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PRODUCT SAFETY LABELING: HARMONIZATION OF U.S. INTERNATIONAL STANDARDS IS ON THE HORIZON

By Geoffrey Peckham†

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I. INTRODUCTION

The use of symbols on product safety signs and labels is indicative of momentum toward harmonization of U.S. and international standards. To give readers practical information about what is occurring in the field of safety labels, this article discusses the importance of symbols on product warnings, reviews the primary international and U.S. standards in use, and examines issues relevant to harmonizing those standards. It must be understood from the outset that I am not a legal scholar with years of litigation experience to bring to bear on this subject. Instead, I have the knowledge gained from playing a leading role in several of the key standards committees dealing with this subject at this time, and the practical experience of supplying 1200+ manufacturers in over 60 different industries with safety labels for their capital equipment products.

At root, the essential function of a product safety label is to

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communicate hazard information that allows a person to safely use or service the product. In addition to improving the safety of the product, safety labels also play an integral role in preventing product liability loss exposure and obtaining CE certification so a manufacturer can sell their products into Europe. Since the safety label is such a visible part of a product, using the wrong label format in a given market broadcasts the fact that a manufacturer is not in compliance with the appropriate standards. With the advent of a global economy and multi-ethnic populations, new issues are introduced into the safety label equation. Ten years ago when U.S. manufacturers were developing safety labels their primary concern was to meet their legal duty to warn. Now these same manufacturers must also address questions concerning how their products fit into an international market, which standards apply to this larger marketplace, and using these standards in a way that best conveys safety information to the ultimate user of the product.

II. THE ANSI Z535.4 STANDARD

To set the stage for this discussion, we must first look back to 1991 when the ANSI Z535.4 Standard for Product Safety Signs and Labels was first published. Before this time, there was no overall standard relevant to the format and design of safety signs for use on products. Most manufacturers developed their own safety sign designs, or borrowed the 1972 ANSI Z35.1 sign designs used by OSHA for environmental and facility safety signs (the Z35 standard was the precursor to the Z535 standards and was the basis document for the OSHA regulations on safety sign formats). The result was a proliferation of product safety sign designs, colors, and messages. The 1991 publication of the ANSI product safety sign and label standard was of significance to manufacturers because, for the first time, there was a single cohesive standard that could be used for the development of the majority of product warnings. ANSI Z535.4 defined its purpose in Subsection 2.2:

—To establish a uniform and consistent visual layout for safety signs and labels applied to a wide variety of products.
—To minimize the proliferation of design for product safety signs and labels.
—To achieve application of a national uniform system for the recognition of potential personal injury hazards for
those persons using products.

ANSI Z535 brings a degree of standardization to safety sign formats, colors, signal words, and symbols. The theory behind the Z535 standards is that standardizing the formats, colors and symbols found on safety signs and labels leads to better comprehension, and that better comprehension should lead to fewer accidents. There are those who contend that no matter what approach is taken, safety signs and labels will be ignored; that you cannot prove that warnings prevent accidents because, at root, you cannot change a person’s behavior with a label. The other side to this argument is that we never hear of all of the accidents that did not happen because a warning was heeded. Since human motivation and compliance with a warning is not easily measured, the best we can hope to achieve with a warning label is clear communication of the essential hazard and avoidance information. Standardizing the components of safety labels helps to achieve this goal.

A by-product of the standardization of product safety signs is that the ANSI Z535 standards offer U.S. manufacturers an officially recognized state of the art for product warnings and thus a defense against product liability. Prior to the ANSI Z535.4 standard, many warnings could be challenged in court as inadequate. As readers of this article well know, inadequate warnings and "failure to warn" are leading allegations in product liability lawsuits in the United States. A decision to apply the ANSI Z535 standards can do much to reduce product liability exposure. Yet compliance with the correct standards does not, in itself, satisfy a manufacturers’ duty to warn. Instead, their obligation is to meet or exceed the applicable standards.

