safety ZONE

SAFETY ISSUES—TODAY AND ON THE HORIZON

What's the Risk?

THE PROCESS BEHIND DEVELOPING STANDARD WARNINGS AND SAFETY LABELS USING RISK ASSESSMENT.

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The risk assessment process provides an alternative and clear approach to selecting an appropriate signal word for a product safety label. Risk assessment requirements continue to evolve, pushing warnings and safety label developers to substantiate their decisions concerning warnings and safety labels.

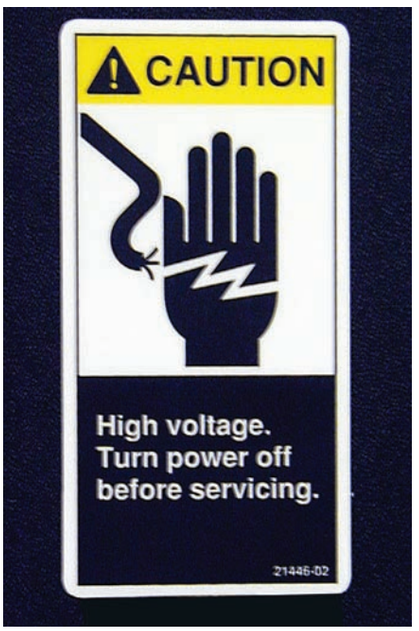
The purpose of a product safety label is to alert persons to a hazard and how to avoid the hazard. Two consensus standards for U.S. and international products guide the use of product safety labels:

- ANSI Z535.4:2006 Product Safety Signs and Labels
- ISO 3864-2004 Design principles for product safety labels

Both standards instruct readers to use risk assessment in developing the product safety labels. To assist the reader, both the ANSI and ISO product safety label standards provide information on risk assessment in informative annexes.

Product safety labels are only one of many methods to reduce risk. Understanding the context of the overall risk assessment process is useful in product safety label development because warnings should be viewed in the context of reducing risk rather than as an independent outcome.

Similar to product safety labels, risk assessment also applies to many different applications. Risk assessments are performed for packaging machinery, industrial machinery and consumer products. Many industries such as packaging machinery, robotics, machine tool, elevators, medical devices, aviation and



semiconductors have incorporated the risk assessment process into standards and guidelines. The recently revised ANSI/PMMI B155.1-2006 is a key example of this progress. These guidelines and standards are often single, industry-specific approaches. Risk assessment also appears in cross-industry applications such as process controls, control of hazardous energy (lockout/tagout), environmental, food and others.

Readers of the product safety label standards face some steep challenges. The ANSI Z535.4 presentation is potentially confusing and more complicated than it needs to be, and the ISO 3864-2 presentation includes a subtle inaccuracy.

SIGNAL WORDS

A key element of a product safety label or warning is the signal word. Z535.4 defines the term as follows:

Signal word: The word that calls attention to the safety sign and designates a degree or level of hazard seriousness. The signal words for product safety signs are Danger, Warning, Caution and Notice.

Both ISO 3864-2 and ANSI Z535.4 base the selection of the signal word on the level of risk. In Annex E of ANSI Z535.4, the basis for selecting a signal word is explained as follows:

"Signal words are selected based on the risk that results from not following the safety message. The level of risk determines signal words, safety colors and whether or not to use the safety alert symbol. In order to select the appropriate signal word, risk must be estimated for the particular hazardous situation or situations."

Both documents have the same three signal words for personal injury situations: Danger, Warning and Caution. However, the documents present slightly different approaches to arriving at the signal word.

ANSI Z535.4 states:

"Product safety signs and labels are classified according to the relative seriousness of the hazard situation. The classification is based on the probability of being injured if the hazard is not avoided, and on the severity of the resulting injury."

Note in this usage "seriousness" seems to refer to the level of risk rather than the severity of harm.

ANSI Z535.4 also states that:

"Risk depends on the probability of harm. For the purpose of signal word selection, probability of harm includes the probability of an accident, and the ▶

probability of the worst credible severity of harm occurring if there is an accident.

"The probability of the hazardous situation occurring (i.e., the probability of the safety message not being followed) should not be included in an estimate of risk for signal word selection."

Annex E of ANSI Z535.4 uses two levels of probability: *will* and *could*. The will rating indicates near certainty whereas the could level indicates an event is possible but not certain.

These two probability levels are used to rate two separate probabilities:

- probability of an accident if the hazardous situation occurs (i.e., if the safety message is not followed), and
- probability of the worst credible severity of harm occurring.

GLITCHES IN SELECTING A SIGNAL WORD

Selecting a signal word using ANSI Z535.4 is potentially confusing. When selecting the signal word, ANSI Z535.4 provides the following guidance:

"The probability of the hazardous situation occurring (i.e., the probability of the safety message not being followed) should not be included in an estimate of risk for the purpose of signal word selection.

