

## Product Safety Standards

A standard is a set of characteristics or quantities that describe features of a product, process, service, interface, or materials. Standardization is useful for product safety management and product liability prevention. Standards may provide useful information to product designers, and promote a uniform level of safety between similar products. This level of safety may be used when judging the reasonableness of the actions taken by different product manufacturers. Conformance to standards is also useful in evaluating the degree of control that a manufacturer has over its production operations. This report provides information about the U.S. standards-making process, and the benefits and limitations of standards with respect to product safety and product liability.

Product manufacturers frequently incorporate product safety standards into their product designs. These standards may define the way that a product is to perform or detail specific product characteristics. The standard may be developed internally by the manufacturer or by an independent standards developer.

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This report provides information about the U.S. standards-making process and the benefits and limitations of standards with respect to product safety and product liability.

### Definition of Standard

There are numerous formal definitions for the term “standard.” One definition, developed by the U.S. National Standards Policy Advisory Committee, is:

*“A prescribed set of rules, conditions or requirements concerning definitions of terms; classification of components; specifications of materials, performance, and operations; delineation of procedures; or measurement of quantity and quality in describing materials, products, systems, services, or practices.”*

Another definition, from the International Organization for Standardization (ISO) Guide 2: 1996, is:

*“A document, established by consensus and approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.”*

These definitions show the broad range of uses and meanings of the term. A more useful, working definition of a standard is simply “a set of characteristics or quantities that describe features of a product, process, service, interface, or material.”

## Types of Standards

Standards may be classified several different ways. They may be classified by their purpose, their formality, their intended audience or developer, or by the way by which they specify requirements. Also, standards may be classified based upon whether compliance with the standard is voluntary or mandatory. The following sections describe several aspects of these classification schemes.

### Purpose

Standards may be used for a variety of purposes. They may be used to define fundamental concepts, such as terminology, metrology (i.e., units of measurement), signs and symbols, conventions, etc. They may be used to define the test methods and analyses that will be used to measure a specific product characteristic. They may be used to define product characteristics or specific performance thresholds that must be reached, such as safety requirements, interoperability requirements, or basic fitness for use.

### Mandatory v. Voluntary Standards

Mandatory standards are standards that have been published as part of a code, rule, or regulation by a regulatory government body. Manufacturers are legally obligated to comply with these standards and will receive governmental sanctions (e.g., fines, confiscation of product, or imprisonment) if they do not comply. An example of a mandatory standard is the U.S. Consumer Products Safety Commission (CPSC) flammability standard for fabrics used in clothing.

A voluntary standard is a standard that may be used at the discretion of the product manufacturer and the lack of use will not result in governmental sanction. Voluntary standards may be developed by individual companies, industry groups, or by key market participants. They may be developed by formal procedures or may be informal standards that become adopted by the marketplace. When voluntary standards are formally derived by a consensus of key market participants, they are called voluntary consensus standards.

Voluntary standards may attain the effect of mandatory standards if they are referenced in codes and standards adopted by government bodies. The National Electrical Code (NEC) is an example of this. A private organization, the National Fire Protection Association (NFPA), develops and maintains the NEC for use by its members. It has been adopted as a regulatory requirement by all states, making compliance with the standard mandatory.

A good description of the practical difference between mandatory and voluntary standards is the following: “A voluntary standard indicates the lowest safety level that an industry or manufacturer tends to meet in the product it supplies. A mandatory standard indicates the lowest safety level that the government will accept.”<sup>[3]</sup>

### Design v. Performance

Design standards, which are also called specification standards, are standards that define product characteristics in terms of how it is to be constructed. For example, the standard may include the dimensions of the product, the materials that must be used, the finish that must be provided, specific precautionary labeling, or other detailed criteria that must be met for the product to conform to the standard. Manufacturers must build their products according to these specific requirements in order to conform to the standard.

Performance standards are standards that define a product’s characteristic in terms of how it is to function and defer to the designer

the issue of how to achieve this functionality. For example, the standard might require that a product be designed to withstand a certain imposed force, but not specify a specific method for achieving this requirement. Because performance standards provide fewer restrictions than design standards, they are considered less restrictive to product innovation.

## Standards Developers

In the United States, both governmental agencies and nongovernment organizations develop standards. In addition to the developers themselves, many other groups participate in standards' development and dissemination.

