Safety and Liability Risks for Defense Contractors Entering Commercial Markets

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Defense contractors are increasingly seeking commercial customers and markets beyond traditional Department of Defense (DoD) and other government contracts. Commercial markets offer potential advantages such as large and stable customer bases, more predictable income streams and freedom from the burdensome government acquisition process. However, commercial markets pose unique challenges to traditional defense contractors in terms of product safety expectations, legal liability, and risk assessment and mitigation. This paper explores issues and obstacles that a defense contractor safety professional will face when introducing a product into a commercial environment. What commercial safety standards should be used, and what legal protection do they afford? What types of hazard analysis should be performed, and what additional hazard categories should be considered? How can the manufacturer be protected from customer misuse or modification of its products? And, the most vexing question faced by all commercial product designers: How safe is safe enough?

Introduction

Due to a shrinking and erratic U.S. government (USG) research and development budget that is often subject to political winds, many defense contractors are diversifying into state and local government markets, foreign military sales and commercial product sales. One advantage the defense contractor has in competing in the commercial marketplace is the institutional technical learning obtained from working on state-of-the-art technology funded by the USG. There is also "dual-use" technology developed for both commercial and defense applications, and "spinoff" defense technology to the commercial realm after it has been developed for the defense market. Finally, there may be a "spillover" effect where manufacturing processes developed under USG funding may be used so products can be competitively priced and sold at scale to commercial markets. This paper explores the differing safety, legal liability and risk assessment environments that a traditional defense contractor safety professional will likely encounter in the commercial marketplace.

Why Enter the Commercial Marketplace?

It is widely recognized that products are developed and manufactured for commercial markets at a fraction of the cost of similar products provided by defense contractors. Conducting business with the USG comes with onerous accounting and reporting requirements that increase the overhead costs of running a defense contracting company — estimated to be about 15 to 25 percent above those for commercial enterprises [Ref. 1]. Because the accounting methods are so different, a corporation will often need to separate business entities into commercial and defense markets. Additionally, any product or technology that has been funded by the USG may be subject to government intellectual property rights, export controls and classified restrictions. Thus, the commercial marketplace offers the potential for large and stable customer bases, more predictable income streams and freedom from the burdensome government acquisition process. However, defense contractors will face an unfamiliar legal and regulatory environment, without the traditional protections that government contractors enjoy.

Liability Protection for Government Contractors

As a sovereign, the federal government is immune from suit without its consent. The Federal Tort Claims Act (FTCA) waives the government's sovereign immunity and generally allows private parties to recover for personal injuries caused by the negligent act or omission of a USG employee acting within the scope of his or her office or employment [Ref. 2]. Courts have crafted several "federal common law" defenses that shield government contractors from liability under the FTCA's exceptions, including the "Government Contractor" defense, and the "Combatant Activities" exception.

The Government Contractor defense, articulated in the Supreme Court's decision in *Boyle v. United Technologies Corporation*, is derived from the "discretionary function" exception to the FTCA. The Court determined that the selection of an appropriate design for military equipment is a discretionary function, and the government's immunity for that discretionary function has been extended to contractors that supply goods to the govern-

ment. Under *Boyle*, contractors are not liable for design defects in military equipment where (i) the government-approved precise specifications, (ii) the equipment conformed to those specifications and (iii) the contractor warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States [Ref. 3]. Lower courts have expanded this defense to include failure-to-warn and manufacturing defect cases, non-military equipment, services contracted for the maintenance of military equipment, and even private service contractors integrated into combatant activities over which the military retains command authority [Ref. 4].

Commercial Markets Pose Unique Challenges

Commercial markets pose unique challenges to traditional USG contractors in terms of legal liability, risk assessment and mitigation, and acceptable levels of safety. There is no *Boyle* defense available for commercial product sales, or even for military equipment sold to foreign customers under Direct Commercial Sales contracts. There is no USG customer to specify the required hazard analyses, the Risk Acceptance Codes or the formal risk acceptance decisions [Ref. 5]. Instead, the contractor must set its own safety/integrity targets, identify appropriate safety requirements and standards, determine the scope and depth of hazard analyses, determine appropriate hazard controls and risk mitigation verifications, and accept the residual risk of unmitigated hazards. In other words, the contractor must stand alone and answer the question "How safe is safe enough?" in the context of the existing commercial regulatory and legal environment.