"A signal word is selected according to the risk of harm presented by the hazardous situation that the safety message addresses. That is, signal word selection is based on the risk posed *if the safety message is not followed*."

The above text requires quite a bit of concentration to understand. Selecting a signal word should not be this difficult. An alternate approach simplifies this problem.

THE RISK ASSESSMENT PROCESS

Although many companies and industries use different risk assessment methods, the fundamentals of the risk assessment process are common:

- identify hazards,
- assess risk,
- reduce risk and
- document the results.

The goal of the risk assessment process is to reduce risks to an acceptable (or tolerable) level. Product safety labels are methods used to reduce risk. Understanding the context of the risk assessment process and how product safety labels work within this process is therefore important to achieving acceptable risk.

To achieve acceptable risk, risk needs to be assessed. There are a variety of ways one can use to assess the elements of risk. Different approaches analyze the elements of risk to greater or lesser levels of complexity.

Once the initial risk is estimated, the risk level can be compared to acceptability levels. If the risk is not acceptable, the next step is to reduce the risk. Determining what risks are and are not acceptable is company- and situation-specific.

REDUCING RISK

Identifying risk reduction measures involves a brainstorming effort to first identify a list of potential ideas, evaluating the ideas in terms of feasibility or practicality, and selecting the best solution(s) using the hazard control hierarchy which is the prioritized approach to hazard elimination and control. Several different presentations of the hazard control hierarchy exist. The table on page 166 presents one version of the hazard control hierarchy.

The hazard control hierarchy depicts a way of thinking about hazards and risks and establishes an effective order of action for eliminating or reducing risk. The hierarchy provides a logical approach to eliminate, reduce or control the risks of different hazards.

This hazard control hierarchy or variations of it is commonly accepted across several industries. Part of practicing safety through design is identifying situations where hazards exist and developing the best response to the hazard according to this hierarchy.

Not all potential risk reduction measures are practical or feasible. Many factors determine feasibility or practicality such as technical, cost, usability, productivity or other considerations.

A product safety engineer or manager may decide to use a product safety label to inform users of residual risks, and to help them avoid injury. In many cases warnings and product safety labels are used in combination with other forms of risk reduction measures.

Once feasible risk reduction methods have been selected, nearly all risk assessment guidelines call for a second assessment of the risk factors. These risk levels are referred to as the initial risk level and the residual risk level. The residual risk assessment should be conducted to validate that the selected measures effectively reduce the risk.

Once again severity and probability (or other risk factors) are assessed and combined to obtain the residual risk level using the selected risk scoring system. The risk factors are estimated assuming that the selected risk reduction measures are in place. Since zero risk is not attainable, some level of residual risk always remains.

Once the residual risk is known, a decision needs to be made to accept or further reduce the residual risk. This decision verifies that the protective measures selected have reduced the risks to an acceptable level. The risk assessment team will determine if the risks are acceptable with input from management.

The final step in the risk assessment process involves documenting the results. Every risk assessment standard and guideline requires or recommends that the risk assessment be documented. The risk assessment process should document the tasks, hazards and risk reduction methods employed to reduce ▶

risks to an acceptable level. This includes product safety labels.

The risk assessment process brings clarity and simplicity to the signal word selection. More simply stated, the signal word should be selected based on the initial risk level as determined by the risk assessment, e.g., before risk reduction measures have been selected.

THE ISO 3864-2 PROCESS

Although the ANSI Z535.4 method is more complicated than it needs to be, the careful reader can arrive at a reasonable solution. It is not a flawed process. Unfortunately, the same cannot be said of the ISO 3864-2 method.

In the ISO presentation, risk reduction by design and guarding means is performed before product safety labels are considered. This is consistent with the hazard control hierarchy. Yet this ISO standard calls for an interim assessment of risk that falls between the design and guarding risk reduction efforts and product safety labels. This interim risk level is then used to select the appropriate signal word and develop the product safety label.

Unfortunately, this ISO process does not reflect how risk reduction occurs in practice. Risk reduction most often occurs in a collective whole, that is, the various methods available to reduce risk are considered in sequential combination and the best feasible methods are selected to reduce risk to an acceptable level. Alternate combinations of solutions are often considered such as:

- changing the process to eliminate the task,
- installing a fixed guard,
- installing a moveable guard with a warning,
- using an interlocked guard with special training,
- providing safety glasses, personal protective equipment (PPE) and training to avoid the hazardous area.

Assessing the residual risk occurs on the collective whole of the selected methods and not after each individual selection.

The ISO standard implies that the signal word selection should be based on this interim risk level after design changes and guards are selected.

Often, following the ISO 3864-2 method does not yield results consistent with the practice of using product safety labels in the real world. This suggests that the details of the ISO 3864-2 process are flawed.

Does this represent a significant

problem? Yes, because the intent of standards and guidelines is to clearly communicate to readers the necessary requirements for selecting a signal word. The ISO standard fails in this regard and the ANSI standard presents an unnecessarily complicated approach.

