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Building Safety into Your Products to Gain a Competitive Edge and Protect Your Brand – Overview with Product Risk Assessment Details

Written by Donald Moffett, President Product Integrity Consulting Services, June 2010

Just because your product is legally compliant does not mean it is safe. Over a thousand consumer products, with total quantities of over 50 million units, are recalled from the US market each year because they are considered unsafe or violate safety standards. The estimated cost to consumer products companies? Over $6 billion a year; not including the related PR damage to the company's brand and loss of sales. Many of these safety defects could have been identified and prevented during product design and development. The bottom line: Companies with "best practices" in place have sharply lowered recall rates and gain a major competitive advantage.

In today's litigious environment, meeting legal regulations is not always sufficient to protect against product failures or design defects. Many safety defects that lead to recalls or liability claims can be anticipated and prevented during product design and development by implementing best practices in product safety and quality. As a product safety manager, recruiting more active participation from all departments during product development results in significant cost savings by ensuring quality and safety are built into the product – reducing complaints, product returns, injuries and lawsuits down the road. Designing a safe, quality product the first time also yields faster time to market by eliminating costly redesigns or rework once production has already started.

At the most basic level, a legal compliance review ensures a product complies with any legal regulations that exist for that product type. However, legal compliance reviews will not identify all hazards for all products. Many products do not have legal requirements or even voluntary standards written for them. Even if standards exist, many of the standards are "reactive", meaning they are changed only when a problem occurs in the market. You do not want to be the company that creates the need for a new standard!

Product Risk Assessments can be performed when more information is needed about potential hazards that may exist in a product. Reviews of this type can be done at any stage of the product development process, including concept or prototype stages. While risk assessments have been common in certain industries for some time (aerospace, nuclear, etc.), they are just now beginning to be considered in the consumer product industry; especially for children's products.

Effective risk assessments for consumer products apply a variety of processes including Design Failure Modes Effect Analysis (DFMEA), Data Analysis, Foreseeable Use Analysis, and Hazards Analysis as the primary research tools. These tools should be applied at every stage of the development cycle from Concept through actual production to identify potential hazards.

Once identified, potential hazards can be classified based on their risk characteristics to generate design recommendations that may reduce the product's overall risk to a consumer. These hazards can then either be designed out of the product, safeguarded against (using protective caps or other features), warned against with labels and instruction or simply accepted as part of the acceptable risk of a given product.

Brand Protection starts with safe product designs. Legal compliance, quality, performance and consumer satisfaction are imperative to a brand's reputation. Building these into a product from the very concept using the most effective tools available is the best way to prevent expensive recalls or litigation and will give your company a competitive edge in today's market.

Product Risk Assessment Detailed Approach

The basic engine used in conducting a product risk assessment is the concept of the risk equation. The risk equation states that the overall risk of injury caused by a consumer product can be calculated by factoring the overall hazard and multiplying it by the overall exposure (Figure 1). If a product has a substantial hazard, the overall risk is high because of the increased risk of injury caused by the hazard. However, the equation also states that a product with a small hazard, or perhaps a hazard that is unlikely to occur (low probability) can still become a large risk if the Exposure to the product increases. Most companies are unlikely willing to manage their risk by keeping their exposure low, so the most effective approach is to drive the potential hazard as low as possible. The most effective way to accomplish this is to design the hazard out of the product, or to safeguard it in such a way that a consumer is unlikely to be exposed to the hazard. The product risk assessment process is meant to not only identify the potential hazards, but also to help understand how much risk that potential hazard may cause based on all the variables in the equation.

The most challenging part of this process is how to actually accomplish the specific details of each step involved when conducting a comprehensive risk assessment. Many companies conduct internal product risk assessments and many service providers provide product reviews called “risk assessments”; however, these are found to vary greatly depending on the methodologies used. There is not one perfect product risk assessment in the market because most have to be customized to meet not only the requirements of the company using it, but also the products involved. What is important to realize though is if a person conducting a risk assessment educates himself/herself in the basic methodologies and is challenged to “know what you know, and know what you don’t know”, the final risk assessment will be effective.