### Government Agencies

The National Institute for Standards and Technology (NIST) identified 80 federal government agencies involved with developing standards in 1996. The Department of Defense (DOD) was the most prolific developer and was responsible for over three-quarters of all the standards.

The recent trend has been for federal agencies to adopt standards prepared by nongovernment groups, rather than preparing or revising their own work. Congress promoted this effort through the enactment of the National Technology Transfer and Advancement Act of 1996 (PL 104-113). This law directs federal agencies to focus upon increasing their use of voluntary consensus standards whenever possible to reduce federal procurement and operating costs.

### Nongovernment Organizations

In 1996, NIST identified over 600 nongovernmental organizations developing standards. Of these, approximately 500 were actively developing standards.

In general, product-related, nongovernmental standards developers can be divided into scientific and professional societies, trade associations, standards developing organizations,

and consortia. In addition, individual companies may develop standards for internal use.

Scientific and professional societies are individual membership organizations that support the practice and advancement of a particular profession—for example, the American Society of Mechanical Engineers (ASME). Several societies, particularly in the engineering disciplines, develop technical standards

Trade or industry associations are organizations of manufacturers, suppliers, customers, service providers, and other firms active in an industry sector. Many industry associations develop or sponsor the development of standards for the products manufactured by their members, or for products used by their industry. Examples of trade associations that develop product-related standards include the American Petroleum Institute (API) and the Electronic Industries Association (EIA).

Standards developing organizations (SDO) are membership organizations that are founded specifically to develop standards. They do not limit their membership to an industry or profession, and publishing standards and associated documentation accounts for the majority of their revenue. Examples of SDOs include the U.S. Pharmacopeial Convention and ASTM International (formerly the American Society for Testing and Materials).

Consortia are informal groups of standards developers that get together to address the specific concerns of their group. They are mainly used in the high-technology sector where advances outpace the development time of consensus standards, and are mainly involved in interface and interoperability standards.

### ANSI

The American National Standards Institute (ANSI) does not develop standards, but the private, nonprofit membership organization plays several important roles in administering and coordinating the U.S. voluntary standards system. ANSI sets guidelines for the develop-

ment and coordination of voluntary consensus standards, reviews and accredits many U.S. standards-setting organizations against these guidelines, and approves individual standards. Standards approved by ANSI are designated American National Standards. ANSI also represents U.S. positions in international standards activities.

Over 250 private organizations are ANSI-accredited standards developers. An electronic directory of these developers is available via the Accredited Standards Developer's web page on the ANSI web site, [http://www.ansi.org/rooms/room\\_16/public/accredit.html](http://www.ansi.org/rooms/room_16/public/accredit.html) (this document is in \*.pdf format and is a very large document [over 2MB] that will not download easily over 56K dial-up connections.).

## Voluntary Standards Development

The two most widely used methods for developing voluntary standards are the committee and canvass methods. Either method may be used to comply with the ANSI accreditation guidelines.

Under the committee method, a committee of interested parties is established to develop and maintain the proposed standard. Membership on the committees may be open to individuals within an organization or to all interested parties. When all parties that have an interest in the outcome of the standard have the opportunity to participate and no single interest dominates, the committee is considered to be "balanced." The procedures used to develop the standard itself will vary depending upon the organization developing the standards. These procedures typically address requirements for determining when consensus has been reached, due process, appeal of adverse decisions, and consideration of negative votes or comments.

The canvass method is used by organizations to gain acceptance for standards that they have already developed internally. The proposed standard is submitted to balloting by organizations representing a variety of interests. Any returned objections or comments must be addressed and satisfactorily resolved. The changes must then be reballoted and approved before the standard may be released to the public.

## Benefits of Standards

The use of standards in the design and manufacture of products can benefit product safety. Conformance to recognized standards might also be helpful in the defense of product liability claims.

### Product Safety

Conformance to product standards can improve product safety in several ways. The specific benefits will depend upon the type of standard.

The most important benefit is that product standards are an accumulation of the prior design work involving a product. This knowledge can be used to provide designers with basic safe design information so that they do not have to "reinvent the wheel." It may also alert designers to potential safety problems that they may not have considered.

Use of standardized designs and materials may ensure the compatibility of parts, materials, and processes between product manufacturers. This can reduce the need for specialized testing to ensure that a component meets the expectations of the designer.

