

*Foreseeable Hazards and Misuse*

# Risk Assessment and Product Liability

by Kenneth Ross and Bruce W. Main

**A**ttorneys have commonly counseled manufacturers that documents are potential smoking guns that can mortally wound the defense, especially documents relating to safety and risk decisions. Yet legal counsel also necessarily advise manufacturers to remain current with the state-of-the-art. How can a manufacturer perform and document that it conducted appropriate safety and risk analysis without creating such potentially harmful documents? This is difficult and challenging for any diligent manufacturer.

Originally developed in the 1950s in connection with the U.S. missile program, risk assessment and related engineering evaluations have always been a part of the design and manufacturing process. But, for many manufacturers, it was an informal process with little documentation. Recently, however, risk assessment has become a topic of discussion in legal and manufacturing circles. Industries and standards groups in the United States and Europe have turned their attention to risk assessment and

developed specific methodology for their industries or specific products. Although these individual efforts are conducted with some awareness of other industry activities, the protocols and terminology are necessarily tailored to each industry application. The result is several independent approaches to risk assessment.

This article describes risk assessment in general and the protocols different industries and standards groups are using. It will also discuss the legal requirements and compare them to the requirements of risk assessment. Lastly, this article will discuss the difficulties that can befall manufacturers that do not pay careful attention to how these assessments are performed and documented.

## Legal Requirements

All lawyers should remember the famous description of negligence by Judge Learned Hand in *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947). Judge Hand set forth three criteria for determining whether a person's conduct was negligent: (1) the probability that injury would result from the actor's conduct; (2) the gravity of the harm that could be expected to result should injury occur; and (3) the burden of taking adequate precautions to avoid or minimize injury. Judge Hand went on to express this test in the form of an algebraic

equation: "If the probability be called P; the injury L [loss]; and the burden B [*i.e.*, the burden of precaution to avoid the risk of loss]; liability depends upon whether B is less than L multiplied by P; *i.e.*, whether B is less than PL." 159 F.2d at 173. Negligence, as described by Judge Hand, served as a core concept in the development of product liability in the 1960s and 1970s. It is also consistent with the process of risk assessment and resulting design and manufacturing decisions.

Product liability blossomed in the 1960s with the adoption of strict liability by the California Supreme Court in *Greenman v. Yuba Power Products, Inc.*, 59 Cal.2d 57, 27 Cal.Rptr. 697 (1962), and the inclusion of Section 402A in the *Restatement (Second) of Torts* in 1965.

The *Restatement (Third) of Torts: Products Liability*, published in 1998, continued the tradition of the Learned Hand formula and made it clear that the predominant legal theory for holding a manufacturer liable for product liability is consideration of whether the manufacturer should have made a safer product. Did the level of risk outweigh the burden of taking more precautions? How better to do this analysis than do some type of risk assessment?

This technical analysis is consistent with these legal requirements and theories. As a result, it seems apparent that every manufacturer should consider which kind of risk assessment, even as simple as Learned Hand's, should be done during the design phase.

## What is Risk Assessment?

Risk assessment is a tool for manufacturers to identify possible hazards and provide a basis for considering alternative designs to mitigate or control risks. A risk assessment offers the opportunity to identify hazards associated with intended uses and reasonably foreseeable misuses, and to take steps to eliminate or control them before an injury occurs. This process can be a key factor in successfully reducing risks to an acceptable level.

In some instances, more than one analytical technique is necessary to implement safety-through-design. A preliminary hazard analysis (PHA) and failure mode and effects analysis (FMEA), in combination with risk assessment, are the most frequently used tools. An FMEA is a systemized group of activities intended to: (1) recognize and evaluate the potential failure of a product/process and its effects; (2) identify actions that could eliminate or reduce the chance of the potential failure occurring; and (3) document the process.