Legal Liability

Liability under tort is the civil legal mechanism for compensating individuals injured by others. In that case, the injured party (the plaintiff) may bring a legal action against the injuring party (the defendant). Products liability refers to the obligations or duties of manufacturers, wholesalers or retailers/sellers to consumers, purchasers, users and even "bystanders" when a product is found to be defective. No matter what the theory of liability, the predicate of a suit in products liability is a *defective product*. Most states allow an injured plaintiff to litigate a product liability claim under a theory of negligence, breach of warranty and/or strict liability.

Negligence — This theory usually alleges that the commercial seller or manufacturer breached a duty to the plaintiff by failing to eliminate a reasonably foreseeable risk of harm associated with the product. Such suits typically claim one or more of the following: (i) negligently defective design, (ii) negligent manufacture of the goods (including improper materials, packaging or inspection) and (iii) a negligent failure to provide adequate warnings of hazards or defects.

Breach of Warranty — Warranties are statements by a manufacturer or seller concerning a product during a commercial transaction. Breach of warranty product liability claims usually focus on one of three types: (i) breach of an express warranty, (ii) breach of an implied warranty of merchantability and (iii) breach of an implied warranty of fitness for a particular purpose. Claims can be for breach of express warranties (those identified on the packaging or materials concerning the product) or implied warranties that cover expectations regarding all products (e.g., that a tool is not unreasonably dangerous when used for its proper purpose), unless specifically disclaimed by the manufacturer or the seller. A warranty can also be created by representations contained in advertisements promoting the product.

Strict Liability — Most states have adopted a theory of strict liability that focuses exclusively on the existence of a *product defect*, and not on the conduct of the manufacturer defendant. If a product causes injury (despite reasonable use of the product), the manufacturer likely will be liable even if it took all reasonable quality control measures in the manufacturing process. The most common model for strict liability is described in Section 402A of the American Law Institute (ALI) Second Restatement of the Law of Torts [Ref. 6]. Setting aside the legalese, the following summarizes the most important points of strict liability:

- Unlike negligence theory, Section 402A does not require plaintiffs to prove a breach of duty. It is no defense to a consumer's strict liability lawsuit that the manufacturer exercised all possible care. If a product delivered is deemed to be defective, the manufacturer will be liable for any injury caused by the product, no matter how careful it was to avoid the defect.
- The product must be in a defective condition when sold, and also must be unreasonably dangerous because of that condition. An unreasonably dangerous product is one that is dangerous to an extent beyond the reasonable contemplation of the average consumer.
- The plaintiff must prove that (i) the product was defective in design, manufacture or warnings, (ii) the defect existed at the time the manufacturer

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delivered the product and (iii) the defect caused the plaintiff's injuries.

- The product was expected to and did reach the purchaser without substantial change in the condition in which it was sold. Defendants can avoid section 402A liability where the product was substantially modified by the plaintiff or another party after the sale, and the modification contributed to the plaintiff's injury or other loss.
- The harm resulted when the product was being used in a reasonable foreseeable manner.
- The person harmed was "foreseeable." While liability for personal injury and property damage extends only to the ultimate user or consumer, court decisions have extended protection to bystanders and others who are injured by the product.

Types of Defects

Under any of the three theories of liability discussed here, the plaintiff generally can recover damages only if the product is found to be defective. There are three different types of defects that a product may have: defects in manufacturing, in design and in warning or instruction.

Manufacturing Defect — A product has a manufacturing defect when it is not built according to its specifications and, as a result, is unsafe due to the manufacturer's improper assembly, materials or packaging, or its failure to inspect their products for defects that create a reasonably foreseeable risk of harm. For example, during manufacture, an employee might forget to tighten a nut or there might be a hidden flaw in the metal from which the product is made. There are various formulations concerning the existence of a production or manufacturing defect:

- A product which comes off the assembly line that does not conform to the manufacturer's own specifications or intended design, or is in a substandard condition in comparison with other identical units.
- A defect which results from a fault in the manufacturing process, from improper workmanship, defective materials, or improper or inadequate testing.
- A manufacturing imperfection that occurs in a typically small percentage of products of a given design as a result of the fallibility of the manufacturing process. If there are a large number of individual defects, this will probably be seen as a design defect and not an isolated manufacturing or production defect.

