Take a Risk-Based Approach to Product Safety Compliance
Executive Summary

Adopting a risk-based approach to product safety compliance can result in the design of innovative products that pose less inherent risk of failure and injury, reduce liability and financial risks to manufacturers, and preserve a company’s brand identity and reputation. As regulatory authorities throughout the world continue to develop harmonized standards that incorporate risk analysis procedures, manufacturers who have adopted a risk-based strategy will have a global competitive edge.
Introduction

For manufacturers operating in today's dynamic world of commerce, the challenge of bringing innovative and safe products to market is more daunting than ever. The rapid pace of change driven by new technologies, combined with unrelenting market demand for innovation, quality and value, requires that manufacturers rapidly develop and produce a steady stream of new products to meet the needs and wants of customers.

When it comes to ensuring the inherent safety of those new products and their safe use in the real world, most reputable manufacturers design their products to comply with applicable regulations and industry standards. When required, they also subject new products to testing and certification by independent third-party testing laboratories. These steps are critical in gaining product acceptance from regulators, litigation-conscious wholesalers, distributors and retailers, and increasingly, safety-conscious end users.

But while a product’s compliance with applicable regulations and standards may satisfy a company’s minimum legal obligation to its customers, the job of mitigating a product’s overall safety risk is actually a much larger task. It involves a wide-range of considerations, from the types of materials that will be used in the product’s construction, to how the product will actually be used, to environmental issues related to the product’s use and final disposition.

Leading manufacturers are adopting a broader, risk-based strategy in the development of new products that spans the entire life cycle, from product conception to end-of-life considerations. A risk-based approach has the potential to more broadly anticipate and mitigate the impact of a new product on a wider range of stakeholders, which include the manufacturer, the end user, and society as a whole.

This paper will first discuss the various risks that manufacturers face regarding the safety of their products, and detail-specific risks for three different types of products. We will then compare the benefits of a risk-based approach to product safety with those of the more widely used standards-based approach. Finally, this paper will outline the specific steps that manufacturers can take to implement a risk-based strategy in connection with their product development efforts.
The Risks Associated with the Safety of New Products

From the perspective of many manufacturers, the primary risk associated with a product’s safety is its potential to cause physical harm to its end users. While this aspect of risk is certainly the most dramatic (and, in the case of unsafe products, the aspect most likely to gain media attention), it is by no means the only dimension of risk against which a product can be assessed.

In reality, a manufacturer must consider five separate aspects of risk associated with the safety of their product, as follows:

- Inherent safety, which includes material selection and design;
- Product functionality, which deals with how the product is used;
- Liability issues, covering regulatory enforcement and potential legal action;
- Financial implications, specifically penalties and assessments, and the expense to recall and rework and/or dispose of defective products;
- Impact on the company, which includes lost business and a tarnished reputation with customers.

Inherent Safety Concerns
Inherent safety issues typically occur as a result of inadequate product design, or through the selection of materials that are inherently dangerous or inappropriate for the product’s intended use.

Inherent safety issues related to inappropriate materials can be illustrated by the 2007 voluntary recall of 83 separate children’s toys. In this instance, it was found that the paint used on the recalled toys contained lead in excess of U.S. regulatory standards.

Risks related to inherent safety issues in new products typically generate the greatest attention from manufacturers and consumers, and are often the catalyst for increased regulatory and standards development efforts. For example, the massive recall of toys with lead paint in 2007 was one of several incidents that led to the development of the Consumer Product Safety Improvement Act (CPSIA) in 2008.

Another example of an inherent safety issue related to product design was the recent recall of 2.3 million vehicles in January 2010. The company’s investigation found that the accelerator pedal mechanism in the recalled vehicles could become worn through normal use. The pedal would become harder to depress or slower to return, and in some cases, stuck in a partially depressed position.

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Product Functionality
Despite a manufacturer’s best efforts to design a product that is safe for its intended use, it is often difficult to anticipate all of the possible scenarios in which a product could be used, and to address the potential safety issues associated with a range of theoretical scenarios. While some manufacturers may take steps during the design and development process to assess the risks associated with product functionality, it often takes repeated and well-publicized safety incidents to coax the majority of companies to consider assessing such risks.

Such was the case with handheld electric hair dryers. The heating elements in these now common household appliances are essentially uninsulated electrically charged wires across which air is blown, posing a risk of shock or electrocution if immersed in water. Although the hair dryers are not intended to be immersed in water, they are widely used in bathrooms where multiple sources of water (sinks, bathtubs, and toilets) can be found.

