances must be economically viable as well. It is generally, but incorrectly, assumed that the term *economic viability* is limited to the incremental cost of incorporating the technological advance into the product and how it will affect the direct cost of manufacturing and the subsequent profit margin.

The courts, however, are concerned with another cost in measuring economic viability, in addition to the direct cost of incorporating a safety improvement in the product: the cost to society and ultimately to the manufacturer if the technological advance is *not* incorporated into the product and injuries occur as a result. The technological advances we are concerned with here are those that are likely to enhance safety.

While it is more difficult and certainly cannot be predicted with a great deal of precision, an estimate of costs of the probable harm to product users is part of the equation. An approach to this analysis was described in Section 75.5. Estimating both the probability and seriousness of the harm from a realistic vantage point if the technological advance is *not* incorporated can form the basis for estimating the downside risk of not including the design feature.

75.6.2 Contributory/Comparative Negligence

We have not yet really considered what role, if any, the plaintiff's behavior plays in defending a product against an allegation of defect. We have earlier touched on misuse of the product, which is a use so egregious, and so bizarre, or so remote, that is it termed *legally unforeseeable.* You may recall the example discussing the hypothetical use of a screwdriver as a cold chisel to illustrate what could very likely be considered as misuse.

But what about the plaintiff's behavior that is not so extreme? Does that enter at all into the equation of how fault is apportioned? Yes, it does, in the form of contributory or comparative negligence, if the legal theory embracing the litigation is negligence. You will recall that under negligence, the defendant's behavior is measured by asking if that party was acting as a *reasonable* person (or manufacturer, or engineer) would have acted under the same or similar circumstances. And the reasonableness of the behavior is the result of having foreseen the risks of one's actions by having undertaken a risk/utility balancing prior to engaging in the action.

In a negligence action, the plaintiff's behavior is measured in exactly the same way. The defendant asks the jury to consider whether the plaintiff was behaving as a reasonable person would have under the same or similar circumstances. Did the plaintiff contribute to his or her harm by not acting reasonably? This is called *contributory negligence.*

While some states still retain the original concept that *any* contributory negligence on the part of the plaintiff totally bars his or her recovery of damages, most states have adopted some form of comparative negligence. Generally, the jury is asked to assess the behavior of both the plaintiff and the defendant and apportion the fault in causing the harm between them, making certain the percentages total 100%. The plaintiff's award, if any, is then reduced by the percentage of his or her comparative negligence.

The test of the defendant's negligence and the plaintiff's contributory negligence is termed an objective one. That is, the jury is asked to judge the actions of the parties relative to what a reasonable person would have done in the same or similar circumstances. The jury does not, as a rule, consider whether anything in that party's background, training, age, experience, education, and so on played any role in the actions that led to the injury.

75.6.3 Assumption of the Risk

There is another defense involving the plaintiff's behavior that does consider the plaintiff's characteristics in assessing his or her culpability. It is termed *assumption of the risk.* In essence, this defense argues that the plaintiff consented to being injured by the product. In one common form, used for analyzing this aspect of the plaintiff's behavior, the jury is asked if the plaintiff *voluntarily* and *unreasonably* assumed a *known* risk. To prevail, the defendant must present evidence on all three of these elements and must prevail on all three for a jury to conclude that the plaintiff's "assumed the risk."

The first element, asking whether the plaintiff voluntarily confronted the danger, and the third element, considering whether the risk was known, are both subjective elements. That is, the jury must determine the state of the mind of the plaintiff, assessing what he or she actually knew or believed or what can reasonably be inferred about his or her behavior at the instant prior to the event that led to injury. Thus, the plaintiff's background, education, training, experience, and so on become critical elements in this assessment.

A couple of points should be made here. First, in determining whether the plaintiff voluntarily confronted the hazard, the test is whether or not the plaintiff had *viable* alternatives.