III. THE ANSI Z535.4 FORMAT

A brief summary of the ANSI Z535.4 format for a product safety sign is necessary in order to understand how proposed changes might influence its use. At this time, an ANSI Z535.4 label consists of a signal-word panel, a word-message panel, and an optional symbol panel in either a vertical or a horizontal configuration. Figure 1 illustrates a vertical version. The Z535.4 standard names four items of content that should be communicated by a product safety sign:
—The nature of the hazard.
—The degree of hazard seriousness.
—The consequences of involvement with the hazard.
—How to avoid the hazard.

Signal Word / Color
(Seriousness level)

Pictorial - Optional
(Usually hazard, description and consequence information)

Word Message
(Hazard description, consequence and avoidance information
(sequence and inclusion of all statements is optional).

Figure 1 – A typical ANSI Z535.4 safety label

Of the four key components that make up an ANSI Z535.4 product safety sign or label the first is the signal word; the large word in capital letters on a colored background appearing at the top of the sign. The second component is the colored background behind the signal word. DANGER appears as white letters on a red background, WARNING as black letters on an orange background, and CAUTION as black letters on yellow. Each signal word with its corresponding background color communicates a different level of hazard seriousness. DANGER indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury. This signal word is to be reserved for the most extreme situations. WARNING indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury. And CAUTION indicates a potentially hazardous situation that, if not avoided, may
PRODUCT SAFETY LABELING

Two determinations underlie the choice of the appropriate signal word for a product's safety sign. First, what is the severity of the hazard? If serious injury or death could result, then the choice is between DANGER and WARNING. Then, what is the likelihood that injury will occur if the safety sign's message is ignored? If there is a sense of certainty that serious injury or death will be the result of interaction with the hazard, and that this outcome will occur if the hazard is not avoided, then the signal word DANGER is called for. If injury or death is only a possibility, then the signal word choice should be WARNING.

Note that in the 1998 revision of ANSI Z535.4 CAUTION without the safety alert symbol (the triangle containing an exclamation mark placed to the left of the signal word) is used to indicate hazards that might result in property damage only. This change was made because the safety alert symbol is by definition used to indicate a potential personal injury hazard. The revision now properly limits the use of the symbol to safety labels concerned with alerting people to hazards involving personal injury. The expected 2001 revision of Z535.4 will maintain this distinction for the use of CAUTION for safety signs and labels.

The symbol and the word message are the third and fourth key components of an ANSI Z535.4 safety label; communicating the nature of the hazard, its consequences, and how to avoid it. The ANSI Z535.4 standard makes the use of symbols optional. However, the ability of symbols to communicate across language barriers and the attention-getting speed with which they convey hazard information often make them an integral part of a product (no hyphen) safety labeling program.

The word message typically conveys the hazard description, consequence, and avoidance information. When developing the word message, one must take into account Footnote 2 in the ANSI Z535.4-1998 standard which says, "When information on consequence, avoidance or type of hazard is readily inferred, this information may be omitted from the message panel." Thus, typically a word message would have all three items of content but it does not have to if a portion of the message can be inferred (e.g. inferred from the symbol, other text messages, user training, the context in which the safety label is used). It is necessary to understand this point because the ANSI Z535.4 also says that the word message should be "concise and readily understood." The art of developing
a good safety label is in finding the balance that efficiently communicates the essential information. Unfortunately in practice, those who write safety labels often tend to ignore the requirement that the word message be concise and the essential safety information gets lost in a label that contains too many words. To avoid this situation, the Z535.4 standard allows the manufacturer to refer the product user to the proper instruction manual for additional safety information. It is in this way that manuals can be used to provide a more complete picture of the safe use and servicing of the product. An example of such a label design is shown in Figure 2.

![Figure 2 - A typical "Read and understand manual" label](image)

In practice, the ANSI Z535.4 standard works extremely well. It is firm in its definitions and yet flexible enough to accommodate the great majority of product safety label applications manufacturers confront. Since 1991, many industry-specific safety sign standards have been revised to conform to the Z535.4 format.