Design Defect — This occurs where the design of the product makes it unreasonably dangerous for its intended purpose. Design defect cases frequently involve such factors as (i) the magnitude or severity of the foreseeable harm, (ii) industry practices at the time the product was manufactured, (iii) the state of the art of existing scientific and technical knowledge at that time and (iv) the product's compliance or noncompliance with government and industry safety regulations and standards. Design defect cases generally require objective testimony or a professional opinion from a qualified expert. In recent years, many courts have also required the manufacturer to recall products which were not necessarily defective when they were designed, but which have become defective at a later date, perhaps through obsolescence or the passing of time, especially if there is a substantial risk of harm to a large number of persons and if the change required to make the product safer or substantially more safe would be a minimal one.

Warning or Instruction Defect — This defect exists when the product's manual, instructions, packaging, labels or placards fail to provide adequate warnings of possible dangers associated with the product, or instructions regarding its safe use. Specifically, there is a defect if foreseeable risks of harm posed by the product "could have been reduced or avoided by reasonable instructions or warnings" and this omission makes the product not

reasonably safe [Ref. 7]. Various courts have described a list of requirements and goals of a legally adequate warning. An adequate warning will:

- alert the consumer or user to the severity of the hazard (severity being defined as the magnitude of the hazard and the likelihood of it being encountered)
- clearly state the nature of the hazard
- clearly state the consequences of the hazard
- provide instructions on how to avoid the hazard

In determining whether there was a duty to warn and whether the defendant's warning was adequate, courts often consider other factors besides the reasonable foreseeability of the risk. These include the magnitude or severity of the likely harm, the ease or difficulty of providing an appropriate warning and the likely effectiveness of a warning. The manufacturer may be held liable even if, because of technological limitations, the hazard was unknowable at the time of manufacture. In addition, a manufacturer is required to warn not only about hazards associated with the intended uses of its products, but also about hazards that might arise from any misuse that the manufacturer knows about or should know about. There is no duty to warn where the risk is open and obvious, or when the danger or potentiality of danger is generally known and recognized.

Test for Defects — Most courts will find that a product is defectively designed if the product is more dangerous than an ordinary consumer would expect, or if the benefits of the product's design do not outweigh its risks. The "consumer expectations test" focuses on the reasonable expectations of the consumer or purchaser, and requires the court to determine whether the product "is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner" [Ref. 8]. The "risk-utility" test determines whether the cost of making a safer product is greater than the risk from using the product in its present form. The common factors used for determining risk-utility or risk-benefit include:

- the usefulness and desirability of the product
- the likelihood and probable seriousness of injury from the product as it is manufactured
- the availability of a substitute product that would meet the same needs of the consumer and not be unsafe
- the manufacturer's ability to eliminate the danger without impairing the usefulness of the product or making the product too expensive
- given the nature of a danger, the user's ability to avoid the danger (especially with proper warnings, labels or instructions)
- the user's anticipated awareness of the danger
- whether there were reasonable alternative designs available that were not selected, but which likely would have prevented the injury. An alternative design that was not used is to be considered feasible when a reasonable person would conclude that the magnitude of the danger-in-fact could have been avoided by such alternative design, and the utilization of the scientific technological know-how reasonably available to the defendant outweighed the (i) financial costs of guarding against such avoidable danger, (ii) the impairment of the benefits and (iii) any new danger-in-fact that would have been created by the alternative design [Ref. 9].

Defenses to Liability

There are affirmative defenses that, if proven by the manufacturer, eliminate or lessen the manufacturer's liability regardless of whether the product has been or could be shown to be defective. The most important categories of affirmative defenses are included here.

Carelessness or Misuse of the Product — If a consumer uses the product in a way that is not in accord with the manufacturer's intended use, or the consumer's own negligence contributed to causing the injury, the consumer's recovery may be reduced or eliminated. Most states have adopted a rule of *comparative negligence*, under which the jury assigns percentages to the negligence of the plaintiff and each defendant that caused the injury. Recovery is then reduced based on the plaintiff's percentage. Where the plaintiff does not know a use of the product is dangerous but nevertheless uses it for an incorrect purpose, a defense arises, but only if such misuse was not reasonably foreseeable. If it was, the manufacturer should warn against that misuse.

Subsequent Modification of the Product — To prevail in strict liability, the plaintiff must show that the product was defective when it left the defendant's control. Manufacturers are not liable for misuse, alteration or modification unless they are "reasonably foreseeable" by the manufacturer and could not have been prevented by a different design or a warning. Some courts hold the manufacturer liable even when the alteration is the only reason for the defect — removing a safety guard originally installed by the manufacturer, for example. In such a case, the manufacturer must make the guard difficult to remove and must warn of the dangerous consequences of removing it [Ref. 10].

