

Safety Definitions: Colloquial, Standards, Regulatory, Torts, Heuristic, and Quantitative

by

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Abstract

Scholars of every stripe have confessed that they cannot define pornography; but they know it when they see it. This unsatisfactory state-of-affairs is trivial compared to defining safety. Safety presents cascading levels of subjectiveness each of which defies definition. The current definitions of safety disguise our ignorance and deprive us of both certainty and objectivity. Indeed, as the field of safety continues to exist in a "research-free zone" we are all trying to be the one-eyed man in the valley of the blind. This paper considers colloquial, legal, and technical definitions of safety; all are useful, none are satisfactory. Even worse, none of the definitions pass the idiomatic "laugh test."

1. Introduction

Safety communications among laypersons, juries, attorneys, judges, legal scholars, safety practitioners, safety professionals, and safety scholars require different definitions of safety and different levels of sophistication. All of the definitions are important and useful, but they each must be used with great care because radically different concepts are called by the same name. In mathematics, every country has the same definition for a derivative, an integral, or continuity. Furthermore, the same symbols in Greek letters are used so that mathematical portions of their technical papers require no translation in the international community. Mathematics has developed a discipline that has influenced technology to develop a rational foundation for their various undertakings. Such a foundation is utterly lacking in the field of safety.

A. First Canon of Engineering Ethics

"An engineer shall hold paramount the safety, health and welfare of the public in the performance of their professional duties." (note that welfare includes economic well-being.) [Ref.1]

Observe that the central and controlling engineering activity is to reflect the wishes of society when possible (and legal). The most important subsidiary conditions, safety and cost, are to be held paramount. Others, such as aesthetics, reliability, robustness, religious, and durability, may be incorporated through the judgment of stakeholders.

B. Reasonably Foreseeable Use

All technologists design products for an expected use; this is the goal of the designer. Clearly, the actual use of products by their community of users is broader than the expected use; indeed, the original use contemplated by the designer may be expanded by marketers before the first prototype is finished. Tort law mandates that products be safely designed for their reasonably foreseeable use which includes not only their expected and expanded uses but also their reasonably foreseeable misuses.

There are three elements that must be satisfied for a use or activity or task to be reasonably foreseeable. First, the use must be possible. Next, the use must be foreseeable, i.e., a usage pattern must exist as a prerequisite for forecasting methodologies. Finally, the use must be of significant magnitude to provide a reasonably foreseeable use. If a safety problem is not reasonably foreseeable, it is not unsafe even if it may cause harm.

C. Safety Theorem

The development of various safety definitions requires the application of the following Safety Theorem:

"Every physical entity created by man or nature is a hazard capable of causing harm."

2. Colloquial Definitions of Safety

Protecting the public from harm is the major preoccupation of safety professionals. This general notion can be communicated to the public in broad terms that are useful without cluttering the landscape with detailed terminology. The colloquial language of the layperson and the politician are reflected in dictionaries such as Webster's New Collegiate Dictionary which serves us here from its 1981 edition. The legal perspective is reflected in the Sixth Edition of Black's Law Dictionary, 1990.

A. Colloquial definitions (Webster's):

- Safe Freed from harm or risk; unhurt.
 - Secure from threat of danger, harm, or loss.
 - Not threatening danger; harmless.
- Danger Harm, damage.Exposure or liability to injury, pain, or loss.
- Hazard A source of danger.
- Risk Possibility of loss or injury: Peril.
 - A dangerous element or factor.
 - To expose to hazard or danger.
 - To incur the risk or danger.
- B. Law Dictionary (Black's 6th Edition):
- Safe Untouched by danger; not exposed to danger; secure from danger, harm or loss.
- Danger Jeopardy; exposure to loss or injury; peril.
- Hazard Exposure to the chance of loss or injury.
- Risk Hazard, danger, peril, exposure to loss, injury, disadvantage or destruction, and comprises all elements of danger.
- C. Commentary:

