

Updated Standards

More Guidance for Warnings and Instructions

by Kenneth Ross

The ANSI Z535 set of standards dealing with product safety labels have been in existence since 1991. They have provided manufacturers with good guidance for the creation of safety labels, and where challenged, a pretty good defense. These standards are being revised and a new edition will be published in 2006.

Standards in Europe dealing with safety labels are also being revised. And there is an ongoing effort to harmonize the U.S. and European standards so that manufacturers can, if they choose, sell their products with one set of safety labels around the world.

In addition, the ANSI committee will be expanding the reach of the Z535 standards to include instruction manuals. A new part of the revised standards is set to be published in 2006, which will provide guidance on how to incorporate safety information contained on safety labels attached to the product into instruction manuals.

This article will discuss the U.S. labeling standards and how they will be revised, the

new standard on instruction manuals, and issues related to testing the comprehension of both warnings and instructions.

Basic Duty to Warn and Instruct

The Restatement (Third) of Torts: Products Liability ("Restatement") makes it clear that product sellers must provide "reasonable warnings and instructions" about risks that exist in their products. Restatement, §2(c), cmt. i.

The Restatement differentiates warnings and instructions as follows. "Warnings alert users and consumers to the existence and nature of product risks so that they can prevent harm either by appropriate conduct during use or consumption or by choosing not to use or consume." *Id.* Instructions "inform persons how to use and consume products safely." *Id.*

Additionally, it has been held that warnings, standing alone, may have no practical relevance without instructions, and instructions without warnings may not be adequate. See *Antcliff v. State Employees Credit Union*, 414 Mich. 624, 327 N.W.2d 814 (1982).

Therefore, when the law talks about the "duty to warn," it includes providing warnings on products in the form of safety labels, safety information in instructions, instruc-

tions that affirmatively describe how to use a product safely, and safety information in other means of communication such as videos, advertising, catalogs, websites, etc.

The law says that a manufacturer has a duty to warn where: 1) the product is dangerous; 2) the danger is or should be known by the manufacturer; 3) the danger is present when the product is used in the usual and expected manner; and 4) the danger is not obvious or well known to the user. See *Billiar v. Minnesota Mining and Manufacturing Co.*, 623 F.2d 240, 243 (2d Cir. 1980).

Once the decision has been made to warn, the manufacturer needs to determine whether the warning is adequate. Generally, the adequacy of a warning in a particular situation is a question of fact to be decided by the jury. There are a number of cases, however, where the court has generally described an adequate warning. The United States Court of Appeals for the Fourth Circuit in 1962 stated:

If warning of the danger is given and this warning is of a character reasonably calculated to bring home to the reasonably prudent person the nature and extent of the danger, it is sufficient to shift the risk of harm from the manufacturer to the user. To be of such character the warning must embody two characteristics: first, it must be in such form that it could reasonably be expected to catch the attention of the reasonably prudent man in the circumstances of its use; secondly, the content of the warning must be of such a nature as to be comprehensible to the average user and to convey a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.

Spruill v. Boyle-Midway, Inc., 308 F.2d 79, 85 (4th Cir. 1962). See also *Pavlidis v. Galveston Yacht Basin, Inc.*, 727 F.2d 330 (5th Cir. 1984).

More specifically, various courts and commentators have described a list of requirements and goals of an 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; and
- Provide instructions on how to avoid the hazard.



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The Restatement says that a court must focus on a warning's "content and comprehensibility, intensity of expression, and the characteristics of expected user groups" to determine its adequacy.

The use of terms such as "reasonably be expected to catch the attention of the reasonably prudent user" and "characteristics of expected user groups" makes it clear that, in the United States, the jury gets to decide the adequacy of warnings. Reported trial court and appellate court cases have not been particularly helpful because there are so many variables in hazards, avoidance procedures, and the skills and backgrounds of the readers of the warnings. See Kenneth Ross and Matthew W. Adams, *Legally Adequate Warning Labels: A Conundrum for Every Manufacturer*, For The Defense, October 1998 at 7.

Case law concerning the adequacy of instructions is also not particularly illuminating. Most of the cases talk about the adequacy of warnings either on the product or in the manual. In discussing the adequacy of instructions, the cases only say that manuals should be "adequate, accurate, and effective" and "clear, complete, and adequately communicated." See *Articliff, supra* and *Brousard v. Houdaille Industries, Inc.*, 183 Ill. App.3d 739 (1st Dist. 1989).