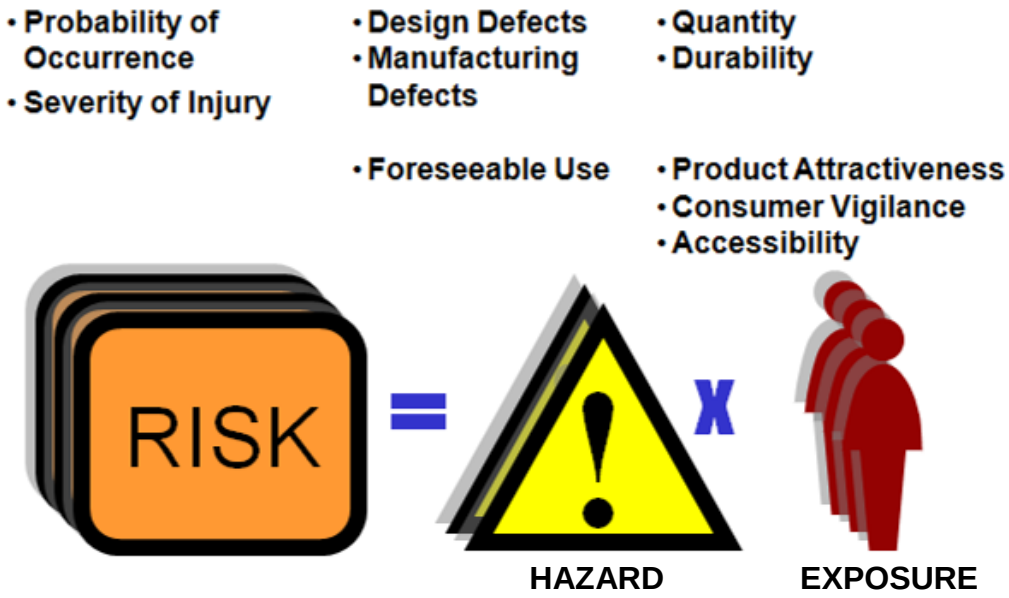

Figure 1: Expanded Risk Equation

This document is not meant to teach every single nuance involved in conducting a risk assessment; this would be impossible to do without authoring a 500+ page book. The author of this article uses training courses lasting 3 to 5 days using over 1,000 Powerpoint slides and dozens of product samples just to introduce students to the basic methodologies of risk assessments. These courses are used just to build a foundation that the students can build from

as they start learning and integrating this complex process into their product review processes. Instead of teaching every nuance, the purpose of this article is to provide some background to challenge the reader into questioning specific hazards and providing simple ideas for how the reader can research issues related to specific hazards. By doing so, this will hopefully stimulate a thought process that will drive the reader to seek out information that may conflict with previously held notions on product safety, but in such a way to allow more effective decisions to be made.

To accomplish this, each critical element of the product risk assessment process will be discussed separately to give a high level summary of how it should be used. The Hazards Analysis section will go into slightly more detail with specific examples on how to avoid specific hazards. Note that this article will be heavily focused on children, but the principles discussed can easily be applied to adults and adult products. The author has personally used this process on products including toys, nursery products (e.g. strollers, bassinets), household cleaning products (air care devices, cleaning tools), food products including packaging, and even devices used on escalators.

Note: The following outline closely follows the Product Hazard Analysis checklist used in the Product Safety Management Program offered by Saint Louis University, Center of Supply Chain Management Studies.

1) Review all legal, voluntary, industry and internal standards

At a minimum, products must meet the legal requirements for the country it is being sold in. Now days though, just meeting legal requirements is not enough since they will not identify all hazards for all products. Many products do not have legal requirements or even voluntary standards written for them. This is why it is important to expand the search beyond legal requirements and look for voluntary standards, industry standards and even international standards (regardless of distribution). The CPSC has also been clear lately that failure to meet industry approved standards (voluntary or otherwise) will be viewed as a substantial product safety defect when a potential injury could occur with a given product.

However, in a risk assessment process it is not only important to know what the standard is, but ***why*** does the standard have specific requirements. In some instances you will find the requirements are based on old information that is no longer accurate, while in other cases they are based on very good science. It is important to know the difference so you can actually understand why something is hazardous. By researching other international standards, any information found can also help you determine if other hazards might exist that have not been built into the legal requirements for the specific country you may be selling to. At that point it becomes a choice to meet the requirement or not, but it is better to understand what is available rather than go into a product design blind. The General Product Safety Directive in Europe actually goes so far as to require companies to take this exact approach, so this is where product safety is heading currently.

In addition to external standards, many companies develop their own requirements based on a collection of information (internal studies, past customer complaints, lawsuits, experience of employees, etc.). While important to create and evaluate against these standards, it is even more important to ensure proper documentation is done during the development of these standards to ensure that rationales for specific decisions are recorded and maintained. Without rationales, it is difficult to trace back decisions once specific decision makers move on from the company.

The final thought for this section is to remember to focus on not only the product *type*, but to also account for the features or characteristics the product has. If the product being evaluated has features that are very similar to a different product category, you may want to research standards for the other category to determine if there are specific requirements in place that relate to the specific characteristic.

2) Perform a product risk assessment or similar review

Any risk assessment or review should be done with a non-biased and/or cross functional team in order to provide a well rounded view of the product. Many times, the developers of the product are too close to the item and will miss obvious issues because of their perception (or misperception) of how their product will actually be used. If the expertise is not available in-house, then it is critical to get experienced help for the areas that are not well known or understood.

In some instances, products may not require a full risk assessment depending on the level of risk willing to be accepted by the company. In general, adult products have a lower risk than children's products, but some adult products have characteristics that automatically require a more detailed analysis. Oftentimes, screenings can be performed to determine if a product has enough characteristics to warrant a full risk assessment or if there are obvious hazards that can be easily addressed. Screenings like this can be done on lower risk or lower volume type items if done as part of an overall risk strategy. This can help streamline a product safety process within a company that has many SKUs. It is critical though to make sure that the individuals doing the screenings are fully trained in risk assessment techniques so the decisions are based on informed decisions and not just personal feelings.

The following tools are used to conduct a product risk assessment.