Passage of Time — Claims with respect to industrial machinery frequently arise from injuries suffered 40 or 50 years after the product was sold. Although such a claim is certainly "stale" in terms of the manufacturer's ability to defend its design decisions, it will not be barred by the statute of limitations as long as the lawsuit is brought within the time limit after the date of the injury. A few states have enacted *statutes of repose* in which a manufacturer is not liable for injuries occurring more than a specified length of time after it first delivered the product.

Government and Industry Standards and Federal Preemption — Violation of a mandatory government regulatory standard results in an automatic finding of negligence in most states. An exception is when a federal statute or regulation requires that a product be manufactured with a particular design or warning, or when the product has received close scrutiny and approval by a designated federal agency. In these cases, the mandated or federally approved design or warning is not considered defective or inadequate under state law via the concept of *federal preemption*. With regard to warnings, compliance with voluntary standards such as the American National Standards Institute (ANSI) Z.535.4 for product safety signs and labels can provide evidence that the manufacturer has used warnings that meet the standard of care. Conversely, non-compliance with ANSI Z.535.4 can provide evidence of negligence or a defect in the warnings [Ref. 11].

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Model Commercial Product Safety Program

Based on the civil laws and case studies of product liability suits discussed earlier, the safety professional needs to craft a commercial product safety program — which may be unfamiliar to the conventional defense contractor. The typical USG contract and Statement of Work generally specifies top-level safety criteria, standards, hazard analyses, required tests and verification, acceptance criteria, and sometimes even the qualifications necessary for the assigned safety engineer. Under the Government Contractor defense, compliance with these criteria will usually shield the defense contractor from liability for harm caused by its product. The commercial product safety professional will need to develop all of these as part of a comprehensive product safety program, and "sell" the safety program (and its commensurate funding) to management often skeptical of anything beyond contract requirements. Also, the safety professional will need to educate management that the company will be fully responsible for design decisions affecting safety, for production and quality processes that prevent safety-critical defects, and for warnings, instructions and manuals necessary for safe operation and maintenance for the life of the product. Most important, management will need to be educated on the concept of "reasonably foreseeable misuse" and the steps needed to create and market a "reasonably safe product" — as well as the fact that the company itself will be the risk acceptance authority, without USG oversight and protection. These are concepts foreign to most defense contractors, and may require the assistance of legal counsel. The following outline for a commercial product or system safety program takes into account the lessons detailed in the first section of this paper.

Determine the Product Safety Goals

The first prong of the "reasonably safe product" goal is to produce a product for which there is no reasonable safer alternative design, based on the current state of the art. The manufacturer must employ experienced and knowledgeable design personnel, closely monitor competing products, keep active in related industry organizations, closely monitor and comply with applicable minimum standards, correct design defects as they acquire knowledge of them and document improvement efforts along the way.

The second prong of the goal is to manufacture the product as designed and without fault, based on an effective quality assurance process. Such an effort begins with the careful purchase and inspection of quality materials and components. Then, closely monitor the manufacturing process to avoid and identify manufacturing anomalies, and inspect completed products for proper operation and compliance with manufacturing standards. Document these inspections and their results.

The last prong is to incorporate adequate warnings and instructions to eliminate risks that could not be eliminated through reasonable design. Once the appropriate warnings and instructions are determined, the manufacturer must take appropriate measures to ensure

that the information is delivered in a manner calculated to reach the end user through the proper placement and distribution of the information. Again, the manufacturer should document delivery of these materials and save contemporaneous copies and samples to be produced later, if needed.

Determine the Limits of the Equipment

An initial determination of the system boundaries and limits of the equipment should take into account all phases of the product or machine's life, the intended uses and the reasonably foreseeable misuses. Consider the expected conditions of use (e.g., lighting, environmental surroundings, noise, etc.), different machine operating modes and user interventions required by malfunctions. Take into account differing anthropometric characteristics (fifth to 95th percentile), differing levels of training and experience, limiting physical abilities (visual or hearing impairment, attentiveness, size, strength, etc.) and persons likely to have little awareness of the machine hazards, such as members of the general public, including children.