Thankfully, the ANSI Z535 standards in the United States have provided some good guidelines on creating safety labels and will provide useful information on how to incorporate safety information into instructions. Unfortunately, these standards only provide formats for labels and instructions. As a result, it is possible to comply with these standards and still have inadequate content, thereby resulting in potentially legally inadequate warnings and instructions.

Current U.S. Labeling Standard

ANSI Z535 was initially published in 1991 with revisions in 1998 and 2002. It provides the basis for developing a safety label system. Unlike some other labeling standards, ANSI Z535.4 sets forth performance requirements for the design, application, use and placement of safety labels. The purpose of this standard is

to establish a uniform and consistent visual layout for safety signs and labels applied to a wide variety of products." It is also designed to create a "national uni-

form system for the recognition of potential personal injury hazards for those persons using products.

ANSI Z535.4 deals with on-product safety labels and provides for a specific format label containing a signal word panel, word message panel and an optional pictorial or symbol panel. The messages required by the standard to be transmitted, with words or symbols individually or in combination, are: 1) nature of the hazard; 2) the seriousness of the hazard or probability that the user will encounter the hazard; 3) the consequences

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of encountering the hazard or the severity of the injury; and 4) how to avoid the hazard. These requirements are consistent with the case law that requires a label to convey the "nature and extent" of the danger.

The ANSI standard defines a symbol or pictorial as a graphic representation intended to convey a message without the use of words. It goes on to say that the symbol or pictorial may represent a hazard, a hazardous situation, a precaution to avoid a hazard, the result of not avoiding a hazard, or any combination of these messages. Z535.4 also states that symbols should be readily understood and effectively communicate the message. The case law also talks about labels that are "comprehensible" to the average user.

In 2002, the ANSI standard was changed to allow the manufacturer to use a symbol to substitute for all or a portion of the required word messages "if it has been demonstrated to be satisfactorily comprehended... or there is a means (e.g., instructions, training materials, manuals, etc.) to inform people of the symbol's meaning." ANSI Z535.4-2002, §11.2.

The original text of the ANSI standard did not allow a manufacturer to substitute a part of the message with a symbol unless the symbol had been tested to confirm that it was "satisfactorily comprehended." The 2002 change was meant to allow symbols to be placed on labels even if they haven't been

tested as long as they were described in the instruction manual.

However, while the 2002 ANSI standard allowed for symbols to take the place of words in the message panel, manufacturers realized that they should be careful before they relied on a symbol to fully communicate the message. Since symbols may represent a variety of messages, it would be unusual for a symbol to be able to replace all word messages that are generally required by the law or the standard.

Also in 2002, the ANSI Z535.3 standard, which deals with symbols on safety labels, was changed to add a reference to the type of symbols used in the European ISO standard. The revision said that the formats for symbols in the ISO standard "may be considered." This was the first attempt to harmonize the ANSI and ISO labeling standards.

ISO Labeling and Product Standards

The International Organization for Standardization (ISO) has a labeling standard, ISO 3864-2, that is very different from ANSI Z535. Symbols are the essential ingredient of this labeling system. Through the use of shape, colors, and symbols, ISO believes that each symbol can adequately communicate a safety message.

Such a system is preferable in Europe because there are many languages spoken and read in different countries and there are open borders that allow products to easily move from country to country. The result can be that for many products, the manufacturer may not know where the product will be used during its lifetime. Having symbols that transmit at least part of the message provides some warning of the hazard.

Another reason for the different systems is that, apparently, European employers provide more safety training on the job than in the United States. The result is that symbols don't have to be readily comprehensible to someone with no training. The assumption is that the employee encountering a symbol on a machine in the workplace will have been educated as to the symbol's meaning.

With consumer products, there are also government safety agencies in many European countries that are active in trying to educate consumers as to the meaning of safety symbols placed on consumer products.

In the United States, it is very different. Manufacturers generally can't assume that

the employee has had safety training, so good safety labels over the years have used word messages and symbols to try to communicate quickly and completely the entire message required by the law and the standards.

There is little attempt by the government and most manufacturers to try to educate consumers on the meaning of safety symbols. This is because most labels have word messages that transmit the entire message.

In any event, the ISO standard has developed a wide-ranging system of symbols that are intended to portray the entire message.

Given the development of the ISO standard and the desire of manufacturers to be able to use one set of labels for worldwide use, the ANSI committee revised the 2002 standards to further harmonize the ANSI and ISO systems in the area of symbols.