During the period from 1984 to 1990, the U.S. Consumer Product Safety Commission (CPSC) received 91 reports of death by electrocution related to electric hair dryers contacting water. However, the number of reported deaths by electrocution declined dramatically after the establishment of voluntary standards mandating the inclusion of an immersion detection circuit interrupter in the design of handheld hair dryers. As a result, during the period from 1998 through 2004, the CPSC received only one report of electrocution due to a handheld hair dryer.

Liability Issues
Beyond immediate safety concerns, the potential liability associated with unsafe products is the next most important aspect of risk assessment. Manufacturers are exposed to liability risks as a result of action by regulators, which can range from mandated product recalls to monetary fines and forfeitures that can run into the millions of dollars. Of course, the magnitude of risk becomes even greater when private litigation enters the picture in the form of civil lawsuits or class actions.

A sobering instance of the risks associated with action by regulators due to unsafe products involved baby cribs and strollers. In 2001, the U.S. Consumer Product Safety Commission (CPSC) reached an agreement with the manufacturing companies to pay a total of $1.75 million in civil penalties for failing to report known product safety defects that caused serious injuries and at least 2 deaths. At the time, the settlement between the companies and the CPSC represented the largest fine against a manufacturer in the agency’s history.
Unfortunately, such penalties pale in comparison with the risks associated with product safety cases that are pursued in the courts. In 2004, a U.S. District Judge in Reno, Nevada ordered a North American auto manufacturer to pay $41.5 million to the family of a three-year old who was killed when his father's truck rolled over him. The family claimed that their son’s death was related to defective parking brakes. The case was eventually settled through arbitration in early 2009, following more than a decade of litigation.

**Financial Implications**
As the above two cases clearly show, the financial risks associated with unsafe products can be significant. But, in addition to the potential monetary implications of adverse action by regulators or a costly civil judgment, manufactures also face financial risks associated with the direct expense incurred in the recall of unsafe products, and the cost of reworking or safety disposing of them.

The auto maker with the accelerator pedal recall referenced on page 3, for example, has estimated that it will spend approximately $2 billion to repair the pedals affected by the recall. While the magnitude of this expense is significant, the amount is not surprising, given the number of vehicles involved and the fact that the recalled products were repaired (it would not have been cost-effective to replace them).

It is also important to take into account the financial risk that can result from the loss of future sales due to an unsafe product. Once a product has been connected with a significant safety issue, the manufacturer has little choice but to stop selling that product, and erase any anticipated sales revenue from its financial projections. And, fairly or not, a single unsafe product can stigmatize a manufacturer’s entire line of similar products, cutting into anticipated sales across the board.

**Impact on Business Reputation**
Finally, an unsafe product can pose a significant risk to a manufacturer’s brand and market reputation. Unless a manufacturer acts swiftly and with complete transparency to deal with allegations of unsafe products, buyers will often stop using their products altogether, or will move their essential purchases to competitors until the circumstances surrounding the alleged unsafe product are better understood. In complex cases, months can pass, by which point many customers will have switched allegiances to other manufacturers. Business schools around the world teach from case studies of both effective management of product recalls and disastrous management of recalls.

In the best case scenarios, most well-intention manufacturers connected with unsafe products eventually reemerge, although the overall impact on a company’s market
reputation can take years to mend. However, in more dire instances, the financial impact and the tarnishing of a manufacturer’s brand identity as a result of an unsafe product can lead to a downward financial spiral that ends with bankruptcy, liquidation or technological irrelevance.

‘Risk Profiles’ for Selected Product Types

While manufacturers should attempt to consider and address the assessment and mitigation of the various aspects of risks identified above, each product category has its own unique ‘risk profile’ that prioritizes the risks of greatest concern. But even when we narrow the scope of concern and focus on specific types of risk, we often find that a standards-based approach is insufficient.

Within this context, let’s examine the limitations of the standards-based approach to product safety compliance in connection with three different product types, medical devices, lithium ion batteries, and photovoltaic (PV) modules.

**Medical Devices**

Because of the critical high-stakes role that medical devices play in healthcare, medical device manufacturers are particularly attuned to the risks associated with the inherent safety and functionality of their products. However, the process of developing updated standards for medical devices, and the adoption of those updated standards by regulatory authorities, often lags that of medical device designs themselves.