One of the more important changes to note concerning the Z535 standards is that both the Z535.2 Environmental and Facility Safety Sign standard and the Z535.5 standard for Accident Prevention Tags were revised in 1998 to express preference for the use of the Z535.4 format over the old Z35 (OSHA) formats. If the 2001 draft proposals of the Z535.2 and Z535.5 standards are accepted, only the Z535.4-style format will be permitted in the Z535 standards. Thus, the DANGER in an oval sign, overall orange WARNING sign, and overall yellow CAUTION sign formats that were included in the original Z35 standard will no longer appear in the Z535 standards. The effect of this change is that the United States will be
moving closer to the realization of a single national uniform standard for hazard recognition.

Figure 3 – Old-style Z35 / OSHA formats will most likely not appear in the Z535 2001 standards

IV. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

Before looking at how symbols fit into the safety label development process, let’s look at the current direction ISO (International Organization for Standardization) standards are taking in the area of safety signs and labels. Five years ago, the gulf between the U.S. and ISO standards for product safety labels seemed too wide, and the conditions the standards were meant to address seemed too different, to sustain optimism about obtaining any measurable degree of harmonization. But now, through tough negotiating and a greater appreciation for each other’s safety label systems, the United States and Europe are on the verge of creating revised ISO and ANSI standards that each incorporate the other’s formats as well as harmonized formats that combine elements from
both standards. The Machinery Directive and EN standards concerning machinery are used here to illustrate the direction Europe is following with regard to safety labeling, but much of the discussion is relevant to other types of products as well.

A. An International Perspective: Symbols, CE Compliance And ISO Standards

The first thing to understand is that symbols are the essential ingredient of international safety signs and labels. Pictogram, pictorial, symbol - with reference to safety labels, all describe the same thing: an illustration that defines a hazard or an action to take to avoid a hazard. Well-designed symbols are able to communicate information quickly and to do so across language barriers. Text-message-only safety labels are practically meaningless to product users who are illiterate or do not speak the language of the label text. This is why symbols are considered to be the state-of-the-art for communicating hazard information.

The Machinery Directive 98/37/CE actually states a preference for a symbol-based system of safety labeling, saying in Annex 1 pertaining to the essential health and safety requirements of machinery design and construction:

Where risks remain despite all the measures adopted or in the case of potential risks which are not evident...the manufacturer must provide warnings. Such warnings should preferably use readily understandable pictograms and/or be drawn up in one of the languages of the country in which the machinery is to be used, accompanied, on request, by the languages understood by the operators. (Paragraph 7.2)

Symbols are preferred to text-based warnings because there are huge practical problems involved with conveying safety information in multiple languages. The ability of symbols to communicate across language barriers is an important benefit in Europe where many languages exist and products often cross borders when they are sold and even during their use.

The citation from the annex to the directive brings up the question of which hazards require warnings. Presumably, the product manufacturer has performed a risk assessment (see EN 1050) before deciding to apply warning labels. This process involves eliminating or reducing risks stepwise. If the hazard cannot be designed out of the product, use safeguarding. If the hazard cannot
be guarded, warn about it. This prioritized three-tier approach to protecting users from hazards is well known and widely used throughout the United States. But even if the hazard is guarded, a warning on the outside of the guard may be necessary because the hazard may not be evident (ref. Machinery Directive Annex 1.7.2); that is, the guard may block the hazard from view. It is becoming more and more common to place safety labels both on a guard and in a location underneath the guard in case the guard is removed (see Figure 4).

![Figure 4 - Typical "Under-guard" labels, ANSI and ISO approaches](image)

B. European Norms

European Norms (ENs) are standards written to give specific guidance. They are used to ensure that the requirements set forth in European directives are fulfilled. A more exacting European perspective on the issue of warnings and text appears in EN 292-2, Safety of Machinery - Basic Concepts, General Principles for Design, which states that "Markings, signs and written warnings shall be readily understandable and unambiguous, especially as regards the function(s) of the machine which they are related to. Readily understandable signs (pictograms) shall be used in preference to written warnings" (Paragraph 5.4(c)). This norm clearly indicates that CEN (the European Committee for Standardization, the body responsible for EN 292-2) prefers symbol-based safety signs. Its vocabulary shows that, to the Europeans, signs and pictograms are the same thing. A safety sign is a symbol.