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The focus of an FMEA is on identifying product or component “failures” and examining the potential effects on the overall system. While failures identified and analyzed in an FMEA are different from the type of safety hazards identified in a risk assessment, many of the same analytical processes are used. The following steps are included in the FMEA: (1) identify the failure and its causes; (2) describe the potential effect of the failure; (3) identify and quantify the severity or seriousness of the effect of the failure; and (4) quantify the probability of the cause occurring.

In the FMEA system, the ways in which this failure can be prevented are identified, and a “risk priority number” is assigned that quantifies the design risk. This number is a product of the severity, probability, and ability to detect the cause. These risks are ranked, and decisions are made as to which failure modes will be reduced by corrective action.

Again, while failures in this system are different from safety-related risks, the analysis that is done and items quantified sound much like the typical risk assessment process. The primary difference between these methods is that where the FMEA looks at product or component “failures,” a risk assessment focuses on the human interactions and “failures” with the product.

Although many different approaches can be taken to performing a risk assessment, certain steps are common. Here is a brief summary of the risk assessment process, step by step.

#### 1) Establish the analysis parameters

The first step in the risk assessment process is to establish the parameters of the analysis. These parameters can be limits of the machine or design, limits on uses, limits on the scope of the analysis, or other limits.

#### 2) Identify hazards

The next step is to identify hazards associated with the product or process design. This step is absolutely critical to the assessment. Different methods are used to root out hazards, and the different industry approaches to risk assessment reflect these differences.

#### 3) Assess risks using two or more risk factors

Once hazards have been identified, the risk assessment effort begins. Several different risk models are used. Some methods use two risk factors (severity of injury and probability of occurrence). Other methods use three or more

factors by breaking probability into components (e.g., frequency of exposure and avoidance).

#### 4) Derive a risk rating

After the risk factors are assessed, a risk rating is derived from a risk matrix. The risk matrix is the combination of risk factors mapped to various risk levels. Different industries use different risk matrices.

The risk assessment process yields a level of risk. If the risk is determined not to be acceptable, it is necessary to reduce that risk by

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implementing protective measures. Determining which risks or levels are and are not acceptable is company-specific and situation-specific. In some instances, individual industries have provided guidance on levels of acceptable risk. In most instances, this decision is left to the user, as it is culture, situation, and time dependent.

Unfortunately, the common law and, in most situations, regulatory law from federal government agencies, are not helpful in determining how safe is safe enough. No matter which decision was made, no matter where the line was drawn, the plaintiff will argue that the product should have been made safer.

#### 5) Reduce risks

Risk reduction activities begin after the risk rating is derived. Remedial actions are taken to reduce risks following the hazard hierarchy (order of precedence) commonly accepted across several industries and authors. The hazard hierarchy is shown in Table 1 on page 36 (derived from Roland & Moriarty, *System Safety Engineering and Management* (1990)).

#### 6) Verify the risk reduction effectiveness

After the risk reduction methods have been identified, most risk assessment protocols call for a second assessment of the risk factors. This second assessment helps to verify that the risks have been reduced to an acceptable level.

#### 7) Document the results

After risks have been reduced to an acceptable level, the risk assessment activities should be documented. The documentation can be added to a technical file for future use.

#### Why the Increased Interest in Risk Assessment?

Although risk assessment methods have existed in various forms for many years, interest has increased in the last few years. Several factors explain this, including:

- **Time.** The design cycle is under ever-increasing pressure favoring its compression, reducing tolerance for post-sale safety fixes.
- **Costs.** Significant opportunities exist for productivity gains and cost efficiencies.
- **Competition.** Reducing costs and increasing productivity through safety-through-design can provide an attractive competitive advantage.
- **International influences.** Through the CE mark, the European Union (EU) explicitly requires an analysis of the hazards in accordance with the hazard elimination and control hierarchy. The CE mark is an identifying symbol and certification that a product meets the applicable European standards and is in fact safe. The first step in obtaining the CE mark is to complete a risk assessment. The assessment must be documented. In most instances, the mark is a self-certification provided by the product manufacturer. The CE mark is required for most products sold in the EU.
- **Quality.** Quality processes such as ISO 14001 and ISO 9000, issued by the International Organisation for Standardization, are beginning to address safety. In the automotive industry, QS-9000 (Quality System Requirements) is the quality standard for Chrysler, Ford, and General Motors; it is based on the 1994 edition of ISO 9001, but it contains additional requirements that are particular to automobile manufacturers.
- **Capturing knowledge.** A completed risk assessment can be used to capture much of the knowledge pertinent to the design