Establish Safety Requirements and Criteria

Establish specific safety performance requirements needed to meet the core program objectives. Starting with requirements from a similar system, incorporate applicable safety performance requirements in system specifications and the specific risk levels considered acceptable for the system. Quantitative requirements may be expressed in terms of either risk, or the probability or frequency of a given mishap severity category, but should *not* reference an acceptable accident or injury rate. (While this may be an accepted practice in the European Union (EU), it must be avoided in the U.S. See Ford Pinto gas tank rupture cases). Mishap risk requirements may be expressed as a level defined by a mishap risk assessment, such as "no serious mishap risks or higher are acceptable." For international products, safety integrity requirements of functions allocated to electronic and programmable systems may be defined in terms of discrete Safety Integrity Levels (SILs) as defined in International Electrotechnical Commission (IEC) Standard 61508 [Ref. 12].

Determine if the product is regulated by federal or state regulations or agencies, most common in the transportation, pharmaceutical, medical, aviation and energy industries. Consumer Product Safety Commission (CPSC) safety standards apply to numerous consumer products, such as toys, cigarette lighters, baby cribs and household chemicals. Compliance with these requirements will be mandatory. If the company is going to market the product in the EU, review the applicable EU Directives. Review of all pre-sale advertising and promotional materials from a product liability perspective is also necessary.

Next, determine the voluntary consensus standards most applicable to the product. If a U.S. standard is not available, such as ANSI, National Fire Protection Association (NFPA) or Underwriters Laboratories (UL), there is almost certainly an International Standards Organization (ISO) standard available. Further, there are many standards for specific safety devices, such as guards, emergency stops, interlocks, etc. Additionally, there are standards that provide general safety practice and principles, such as the familiar military standard MIL-STD-882 or the commercial variant, Government Electronics and Information Technology Association Standard 0010 (GEIA-STD-0010) [Ref. 13]. Another standard, ISO 12100, provides safety risk assessment and reduction principles that align with the liability mitigations in this paper [Ref. 14]. For international standards, a company is better off citing "using the guidance of" instead of "will comply with," since certain areas may not be applicable. Additional safety requirements derived from accepted hazard analyses, such as Failure Modes and Effects Analysis (FMEA) or Functional Hazard Analysis (FHA), should be traceable to top-level hazards identified in the next paragraph.

Perform Hazard Identification

Assume that potential hazards may arise during the product's use, and indicate the likelihood that those hazards will occur and the severity of the potential consequences when they do. The hazards identification process needs to include system hardware and software, system interfaces (including human interfaces), hazardous situations and/or hazardous environments during all phases of the product lifecycle, including dismantling and scrapping. The environments of use to consider should include intended (normal) operation, malfunctions, and *reasonably foreseeable* misuse of the machine or product.

In evaluating the reasonably foreseeable uses and abuses of the product, a manufacturer should consider the following [Ref. 15]:

- expected users, bystanders, and skilled and unskilled operators (including age, mental/physical limitations, size, strength, attentiveness, etc.); foreseeable

misuse may even include criminal acts by third parties [Ref. 16][1]
- expected conditions of use (e.g., lighting, environmental surroundings, noise, etc.)
- anticipated changes (wear and tear, and modifications) during the lifecycle of product
- unintended behavior of the user, such as loss of control, lack of concentration or carelessness, taking the "line of least resistance" in carrying out a task, pressure to keep the product running in all circumstances, and behavior of certain persons (for example, children, disabled persons)
- accident, injury and damage reports, and data for older models of the product, for competitive products and for the entire industry. In some industries, such as energy and rail transportation, it is conventional to consider hostile intentions or sabotage upon the system as a credible hazard.

Perform Hazard Analysis and Risk Assessment

One of the most important tools in minimizing product defects is comprehensive hazard analysis, in order to consider all the possible ways that a product may fail or be misused. In addition to design engineers, the group performing the hazard analysis could include sales staff, field employees, personnel responsible for writing safety warning labels and user instructions, legal counsel and third-party design professionals. Available resources on injuries arising from similar products may contain useful object lessons for product design and instructions. These resources include government injury databases, product recall notices, industry publications, reported and unreported litigation, information within the insurance industry on claims, and various Websites.

Functional Hazard Analysis (FHA) has historically been the most effective technique to determine hazards and develop safety requirements to mitigate risks. Coupled with the use of the system safety risk mitigation order of precedence, FHA can identify early in the lifecycle those risks that can be eliminated by design, and those that must undergo mitigation by other controls in order to reduce risk to an acceptable level. Some manufacturers find it useful to perform a Failure Mode and Effects Analysis (FMEA). A FMEA explores ways in which each product component could possibly fail during use and misuse, the probabilities of each such failure, and the consequences or effects. The idea is to have a design that either eliminates the significant hazards that might arise from failures or reduces the probability of a particular failure mode so that it is unlikely to occur during the life of the product. Once the hazard analysis concludes, engineers should have a complete list of the ways in which the product might fail or potentially cause injury or damage.