Although the ANSI Z535.4 approach does not appear to include the flaw of the ISO method, the language used in the ANSI Z535.4 standard lacks the clarity and simplicity which could easily be used.

The net result from the process flaw and the unnecessarily complex language is a potential to confuse the reader. Since the intent of a standard is to provide guidance to the reader, these conditions detract from the message of the standard.

IMPACT ON RESIDUAL RISK

The goal of risk assessment is to reduce risks to an acceptable level. The risk reduction process is not completed until tolerable risk is achieved. The goal of the product safety label standards is considerably narrower—to guide readers to arrive at a product safety label with an appropriate signal word and label for the hazard. There is an implied assumption in the standards that the use of the appropriate signal word in the safety label in accordance with the standards will help reduce the risk of harm. The scope of each standard avoids the more significant and challenging issue of the actual impact(s), if any, of the product safety label on reducing risk.

The risk assessment process clearly defines both the initial risk before risk reduction measures are selected, and the residual risk after the measures are in place. This helps to ensure that the combination of risk reduction methods achieves the goal of acceptable risk.

Neither ANSI Z535.4 nor ISO 3864-2 require an assessment of the residual risk after a product safety label has been selected as a method to reduce risk. This abbreviated approach may be satisfactory for a product safety label standard, but it does not assist the designer in achieving the overall goal of acceptable risk.

The ability of warnings to change user behavior and/or reduce risk has been addressed by many authors and is beyond the scope of this article. There are many reasons for product suppliers to include product safety labels and warnings with their products. Product safety labels and warnings are, and will continue to be, an important part of

helping product users avoid hazards.

However, the impact on risk by the use of a product safety label or warning can be examined independent of any particular product or application. The risk level will be based on the severity of injury and the probability of the occurrence of harm.

As a stand-alone risk reduction method, a label or warning alone does not usually change the severity of harm, nor does it change the probability of the occurrence of harm sufficiently to change the risk level in the risk scoring system. A warning alone is not likely enough to reduce the probability to Remote and the risk level to Low.

This is part of the reason that warnings are usually not the sole risk reduction method used where it is feasible to do more. For example: guards may be used in combination with warning labels, information is included in the instruction manual(s), signals or alarms may also be utilized, users are restricted to those with appropriate training (in the industrial setting), safe work practices are required, etc. In these instances the combined risk reduction measures reduce risk to an acceptable level. Conversely, in other instances the only feasible risk reduction approach is a warning. In those situations although the residual risk level may be higher than desired, the residual risk with a product safety label is often deemed acceptable.

The risk assessment process is more comprehensive so it provides a more complete context for a product safety label. The risk assessment places the product safety label in context with other risk reduction measures and enables users to combine product safety labels with these other measures.

The risk assessment process is quickly gaining momentum because companies are finding value in the results. The goal of the designer in developing a product safety label is not to achieve the appropriate signal word or message panel, but to reduce risk to an acceptable level—whether as a stand alone label or in combination with other risk reduction methods. The risk assessment process helps in achieving this goal.

What does this mean to packaging machinery manufacturers? Selecting a signal word based on the initial risk level as described in ANSI/PMMI B155.1 will simplify the selection considerably. Also, using the ISO 3864-2 approach can create problems in signal word selection because it can underestimate the appropriate risk level. The product safety label standards should be used to determine the content and the format of the labels, but the signal word selection will be made easier with the risk assessment process.

To effectively design warnings and product safety labels requires an assessment of risk. Warnings and safety labels are methods used to inform product users of hazards and risks, and ways to avoid injury or harm. The goal of the risk assessment process is to reduce risks to an acceptable level, and warnings and product safety labels are used to achieve acceptable risk.

Risk assessment helps in the designing of warnings, safety labels and user information by placing the effort in the context of achieving acceptable risk using singular or combinations of risk reduction methods.

Risk assessment requirements continue to evolve pushing warnings and safety label developers to substantiate their decisions concerning warnings and safety labels. As a result, supporting risk assessments will become nearly as critical as the resulting warnings and safety labels themselves. PMT

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THE HAZARD CONTROL HIERARCHY

MOST EFFECTIVE	**1. Elimination by design**	• Substitute less hazardous material • Reduce speed, force, amperage • Reduce pressure, temperature • Change process to eliminate noise • Perform task at ground level • Automated material handling
↓	**2. Guards and devices**	• Ventilation systems • Machine guarding • Sound enclosures • Circuit breakers • Platforms and guard railing • Interlocks • Lift tables, conveyors, balancers
↓	**3. Warnings**	• Signs • Backup alarms • Beepers • Horns • Labels
↓	**4. Training**	• Safe job procedures • Rotation of workers • Safety equipment inspections • Changing work schedule • Training • Hazard Communication Training • Confined Space Entry
LEAST EFFECTIVE	**5. Personal Protective Equipment**	• Safety glasses • Hearing protective • Face shields • Safety harnesses and lanyards • Gloves • Respirators