A specific example of this challenge is the adoption of the 3rd Edition of IEC 60601-1, the most recent revision to the international standard for medical electrical equipment. The 3rd Edition of this standard, which was originally released in December 2005, represents a significant advancement over the 2nd edition in the mitigation of safety risks associated with medical devices. It mandates the performance of a risk management process as part of the overall product assessment, and also includes “essential performance” (EP) requirements, defined as the performance necessary to achieve freedom from unacceptable risk. IEC 60601-1 3rd Edition also requires the creation of a risk management file (RMF), which documents the risk management process adopted.
by the manufacturer and the EP requirements applicable to a particular device.

Unfortunately, the adoption of IEC 60601-1, 3rd Edition by worldwide regulatory bodies and testing agencies has proceeded at a slow, uneven pace. In the United States, the U.S. Food and Drug Administration (FDA) announced in March, 2010 that it would formally recognize the 3rd Edition of IEC 60601-1. Notice of the FDA’s recognition of the 3rd Edition is expected to be published in the Federal Register in June 2010, and manufacturers are expected to have three years (2013) to transition to the new requirements (a full eight years following the 3rd Edition’s release).

Elsewhere, the European Union (EU) has reportedly set June 1, 2012 as the date by which compliance with earlier versions of IEC 60601-1 will no longer be given a “presumption of conformity.” Further, under the IECCE’s CB Scheme, which is applicable in over 45 countries, acceptance of the 3rd Edition still varies from country to country. Meanwhile, the 2nd Edition of the standard, which does not mandate a risk management process, is still valid in some CB Scheme countries, and is still being used to assess the overall safety of medical electrical equipment.

Of course, there are many legitimate reasons for the delay in the implementation of new product safety standards, and the introduction and acceptance of revisions to existing standards. But, as the case of IEC 60601-1, 3rd Edition illustrates, a manufacturer who relies exclusively on a standards-based approach to risk management is vulnerable to known safety issues that are not reflected in current versions of a given standard, as well as risks that lie outside the scope of the standard.

**Lithium-Ion Batteries**

Since they were first introduced nearly twenty years ago, lithium-ion batteries have now become the preferred power technology for millions of portable consumer electronic products, from laptop computers and cell phones to portable electronic games used by children of all ages. Since Sony introduced the first lithium-ion battery in 1991, battery manufacturers have worked continuously to increase battery runtimes, reduce their size, and improve their overall safety and reliability. Improvements range from working with different battery materials to decrease internal resistance, and the inclusion of safety features, such as shut-down separators and thermal interrupts to prevent overcharging.

Because of several high-profile incidents involving overheated lithium-ion batteries used in laptop computers, standards development organizations have been
particularly active in ensuring that technical requirements keep pace with safety concerns. For example, ongoing research into alternative testing methods, such as the blunt nail pressure (BNP) test, are intended to ensure that technical standards remain relevant to newer lithium-ion battery technologies, and more effectively simulate real-world operating conditions.

But, despite widespread efforts to ensure the highest possible levels of safety in the operation of lithium-ion batteries, there still exist a range of risks from their use that are difficult to anticipate, even by the most far-sighted technical standard. For instance, a lithium-ion battery in normal operation might encounter a random static electric charge (from a charged user, for example) that destroys the battery’s internal protection circuit. Without such protection, the battery would be defenseless against overcharging and other types of misuse.

There is also a potential risk from attempting to recharge the battery at low temperatures. Below approximately 0°C, efforts to charge a lithium-ion battery may lead to the formation of metallic lithium, which results in the precipitation of lithium on the anode. The dendrites that result from this plating are permanent and cannot be removed, and have the potential to cause internal short circuits in the battery cell, increasing the risk of overheating and thermal runaway.

So, while the work of conscientious manufacturers and diligent standards development committees has greatly reduced the operational risks associated with the use of lithium-ion batteries, the above examples serve to illustrate the limitations of any standard in anticipating all use conditions, and in reducing or eliminating product safety risks.

**Photovoltaic (PV) Modules**

Because there is a virtually inexhaustible supply of free sunlight, the development of photovoltaic (PV) technologies is perhaps the most active of current efforts to implement so-called “green” approaches to addressing our ever-increasing energy requirements. As such, the race is on to develop increasingly efficient and more cost-effective PV modules for use in solar energy panels and other applications.