2.1) Design Failure Modes Effect Analysis (DFMEA)

There are hundreds of books on how to conduct DFMEAs. This article is not meant to teach this process, but there are a few key elements that should be considered when using DFMEA as part of a risk assessment. A DFMEA process is a very time consuming process that can take hundreds of man hours to effectively complete. Therefore, doing detailed DFMEAs can be reserved for those products that have the highest complexity and/or highest risk profiles. Simpler products can use the basic DFMEA principles while using the tools outlined in the remainder of this article to effectively manage resources.

The first step of any DFMEA process is to perform a detailed overview of the product to understand all features that plan to be included and/or advertised. A product could be viewed as reasonably safe during normal use, but a non-obvious feature could end up being extremely dangerous. If ALL features are not explored fully during the risk assessment, the mistake could cost a company millions of dollars in recalls or lawsuits. It is also critical to have a cross functional team involved in the process, even people not remotely involved in the development, to best understand how an average consumer may interact with the product.

Calculating and using RPNs (Risk Priority Numbers) as a sole basis for risk assessments should be done carefully as they can be highly subjective and could even be misleading. Some companies use extensive research techniques to quantify the numbers used in RPNs, but this is beyond the capabilities or resources of most companies. The DFMEA process is best used to identify potential uses and hazards that may need to be addressed before the product launches. A given product may require 2 or 3 DFMEAs during the development cycle depending on how much the product changes during development.

Some companies may want to incorporate other tools into the DFMEA (fishbone diagrams, Process FMEAs, marketing studies, etc.). This should be encouraged as the more information available early on allows more effective decisions. All of the tools discussed in later sections must be included into the DFMEA process to have the best, most comprehensive review.

2.2) Data Analysis

Data analysis is an effective tool that should be used to learn from events that have already occurred or from information that has already been collected. When conducted for a product, it can be used to identify past mistakes made by companies, how consumers use products and even determine quality expectations of consumers. This tool can provide the majority of information needed for a full risk assessment.

There are several sources to obtain "data" for a risk assessment. Recall databases, injury databases, internal consumer calls or complaints and even consumer research can all be used to obtain valuable information. However, much like what was discussed in the standards section, it is important to look at the features and characteristics and not just focus on the product type. The U.S. CPSC has some of the most useful databases for this type of research (NEISS, Death Certificates, Reported Incidents) but the volume of available data makes it very difficult to research without effective database tools. Some service companies have built effective interfaces with this data to make the searches more user friendly for their clients, while some product companies develop their own internal databases to research this data more effectively. The CPSC has an online tool to search that can be helpful for some limited research, but there are several limitations with the system that restricts the amount of information you can obtain.

There are some warnings about the use of injury data though. There are many instances where injury statistics will be dramatically different from fatality statistics. Additionally, if a specific characteristic is relatively new to the market, injury trends may not be readily available. Just looking at statistics and charts of the numbers may not get you the real picture of what is happening. The most effective use of injury data comes from reading the actual incident reports and conducting custom analyses based on the actual injury patterns. Some narratives may also give you "early warnings" of events that could have been more serious under slightly different circumstances. All of these factors must be considered when doing any injury analysis. One final legal warning, conducting a data analysis on an existing product line should be done under the advice of legal counsel due to discovery and liability issues, but is still recommended to ensure consumer safety if there are potential concerns about a given product.

2.3) Foreseeable Use

Foreseeable Use discussions tend to focus primarily on children instead of adults, mainly because children represent the most vulnerable group of consumers and their behavior is extremely important to understand. Knowledge gained about children can in many ways be applied to adults as well, but it is important to know that Foreseeable Use is not only about children; it is about predicting *consumer* behavior with products.

Foreseeable uses can almost always be predicted, although some uses on new or complex products can be difficult to predict. There are several methods that assist when predicting foreseeable uses. These include, but are not limited to, understanding the product and all features (as described in DFMEA), data analyses, consumer studies, child development and psychology knowledge, adult behaviors and actions, and, most importantly, personal experiences – direct or indirect. All of these methods must be understood along with the influential factors that increase the risk of injury for specific groups.

The attractiveness of a product directly correlates with the exposure of the product to a given user. A product's attractiveness influences the probability of a person noticing the product, the amount of interest the person has in obtaining the product (and also the amount of effort spent), how long the person will use the product, the number of other uses that will be found for the product as well as the length of time the product will be kept or maintained. A product designed for adults that has specific features added that make it attractive to children could end up having to meet more stringent safety requirements based on the attractiveness alone.

The amount of care a consumer will exercise when using a product or a specific feature is oftentimes referred to as consumer vigilance. High vigilance means the consumer would be very careful when using the product, whereas low vigilance indicates they would not be giving the product their full attention. For children, the vigilance becomes the responsibility of the parent or caregiver and a determination must be made of how likely an average caregiver will allow a child to interact with a given product. This vigilance combined with the accessibility of a product or a specific hazard helps to define the Exposure side of the risk equation shown in Figure 1.

Warnings and instructions are often considered as an option to try to influence the user of a product to use a product properly. However, it must be kept in mind that warnings and instructions do nothing to change the actual hazard. If the goal of a risk assessment is to design hazards out of a product (as described at the start of the Risk Assessment Detailed Approach section), a warning label or instruction is only trying to manage the exposure of that hazard. In some cases, this is the only effective way to deal with a given hazard, but it should only be used after all options to design out the hazard have been exhausted.