The colloquial and legal definitions were taken directly and accurately from their sources. They represent the language of safety that governs our wellbeing as laypersons. Unfortunately, the binary notion of safe v. unsafe does not allow the safety community to exercise control over mother nature which is a primary goal of technology. The following observations arise from the definition set:

- 1. The most important shortcoming of the definition set is that its qualitative and not quantitative.
- 2. The colloquial and legal definitions of "safe" each state, "secure from threat of danger, harm, or loss." The Safety Theorem establishes that "safe" is a fantasy because every physical entity created by man or nature is a hazard capable of causing harm.
- 3. Hazard is the only concept in the definition set that is unequivocal.
- 4. The words Risk and Danger share the same definition.
- 5. One of the antonyms of danger is safety.
- 6. Darwin's process of natural selection gives rise to life forms that evolve around the concept of safety to ensure the survival of species.

3. Qualitative Safety Definitions

The product liability system by and large pays or awards injured parties when their mishaps involve a defective product. The declaration that a product is defective is equivalent to defining it as unsafe, or not reasonably safe, or unreasonably dangerous, or in violation of some safety code, standard, or regulation. The various legal concepts by which a chattel is judged arise from the US Federal Government and each of the fifty states and US Territories. Navigation through these concepts is a challenge for technologists who typically have an impoverished legal background. The journey is exacerbated by the fact that the law is constantly changing. Notwithstanding the foundational problems of the product liability system, there are important theories of liability that prescribe the architecture of our society.

A. Standard, Codes, Regulations

The a priori deliberations of a body of stakeholders on the safety of some product are often reduced to writing in the form of safety standards, codes, or regulations. Compliance or Non-Compliance with a safety standard forms the criterion for determining whether or not adequate safety has been achieved. The salient features of standards are explored in Reference 2 where their subtleties are characterized. For example, in the US, compliance with a safety standard is treated as a necessary but not sufficient condition for precluding liability. The fundamental argument against the sufficiency of standards stems from a 1932 decision by Judge Learned Hand [Ref. 3]: "Indeed in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices."

Most states will not accept code compliance as a defense in a product liability case and sometimes judges will not allow standards to be introduced. Defendants in product liability actions present code compliance merely as a persuasive argument in favor of their position.

In the USA, non-compliance with a standard usually means the product is unsafe. Compliance never defines a safe product.

B. Negligence Theory

Negligence theory regards a product as unsafe if its creator fails to use the same care, skill, and diligence in and about the process of manufacture that a reasonable, skillful, and prudent person, "reasonable man," would use under similar circumstances. The concept focuses on the conduct of the manufacturer. The circumstances which may constitute negligent manufacture are infinite and are usually a question of fact to be decided by the trier of fact. In American jurisprudence, this means either a single judge or, at the option of one of the parties to a lawsuit, a jury of six or twelve individuals drawn from the community. [Ref. 4]

C. Strict Liability

By far the most common basis of recovery in a product liability action and the easiest to prove is that of strict liability. The doctrine of strict liability, which defines an unsafe product, is defined as follows [Ref. 4]:

Strict Liability - Restatement, Second Torts § 402A

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

The defective condition referenced in the doctrine presents as either a design defect, a manufacturing defect, or a warning defect. A product is "in a defective condition" if, at the time it leaves the seller's hands, it is in a condition not contemplated by the ultimate consumer and which will be unreasonably dangerous to the ultimate consumer. An improperly designed machine which lacks a guard may be "unreasonably dangerous" and thereby unsafe. On the other hand, whisky is not "unreasonably dangerous" even though it can cause drunkenness; it has an acceptable level of safety.

Note that the concept of strict liability focuses on the nature of the product rather than the behavior of the manufacturer. Also, both negligence and strict liability are compatible with the First Canon of Engineering Ethics which will not support the introduction of a defective product into the stream of commerce.

D. Risk-Utility Theory

The Supreme Court of California, in the case of Barker v. Lull Engineering Co. 573 P. 2d 45d (1978), stated that "a product may be found defective in design, so as to subject a manufacturer to strict liability for resulting injuries, under either of two alternative tests...