**Table 1: Hazard Elimination and Control Hierarchy**

- Eliminate hazards** through the design
- Protect or guard** against the hazard
- Warn the user** about the hazard
- Train the user** to avoid the hazard
- Personal protective equipment**

being considered, which can in turn be applied to similar designs.

- **Product liability.** Risk assessments help reduce exposure to hazards and can assist in building a successful defense against a product liability claim.
- **Lack of standards.** When standards do not exist or have not kept pace with technological change, risk assessments provide a basis to make credible design decisions.
- **Schedule control.** A risk assessment permits a company to make reasoned decisions and move quickly to implement them.
- **Customer requirements.** Some advanced industrial customers are beginning to request that suppliers conduct risk assessments.

A more detailed discussion of these factors is contained in Christensen & Manuele, eds., *Safety Through Design* (Institute for Safety Through Design 1999). See <http://www.asse.org> and/or <http://www.nsc.org>.

### Company Approaches

Risk assessments have been integrated into design processes in varying degrees. Some manufacturers have a wealth of experience in conducting risk assessments as they have been conducting these analyses for many years. Some military contractors have been conducting analyses for as long as 50 years. These companies are typically leaders in risk assessment activities.

Conversely, many manufacturers are just starting down the risk assessment path. They are investigating and benchmarking the different methods available, and are working to begin integrating safety-through-design via risk assessments. These new arrivals to risk assessments face the challenges of changing their existing design processes to more clearly and comprehensively include risk assessment.

In all manufacturers, an increasing emphasis has been placed on formalizing hazard analysis and risk assessment activities, including documenting the analyses and re-

sults. Pressure to improve the existing design processes is also prevalent; these pressures spark change, innovations, and discovery. As risk assessments are conducted, hazards and risks come to light and design innovations result. Innovations lead to reduced risk, increased productivity and cost efficiencies, better overall effectiveness, and decreased risks to all stakeholders.

### Industry Approaches

A recent technical report gathers and documents the current state-of-the-art in several industries. *Risk Assessment Benchmarks 2000: Getting started, making progress* (<http://www.designsafe.com>). The report includes a generalized risk assessment protocol and an outline of each specific industry approach. A discussion examines the factors influencing the current increased momentum of risk assessments. The report is intended to permit easier benchmarking of these methods for managers, engineers, and safety professionals interested in introducing or refining risk assessments in their design processes. It should be particularly helpful to those who wish to start a risk assessment process, as it will eliminate much research and help focus development efforts.

*Risk Assessment Benchmarks 2000* reveals that several industries have well-developed procedures, and other industries are beginning the process. Here are a few examples.

#### Robotics

The Robotics Industries Association (RIA) has developed a risk assessment methodology for the manufacturers, re-manufacturers, installers, and end users of industrial robot systems. See *Safety Requirements for Industrial Robots and Robot Systems*. It includes an approved and voluntary industry standard, designated ANSI/RIA R 15.06-1999. A software tool, *Robot Risk Assessment*, is also based on the standard. Copies can be obtained at <http://www.robotics.org>.

#### Machine tools

The Machine Tool Safety Standards Committee of the American National Standards Institute is responsible for writing and revising standards for the machine tool industry, including a risk assessment procedure. The resulting technical report is titled ANSI/B11 Technical Report #3, *Risk Assessment and Reduction—A guideline to estimate, evaluate and reduce risks associated with machine tools*.