Example: Work or Walk

In a workplace setting, a worker is given a choice of either using a now-unguarded press or being fired. The press had been properly guarded for all the time the plaintiff had used it in the past, but the employer has removed the guards to increase productivity and now tells the employee either to use the press as-is or be fired. The courts do not consider that the plaintiff had viable alternatives, since the choice between working on an unguarded press or being fired is no choice at all. The lesson to the engineer in this example is that the guarding slowed productivity and was removed, leaving the press-user in a no-win situation. The design should have incorporated, to the extent possible, guarding that did not *slow production.*

Second, the same in-depth consideration must also be given to knowledge of the risk by the plaintiff. The plaintiff's background, education, and so on must provide a reasonable appreciation of the actual nature of the harm that could befall him or her.

Example: The Truly Combustible Car

The driver of a car is confronted by a slight smell of smoke the first time the windshield wipers are used, and is trying to bring the car to the dealer in a rainstorm to see what the trouble is when the car literally bursts into flames, causing injury. Has the driver assumed the risk of injury by continuing to drive after smelling smoke? Can the car manufacturer successfully argue that the risks of injury were known to the driver? The question can only be answered by examining those elements in the driver's background that could, in any way, lead a jury to conclude that the driver should have recognized that smoke from electrically operated wipers could lead to a conflagration. The old adage of "where there's smoke, there's fire" is insufficient to charge the plaintiff with knowledge of the precise risk he or she faced without more knowledge of the driver's background.

The final element of assumption of the risk, the unreasonableness of the plaintiff's choice in voluntarily confronting a known risk, is an objective element, exactly the same as in negligence. That is, what would a reasonable person have done under the same or similar circumstances?

Example: The Truly Combustible Car Meets the Good Samaritan

A passerby observes the car from the previous example. It is on fire, and the driver is struggling to get out. The passerby rescues the driver, but is seriously burned and suffers smoke inhalation in the process. The driver files suit against the manufacturer alleging a defect that created *unreasonable danger when the wipers were turned on. The passerby also files suit against the automobile manufacturer to recover for the injuries suffered as a result of the rescue, arguing that the rescue would not have been necessary if there had been no defect. Would this good Samaritan be found to have assumed the risk of injury? Clearly the choice to try to rescue the driver was voluntary and the risks of injury were from a fire were apparent to anyone, including the rescuer. But was the act of rescuing the car's occupant a reasonable or unreasonable one? If the jury concludes that it was a reasonable choice, the passerby would* not *have been found to have assumed the risk, despite having voluntarily exposed himself to a known risk.*

The defendant must prevail in all three of the elements, not just two. Needless to say, raising and succeeding in the defense of assumption of the risk is not an easy one for the defendant.

One final word about these defenses: While the "assumption of the risk" defense applies both in a claim of negligence and strict liability, the contributory/comparative negligence defense does *not* apply in strict liability. The reason is that strict liability is a no-fault concept whereas negligence is a fault-based concept. It would be inconsistent to argue no-fault theory (strict liability) against the defendant and permit the defendant to argue a fault-based defense (contributory negligence) concerning the plaintiff's behavior.

75.7 RECALLS, RETROFITS, AND THE CONTINUING DUTY TO WARN

Manufacturers generally have a post-sale or continuing duty to warn of latent defects in their products that are revealed through consumer use.

Sometimes, however, even a post-sale warning may be inadequate to render a product reasonably safe. In those circumstances, it may be necessary for a manufacturer to retrofit the product by adding certain safety devices or guards. Moreover, there may be instances where it is not feasible to add guards or safety devices, or where the danger of the product is so great that the product simply must be removed from the market by being recalled.

75.7.1 After-Market Hazard Recognition

The manufacturer is responsible for establishing feedback mechanisms from customers, distributors, and sales personnel that will ensure that post-sale problems are discovered. Applicable data may include product performance and test data, orders for repair parts, complaint files, quality-control and inspection records, and instruction and warning modifications. Another source of hazard recognition information comes from previous accident investigations, claims, and lawsuits. The manufacturer should also have an ongoing program of compiling and evaluating risk data from historical, field and/or laboratory testing, and fault-tree, failure modes, and hazard analyses.