Problems arise from the statements concerning safety labeling found in the Machinery Directive and EN 292-2. The qualification
that the pictograms be readily understandable makes sense but can be difficult to achieve in practice. Several factors are involved: First, it is preferable to use an existing symbol if one can be found for the hazard in question. Yet no single standard illustrates a large number of the available safety-related graphics. Finding the appropriate graphic for a specific hazard can be a daunting task in and of itself. Next, because standardized graphic design leads to higher symbol recognition, it is essential that, if a new symbol must be developed, the right graphic design principles be employed to properly depict the hazard or hazard avoidance information. Again, the problem lies in the fact that no general ISO standard exists that defines a method for designing safety-related graphics. Third, the quoted documents say that symbols must be readily understandable but describe no method for ensuring that they will be comprehended. And is comprehension testing mandatory? If so, then the national standards of many European countries are questionable, because the vast majority of symbols appearing in them have never been tested for comprehensibility.

The Machinery Directive and EN 292-2 set the mandatory legal requirements machinery must meet to be sold in Europe. Individual national standards and CEN have agreed to give ISO and IEC authority over the realm of safety signs and symbols. Work currently under way in ISO Technical Committee (TC) 145 is of critical importance to the quest for standardization in this area. A European perspective, unsurprisingly, dominates ISO/TC 145; of 13 members, 9 are European. Thus, the concerns of U.S. manufacturers must often struggle to be understood.

V. ISO/TC 145 AND ISO 3864

ISO/TC 145 is in charge of several standards involving graphical symbols, including ISO 3864, Safety Colours and Safety Signs, the principal international standard concerned with the appearance of safety signs. This standard was last published in 1984. The technical committee has been working on its revision since 1996.

FORMATS. ISO 3864 defines four basic formats for safety signs, which are illustrated in Figure 5. Through a vocabulary of shape, color, and symbol, each format communicates a particular type of safety message. The blue-and-white circular mandatory-action and yellow-and-black triangular warning sign formats are unfamiliar to many people in the United States, though more and more manu-
manufacturers are using them or considering them for use in the near future. The one ISO 3864 sign format that does have a high comprehension value in the United States is the prohibition symbol. However, it is now used to indicate many types of activities prohibited for reasons having little or nothing to do with safety.

Figure 5 – ISO 3864 Safety Sign Formats (clockwise from top) Warning Sign, Prohibition Sign, Mandatory Action Sign, Safety Information Sign.

At the ISO/TC 145 plenary meeting in Lisbon in March 2000, production of a guideline for the development of safety symbols was discussed at length. The need for such guidance was illustrated with the example of how the prohibition sign is used to indicate prohibitions that are not safety messages: Does the No Smoking sign serve to secure the comfort of nonsmokers, to indicate long-term health risk, or to indicate an immediate hazard, such as a possible explosion at a gas station? Other ways to signify negation or prohibition include placing an X or a single diagonal bar over the
Might these design elements be more appropriate for the No Smoking symbol than the prohibition circle with slash when a non-safety message needs to be conveyed in symbolic form? Committee members at the Lisbon meeting decided to proceed with the development of a graphical symbol design guideline that would cross the boundaries of several standards to assist those who design and apply safety signs and labels.

VI. REVISION OF ISO 3864

In order to better define its application, ISO 3864 is divided into three parts in the proposed revision:
—Part Two: Safety Signs in Workplaces and Public Areas·Overview of Standardized Safety Signs.