2.4) Hazards Analysis

An accurate hazards analysis is the final but most important part of the product risk assessment process since it is the step that will clearly define the specific hazards that need to get addressed; however, it is this tool that requires the broadest knowledge given the many hazards that could exist depending on the complexity of the product. To perform an effective hazards analysis requires a basic understanding of physics, foreseeable use (as discussed in section 2.3) and most importantly an understanding of the anatomy specific to the hazard being evaluated. In many cases existing standards will provide insight into hazards that exist with a given product type, but these are typically only the known hazards that have already been found to cause issues. The last thing you want to do is develop a product that creates the need for a new standard because of a hazard you failed to identify!

This section will explore the major hazard categories that are known to create the majority of the injuries with typical consumer products. However, there are other hazards that may exist that will only be identified using the additional tools already introduced (DFMEA, Data Analysis, Foreseeable Use). Each hazard category will have the hazard briefly described with some of the known essential safety requirements that may want to be considered.

2.4.1 Asphyxiation – Airway Obstruction

Asphyxiation occurs when air cannot reach the lungs, cutting off the supply of oxygen to circulating blood. This can cause irreparable damage to the brain when cells are deprived of oxygen. Airway obstruction is the physical mechanism of injury caused by the ***internal*** obstruction of the respiratory system, commonly referred to as choking. However, note that airway obstruction is also commonly referred to as “suffocation” in injury data and news reports, which is a very different mechanism as defined in this article. It is important to note the distinction and understand the true mechanism of injury and not just the wording used.

There are three primary injuries that can occur with airway obstruction that are typically defined based on the location of the object during the incident. “Choking” injuries typically involve an object ending up in the oral cavity or pharynx (see Figure 2). “Aspiration” injuries typically involve objects that pass beyond the oral cavity and end up in the respiratory system (larynx, bronchi or lungs). “Ingestion” injuries typically involve objects that pass beyond the oral cavity and end up in the digestive system (esophagus, stomach, bowel). Each of these injuries tends to have differing levels of severity, with choking and aspiration injuries typically having the highest fatality rates.

Airway obstruction injuries can lead to acute injuries as well as chronic injuries. Acute injuries occur when the object causes an immediate blockage of the airway. A complete blockage of the airway will lead to a fatality in 2-3 minutes. Chronic injuries occur when an object is aspirated and remains in the airway undiagnosed for a period of time. Sometimes incidents of this nature present as asthma or other respiratory problems until properly diagnosed. Acute and chronic injuries can be caused by either direct means or indirect means. Direct airway obstruction can be caused by conforming materials that seal to the internal structure blocking air (e.g. balloon fragments), small parts that get aspirated or ingested, or by direct obstruction of the oral cavity that creates a plug. Indirect airway obstruction can be caused by esophageal wall protrusion (where an object is partially swallowed causing tissue to be pushed into the airway) or soft palate displacement (typically caused by ball like objects between 1.5″-1.75″ in diameter).

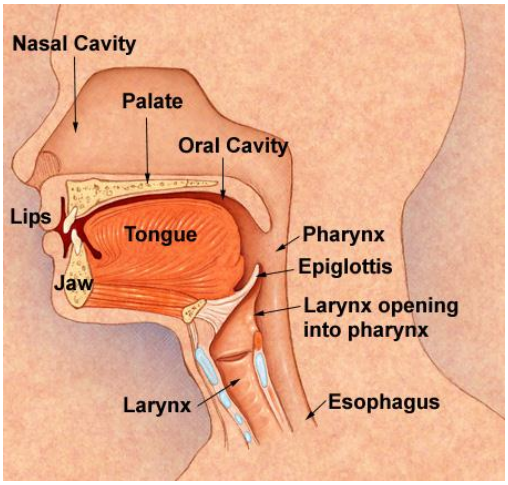

Figure 2: Anatomy of Airway Obstruction

Airway obstruction for children's products may seem like it would be one of the most regulated and well understood hazard given the CPSC introduced a Small Parts Test Cylinder in the 1970s to address small parts. However, what is not widely known is that this cylinder was created based on a premise to fail small balls and sewing needles (the two most common injuries at that time)[1], yet this standard was eventually adopted worldwide for choking hazards on a broad range of products. Since that time, numerous fatalities have occurred with products that meet the small parts cylinder and standards committees are having to continuously create special requirements based on products that meet the requirement yet are still dangerous (as of February 2010 the ASTM F963 committee is still trying to find a way to reword the toy standard to address the recall in September 2006 of a Playschool™ Toy Bench and subsequent recall in August 2009 of a Little Tikes™ Workshop Set). While the small parts cylinder has been very beneficial and has dramatically reduced injuries and fatalities for young children, it is important to note that it has significant limitations. If interested in effectively managing the risk of injury for products, especially products that are designed for or are attractive to younger children, just meeting this requirement will not significantly reduce the hazard and overall risk of airway obstructions.

To effectively manage airway obstruction, some of the leading premium suppliers have implemented a different set of gauges that go above and beyond regulatory requirements and use these gauges to assess for airway obstruction hazards. The gauges are a 1.5″ diameter 2-lb. weighted gauge and a 1.75″ diameter 2-lb. weighted gauge that were developed based on an extensive research study and analysis of thousands of actual airway obstruction injuries.[2] This research looked into the actual size and physical characteristics of the objects that were actually involved in injuries and fatalities.