The machine tool industry's approach to

risk assessment is instructive. Here is an excerpt from its report:

This technical report is part of the ANSI B11 series of reports and standards pertaining to the design, construction, care and use of machine tools. It is a guideline—not a standard. This report defines a method for conducting a risk assessment and risk reduction for machine tools, provides some guidance in the selection of appropriate protective measures to achieve tolerable risk, and describes the risk assessment and risk reduction responsibilities of both the machine tool supplier and user. This method requires gathering the appropriate information, determining the limits of the machine, identifying tasks and hazards over the life-cycle of the machine using a task-based approach, estimating risk associated with the task-hazard pairs, reducing risk according to a prioritized procedure, and documenting the results. The risk reduction process is not completed until tolerable risk is achieved. Flow charts illustrate the process. Checklists of tasks and hazards are included in the document. This technical report explicitly recognizes that zero risk is not attainable. This guideline is intended for use on all new or modified machines and equipment designs and processes. The user may also utilize it to assist with risk assessment and risk reduction for existing tasks and hazards.

One of the significant advances made in the machine tool industry's report is the recognition that both the supplier of the machine and the user of the machine have risk assessment and risk reduction responsibilities. Another significant advance is the recognition that the identification of tasks results in the identification of more hazardous situations. Many of these may be high risk but were simply overlooked using traditional risk assessment because the work was not identified.

The machine tool report went through numerous drafts and was carefully crafted by experts in the subject after an analysis of other risk assessment processes. For more information, see <http://www.mfgtech.org>.

#### Chemicals

The chemical industry has been involved in chemical safety and risk management methodologies from its earliest days. The rich safety engineering history in the chemical industry has led to considerable integration of safety concepts. Chemical engineers commonly use

safety analyses in their design and evaluation processes.

The chemical process industry uses the umbrella term “risk management” to include hazard identification, hazard (risk) assessment, risk mitigation, and other elements (e.g., audits, incident investigation). Its risk assessment tools include fault tree analysis, explosion and fire analysis, assessment of health effects from chemical releases, and quantitative risk assessment.

### Automobiles

In the automotive industry, General Motors Corporation has been a leader in developing and integrating risk assessment protocols in its design processes. The company uses a proprietary software program to speed the risk assessments.

The auto industry also makes extensive use of failure mode and effects analysis, a technique very similar to risk assessment. (See description of FMEA above.) In 1993, General Motors, Ford, and Chrysler first published a reference manual for performing potential FMEA that is the technical equivalent of the Society of Automotive Engineers (SAE) J-1739. The analysis is to be performed by companies subscribing to QS-9000.

### Medical devices

Risk assessment in the medical device industry is presented in the AAMI/ISO 14971-1—1998 *Medical devices-Risk Management—Part 1: Application of risk analysis*. That document specifies a procedure for investigating the safety of a medical device, identifying hazards, and estimating the risks associated with the device. Copies can be obtained at <http://www.aami.org>.

### Packaging machines

The packaging machine industry incorporates risk assessment in its current industry standard, ANSI/PMMA B155.1—2000, *Safety Requirements for Construction, Care, and Use for Packaging Machinery and Packaging-Related Converting Machinery*. Although this standard does not put forth a specific risk assessment methodology, it discusses the process and documentation requirements.

### United States armed forces

The U.S. military developed one of the earliest and still most pervasive risk assessment approaches. It is contained in MIL-STD-882, and applies to defense contractors. The mili-

tary standard details an entire system’s safety program, of which risk assessment is just one small component. The standard explicitly requires a risk assessment.

### Products sold in Europe

The European approach to risk assessment originally appeared in EN 1050-1996, *Safety of machinery, risk assessment*. Through the CE mark, the countries of the European Union explicitly require an analysis of the hazards in accordance with the hazard elimination and control hierarchy (Table 1).