Part One and Part Two are intended for signs found in buildings, on walls. The U.S. technical advisory group (TAG) has taken the initiative of informing the other country delegations about the special signage requirements of products. Understanding that providing safety information on products raises distinct issues, TC 145 decided to expand upon the principles defined in ISO 3864 Part One in a separate part of the standard covering the requirements for product safety labeling. Importantly, the United States is in charge of the drafting of Part Three of ISO 3864. One of the significant accomplishments of the U.S. TAG has been the acceptance for ISO 3864 Part Three of the ANSI Z535 formats. This will enable U.S. manufacturers to use identical formats for both their domestic and international safety labels.

The decision to create a catalog of symbols for inclusion in ISO 3864 Part Two is a major step forward in the attempt to standardize symbols across many industries. At the March 2000 Lisbon meeting, TC 145 resolved to develop standardization procedures and design guidelines for safety symbols similar to the standardization of function and control symbols in ISO 7000, Graphical Symbols for Use on Equipment, another of its standards. Comprehension testing will most likely be a step in the procedure that qualifies a symbol for inclusion in ISO 3864 Part Two. Having a set of standards that collects the symbols, provides design guidelines, and uses comprehension-testing procedures will help to alleviate the problems relating to compliance with the Machinery Directive and
EN 292 noted earlier.

One major point of contention has been the insistence of the European ISO/TC 145 delegations that the standard surround shape and color be maintained for the symbols to be used on product safety signs. Their concern is rooted in the fact that their visual vocabulary of signage defines a safety sign in terms of shape, color, and symbol combined in a single unit. Most U.S. symbols now have no surround shape and color. A compromise has been incorporated into the working draft of ISO 3864 Part Three to the effect that any symbols standardized in Part Two will maintain their surround shape and color if they are used on product safety labels. For example, the lightning bolt that symbolizes an electrical hazard would always appear on a product label within a yellow-triangle-with-black-band surround shape.

Another ongoing debate within ISO/TC 145 concerns the need for comprehension testing and education to ensure that people understand standardized safety symbols. The considerable cost of undertaking symbol-comprehension testing programs cannot be borne by the ISO committee; industries must come forward to sponsor the work. It is quite possible that a core group of cross-industry symbols will be standardized initially, and that subsequent sets of symbols will be included in ISO 3864 as specific industries come forward to sponsor symbol development and comprehension testing.

A fourth part may be added to ISO 3864 to collect product-related safety symbols, or the scope of Part Two may be revised to include such symbols. The issue of the necessity for surround shape and color will probably be a contentious element of this decision, too, if ISO/TC 145 accepts the responsibility for standardizing all product safety symbols.

A side note: The IEC standard 1310-1, Safety of Machinery - Indication, Marking, and Actuation (1995), sets forth the requirements for visual, auditory, and tactile signals for machinery. The section of this standard that contains safety sign formats gives some examples of ISO 3864-formatted signs, several of which would never actually be considered for machinery. That is because this section of IEC 1310-1 was copied from an early draft revision proposal for ISO 3864. After ISO/TC 145 completes its revision of ISO 3864, IEC 1310 probably will be revised accordingly and its presentation of symbols reduced to those pertaining to machinery. The symbols that remain will also be in accordance with the new ISO
VII. HARMONIZATION OF PRODUCT SAFETY LABEL STANDARDS

Harmonization of U.S. and international safety sign design standards is complicated but possible. Back in 1995, the U.S. delegation to the standardization activities of the ISO felt that all it could achieve was possible harmonization of the colors and symbols stipulated in the ANSI Z535 and ISO 3864 standards. But as the revision process for both standards continues, both ANSI and ISO committees will likely accept a degree of flexibility in the safety label formats that are included. Final publication of the next revision of the ANSI Z535 standards is scheduled for December 2001. The various parts of ISO 3864 are also expected to be published in 2001.

The Z535 committee is considering revising the Z535.4 product safety label standard to allow the use of graphic-only ("non-word") formats that are identical to those defined by ISO 3864. A proposed addition to the foreword of the standard, after noting the international precedent, will say something along the lines of, "whether to convey some part of the necessary hazard communication with words and whether to include a signal word panel are choices based on many factors. Such factors include, but are not limited to, the product's anticipated market, the movement of the product from country to country during its expected life, the target audience's characteristics, the severity and risk of engaging the hazard, the difficulty of providing for translations, space limitations on the product, and common industry practices. It should be noted that as of this time, non-word product safety labels have not been tested in litigation."