Once the manufacturer has determined that a previously sold product is defective (that is, contains unreasonable dangers) and is still in use, it must decide what response is appropriate. If the product is currently being produced, an initial assessment as to the seriousness of the problem must be made in order to decide whether production is to be halted immediately and inventories frozen in the warehouses and on dealers' shelves in order to limit distribution.

Following this assessment, the nature of the defect must be established. If the problem is safety-related, and depending upon the type of the product, appropriate regulatory agencies may have to be immediately notified. The manufacturer must then consider the magnitude of the hazards by estimating the probability of occurrence of events and the likely seriousness of injury or damage. The necessity for postulating such data is to provide some measure of the magnitude of the consequences if no action is taken, or to decide the extent of the action to be taken in light of the estimated consequences. Alternatively, if the consequences of even a low probability of occurrence could result in serious injury or death, or could seriously affect the marketability of the product or the corporate reputation, the decision to take action should be independent of such estimates.

Once the decision to take action is made, the origin, extent, and cause of the problem must be addressed in order to plan effective corrective measures. Is the origin of the defect in the raw material, fabrication, or quality control? If the problem is one of fabrication, did it occur in-house or from a purchased part? Where are the faulty products—that is, are the products in inventory, in shipment, in dealers' stock, or in the hands of the buyers? Does the defect arise from poor design, inadequate inspection, improper materials, fabrication procedure, ineffective or absent testing, or a combination of these events?

75.7.2 Types of Corrective Action

After the decision to take action has been made, and the origin, extent, and cause of the problem have been investigated, the appropriate corrective action must be determined. Possible options are to recall the product and replace it with another one; to develop a retrofit and either send personnel into the field to retrofit the product or have the customer return the product to the manufacturer for repair; to send out the parts and have the customer fix the product; or simply to send out a warning about the problem. This process should be fully documented to substantiate the reasons for the selection of a particular response. The urgency with which the corrective action is taken will be determined by the magnitude of the hazard.

Warnings

A manufacturer is not required to warn of every known danger, even with actual knowledge of that danger. A warning is required where a product can be dangerous for its intended and reasonably foreseeable uses and where the nature of the hazard is unlikely to be readily recognized by the expected user class. When a hazard associated with a product that was previously unknown to the manufacturer becomes apparent after the product has been in use, the manufacturer has a threshold duty to warn the existing user population.

Factors to consider in determining whether to issue a post-sale warning include the manufacturer's ability to warn (i.e., how readily and completely the product users can be identified and located), the product's life expectancy (the longer life expectancy, the greater risk of potential harm if post-sale warnings are not given), and the obviousness of the danger. Thus, the practicality, cost, and burden of providing an effective warning must be weighed against the potential harm of omitting the warning.

Recalls

Where the potential harm to the consumer is so great that a warning alone is not adequate to eliminate the danger, the proper remedy may be to institute a recall of the product either for repair or replacement. For some products, a recall may be mandated by statute or a governmental regulatory agency. Where a recall is not mandated, however, the decision to institute a product recall should be made using the analysis undertaken in Section 75.7.1.

Retrofits

A recall campaign may not be an appropriate solution, particularly if the equipment is large or cannot be easily removed from an installation. For equipment with potentially serious hazards or requiring complicated modification, the manufacturer should send its personnel to perform (and document) the retrofit. For equipment with relatively minor potential hazards for which there is a simple fix, the manufacturer may opt to send to the owners the parts necessary to solve the problem.

Regardless of the type of corrective action program selected, it is essential that all communications directed to the owners and/or users urging them to participate in the corrective action program be clear and concise. Most important, however, is the necessity for the communication to identify the nature of the risks and the potential seriousness of the harm that could befall the product user.