A flowchart of how the gauges are used is provided in Appendix 1 of this article. The flowchart is based on not only the injury data found in the research, but also on anatomical markers and product characteristics that have been found to be hazardous. The critical characteristics involved in assessing airway obstruction are the overall size of the object (to determine if it can enter the oral cavity or pharynx – assessed with the gauges), the length of the object (to determine if it can rotate deeper into the airway), the size of the end of the object that enters the oral cavity (to determine if it is large enough to block the flow of air) and the shape of the end of the object that

[1] RAM Safety Innovation, Issue No. 1, www.ram.com/live/content/news_ezine_research.shtml

[2] Rider G., C. Wilson, "Small Parts Aspiration, Ingestion, and Choking in Small Children: Findings of the Small Parts Research Project", Risk Analysis, Vol. 16, No. 3, 1996.

enters the oral cavity (to determine if it can form an effective seal against the structure of the airway). While the gauge criteria can be restrictive for some products (adult, older child, etc.), it has been proven to be extremely effective in preventing airway obstruction injuries and fatalities.

In some instances, a company may be willing to accept the risk of producing a product that is capable of causing airway obstruction injuries, but would still like to reduce the potential for fatalities. This may want to be done for older children's products or adult products that have a certain level of child appeal. Decreasing the risk profile for small parts typically involves looking at how the overall size, shape and detectability impacts the potential hazard. The size will dictate how far into the airway a part could travel, whereas the shape will determine how much airflow is blocked should it become lodged in the airway. Making the part more readily detectable with medical devices (i.e. metal shows up well on x-rays) makes it easier for medical intervention if needed. Looking at standards like the British Marker and Pen Cap standard (BS 7272) provides insight into how this type of methodology could work to mitigate risks.

2.4.2 Asphyxiation – Suffocation

Suffocation is another form of asphyxiation, but the physical mechanism of injury is caused by the *external* obstruction of the respiratory system caused by blocking the nose and mouth. Suffocation has two primary mechanisms; Resistance Suffocation, where an object covers the nose and mouth of a victim causing direct airway obstruction, and Carbon Dioxide Accumulation, where decreased oxygen supply causes a rise in carbon dioxide leading to asphyxiation.

Resistance suffocation incidents have occurred with items like dry cleaning bags or other film-like objects that form a seal over the nose and mouth of a child. These incidents have also been caused by rigid containers that get suctioned / sealed to the face of a young child. To minimize this potential hazard, it is critical to find a way to prevent a seal from forming over the nose and mouth. For films, this can be done by increasing the bending stiffness of the film making it stiffer. Holes can be perforated into the film, but they would need to be spaced close together and in large quantities to effectively reduce the hazard. For rigid containers, avoiding circular openings with smooth rims, or including through holes or large volumes are all effective ways to minimize the hazard. More guidelines for rigid containers can be found in ASTM F963 or EN 71.

Carbon dioxide accumulation incidents can occur when a child is placed face down in a soft, pillow-like surface that does not provide good oxygen exchange (e.g. bean bags, pillows in cribs ,etc.). Carbon dioxide accumulation incidents can also occur when a person gets trapped in enclosed spaces that do not have ventilation (e.g. old toy boxes, refrigerators). There are several safety requirements that have been added to these products that have reduced fatalities of children, but it is important to remember these characteristics when designing any product that may share characteristics similar to those products.

2.4.3 Asphyxiation – Strangulation

Strangulation is the physical mechanism of injury caused by the *external* obstruction of the respiratory or circulatory system caused by external pressure to the neck region. The airway or circulatory system can be blocked by external pressure that is exerted on the neck by a cord or other strap-like object (e.g. window blind cords, drawstrings, etc.), or can be caused if a person (especially children) gets trapped in a position that causes an object to exert pressure on the neck. Strangulation can also occur by positional asphyxiation, which is when the head tips forward causing tissue to exert pressure in the neck area.

To minimize strangulation of children caused by straps or cords, there are some critical dimensions that can be used that are based on anthropometric data. Continuous loops should be designed to be less than 13.94″ (35.4 cm) to minimize the chance of the loops being placed over the head of a child. Loose ends of strings without attachments should be kept to a combined length of less than 8.66″ (22.0 cm) to minimize entanglement around a child's neck, while loose ends of strings *with* attachments should be kept to a combined length of less than 7.0″ (17.8 cm). Cords or straps that cannot meet these requirements for functional reasons should use wider

straps to distribute the load over a large area, or implement reliable breakaway mechanisms. Some of the more stringent requirements for cords and drawstrings in clothing can be found in European standard EN 14682.

For other objects that can exert pressure on the neck, many juvenile product standards have strangulation or entrapment requirements that can be studied for specific evaluation tools. There are head probes, torso probes and neck probes that are used to evaluate products like child gates, playground equipment, bunk beds and play yards. Using these tools to evaluate a product may be appropriate depending on the design and marketed use of a given product.