## A good argument

**may be made that the documentation of the assessment is protected by attorney-client privilege.**

The first step in obtaining the CE mark is to conduct a hazard and risk assessment in accordance with EN 1050, a requirement for all manufacturers selling their products in the EU. The standard “provides advice for decisions to be made on the safety of machinery and the type of documentation required to verify the risk assessment.” It describes risk assessment as a procedure “by which the knowledge and experience of the design, use, incidents, accidents and harm related to machinery is brought together in order to assess the risks during all phases of the life of the machinery.”

In 1999, the EN 1050 protocol was incorporated directly into the European standard EN 292-1/ISO 12100-1, *Safety of machinery—Basic concepts, general principles for design, basic terminology, methodology*.

Additional risk assessment standards and details on the above approaches can be found in the *Risk Assessment Benchmarks 2000* report. In addition, more recently, new computer tools specifically designed to guide and speed the hazard analysis process have become available. See <http://www.designsafe.com> to download a sample risk assessment.

### Documenting the Risk Assessment

Any lawyer knowledgeable in product liability understands the dangers of evaluating risk with the exactitude of these risk assessment processes. However, the same can be said for

any manufacturer performing the Learned Hand analysis. No matter which actions the manufacturer took, the plaintiff will argue that more could have been done and should have been done. Or, the plaintiff will argue that the manufacturer intentionally quantified the level of risk so low that it would not be required to “design out” the hazard. Documentation of the risk assessment is a roadmap for the plaintiff and the plaintiff’s expert to challenge any and every calculation and assumption made in the design process.

This problem cannot be dealt with easily. The reality is that risk assessment standards, requirements, and guidelines exist. If they apply to a particular product, the manufacturer must decide whether to perform the assessment. If it is performed, it must be documented. It is possible that the manufacturer’s customer requires it or requires the report to be provided. This is particularly true for component part manufacturers selling to original equipment manufacturers (OEMs) who perform their own risk assessments. If the assessment is conducted, very little leeway can be found in how to document it. Under any type of risk assessment, the manufacturer will need to list the hazard, the probability and severity of harm, and the methods by which the risk can be minimized. Of course, this document, as with all company documents, should be subject to the company’s record retention system, and it should not be necessary to keep it forever.

The best advice is to perform the appropriate assessment and be prepared to stand behind the process and conclusions. While a plaintiff and his or her expert may disagree with your analysis, you can argue that you employed state-of-the-art safety analyses to produce a reasonably safe product and you believe that you succeeded. At the very least, performing risk assessments or some equivalent safety analysis will minimize the number of accidents. Then, if they do occur, a plaintiff will not be able to claim that you consciously disregarded safety, with the prospect of a punitive damages award.

### Implications

The plaintiff will not cease arguing that products are defective even if the manufacturer performed a risk assessment. However, risk assessment can impact the nature of the argument considerably. Without evidence that a risk assessment was performed, the plaintiff can attack both the decision process (or lack of a process) and the decisions. With a documented risk assessment, the argument pri-

marily involves issues of judgment about the decisions made.

One of the more significant implications of advances in risk assessment is the role counsel may play in controlling access to the documents. If a risk assessment is performed to assist counsel in providing legal advice on final design decisions, a good argument may be made that the documentation of the assessment is protected by attorney-client privilege. In that case, the defense may choose to share the risk assessment to assist its case, but only if it wants to and when it wants to.

In the event of litigation, a risk assessment may be useful to frame the discussion before the court. Rather than isolating one hazard that the plaintiff encountered, the defense can use the risk assessment as evidence of the many hazards evaluated, how the risks interact (reducing risk of one hazard may increase risk of

another), and demonstrating that successful risk reduction efforts were implemented for all of the risks.