ANSI 2006 Revisions Related to Symbols

In Annex C to the current ANSI Z535.4, it says that "it may be possible for a safety sign or label to be in conformance with ANSI Z535.4 and an ISO standard." It didn't describe how it may be in conformance and the Annex is not an official part of the standard. As a result, while the committee in 2002 raised this possibility, it did not officially allow for the manufacturer to say that a particular label complied with both the ANSI and ISO standards.

This issue was addressed and resolved by the ANSI Z535 Committee in September 2005. The committee intends to include in the 2006 version language that will allow the manufacturer who sells in the United States to comply with the ISO standard and be able to say that they also comply with the ANSI standard. In a reference to ISO 3864-2, the new version of the ANSI standard will say that "[P]roduct safety information may be conveyed by ISO formatted safety labels in compliance with ISO 3864-2..." ANSI Z535.4, §3.1.1 (proposed revision).

The result of this revision is that manufacturers will finally be able to use symbol-only labels in the United States without running the risk of having a plaintiffs' lawyer claim that their label violated the ANSI Z535 standard. However, a fair reading of the standard is that a symbol-only label must still transmit the required messages.

The requirements in the law and in the ANSI standard for warning adequacy may

not be satisfied with some symbol-only labels. In some cases, it may be very hard to create a symbol that portrays all of the message requirements. Symbols are excellent at portraying the hazard and injury that can be suffered if encountering the hazard and, in some cases, not so good at portraying the severity of the injury, the probability that the injury will occur, and how to avoid the hazard.

Despite this, it is very possible that some symbols that do not transmit all of this information will be deemed legally sufficient without words because they provided enough information to put the reader on notice of a potential hazard and put the responsibility on the reader to get more information about the severity, probability, or how to avoid it.

Some courts have encouraged the use of symbols when potential readers are illiterate or do not read English. These courts feel that transmitting at least the hazard should be sufficient to put the reader on notice. This rationale can be made when symbol-only labels are used that do not contain the entire message.

However, some safety experts are skeptical about the use of symbol-only labels. The British Department of Trade and Industry (DTI) said:

Pictograms are not the language-free answer to written safety warnings. There is no clear objective evidence to suggest that they have any significant effect on ultimate compliance with safety warnings on products. Therefore the desire to decrease text information on packaging due to the internationalisation of markets must not take the route of language free pictorial warnings unless they have been proven to be effective across all the relevant cultures.

See S. Davies, *et al.*, *The Role of Pictograms in the Conveying of Consumer Safety Information*, Report to the Department of Trade and Industry Consumer Safety Unit, p. 31.

DTI mentioned that it is acceptable to use symbols if they have been "proven" to be effective. This probably means that the symbols have undergone comprehension testing with all relevant cultures where the product will be sold.

As more manufacturers decide to go to symbol-only labels, more of them are considering comprehension testing in the

United States and Europe. The ANSI Z535.3 standard contains a testing protocol for testing in the United States. There is also a specific ISO standard for testing the comprehension of symbols. This will be discussed below.

ANSI Standard on Instructions

No matter what the manufacturer does to meet its "duty to warn" with on-product labels, with most products some instructions will be required. Given the limited space on products and the ever-expanding need to warn about even remote risks, safety information in instructions is taking on increased importance.

With some products, there is only room for one label referring the user to the instructions that need to be read before the product is used. Some courts have allowed manufacturers to not put all warnings on the product, but instead attach one label to the product referring the user to all of the safety information in the manual. *Broussard v. Continental Oil Co.*, 433 So.2d 354 (La. App), cert. denied, 440 So.2d 726 (La. 1983).

The current ANSI Z535.4 standard has no requirement that instructions be provided. It merely says that if instructions are provided, they should discuss replacement and maintenance of safety labels.

The ANSI committee found that while there are a number of other guides or standards that discuss instructions, there are none dealing specifically with incorporating safety information into instructions and how to interrelate these instructions with ANSI Z535 safety labels.

Therefore, it established a new subcommittee that has drafted a new part of the standard, ANSI Z535.6. This new standard was approved by the committee in September 2005 and will be published in 2006. The purpose of the new standard is as follows:

- ...(1) address the applicability of elements of other ANSI Z535-series standards to collateral materials,
- (2) establish a uniform and consistent visual layout for safety information in collateral materials for a wide variety of products,
- (3) minimize the proliferation of designs for safety information in collateral materials,
- (4) establish a national uniform system for the recognition of potential personal injury hazards for those persons using products,
- (5) assist manufacturers in

providing safety information in collateral materials, and (6) promote the efficient development of safety messages in collateral materials.

ANSI Z535.6, §2.2 (proposed).