Positional asphyxiation typically occurs with infants who do not have sufficient head control, so any products designed to support or interact with infants or younger children should be evaluated to consider how the child is supported relative to this type of hazard.

2.4.4 Asphyxiation – Submersion / Drowning

A final form of asphyxiation is caused by submersion in a liquid or other substance, otherwise known as drowning. This can be caused directly by a product that holds fluids, for example a bathtub or bucket that holds water that a child can fall into, or can be caused indirectly when a product intended to be used as a safety device in water fails (e.g. a child flotation device that has a seat break allowing the child to slip into the water). Some devices can also give a false sense of security to parents that cause them to provide less supervision for a child (e.g. there is currently a large debate about bath seats because parents will leave the bathroom thinking their child is safe in the seat).

To protect against this hazard, any product capable of holding over 2 inches of water should be carefully reviewed. If the product is intended for children or attractive to them, the hazard may need to be designed out by limiting the ability for liquid to collect by placing holes in the product, or it should be designed such that a child cannot get his/her head where the liquid is (the strangulation guidelines can be used for head dimensions or head probes from other standards). For products intended to be used in or near water, the foreseeable use must be considered and special structural integrity and dynamic testing should be developed as needed.

2.4.5 Kinetic Energy – Impact

Impact injuries typically occur when a person collides with or strikes an object due to their motion. An object can also collide with a person, typically after being thrown, swung or otherwise put in motion (e.g. projectile products fall into this category). Impact injuries can cause a variety of injuries from contact with the object ranging from contusions / abrasions to broken bones or fractures from more severe impacts.

The characteristics in products that increase the risk of injury from an impact includes sharp points and edges, small contact surface areas, large mass (heavy objects), hard outer materials and the potential kinetic energy of object (when swung or moved). Specifically for projectiles, increased mass of the projectile and high velocities will increase the risk of injury. While there are some tools that can be used to assess these characteristics (e.g. sharp edge and sharp point testers), evaluating for this hazards can use a subjective evaluation for the above characteristics.

2.4.6 Kinetic Energy – Fall

Fall injuries can occur when a person falls off a product intended to support them. Products can also cause falls when they cause a person to trip or slip. Fall injuries can cause a wide variety of injuries ranging from contusions and abrasions caused by the impact with the ground or other surrounding objects to broken bones or concussions from more severe impacts. The elderly tend to be more at risk from fall injuries.

There are many characteristics of products that can lead to a fall related injury. Products that are unstable under foreseeable use can tip over or fall themselves. Weight distribution can oftentimes be a factor in this. Weakness or failure under dynamic loading conditions of an object supporting

a person can also lead to falls. Uneven surfaces or protrusions extending outwards can cause tripping, especially if the unevenness is not expected. Slippery surfaces or products that cause surfaces to become unexpectedly slippery can also cause falls. Features that interfere with movements or that can get trapped in exterior objects (e.g. long cords from clothing on escalators or bus doors) also increase the risk of injury. There are very few test methods developed in standards to address falls, so subjective evaluations are typically needed.

2.4.7 Kinetic Energy – Explosion

Explosion injuries occur when internal pressure causes the object to break apart. The pressure can be created by physical, chemical or electrical reactions within the product. Explosion injuries can be severe causing contusions or abrasions from the exploding pieces, or even amputations from the force of the explosion.

When dealing with items that may become pressurized, the structural integrity of the vessel becomes critical. Placing relief valves or designing ways for the product to fail in a safe manner becomes critical. For items that are going to be heated or have some other energy imparted (by physical, chemical or electrical means) it is important to understand all of the potential effects that can occur when used properly and improperly. In many instances, understanding exactly what it takes to make the product fail can help define the risk profile (e.g. if an item is supposed to be heated in a microwave for 40 seconds, and at 60 seconds it explodes, that may be a critical design flaw).

2.4.8 Mechanical – Laceration

Laceration injuries occur when contact is made with a sharp edge or point. This can occur both with intact products but also broken ones. Secondary laceration injuries can also occur when tools have to be used to open a package. Laceration injuries can range in severity from minor lacerations or scratches that can easily heal, but can also be quite serious leading to amputation or fatalities due to blood loss.

Sharp edges are typically the cause of lacerations, with edges on metal, wood or rigid plastic typically increasing the likelihood and severity of injury. The location of edges and accessibility to the user of the product are major factors in an injury occurring. Sharp edge and sharp point testers are used in regulatory testing; however, subjective evaluations of products can oftentimes identify hazardous edges that would pass the regulations. In some instances, it may be important to understand how a product will break to minimize sharp edges after the break (e.g. for high risk items likely to be used by young children). The design can then be modified to either be stronger (to prevent the break) or be modified to break apart in a safe manner.

2.4.9 Mechanical – Puncture

Puncture injuries typically occur when contact is made with a sharp edge or point. However, punctures can also occur when a person falls onto an object with a small surface area (impalement). Puncture injuries can range in severity from minor punctures that can easily heal to severe punctures, or impalements, that can cause fatalities.