Identify Hazard Controls and Risk Reduction Measures

Risk reductions are achieved by understanding risk drivers, reducing risk according to the system safety mitigation order of precedence and then reassessing the risks. Hazards should be prioritized so that corrective action efforts can be focused on the most serious hazards, according to the mishap risk potential they present. Mitigators may serve to eliminate the hazard, or reduce the severity or probability of potential mishaps. Identify potential mishap risk mitigation alternatives and the expected effectiveness of each alternative or method. The mitigators should be implemented according to the order of precedence and consists of eliminating the hazard through design selection or inherently safe design measures, incorporating engineered features or devices guarding against the hazard, providing detection and warning devices, and/or providing applicable warnings, instructions, procedures, training and other "information for use" on how to avoid potential hazards while using the product. After mitigators have been selected, the residual mishap risks must be reassessed to ensure that risks are "as low as reasonably practicable" (ALARP) [Ref. 17][2].

Minimizing Design Defects

Design defects are the main theory of liability in most product liability cases. If a product's design is deemed

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1. A big rig truck driver who suffered severe brain damage when a 15-year-old boy intentionally threw a 2.5 lb. chunk of concrete through his windshield from the top of a levee, filed an action against the manufacturer of the truck. The plaintiff alleged that the windshield of the truck was defective due to its inadequate resistance to penetration, and that the manufacturer had a duty to design its trucks to withstand common road debris, including even intentionally thrown rocks and concrete chunks. The court held that the defendant may be liable for the harm resulting from the intentional or criminal act.
2. The ALARP principle is commonly used to make decisions in safety-related systems in the UK and is typically defined as the act of reducing risk such that further reduction of risk is grossly disproportionate to the cost benefit gained. See IEC 61508-5.

defective by a court, then all products with that design are potentially defective. Therefore, incorporating risk assessment techniques into the design process is critical. A starting point may be one of the company's other products within the same family of products or similarly designed products. Next, the product should be assessed against applicable industry standards. Groups that create industry standards, in effect, are engaging in risk assessment in deciding on the final standards. And even though standards may be considered minimum requirements, compliance with relevant standards may be adequate in many instances. Finally, an analysis of accidents and lawsuits involving similar products can be useful in helping to quantify future risk and the likelihood of accidents and adverse verdicts with certain designs.

Minimize Manufacturing Defects

To prevent manufacturing defects, manufacturers, at a minimum, need to ensure that their products have been manufactured and assembled according to all design and manufacturing specifications, and that those specifications comply with all relevant voluntary or mandatory standards. Each product sold must be the same as all other similar products sold. Various quality control inspections and tests must be performed throughout the production process. Proper documentation of quality control inspections and testing must be kept.

Minimize Defects in Warnings and Instructions

Manuals, instructions and warnings should be considered an integral component of product design. Address reasonably foreseeable failures, misuses, modifications, lack of maintenance, and unskilled users, and utilize ANSI Z535.4 warning and label design criteria. ANSI Z535.6 addresses how to incorporate safety information that is contained on product labels into instructions [Ref. 17]. The standard provides requirements for the purpose, content, format and location of different kinds of safety messages. Grouped safety messages are commonly referred to as a "safety section." It usually appears at the beginning of the manual, and describes the risks involved in the use of the product and how to minimize or avoid them. These sections should include definitions of the "signal" words — "Danger," "Warning" and "Caution" — that are used on labels and in the manual, as well as reproductions of the labels in an illustration showing where they are attached to the product. Embedded safety messages are contained within a specific procedure. For example, "To prevent burns, wear protective gloves when performing this procedure."

ISO 12100 addresses "information for use," and contains valuable guidance on defending against an allegation of "failure to warn." The "information for use" should address the following:

- operating procedures for the use of the system consistent with the expected ability of personnel who use the product, or other persons who can be exposed to the hazards associated with the product
- the recommended safe working practices for the use of the product, and the related training requirements adequately described
- sufficient information, including warning of residual risks for the different phases of the life of the product
- a description of any recommended personal protective equipment, including detail as to its need, as well as to training needed for its use
- the risks and hazards of reasonably foreseeable product failure modes, misuses, modifications, or lack of maintenance and upkeep

Keep in mind that "information for use" must not be a substitute for the correct application of inherently safe design measures, safeguarding or complementary protective measures.