- 1. "A product may be found defective in design if the plaintiff establishes that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.
- 2. A product may alternatively be found defective in design, if the plaintiff demonstrates that the product's design proximately caused his injury and the defendant fails to establish, in light of relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design."

Among the "relevant factors" the jury may consider when weighing the benefits of the design against the risks, in the second tests, are: "(a) the gravity of the danger posed by the challenged design; (b) the likelihood that such danger would occur; (c) the mechanical feasibility of a safer alternative design; (d) the financial cost of an improved design; (e) the adverse consequences to the product and to the consumer that would result from an alternative design."

It is important to acknowledge that in 1978, the legal profession no longer regarded danger as merely unsafe. It spoke separately of the gravity of the danger (severity) and the likelihood that such danger would occur (exposure). The Risk-Utility theory presents two tests which define an unsafe product. The second test introduces a new concept, utility, which is just as difficult to define as the word safety. Among the relevant factors that a jury is admonished to consider in the second test is the notion of a safer alternative design that is feasible, economically practicable, and without adverse consequences.

E. Alternative Design Theory

The American Law Institute (ALI) finalized its formulation of the Doctrine of Alternative Design which it adopted and promulgated on May 20, 1997 as Restatement of the Law Third; Torts: Product Liability. The alternative design doctrine for defective (unsafe) product design is defined by both subparagraph 2(b) of the Restatement and about 150 pages of commentary. This may be distilled into the following approximate statement of analysis theory [Ref. 5]:

A product is defective in design if a safer reasonable alternative design could have been adopted at the time of sale where reasonableness is judged by a broad based safety-utility balancing analysis.

The adoption of the Doctrine of Alternative Design for product design purposes rather than analysis is explored in Reference 5.

Ultimately all of the product liability theories, except for standard violations, rest on the definition of defect which remains elusive especially in the face of the Safety Theorem which guarantees that every product will produce injuries or damage. ALI/Third provides guidelines for identifying defects, to wit,

§2. Categories of Product Defect

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings.

A product: (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product; (b) is defective in design when (i) the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, (ii) and the omission of the alternative design renders the product not reasonably safe; (c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the

instructions or warnings renders the product not reasonably safe.

Also, ALI Commentary f indicates that a broad range of factors may be considered in determining whether an alternative design is reasonable and whether its omission renders a product not reasonably safe. The factors include the following:

- 1. "Magnitude of the foreseeable risks of harm (severity).
- 2. Probability of the foreseeable risks of harm (exposure).
- 3. Product instructions.
- 4. Product warnings.
- 5. Nature and strength of consumer expectations regarding the product.
- 6. The relative advantages and disadvantages of the product as designed and as it alternatively could have been designed.
- 7. The effects of the alternative design on:
 - a. Production costs.
 - b. Product longevity.
 - c. Maintenance.
 - d. Product repair.
 - e. Product esthetics and styling.
 - f. Intended product use.
 - g. Product desirability.
 - h. Overall product safety.
 - i. Product utility.
- 8. Range of consumer choice among products.
- 9. The financial costs of an improved design.
- 10. Codes and Standards."

A very alarming shortcoming of balancing risk and utility is related to comparing apples and oranges. For example, are three units of utility greater than two units of risk? Add to this problem the fact that most of the factors are subjective. Do we expect the same evaluation among different people and from the same person at different times?