The standard applies to all “collateral material” that accompanies a product but does not include safety information placed in advertising and promotional material, or audio or visual material such as safety videos and websites.

The new standard:

...sets forth a hazard communication system developed specifically for product safety information in collateral materials. It incorporates elements of the graphical approaches used by other ANSI Z535-series standards into a common design direction selected to provide product safety information in an orderly and visually consistent manner.

ANSI Z535.6, Introduction, §1 (proposed).

The standard provides requirements for the purpose, content, format, and location of four different kinds of safety messages:

- supplemental directives
- grouped safety messages
- section safety messages
- embedded safety messages

Supplemental directives direct readers to read the entire manual or to the safety information in the manual. They can be located on the cover of a manual or on the first page of a section in the manual. For example, while the standard doesn't specify any such language, a boxed message on the cover should say something like “Read this manual before using this product. Failure to follow the instructions and safety precautions in this manual can result in serious injury or death.” It should also say “Keep this manual in a safe location for future reference.”

Grouped safety messages are commonly referred to as a “safety section.” This section usually appears at the beginning of the manual, before or after the table of contents, and generally 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. If the product has symbol-

only labels, the manual should describe the meaning of all symbols.

Section safety messages are included at the beginning of a chapter (i.e., “Maintenance,” “Installation” or “Operation”) or within a chapter, and do not specifically apply to a procedure. They include general messages such as “Do not perform maintenance without first reading this chapter and the safety precautions at the beginning of this manual” or “Failure to follow safety precautions in this chapter could result in serious injury or death.”

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Embedded safety messages are contained within a specific procedure. For example, “To prevent burns, wear protective gloves when performing this procedure.”

These different kinds of messages have been in use for decades (a military standard from many years ago required a safety section in instruction manuals for products sold to the military), so many manufacturers' manuals will not change significantly. However, for the first time, the ANSI committee is giving guidance, which didn't exist before in the ANSI standards, on how to locate and format the Z535-related information in the text of the manual. Those manufacturers whose manuals did not do a good job of incorporating safety information will now have good guidance on incorporating Z535 safety information into future editions of their manuals.

In addition to this new standard, there are many other sources of good information on instruction manuals that are readily available on the Internet. The U.S. Consumer Product Safety Commission has a booklet entitled *Manufacturer's Guide To Developing Consumer Product Instructions* that was published in October 2003. The British Department of Trade and Industry published an excellent booklet called *Writing Safety Instructions for Consumer Products* in November 1998. In 1993, the FDA published *Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices in Home*

Health Care that incorporates ANSI Z535 concepts. In addition, there are several useful guides available for purchase: *ANSI Guide for Developing User Product Information* (1990) and *Instructions for Use of Products of Consumer Interest*, ISO Guide 37 (1995).

With the passage of this new part of the standard, the ANSI committee will have produced a useful guide to accompany the other publications listed above. As technological capabilities continue to develop, however, the standards groups, including ANSI, must move forward.

Today, providing more interesting, compelling and understandable safety information can be transmitted by video, CDs and webcasts, in combination with written literature. The challenge for manufacturers in the future will be to provide information in a way that is more likely to be read. While the law doesn't specifically require it, it is important for manufacturers to consider doing more to encourage people to read or view their instructions and to use their products more safely.

Testing Labels and Manuals for Comprehension

There are no legal requirements for a manufacturer to test its warnings or instructions for comprehension or effectiveness before they are used in the market place. While the case law talks about labels that are “comprehensible,” that does not mean that they must have been officially tested to prove it.

The ANSI standard, Z535.4, and a related standard, Z535.3, discuss testing of symbols on labels for comprehension. In fact, in Annex B, which is not an official part of the standard, Z535.3 has a suggested procedure for evaluating new symbols. However, the ANSI committee is not testing or gathering tested symbols for general use by manufacturers.

ANSI Z535.4-2002 says that a symbol may only be used to substitute for a portion or all of a word message if it has been demonstrated to be satisfactorily comprehensible (such as passing the test in Z535.3) or if instructions inform product users of the symbol's meaning.

But none of the current or revised standards, including ANSI Z535.6, provide guidelines for evaluating the comprehensibility of the word messages contained in warnings or instructions. Since most warnings today

contain words and some contain words and symbols, when a manufacturer is considering testing, it is important to consider when and if the symbol *and* words should be tested for comprehension.

Many communications experts and human factors experts have developed their own methodology for performing tests which study the comprehension of words and symbols. Some test procedures have evolved from ISO 9186 and from an Australian standard, both of which are referred to in Annex B to ANSI Z535.3.