Conduct Test and Verification

Tests must be defined and conducted to verify the effectiveness of selected mitigators. Mitigators must be evaluated to ensure implementation and confirm effectiveness by means of appropriate analysis, testing and inspection. When it cannot be analytically determined whether the corrective action taken will adequately mitigate a hazard, conduct safety tests to evaluate the effectiveness of the mitigators. Test or demonstrate safety-critical components and procedures to establish the margin of safety of the design. Consider induced or simulated failures to demonstrate the failure mode and acceptability of safety-critical functions. Where costs for safety testing would be prohibitive, safety characteristics or procedures may be verified by engineering analyses, analogy, laboratory test, functional mock-ups, or subscale and model simulation. Integrate safety testing into appropriate system test and demonstration plans to the maximum extent possible. New hazards identified during testing must be routed back to the Hazard Control and Risk Reduction step.

Residual Mishap Risk Acceptance

The safety professional must ensure that all reason-

ably foreseeable hazards are identified, evaluated and mitigated to a level compliant with applicable laws and regulations, contractual agreements and, ultimately, company policy. The safety professional must provide company management with sufficient information for them to make informed decisions regarding the acceptability of any residual mishap risk, and the costs of additional recommended risk-mitigating measures. The company risk acceptance authority must then determine whether the mishap risks have been reduced to ALARP within the constraints of company objectives, resources and risk tolerance — and either accept the risk or take action and allocate additional resources to further reduce the risk. If the final residual risk is not acceptable, the company should not market or deliver the product into commerce.

Following the implementation and verification of the risk reduction measures, the question "how safe is safe enough" can be addressed. One approach is that adequate risk reduction has been achieved when the following has been satisfactorily completed:

- All intended operating conditions and foreseeable users have been considered under both normal operation and foreseeable fault conditions.
- All credible hazards have been identified, taking into account the intended uses and the reasonably foreseeable misuses through all phases of the product life.
- A substantive hazard analysis has been conducted that considers all credible ways that a product may fail or be misused, and the risk assessed in terms of probability of occurrence and severity of the resulting mishap.
- The identified hazards have been eliminated or risks reduced to ALARP, with emphasis on minimizing defects in design, manufacturing, and warnings and instructions while following the risk mitigation order of precedence. Any new hazards introduced by the protective measures have been properly addressed.
- The effectiveness of safety requirements and risk mitigators has been verified by a thorough test program that confirms that the protective measures do not adversely affect the usability of the product.
- Users have been provided with information necessary to safely use and maintain the product, and are sufficiently informed and warned about the residual risks.

> "Depending on the circumstances and the industry involved, a recall of the product may be the appropriate course of action. A recall typically involves the return of the product for replacement, modification or refund. Because recalls often require swift action, a recall plan should be in place, ready for execution."

Post-Production Support

The safety professional should be cognizant of a company's duties and responsibilities after the product has been delivered to customers and users.

Under the laws of many states, a manufacturer must continue to exercise reasonable care to warn consumers of hazards discovered by the manufacturer after its product is delivered. This can be true even if the manufacturer no longer manufactures the product line. If information received after delivery of the product indicates that its original instructions or warnings did not adequately advise users of a particular hazard, updated information should be communicated to product users. It is important to have a system to facilitate this communication.

In some instances, a newly discovered hazard may prompt a change in the product's design to eliminate the hazard, or reduce the possibility of its occurrence or the severity of its consequences. Every time a manufacturer makes safety improvements, whether or not based on incidents, it must decide whether to make a change for only future products or to offer the improvement to prior customers. This analysis results in the manufacturer evaluating the risk of the product with the safety improvement against the risk of the product without it. In such a case, it may be wise to make current product users aware of the design improvement and to offer a retrofit kit with which they can make the change to their product. If safety improvements are made and not offered to prior customers, plaintiffs may argue that the improvement is evidence that the original product was defective. But informing prior customers of every product improvement can be very costly, unless the manufacturer charges for the new design (e.g., a safety guard) or new warnings and instructions. However, this violates the precept that "safety should not be optional," so a rational and defensible decision needs to be made.