If the proposal to include symbol-only label formats passes, it will break a 20-year tradition in development of this standard. Because of the important role product safety labels play in fulfilling manufacturers' legal "duty to warn," legal precedent to a large degree has governed the course of ANSI Z535. Even though symbol-only formats have not been subjected to this litmus test, in some situations such labels may prove to be more effective in their ability to warn than labels with words. Consider the warnings that appear on power tools. A small amount of space limits the text of warning labels to a barely legible size. Do people actually take the time to repeatedly read such warnings prior to using such tools? Most likely not. If well-designed symbols were used instead, their mes-
Sage could possibly be conveyed in a glance, thereby proving to be a superior method of communicating safety information.

In this light, permitting symbol-only formats in a revised Z535.4 standard would allow manufacturers the flexibility to determine the best labeling approach for any product. A key issue is the question of how manufacturers will choose to enhance or verify the comprehensibility of their symbol-only labels. Possibilities include comprehension-testing safety symbols prior to using them on safety labels, providing symbol-training materials to a product's users, and reinforcing of the meaning of safety symbols in product manuals.

Another approach to safety labeling that currently meets the ANZI Z535.4 standard and is under consideration in ISO 3864 is the "harmonized" format illustrated in Figure 6. By placing the symbol in the ISO surround shape and then placing this international "safety sign" in the symbol panel of a Z535.4 sign, the grammar and vocabulary of both standards are used. The harmonized safety sign format raises the question of whether translation of the label text is necessary when equipment manufactured in the United States ships to a non-English-speaking country. Many CE compliance services argue that the symbols on the sign constitute the international safety sign and that the text portion can be considered to be a supplementary sign and thus, does not need to be translated on the label. (Note that, because the message on the label is safety related, it would have to be translated in the product manual.) This seems like a workable solution; however, any manufacturer's decision concerning translation will ultimately depend on satisfying the desires of the customer and the market, as well as the CE-compliance consultant.
The U.S. and international product safety label standards are converging as efforts to standardize safety symbols and label formats continue. The United States is playing a major role in these developments because identification of product warnings is considered to be critical to U.S. manufacturers. Such standardization efforts are all the more important when, in an increasingly global economy, the use of common symbols to communicate safety information becomes practically essential.

For products now intended for use in the United States, it is highly advisable that safety labels comply with ANSI Z535.4, even though the standard is voluntary. Reasons related to both product safety and product liability support using its state-of-the-art guidance. At this time, most capital equipment manufacturers seem to use ANSI Z535.4 safety labels for equipment sold in the United States and ISO 3864 symbol-only safety labels on equipment for export. Such an approach supports compliance with existing U.S. and international standards. The harmonized format is now also starting to be used as manufacturers seek a single-formatted safety label to meet both U.S. and international requirements. The degree to which translation is an issue will soon become apparent.

Another option for a manufacturer who can manage the logistical problems of inventory and assembly is to produce translated versions of its Z535 labels for each country it sells to (see figure 7). This approach allows for a consistent use of formats, words, and symbols throughout a product line, though anticipating inventory requirements would be a challenge. All of these scenarios meet the Z535 and CE compliance requirements. The challenge is to decide which approach is most appropriate for a particular product and market while at the same time keeping informed of ongoing developments regarding the ANSI and ISO standards.

Finally, if the proposed revisions to the ANSI Z535.4 Standard are accepted, another possible approach will be the use of symbol-only safety labels on products in the U.S. As discussed above, using such an approach may very well be an appropriate way to “adequately” warn people to hazards. And, given the international scope of the marketplace, manufacturers may turn to this approach in order to uniformly communicate safety information to a worldwide audience.
Figure 7 Translated ANSI Z535.4 labels also provide a means to satisfy international safety labeling compliance.