4. Quantitative Development – Safety Definition

- A. Heuristic Development
- In the decade of 1970 there was a growing recognition that safety or its antonym danger is a combination of two and only two concepts; "how badly are you hurt (severity)" and "how often are you hurt (exposure)." A mathematical transliteration of this notion was expressed in the popular form

Risk = f (hazard severity, hazard exposure) (1)

where f is a function of the independent variables (hazard severity) and (hazard exposure). The dependent variable Risk became the more popular name for this combination of severity and exposure [Ref. 6]; Danger, which is a better name with less ambiguity, was another popular version that safety practitioners must recognize in order to understand the literature. [Ref. 7]

- 2. When the "hazard severity" increases, Risk should get larger. This implies that the risk function f is a monotonically increasing function of severity. Using the vast archives of available data, it is a straightforward task, albeit labor intensive, to construct a continuous risk-severity curve.
- 3. When the hazard exposure increases, Risk should increase. Once again, this implies a monotonically increasing risk function f with respect to the independent variable "hazard exposure."
- 4. Because of the Safety Theorem, only the absence of a hazard can produce zero risk. Also, when there is no hazard, logic requires that the hazard exposure is zero. Thus.

 $\lim_{x \to 0} \text{Risk} = 0$
severity $\to 0$

lim Risk = 0
exposure $\rightarrow 0$

This leads to the following theorem:

Theorem: In a subsystem that presents only a single hazard, its elimination provides the only Risk-Free design possibility and the only Risk-Free remediation protocol. As an example, this theorem advises that the asbestos hazard can only be eliminated by the complete removal of the asbestos.

- 5. If every possible risk could be represented by a single risk function f, its upper bound might be taken as human extinction. This risk level is associated with nuclear excursions, pandemics, and asteroid impacts. For special subsystems, such as machine tools, the "worst case scenario" would serve as the upper bound on f.
- 6. Without additional information Equation 1 cannot answer key quantitative safety questions such as,

- What level of Risk is acceptable?
- Is chattel A less risky than chattel B?
- Is protocol A less risky than protocol B?

Nevertheless, the contemplation of Equation 1 provides important insights into the general problems of safety, e.g.,

• If a hazard can be eliminated, the associated risk is eliminated.

• Risk is reduced by lowering the hazard severity, e.g., lower speed limits or perform maintenance under conditions of Zero Mechanical State (ZMS) or Lockout/Tagout (LOTO).

- Hazard Severity is lowered with improved medical intervention, i.e., cures, protocols, and vaccines.
- Decreasing hazard exposure lowers the Risk, e.g., introduce barrier guards, safeguards, awareness barriers, and fencing.
- Reduce the Risk through the introduction of robots and automation which remove operators from production machines.
- Decrease Hazard Exposure by improving personal vigilance, e.g., warn and instruct.
- Use personal protective equipment to decrease hazard exposure, e.g., hard hats, safety eyewear, steel-toe boots, and safety harnesses.
- After over forty years, Equation 1 has appeared in the 2014 ISO/IEC Guide 51: 2014(E), Safety aspects – Guidelines for their inclusion in standards [Ref. 8]. Figure 1 from this publication, Elements of Risk, is depicted in Exhibit 1. No description or protocol is given in Guide 51 for transforming the risk equation into a working formula which quantifies the risk
- B. Risk Estimation Matrix

The American National Standards Institute has promulgated a risk assessment method for machine tools of the type included in the B11 series of machine tool standards; ANSI B11.TR3-2000, "Risk Assessment and Risk Reduction – A Guide to Estimate and Reduce Risks Associated with Machine Tools." [Ref. 9] Their risk assessment follows the structure of Equation 1 using a transliteration into the Matrix shown in Table 1. Here, the independent variable "hazard severity" is divided into a four-level scale, Hazard Severity

<u>Catastrophic</u> – death or permanently disabling injury or illness (unable to return to work).

<u>Serious</u> – severe debilitating injury or illness (able to return to work at some point).

<u>Moderate</u> – significant injury or illness requiring more than first aid (able to return to same job).

 $\underline{\text{Minor}}$ – no injury or slight injury requiring no more than first aid (little or no lost work time).

In a similar fashion the "hazard exposure" is also divided into four levels of intensity,

<u>Very likely</u> – near certain to occur. <u>Likely</u> – may occur. <u>Unlikely</u> – not likely to occur. <u>Remote</u> – so unlikely as to be near zero.