In some cases, part of the legal argument involves whether the plaintiff's use of the product was reasonably foreseeable. After an incident, a manufacturer may have a difficult time showing that any particular use or misuse was not foreseeable. However, a completed risk assessment could help, as an analysis completed before an incident should identify and address those uses and misuses that are reasonably foreseeable based on the information available. If the plaintiff's use or misuse does not appear on the risk assessment, one could conclude that the action was not reasonably foreseeable. If it does appear on the assessment, the arguments should focus on whether the risk reduction employed reduced the risk to an acceptable level.

Although interest in risk assessment has grown, engineering design and manufacturing processes do not yet commonly integrate such assessments. While some companies have been conducting and documenting risk assessments for as long as ten years, the vast majority of manufacturers are just beginning to learn of the process and its advantages.

Legal counsel can assist by making its introduction and integration a smooth process. Counsel should also help evaluate the risk of doing such analyses and educate employees on how to make certain judgments and properly document the process.

Defense counsel may raise an objection that risk assessments have not been thoroughly tested, that there are problems with documentation requirements, and that, if not conducted correctly, the risk assessment could be very damaging. These criticisms are not unfair. However, these are not justification for refusing or ignoring the risk assessment process. Like it or not, requirements for documented risk assessments are here. Failing to conduct and document a risk assessment will soon be a problem, too.

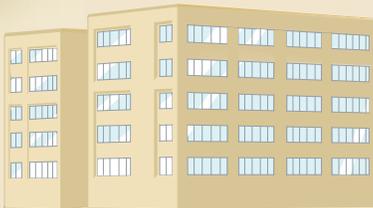
Performing a risk assessment may not prevent a plaintiff from convincing a jury that a safer product could and should have been produced. Despite that, the existence of a conscientiously performed assessment, or even a good faith attempt to comply with the requirements, should allow defense counsel to argue that punitive damages are not warranted and should not even be allowed to go to a jury.

### Conclusion

Although risk assessments and safety-through-design have been around for many years, their integration into general industry is relatively new. Significant activities, from both domestic and international sources, are pushing safety-through-design. Meeting the most recent state-of-the-art in safety analysis offers manufacturers the opportunity to improve product design, reduce accidents, and curb liability exposure.

Unfortunately, safety is an issue that sometimes only receives considerable attention after an incident occurs. This is not a wise attitude for the manufacturer. Companies that proactively seize the opportunity to improve safety-through-design can minimize the likelihood that an injury event will occur. The company will reap the benefits of cost efficiencies and productivity improvements. **FD**

## DRI Corporate Member Profile



### Deere & Company

**DRI Corporate Member since**  
1990

#### **DRI Contact**

Dan Harvey, Senior Counsel

#### **DRI Committee Activity**

Product Liability

#### **Company Profile**

Deere & Company, a Fortune 100 company, is the world's leading producer of agricultural equipment and a leader in the production of equipment for construction, forestry, and lawn and turf care. It is based in Moline, Illinois, with operations worldwide.

#### **Recent DRI Involvement**

Deere & Company has continued its very active participation in DRI. Dan Harvey co-chairs the Product Liability Committee's Specialized Litigation Group on Agricultural, Construction, Mining, & Industrial Equipment (ACMIE). In 2000, Deere staff attended the Product Liability Conference in Las Vegas, and the Repetitive Stress Disorders seminar in Chicago. At the DRI Annual Meeting in New Orleans, Dan Harvey served as a panel member together with counsel from other heavy equipment and consumer goods manufacturers.

Deere & Company has held successful national panel counsel meetings in conjunction with DRI events.

"DRI has been a great resource for our company," said Dan Harvey. "We recently had a case where a plaintiff was alleging RSD injuries. DRI's specialty seminar on this topic was timely and extremely helpful to our office as we defended this action."

For information on DRI Corporate Membership, contact Mary Cosgrove at DRI Headquarters, at (312) 795-1101 or [mcosgrove@dri.org](mailto:mcosgrove@dri.org), or Richard Boyette, Membership Committee Chair, at (919) 863-8727 or [rtb@cshlaw.com](mailto:rtb@cshlaw.com).