Depending on the circumstances and the industry involved, a recall of the product may be the appropriate

course of action. A recall typically involves the return of the product for replacement, modification or refund. Because recalls often require swift action, a recall plan should be in place, ready for execution. The company may also be required by law to report information discovered about hazards in the product to certain federal and state government agencies, such as the CPSC for consumer products and the National Highway Traffic Safety Administration (NHTSA) for automobiles. In recent years, many courts have also imposed a duty on the part of a manufacturer to recall products that were not necessarily defective when they were designed, but which have become defective at a later date, perhaps through obsolescence or the passing of time. This is especially true if there is a substantial risk of harm to a large number of persons and if the change required to make the product safer would be a minimal one.

Customer and warranty returns, and reports of product failures and incidents, should be assessed to identify possible product misuses or design weaknesses. Marketing literature, advertisements, press releases and presentations associated with the product should be continuously reviewed to ensure that statements about the product remain consistent with the product's intended usage. Express or implied representations about the product that are inconsistent with its design intentions and capabilities will create liability even though the product might have otherwise been "reasonably safe." In addition, over-promotion of a product may diminish the effectiveness of any warnings given for the product.

Document Retention

Many companies don't understand that they must document the alternative designs they have considered and why they rejected them. Even if the engineers have documented the basis for their choice of design in handwritten notes, their defense may be stronger if they can show they had a plausible reason to reject an alternative to the design actually selected. If a lawsuit is filed based on an alleged design defect in a product manufactured 15 years earlier, it becomes essential to have documentation of design alternatives that were considered at the time of manufacture, because memories will have faded and design engineers will have retired or otherwise become unavailable. The company should establish a document retention policy to help ensure preservation of documents important to the investigation and defense of product liability claims. Such documentation should include:

- records that document the design and configuration history for each model of product; keep copies of customer design specifications and product orders, including customer sign-off on final designs
- records of prototype testing, engineering analysis, design reviews, certification by outside consultants and other developmental work that resulted in the product's final design
- quality and conformity records at each of the quality control points; manufacturing records that describe each individual product's condition and as-built configuration when it left the company, verifying that it was properly inspected, tested and met industry or government standards
- records showing that customers were given (i) instructions regarding the proper use of the product, (ii) warnings regarding the product's hazards and (iii) notice of the availability of design options and improvements
- an archive of each version of the instruction, maintenance and other manuals for the product
- service bulletins, recall letters and other communications to customers concerning remedial action recommended for the product, a record of whom each was sent to, and a record of any response or customer reply
- records that contain disclaimer and indemnity agreements with suppliers, subcomponent manufacturers and purchasers
- for defense contractors, all records of communications with the governmental procurement office about the design of the procured products, drawings and specifications for those products, proposals to change the design or operating instructions for the products, procurement contracts, and documents evidencing military approval of the products' designs

Finally, recognize that seemingly appropriate and valuable writings can be harmful if misused to suggest that a product was defective when, in fact, it was not. A few illustrations include [Ref. 18]:

- **Cost-Benefit Analyses.** It can be damaging when a manufacturer's own documents are written in such a way that it appears the manufacturer believed it would be cheaper to pay for injuries than to fix a product. There have been cases in which manufacturers have expressly assigned monetary values to potential deaths and injuries, and compared those amounts with the cost of corrective action. Such cost-benefit analyses are not likely to sit well with a typical American jury.

- **"CYA" Memos.** Typically, the memo writer wishes to create a record to show in advance that someone else is responsible for some undesired event that either has occurred or may occur. For example, "I told the manufacturing department for weeks that the pinion gear would fail unless they increased the torque on the retaining nut." There may, in fact, be a real question as to whether the gear failed because of improper torque or because the consumer operated the machine above its specified limit. A plaintiff's lawyer who has the "CYA" memo will have an easier time convincing a jury that torque is the problem.
- **Computer print-outs of service difficulties.** Most manufacturers receive feedback from consumers, distributors, agents and others about problems with their products. The feedback is frequently unverified and often wrong. With enough of these questionable or erroneous entries, however, a plaintiff's lawyer can argue that the company's own records show that the product is unreliable — or at least that the company had notice of a potential problem and failed to take effective action.
- **Rough drafts.** A service engineer writes a first draft of a recall letter suggesting that a product be modified by December of that year. For good reason, the effective date of the recall is changed in the final draft to July of the following year. The first draft languishes forgotten in the service engineer's desk until it is produced for a plaintiff's lawyer whose client was injured in May. The lawyer will probably argue that the service engineer was correct the first time and was overruled by managers willing to risk safety rather than adjust the schedule.

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