As a result of the above, manufacturers would appear to have a great deal of flexibility in deciding whether to test their safety messages for comprehension and how to perform the test. Deciding when to test, however, is a difficult question. The decision must be based on a number of factors including the similarity of the newly developed label to prior labels or labels by competitors or whether the symbol and word messages are significantly different from other labels that appear on the manufacturer's products or other products.

Familiarity does not necessarily breed understanding and it is possible that a symbol, although used for many years by a number of manufacturers, may still not be understandable. As a result, deciding whether a manufacturer should rely on previously used labels will depend on that manufacturer's analysis of whether it is likely that the label will be deemed legally adequate in the future.

The best advice I have been able to glean from the various experts, and from my own experience, is that a manufacturer should consider testing the label if it might be helpful in answering the question: "What did you do to be sure that the label or other safety information you provided with your product would be understood by the reasonably foreseeable user?"

In many cases, if a label has been in use for many years, and no claim has ever been made that the warnings or instructions are inadequate or unclear, then testing probably is not necessary. Actual field experience can be used to show that the labels are understandable, and in some situations (e.g., new labels), the question might be better answered by the use of simple common sense rather than testing. In some cases, a full blown study might need to be per-

formed. This decision must be made by the manufacturer along with legal and communications professionals who can help analyze the necessity to test and the extent of the test if one is appropriate.

Use of Test Results in Litigation

Research and my informal survey have identified some litigation where such testing has been done by manufacturers during product development, or done by plaintiff's experts or defense experts, to challenge or defend the adequacy of the label.

In one situation, a plaintiff hired a communications expert to perform a study *after* the accident to support the expert's opinion that the warning was not understandable or effective for the foreseeable user. In another situation, a plaintiff's expert observed the manufacturer's products in use and saw that no one complied with the label's requirements. In those situations, a manufacturer must retain its own expert to rebut the plaintiff's expert's study and opinion concerning the understandability and effectiveness of the label.

In other cases, defense experts say that tests done during product development have been very helpful in convincing the plaintiff's attorney to not bring a failure to warn claim. Test results could be used by the in-house engineer or product designer to help describe why the product and its warnings and instructions turned out the way they did. The fact that a study was done provides testimony about how careful and concerned this manufacturer was in trying to produce a product that was reasonably safe.

In addition, the study could be used by the manufacturer's outside warnings expert to bolster the expert's opinion as to the adequacy of the label. Even if the report itself could not be admitted into evidence (and there might be a good reason not to have it admitted), the expert should be able to use the report as one basis for their opinion.

Many defense counsel may be reluctant to advise their clients to have such tests performed. Obviously, the test might show that the warning developed or proposed by the manufacturer is not understandable to foreseeable users. In addition, the study might show that no warning would be understandable for this particular product. If such is the case, the manufacturer would hope-

fully react responsibly and either re-design the product or re-design the warnings and instructions or, in some other way, better communicate the important safety information.

As long as the accident occurs, it is possible for a jury to believe that the warning was not adequate. Even if a test was done during label development, the plaintiff could always find an expert who will say that more people should have been tested, or different people should have been tested or different words would have made a difference. Despite this, the manufacturer should do what they believe is appropriate in trying to confirm the understandability of the label.

Conclusion

Allegations of inadequate warnings and instructions are dangerous because it is so easy for a plaintiff to argue that the manufacturer should have done something different. If the label had words, then all they had to do is add a few more words and the accident would not have happened. If there are only symbols, then the plaintiff didn't understand it and all they had to do was test the label for comprehension. The remedy is cheap and simple and it may be hard to defend a particular label given a serious injury and sympathetic plaintiff.

There is a similar argument for instructions, either in the form of manuals that accompany the product or that exist on a website. The plaintiff couldn't understand the information, or it was inconsistent with the label and they became confused, or it didn't have certain information.

Manufacturers, with the assistance of counsel who are familiar with the law and practice in the area of warnings and instructions, should be sure to comply with any applicable standards that apply to safety communications. And, they should not do any testing without carefully analyzing whether such an effort is truly necessary and appropriate.

Manufacturers can certainly use symbol-only labels in the United States and not violate ANSI Z535. Compliance with a voluntary standard, however, is not an absolute defense. Therefore, they need to be prepared to prove how the symbol transmitted the required information.

As more and better warnings are placed on products and more safety information

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is created in manuals and elsewhere, plaintiffs' experts will attack the adequacy of the labels on understandability and effectiveness. Every manufacturer needs to be prepared to rebut this argument by any available means. **FD**