Exhibit 1: Elements of risk (ISO/IEC 2014)

Table 1 –	Risk	Estimation	Matrix
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	Severity of Harm					
Probability of Occurrence of Harm	Catastrophic	Serious	Moderate	Minor		
Very Likely	High	High	High	Medium		
Likely	High	High	Medium	Low		
Unlikely	Medium	Medium	Low	Negligible		
Remote	Low	Low	Negligible	Negligible		

An example: a "serious" severity of harm and a "likely" probability of occurrence of that harm yields a "high" level of risk.

When one of sixteen possible combinations of severity and exposure is inserted into the matrix, one of four possible risk categories will be revealed: High, Medium, Low, and Negligible.

The following observations are noteworthy:

- 1. Safety is defined by the four risk categories High, Medium, Low, and Negligible. A Negligible risk provides the greatest safety.
- 2. The risk estimation Matrix provides a ranking system as opposed to an actual quantitative definition of risk.
- 3. Dividing the range of risk into only four parts does not enable one to compare competitive designs such as fixed guard candidates.

- 4. Hundreds of sophisticated criteria are presented in the ANSI Guide for determining severity and exposure in an unbiased and accurate manner. Almost every suggestion is subjective.
- 5. The risk estimation matrix is a rule-of-thumb that has been widely promulgated as the foundation for protocols that determine acceptable risk or that design products that provide acceptable risk.
- 6. Beware, the risk estimation matrix allows the inept, the inexperienced, and the corrupt to rapidly perform a risk assessment.
- The concept of a risk assessment matrix is used for System Safety in MIL-STD-882D [Ref. 10], 10 February 2000 and for Robotic Safety in ANSI/RIA R15.06-1999 [Ref. 11].



Figure 1: Quantitative Safety Definition

C. The Exact Definition of Safety

The technical definition of safety is given by Equation 1 which provides the form of a relationship among four concepts: hazard severity, hazard exposure, the risk function f, and the derived Risk for some artifact. The quantitative determination of Risk requires that the risk function f is known together with relationships that size the severity and exposure for a given contrivance. Three standards that are referenced in this paper use a matrix to define each of the four concepts. Here, we shall assume that the hazard severity can be obtained from a continuous equation between the severity magnitude and the artifact characterization, see Figure 1c. Similarly, the magnitude of the hazard exposure is related to the artifact characterization by a continuous function, see Figure 1b.

A Risk Diagram is shown in Figure 1a where the existence of a risk function f is assumed that reflects the features discussed in our heuristic development. Observe that the continuous Risk surface has an origin at severity = 0 and exposure = 0. The curve depicted in the Risk-Exposure plane is a continuous monotonically increasing function. The same is true for the curve illustrated in the Risk-Severity plane. Each pair of points developed for an artifact (severity, exposure), appears as a single point on the Risk surface. In summary, the Risk Surface provides a numerical value of Risk for any combination of severity and exposure. If this Risk is "acceptable" we would colloquially declare the associated artifact safe. If two designs have risks that appear on the same contour, their safety levels are equal. Different designs will generally exhibit different Risks; the lowest Risk candidate is the safest.

Figure 1 provides the exact definition of safety in a form that exposes our intellectual shortcomings and the daunting challenge presented by our quest for a quantitative safety definition. A prodigious level of scholarship is required to quantify each of the four elements that make up the definition protocol. A few closing remarks will reinforce this observation.

Hazard Severity

No universal measurement exists for severity which has been characterized by economic loss, lost workdays and relative ranking on various lists which purport to reflect a hierarchy of human misery beginning with death as the most severe consequence. The subjective nature of severity is illustrated by considering the loss of a hand to a mathematician, a pianist, a person born with only one hand, and a onehanded mute person who will no longer be able to sign. Assigning a severity level in such circumstances cannot presently be done within a rational system even though juries do it every day. Because verdict value is a possible measure of severity, instructions to juries generally contain considerations of loss of consortium, compromised lifestyle, pre-existing maladies, the victim's age and the age of family members, the availability of a prosthesis, consequential damages, and perhaps punitive damages.