Product standards may improve communication between product manufacturers and their component suppliers. Reference to a recognized product standard for a component replaces the need for a manufacturer to specify detailed performance criteria in supply contracts. Also, product standards may promote uniform criteria or methods for evaluating the performance of similar products made by different manufacturers.

## Product Liability

Compliance with product safety standards may be useful in the defense of product liability claims based upon negligence. The amount of usefulness will depend upon whether the standard is a mandatory or voluntary standard, and on the specific facts of the case. The key issue is whether the standard establishes a recognized duty, or standard of care, for the manufacturer.

A federal statute may impose a duty or standard of care or conduct on a product manufacturer and may pre-empt particular state statutes or rules of common law. Evidence of compliance with this standard may free a product manufacturer from product liability. The pre-emptive effect of federal product safety statutes on product liability claims is a fiercely litigated area and there is a substantial body of case law interpreting individual statutes.

Statutes, regulations, or ordinances may define a duty or standard of care without eliminating common-law negligence liability for defective products. Compliance with these mandatory standards may be used as evidence that the manufacturer acted in a nonnegligent manner. Conversely, in some jurisdictions, courts may consider evidence of noncompliance with a mandatory standard sufficient to render the manufacturer legally negligent.

In general, compliance with voluntary standards will not have the force of law and will not define a duty or standard of care. Compliance or lack of compliance with a voluntary standard will simply be another fact for the jury to consider when weighting the reasonableness of the manufacturer's conduct under the circumstance of the case. The adequacy of the voluntary standard will be at issue since such standards will not have the presumption of validity that a mandatory standard would have.

## Limitations of Standards

There are several important limitations to the use of product standards in product safety management and product liability defense.

There may not be any standards available, the standards that are available may be inadequate, and lack of timely review may render otherwise-adequate standards outmoded. Also, from a product liability perspective, in most case, compliance with a standard will not automatically bar product liability claims based upon negligence.

Many products are not covered by industry-wide safety standards. Either the products represent proprietary designs or there is not sufficient interest to develop a formal standard. The National Commission on Product Safety released a study in 1970 that found that, of the 44 product areas that generated the largest number of annual injuries, 26 were not covered by product safety standards.

The standards that are available may be inadequate. There are numerous types of inadequacies. The standard may not address all hazards associated with a product design. The requirements of the standard may be difficult to understand, lack detail, or lack completeness. Standards developed by a consensus process are by nature minimum standards. Also, lack of coordination between multiple standards may result in contradictory requirements.

Standards that are not reviewed and updated in a timely manner may no longer represent the "state of the art" for the product area. Strict compliance with such standards may actually cause the safety of a product to be lessened.

Most importantly, conformance to a standard will not be sufficient to defeat a claim that a product was negligently designed if it can be shown that a reasonable manufacturer would have taken additional precautions. This is to prevent situations where the level of safety is intentionally set low to insulate

the standard's user from liability. Also, compliance with a standard will be irrelevant if the product aspect that caused the injury was not addressed by the standard.

## Loss Control Recommendations

The following section information provides general recommendations for using standards for product safety management and product liability prevention.

Product manufacturers should identify all mandatory safety standards applicable to their product. These mandatory standards may include state, federal, or international requirements depending upon where the product will be marketed. Product designs should incorporate these requirements, and finished products should be tested for conformance to these requirements. Occasionally, a product design may advance the state of the art in product safety beyond mandated requirements and the design improvement may conflict with the mandated requirement. In such cases, the manufacturer should request a formal exemption or waiver from the requirement from the respective authority having jurisdiction. This documentation should be maintained in the product file along with the design technical information and materials to support the request.

Product manufacturers should identify any voluntary safety standards applicable to their product. Product designers should review the voluntary standards for adequacy. The standards review should be documented in the development file for the product. Manufacturers should consider adequate standards when designing products and reviewing product designs. Manufacturers should conform to voluntary requirements that improve the safety and operability of their product. An evaluation program should be established to assess the conformance of produced products to the design standards. Manufacturers should consider product certification of key safety features.

Product manufacturers should monitor standards' activity in areas affecting their products. This review should include new standards under development and standards being reviewed. Manufacturers should consider participating in the development and maintenance of safety standards affecting their products.

Product manufacturers should incorporate standard components, whenever feasible, to reduce the amount of specialized testing and conformity assurance required. They should also reference product standards in purchase orders and supply contracts, where applicable, to avoid confusion with suppliers.

## References

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