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Strictly Speaking The Newsletter of the Product Liability Committee

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Product Liability Prevention

New International Standard on Consumer Product Safety

by Kenneth Ross

An effective product safety management program, before and after sale, is a key ingredient for any manufacturer, distributor or retailer to implement that will help minimize future product liability and contractual liability. I have previously written on this subject where I discussed various new standards and guidelines that have been disseminated concerning such management programs. See *Product Safety Management – Its Time Has Come, Strictly Speaking, Spring 2010.*

One project I did not report on has now issued its first draft. The International Organization for Standardization ("ISO") created a project committee called PC 243 in 2008 whose charter was to create an international standard for suppliers of

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consumer products. In May of 2011, ISO released a Committee Draft for comments referred to as ISO 10377 and entitled *Consumer Product Safety: A Practical Guide for Suppliers."* It is anticipated that this standard will be completed and published in 2012.

Representatives from 19 countries have participated in the development of the standard, while another eight countries have observed. The chair of the standards group is Dr. Elizabeth Nielsen, a safety expert who previously worked for Health Canada. In addition, there is active participation by representatives from Underwriters Laboratory.

The rationale for the creation of this new standard is to assist small and medium-sized product suppliers in trying to produce safe consumer products and comply with the new safety legislation and regulations that have recently been enacted by various countries. The problem perceived by the drafting committee is that many suppliers have "limited experience, few available resources, or practical reference documents to guide them through this process."

Specifically, this standard:

> …presents what needs to be done to

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identify the hazards and to assess and manage the risks - from the design of the product, to the input of raw materials, to production, to distribution, to retail and to the ultimate product end- user and disposal. It does not necessarily explain how it should be achieved. This guidance standard should be particularly valuable to small and medium sized enterprises and suppliers who do not design or produce products but are responsible for their safety in many jurisdictions.

It is intended that this standard be consistent with international best practices and be able to be applied consistently across jurisdictions. The result, as hoped for by the committee, is that there are fewer injuries and deaths, fewer recalls, and fewer problems with customers and enforcement authorities.

The standard contains sections on basic principles and general

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requirements that apply to all suppliers including designers, manufacturers, importers, distributors and retailers. In addition, there are separate sections on safety principles for design, manufacturing and post-sale that apply to different portions of the supply chain.

Basic Principles and General Requirements

These two sections discuss promoting a product safety culture within the organization and outside the organization. In addition, they discuss the organization's commitment to providing safe products and to ensuring that these products undergo continuous improvement.

Also, there are discussions concerning an organization's commitment to providing appropriate training of its employees, adequate resource allocation and appropriate records management and document control.

Lastly, the general requirements section discusses an organization's commitment to complying with all applicable laws, regulations and standards and to undertake activities which allow the product supplier to both identify and trace that product back to its original producer.

Safety in Product Design

This section describes best practices in design specifications, evaluation of "predictable" use and misuse, exposure analysis, hazard identification, risk evaluation and risk reduction. In addition, this section includes warnings and instructions and how to document the design specification process.

Safety in Production

This section deals with how to minimize or reduce product defects, production planning, order fulfillment, post production, production auditing and documenting the production process.

Safety in the Marketplace

This section discusses how product purchasers, such as importers, distributors and retailers, should assess and verify compliance with various laws, regulations and safety practices. In addition, this section talks about the ways in which they should collect and analyze data concerning products in purchaser's hands. This includes an assessment of product conformance, an analysis of warranty and service experience and appropriate ways to investigate product incidents.

This standard does not include a discussion of product recall best practices. The reason for this is that a separate committee, PC 240, is drafting a standard, ISO 10393, entitled Guidance Standard on Consumer Product Recall and Corrective Action: Code of Good Practice. This standard is somewhat behind ISO 10377 in its development, and probably will not be finished until late 2012 or sometime in 2013.

Annexes and Other References

The current draft of the standard contains several annexes which provide among other things, a list of informative sources of information. In addition, near the beginning, there is a reference to a number of other ISO standards or guides pertaining to product safety.

Some of these other ISO documents deal with principles and guidelines concerning risk management, risk assessment and risk reduction in machinery safety, quality management systems and instructions for use.

Observations

I have been counseling manufacturers and product sellers on these issues for over 30 years. In addition, I have

presented seminars and written many articles on product safety since the 1970s.

The available techniques and best practices in product safety were developed starting in the 1950s and became more widely known in the 1970s. A quick review of this draft standard seems to track the techniques that those of us in this area have been recommending for years. However, this standard performs a useful service by identifying and assessing these techniques and best practices and organizing and restating them in an understandable way.

Unfortunately, as one would expect, it is not as practical as companies would probably like it to be. It is impossible to create a standard or recommendations telling all companies how they should manage safety. Therefore, in the Introduction, it says "[The standard] does not necessarily explain how it should be achieved." This means that it still requires the supplier to decide which of these best practices are appropriate and necessary for their company.

There are very few absolutes in product safety management and product liability prevention. Some company's products have such a low risk that many of these best practices

are not necessary to undertake. In addition, some products can be reasonably safe and pose no unusual risk if they just comply with applicable technical standards. However, the standard, as written (by liberal use of the word "should"), requires companies of any size and for any consumer product to implement certain processes and techniques which may not be needed for their particular company or product. The standard should provide more flexibility and be written so it doesn't create an unnecessarily high bar for all companies to meet.

In addition, the standard is general and somewhat vague in discussing some of these techniques. This is necessary in that there are no clear answers to certain questions, such as what is tolerable risk or what are essential warnings and instructions for safe use of a product. For example, the standard defines tolerable risk as that "which is acceptable for a specific user group based on the current values of society." And then it says, "…if the risk cannot be reduced to a tolerable or acceptable level, the product should not be permitted to reach the marketplace." This is not that helpful for a company who just wants to know how safe to make its product.

This is certainly not meant as a

criticism of the standard but merely to point out its limitations. The introduction to the standard states that it does not intend to explain how the goals of safety should be achieved, but merely provide a discussion of the techniques that should be considered by suppliers to assist them in assessing and managing consumer product safety. To that extent, it meets its goals. However, it should be rewritten to make it clear that no company needs to adopt all of the techniques described in the standard.

From my perspective, such a document can best be used to help educate suppliers on these techniques and best practices so that they can then decide which of these to adopt and implement in their company and which to reject. But, before making any such decisions, I suggest that they consult with outside legal and technical resources experienced in product safety and product liability. These outside professionals can help a company identify and quantify legal and practical risks involved in selling their products, help them decide on which of the techniques in this standard and other documents should be implemented, and help them document the rationale for their selections.

Given that this standard is being created by people who are experienced in product safety, any company producing consumer products should be knowledgeable about the final version of this standard and be prepared to justify their decision as to the techniques and practices they selected as appropriate for their company and their products. Some resourceful plaintiff's lawyer may use this document and others like it to try to prove that the defendant in their case fell below the minimum standard of care in establishing an internal safety program. This should be anticipated and guarded against.

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