75.8 DOCUMENTATION OF THE DESIGN PROCESS

There are conflicting arguments by attorneys about what documentation, if any, the manufacturer should retain in the files (or on the floppies, the hard drive, or tape back-up). Since it would be well-nigh impossible to run a business without documentation or some sort, it only makes sense to preserve the type of documentation that can, if the product is challenged in court, demonstrate the care and concern that went into the design, manufacturing, marketing, and user communications of the product.

The first principle of documentation is to minimize or eliminate potential adverse use of the documentation by an adverse party. For example, words such as *defect* should not appear in the company's minutes, notes, and so on. There can be *deviations, flaws, departures,* and so on from specifications or tolerances. These are not defects unless they could create unreasonable dangers in the use of the product.

Also, all adverse criticism of the product, whether internally from employees or externally from customers, dealers, and so on must be considered and addressed in writing by the responsible corporate person having the appropriate authority.

Apart from these considerations, the company should make an effort to create a *documentation tree,* delineating what paper is needed, who should write it, where it should be kept, who should keep it, and for how long. The retention period for documents, for the most part, should be based on common sense. If a government or other agency requires or suggests the length of time certain documents be kept, obviously those rules should be followed. For the rest, the length of time should be based upon sound business practices. If the product has certain critical components that, if they fail before the end of the product's useful life, could result in a serious safety problem, the documentation supporting the efficacy of these parts should be retained for as long as the product is likely to be in service.

Because the law requires only that a product be reasonably safe, clearly the documentation to be preserved should be that which will support the argument that all of the critical engineering decisions that balanced competing tradeoffs were reasonable and were based on reducing the risks from all foreseeable hazards. The rationales underlying these decisions should be part of the record, for two reasons. First, because it will give those who will review the designs when the product is to be updated or modified in subsequent years, the bases for existing design decisions. If the prior assumptions and rationales are still valid, they need not be altered. Conversely, if some do not reflect current thinking, then only those aspects of the design need to be altered. Without these rationales, all the design parameters will have to be re-examined for efficacy.

Secondly, and just as importantly, having the rationales in writing for those safety-critical decisions can provide a solid legal defense if the design is ever challenged as defective.

Thus, the documentation categories that are appropriate both for subsequent design review and for creating strong legal defense positions are these:

- Hazard and risk data that formed the bases for the safety considerations
- Design safety formulations, including fault-tree and failure-models and effects analyses
- Warnings and instructions formulation, together with the methodology used for development and testing
- Standards used, including in-house standards, and the rationale for the requirements utilized in the design
- Quality assurance program, including the methodology and rationale for the processes and procedures
- Performance of the product in use, describing reporting procedures, follow-up data acquisition and analysis, and a written recall and retrofit policy

This type of documentation will permit recreating the process by which the reasonably safe product was designed, manufactured, and marketed.

75.9 A FINAL WORD

In the preceding pages, we have only touched on a few of the areas where the law can have a significant impact on engineers' discharge of their professional responsibilities. As part of the process of product design, the law asks the engineer to consider that for the product that emerges from the mind of the designer and the hand of the worker to play a role in enhancing society's well-being, it must

- Account for reasonably foreseeable product misuse
- Acknowledgment human frailties and the characteristics of the actual users
- Function in the true environment of product use
- Eliminate or guard against the hazards
- Not substitute warnings for effective design and guards

What has been discussed here and summarized above is, after all, just good engineering. Our objective is to help the engineer recognize those considerations that are necessary to bridge the gap between the preliminary product concept and the finished product that has to function in the real world, with real users and for real uses, for all of its useful life.

Apart from understanding and utilizing these considerations during the product design process, engineers have an obligation, both personally and professionally, to maintain competence in their chosen field so that there can be no question that all actions, decisions, and recommendations, in retrospect, were reasonable.

That is, after all, what the law requires of all of us.