Although the widespread attention to the development of PV modules is still relatively recent, standards efforts in this area are already well-established. At present, there are at
least five different international technical standards dealing with PV modules, as follows:

- IEC 61215, “Crystalline silicon terrestrial photovoltaic (PV) modules—Design qualification and type approval”
- IEC 61646, “Thin-film terrestrial photovoltaic (PV) modules—Design qualification and type approval”
- IEC 61730, “Photovoltaic (PV) module safety qualification”
- IEC 62108, “Concentrator photovoltaic (CPV) modules and assemblies—Design qualification and type approval”
- IEC 61701, “Salt mist corrosion testing of photovoltaic (PV) modules”

However, a key factor constraining the successful commercialization of PV technology is the absence of widely-accepted standards that deal with the connection of current PV-based energy generation technologies to the existing electricity grid infrastructure. Existing grid interconnection standards are based on the passive participation of PV systems in the grid structure, and are only now beginning to address the prospect of PV technologies that can produce sufficient energy to serve as an alternative power supplier to the grid.

As new grid interconnection standards emerge, they will undoubtedly expand the range of technical requirements, as well as safety issues impacting manufacturers of PV modules. Unfortunately, those who have pursued a standards-based approach to product safety instead of a broader risk-based approach will undoubtedly face bigger challenges in mitigating risks associated with their products.

**Standards-Based versus Risk-Based Approaches to Product Safety Compliance**

The above examples illustrate some of the key limitations of relying exclusively on a standards-based approach to mitigate product safety risks. First, the standards development process inevitably lags technological advances. This is not the fault of the standards process itself, but rather a reflection of the length of the process, and the fact that standards are inevitably based on then-current technologies, and never fully able to anticipate technology advances.

Second, even when standards exist to cover all of a product’s design elements, compliance with multiple standards carries no guarantee that the product will be free of risk. Simply demonstrating compliance with the requirements of a given standard is not sufficient to fully ensure the safety of that product. For example, there are many
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A risk-based approach starts from the premise that each product poses a wide range of risks. Beginning from this point, the manufacturer’s job is then to identify all of the potential risks that exist, and work to eliminate them or mitigate to the extent possible their potential impact. Testing a product to the requirements detailed in the relevant technical standards is the last step in the process, and is a tool for verifying that a particular risk (e.g., fire, electric shock, mechanical hazards, etc.) has been eliminated or minimized.

situations in which a product has met a standard, but presents risks even when operated for its intended use.

Third, a standards-based approach to product safety compliance can actually serve to impede innovation. Manufacturers must seek ways to ensure that their new products comply with existing standards, even when those standards fall short of addressing the design challenges mandated by changing marketplace demands. Instead of spending precious resources on the development of breakthrough design approaches that might lead to inherently safer products, time is consumed instead in the pursuit of less-innovative but more compliant designs.

The following example illustrates the difference between the two approaches. In a standards-based approach, the manufacturer of a manually propelled wheelchair would identify the applicable standards, review their technical requirements, and then conduct testing to demonstrate compliance with those requirements.

For the manufacturer pursuing a risk-based approach to product safety, the process would begin with research to identify all of the hazards that could potentially be associated with its use. For instance, the manufacturer might list all materials, parts, and assemblies used to produce the wheelchair. It is also imperative to identify the possible failure modes related to each item. This exercise would identify the different scenarios in which the user could be injured or killed. Actions would then be taken to eliminate or mitigate these possibilities.
Adopting a Risk-Based Strategy for Product Safety Compliance

Adopting a risk-based approach to ensure product safety compliance is a complex process, as illustrated in the figure below. From a logistical standpoint, manufacturers need to assemble risk analysis teams who understand the principles and procedures of a risk-based approach. Product development schedules must be altered so risk analysis can be performed as early as possible in the design process, enabling designers to make modifications that will eliminate or mitigate risks.

Figure: Risk assessment flowchart
In general, manufacturers who are considering the adoption of a risk-based strategy to ensure product safety compliance should consider the following principles as essential elements of their approach:

- Eliminate or reduce risks as far as possible. Any remaining undesirable side effect must constitute an acceptable risk when weighed against the performance intended.

- Protect products, end users, and operators against risks resulting from the influence of environmental conditions that are reasonably foreseeable (e.g., electromagnetic fields).

- Where appropriate, integrate protective measures such as alarms and interlocks into the design to mitigate risks that cannot be eliminated.

- Inform users of the residual risks associated with failures of the protective measures.

- Clearly define the product's intended use and reflect that use in the labeling and other instructions.