Sharp points and edges can lead to punctures, as can projections/protrusions that have small surface areas. Long slender components in young children’s products can also be especially dangerous since they are likely to be inserted into ears and lead to eardrum ruptures. Subjective evaluations should be used to assess for this hazard. To address potential ear injuries, long slender components should be made either wider than 0.25" (6.35 mm) or shorter than 0.75" (19 mm). Any product that has a stable base should be evaluated to determine if there is a potential for impalement. Making the base unstable or enlarging the cross sectional area of the projection can reduce the potential hazard.

2.4.10 Mechanical – Entrapment

Entrapment injuries can occur when a body part is inserted into an opening that is too small and is unable to be removed due to swelling of body part. They also occur when a body part is

inserted into an opening that changes size causing the body part to be trapped. Entrapment can also occur through non-mechanical means (e.g. pressure induced suction). Entrapment injuries can range in severity. While most entrapments result in minor injuries and are more of a perceived or nuisance hazard, some entrapments can result in amputation due to loss of blood flow in the body part. More severe entrapments can result in fatalities.

Entrapment injuries occur based on the size of the body part being entrapped, which makes them one of the more challenging hazards to address. In general, round openings tend to be more hazardous than rectangular or irregular openings since round openings are more likely to restrict the blood flow of the body part. Due to the wide variety of body part sizes, and the fact the size changes depending on the age of the person, entrapment hazards typically require a detailed analysis on anthropometric data for the specific body part and age group being addressed.

Juvenile product standards use finger probes that are 0.210" (5.3 mm) and 0.375" (9.5 mm) in diameter. Openings that allow the small probe must also allow the large probe to minimize entrapment. However, these dimensions only cover younger children and other standards use different requirements. Reviewing anthropometric data shows that for children up to 7 years of age, a 0.65" (16.5 mm) probe would be more accurate due to larger fingers. One of the challenges though is if you make an opening large enough not to be a finger entrapment hazard, it may get into a range of being a hand or foot entrapment. Going larger could even make it a head or torso entrapment. It is important to understand the dimensions for the age group that is most at risk for the product being evaluated.

2.4.11 Mechanical – Pinching / Amputation / Crushing

Pinching, amputation and crushing injuries occur when a body part is physically inserted between moving parts or is otherwise pulled into moving parts in some manner. The body part can be compressed or a tourniquet-like effect can restrict blood flow. As the names indicate, these injuries can range in severity. Pinching incidents are typically minor, with crushing and amputation being the more severe incidents.

To minimize this hazard, any moving parts or items capable of creating a tourniquet need to be closely evaluated. Openings or gaps capable of catching body parts or skin need to be designed to prevent access. Sharp edges and rigid materials used on the edges of moving parts can increase the potential to catch a body part and pull it into a mechanism. Finger probes can be used to determine if a finger can be inserted into a specific opening. For hinges, going to a single hinge or removing pivot points all together can minimize this hazard. Thin strings or wires capable of easily twisting around a body part can also be hazardous for certain age groups, especially if located in clothing items for infants or toddlers since children that age are not able to effectively communicate if something is wrong.

2.4.12 Mechanical – Foreign Body

Foreign body injuries occur when an object gets intentionally or unintentionally inserted into the ear, nose, other body cavity, skin or other body surface. Foreign body injuries can cause a variety of injuries from lacerations and punctures to infections caused by the wound.

The most common foreign body type injury is caused by splinters, when a sliver of wood or metal comes off a product and lodges under the skin. Care must be taken when designing and manufacturing wood products to avoid splinters, especially if the product is going to be used by at risk groups. Foreign body injuries can also occur when a product unexpectedly releases a small part or substance that gets into the eyes or skin. Typically, this hazard is evaluated subjectively depending on the choice of materials being used.

2.4.13 Mechanical – Strain

Strain injuries occur when a person overexerts or overworks a muscle. Strain injuries can be severe but most strains heal over time or with therapy. Some strains can be permanent or cause an increase in the reoccurrence of the injury.

Strains can occur if a person tries to lift a heavy object, especially if the weight is unexpected. They can also occur if a product causes a person to move or twist awkwardly during use. A product that breaks or disengages unexpectedly during use can also cause muscles to become strained. This type of hazard is typically found during subjective evaluations or during DFMEAs. In some cases, custom testing or failure analysis must be performed.

2.4.14 Vibration / Sound

Vibration and sound hazards are two very different hazards, however they are grouped together because both are caused by vibration (sound is nothing more than vibrations through the air). Prolonged exposure to excessively vibrating products has the possibility of causing capillary or vascular damage. While not a very likely event, it is still a hazard to consider in some special circumstances and should not be ignored. Products that cause extended exposure to vibration or a localized concentration of vibration should have a DFMEA or other research conducted to better understand if there is any potential risk of injury.

Sound hazards occur when high sound levels or loud sounds at certain frequencies cause hearing loss. Extremely loud sound levels or very loud low amplitude sounds have the possibility of causing internal organ damage, but this is not typically seen with most consumer products. Sounds waves themselves have two characteristics that are focused on for this type of evaluation; amplitude and frequency. Exposure to a loud sound (high amplitude) for a long period of time can cause the hair cells in the inner ear to become permanently damaged. The hair cells can also become damaged though if exposed to a very loud sound for a short period of time. The potential risk of permanent damage also rises as the frequency increases (a higher frequency sound causes damage much quicker than low frequencies). Toy standards in the US (ASTM F963) and in Europe (EN 71) both have extensive sound requirements for toys that can be referenced when designing products.