Hazard Exposure

Exposure to a hazard produces a harmful incident. The probability of occurrence of that harm is consequently one possible measure of exposure. Hence, one can look at ordinary accident statistics as a method for establishing the magnitude of hazard exposure. Recall that Exhibit 1 presents a three-level breakdown of the probability of occurrence of harm (hazard exposure),

- Exposure to a hazardous situation.
- The occurrence of a hazardous event.
- The possibility to avoid or limit the harm.

Note that just knowing the occurrence probability does not provide information for influencing exposure magnitude. On the other hand, the factors detailed in the various risk assessment standards provide the information necessary for reducing the hazard exposure. These are the same factors that are provided to jurors when Risk-Utility is used in product liability litigation.

The construction of the <u>exposure-artifact</u> <u>characterization</u> curve shown in Figure 1b would be reasonably straightforward for special subsystems if their associated manufacturers would release their proprietary accident statistics and their litigation history. On the other hand, technical difficulties are available to confound the process. For example, safety devices that normally reduce Risk may sometimes compromise it [Ref. 12]. Consider the following situations.

- Emergency Stop Controls that normally enhance safety by shutting off electrical power may eliminate the braking capability of machines that depend on reverse-plugging.
- Adding new punch presses with single stroke safety devices to a shop filled with presses without this capability, is dangerous when operators are interchangeable.
- A machine with ten hinged guards requires that workmen remain vigilant to ensure motionless behavior during maintenance. If

nine of the guards are interlocks an operator might assume that all guards are interlocked.

Risk Function f

Can severity and exposure, each with a different metric, be combined empirically or analytically to represent safety? Further, if a safety function or a risk function f does not exist, can the field of safety represent itself as a profession as opposed to a craft? It should be noted that proposals have been advanced that risk, or danger, or safety should be defined as

$$Risk = Severity \ x \ Exposure \tag{3}$$

For example, Friend and Kohn have adopted this equation without proof [Ref. 13]. No research supports this simplistic thesis. Does one unit of severity have the same effect on safety as one unit of frequency or exposure? All the speculations in this paper on the form of f are satisfied by Equation 1 even though it is not valid.

<u>Risk</u>

Risk is calculated numerically in units imposed by the risk function f. This number must now be interpreted for a given artifact by comparing its Risk to a value system to evaluate the following questions:

- Is the Risk acceptable (how safe is safe enough)?
- What is the residual risk, i.e., the remaining risk after protective measures have been taken?
- Is there a less costly alternative design with an acceptable risk?
- Is the Risk reasonably foreseeable?

The following sources may be valuable for establishing the acceptability of a calculated Risk:

- Consensus Value Systems (ANSI, State-of-the-Art)
- Regulatory Value Systems (OSHA, CPSC, ISO)
- Legislative Value Systems (Building Codes)
- Judicial Value Systems (Case Law)

5. Remarks

A. Technology has failed ignominiously to produce a definition of safety or its counterpart risk that will provide a protocol for the quantitative determination of risk. We are a pipe-dream away from accomplishing this task.

- B. Without research support, technologists have cobbled a Risk-Matrix that provides very rough levels of estimated risk. The protocol depends on concepts that are more abstract than risk itself; e.g., hazard severity, hazard exposure, reasonably foreseeable misuse, human error, utility, reliability, human factors, warnings, and robustness to name a few.
- C. From the point of view of defining safety, the technical Risk-Matrix method is just as subjective as the product liability theories. These impoverished underpinnings have impeded the growth of safety philosophy.
- D. Theoretically, the best qualitative safety definition is provided by Compliance or Non-Compliance with safety standards, codes, or regulations. This is especially true of C-Type standards that provide specifications for a given category of machinery [Ref. 14]. When compared to product liability theories, standards, codes, and regulations present a priori considerations that have certitude, objectivity, and expertise not readily attributable to the concept of "reasonable man,"
- E. Without research, safety will remain an art form.

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