- Clearly and unambiguously document the process of determining what risks were considered to be "reasonably foreseeable." Seek outside assistance, if needed, from clinical experts.

- Wherever possible, use technical consensus standards to verify that the identified risks have been minimized during the design phase.
Intertek’s Approach to Risk Management

Intertek offers comprehensive support for manufacturers considering the adoption of a risk-based approach to product safety compliance. The following five services are just a few of those offered by Intertek, and can help to ensure the successful implementation of the broadest possible risk management strategy available to manufacturing clients.

1.) Foreseeable Use Assessment
The core principle behind Intertek’s approach to risk management is that of foreseeable use; that is, not just how a product is intended to be used, but also how it might be used in real-world conditions. The analysis starts by identifying foreseeable use conditions associated with the product concept, and then evaluates the results of this analysis against Intertek’s extensive research resources and databases, including injury/fatality data, critical parts research and human factors assessments. In this way, Intertek can predict the wide range of possible risks associated with the anticipated foreseeable use of a product.

2.) Design Hazard Analysis
With foreseeable use data in hand, Intertek’s design hazard analysis begins at the start of the new product development process, typically at the design specification stage. By working closely with manufacturing clients to assess the interaction between a product’s design and foreseeable use hazards, potential risks can be addressed through design modifications at the point where such changes can be made easily and inexpensively, and without impacting the overall development schedule. In addition, the design hazard analysis can serve to uncover additional potential risks introduced by choices made during the design process itself.

3.) Physical Hazard Assessment
Physical hazards associated with products can include suffocation, strangulation, unintended impact, and burn injuries. For certain types of products, a physical hazard assessment is essential to identify potential interactions between a product and the people who will use it. Intertek’s virtual and physical models of the human anatomy include safety criteria, specialized gauges, and digital simulations that can effectively identify and diagnose hazardous product characteristics of products that come in direct contact with humans.

4.) Product Testing and Certification
Intertek conducts compliance testing to international product safety standards, and can issue certification marks that are essential for legal market access throughout the
world. Intertek issues certifications supporting the use of a number of widely-recognized product safety marks, including the ETL Listed Mark (covering electrical products in North America), the BEAB Mark (covering electrical products in the European Union), the CCC Mark (covering 132 product categories in China), and the ASTA Diamond Mark (covering electrical distribution and plug products in over 40 different countries.

Intertek is also a Certification Body (CB), operating under the auspices of the IECEE’s CB Scheme, allowing for the exchange and acceptance of product safety test results among participating laboratories and certification organizations in over 45 countries around the world.

5.) **Comprehensive Risk Assessment Screening**
Finally, Intertek offers manufacturers comprehensive screening services to identify and evaluate potential risks associated with both new and existing products from every conceivable angle. Risk assessment screening can help to single out for further review potentially unsafe products, and has the added benefit of providing evidence of a manufacturer’s due diligence in ensuring the safety of its products.

These and other risk-management services can significantly reduce exposure to the wide range of risks that manufacturers face when it comes to the safety of their products. But Intertek’s approach to risk management offers manufacturers added benefits as well, including the following:

- **Time:** Product safety risks identified at the outset of product development can be addressed more efficiently, and help to avoid unnecessary reworking of product designs;

- **Cost:** Early identification and resolution of potential safety issues reduces costs during the design and production phases, and mitigates financial exposure resulting from post-sale safety issues;

- **Confidence:** Intertek’s approach to risk-management serves to increase the manufacturer’s confidence in both their products and in the product development process itself.
Conclusion

Manufacturers who are interested in exploring the potential advantages of a risk-based approach to product safety compliance should remember that the standards-based approach still prevails as the primary means of demonstrating product safety, and is mandated for many types of products in many geographic markets. However, as worldwide standards harmonization continues, the adoption of a risk-based strategy will gain broader acceptance, and provide manufacturers with greater assurance regarding the overall safety of their products.

Intertek’s approach to risk management can minimize a manufacturer’s exposure to risk associated with unsafe products, but can also reduce overall development costs while bringing new products to market in less time. Finally, Intertek’s risk management strategy offers manufacturers the confidence that comes from adopting a reliable, risk-based approach to product safety compliance.

About Intertek

Intertek provides quality and safety solutions to a wide range of industries, through a network of 25,000 people in 1000 laboratories and offices in 100 countries around the world. For more information about how Intertek can help your company implement a risk-based product safety compliance strategy, or for more specific information about our testing and certification services, visit our web site at www.intertek.com.

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