2.4.15 Interference with Safe Activity

Interference with Safe Activity injuries occur when a product interferes with a person's senses (sight, hearing, etc.) or with a person's ability to move freely. While some products with this hazard can directly cause injuries (headaches if vision is distorted), interference typically results in serious secondary accidents (falls or entrapments).

Products must be designed in such a way to limit features that block or impede normal or peripheral vision or that cause any temporary loss of any sensory functions. These effects are typically found during DFMEA reviews or subjective reviews while considering foreseeable uses.

2.4.16 Thermal Effect – Flammability and Burns

Highly flammable products can cause severe burns or cause other objects to catch fire, sometimes with catastrophic results. Many products have specific flammability requirements that must be met due to regulatory actions over the years (e.g. mattresses, sleepwear, toys, etc.). However, there are still many products recalled every year for flammability/fire hazards that do not have regulations, but that have significant design related hazards. For example, a quick look at candle recalls in the U.S. will display a large number of candle holders that have geometries that place one candle under another, or use material coatings that are flammable. To prevent these hazards, it is important to perform detailed DFMEAs or develop custom testing during development to ensure this hazard doesn't exist.

Burn injuries themselves are typically caused by a person contacting hot surfaces (thermal burns) or from hot liquids contacting skin (scald burns). Many people believe burn injuries occur only due to the temperature of an object alone; however, the likelihood and severity of a burn is actually a function of the thermal dose, which is the amount of time the skin is exposed to a specific temperature. Skin can be exposed to a temperature of 55 degrees Celsius for approximately 20 seconds before a second degree burn occurs; however, increase that temperature to 65 degrees and a burn occurs in less than a second.

Surfaces that become heated, either directly or indirectly, must be closely evaluated to determine if the surface is capable of being heated to a hazardous level. Objects or materials that have a high thermal load capacity can also have a higher risk of causing injury (e.g. an aluminum bar heated to a specific temperature will be much more likely to cause a burn than aluminum foil since the temperature in the foil dissipates quickly due to the thinness of the material). Containers or items intended to be used for cooking must consider how people will handle them once heated and provide safe ways to handle the container. The structural integrity should also be studied to ensure it can withstand the heating cycles without failing.

2.4.17 Thermal Effect – Hypothermia / Cold

Hypothermia or cold burns are caused when the skin or body is exposed to low temperatures. Cold burns can be localized effects at the point of contact while hypothermia is typically characterized by a drop in body temperature. Cold burns can cause localized skin necrosis while hypothermia can cause death if not treated quickly.

Products that have accessible surfaces kept at very cold temperatures can have an increased risk of causing cold burns. Products with a high thermal load capacity that will come into contact with moistened body parts also have an increased risk (e.g. having a tongue stuck on a metal flag pole in winter). Products that can lead to a rapid drop in core body temperature can have an increased risk of causing hypothermia, as can products that claim to protect against cold but do not.

2.4.18 Electrical

An electrical hazard can cause a person to get shocked or electrocuted, it can create an electric arc between objects and cause a fire, a person can contact an electric source and get burned, or electricity can be an ignition source for an explosion. Electricity can cause mild to severe burns and can also lead to cardiac arrest.

Electrical hazards are addressed in many industry standards that use “best practices” to minimize the risk of shock or other electrical failure. It is critical to make sure any product that uses electricity (be it AC or battery powered) gets evaluated to these industry standards to ensure the electric design is appropriate. However, these standards do have limitations and do not always account for the foreseeable uses of products or failures that may occur after repeated mechanical uses. The many foreseeable uses of a product must be considered and special tests may need to be created to ensure the design will be safe based on the predicted uses. For example, a product designed for use in a bathroom or kitchen may need to have an immersion protection designed in case it gets knocked into a sink of water while plugged in. If a product has moving parts, it is important to look at where and how the parts move to see if minor repeated damage could occur that could lead to a catastrophic failure. A product may also want to be designed in such a way that it will always fail “safe” by using fuses (current limited or thermal) or other protective devices that will shut off a device before a critical failure can occur. For children’s products, it is especially important to minimize access to any circuitry and ensure that any parts (including batteries) are protected in such a way that a tool must be used to gain access.

2.4.19 Radiation and Light

There are many types of radiation including infrared, microwave and ionizing. Visible light and ultraviolet light are also a form of radiation and tend to be the primary focus when discussing this hazard. However, depending on the product, the other forms of radiation may need to be considered.

Light injuries are broken into two different mechanisms for injury. Direct light hazards can cause thermal burns to the eye or have a photochemical hazard, while indirect light hazards can cause interference with safe activity. Light injuries can cause temporary loss of function of eyes, partial blindness or spot blindness, irreversible damage to eye or even permanent blindness.

Thermal eye hazards are similar to thermal burns resulting from touching a hot object or using a magnifying glass to focus the sun's rays onto your skin. They can occur in the eye when the cornea and lens focus high-intensity light onto the retina. This type of injury is rare with electric light sources and is typically only seen with high power lighting systems, but this type of hazard can be caused by lasers and potentially with LEDs due to the focused beam of light that can be produced by these devices. Consumer products that utilize light sources for non-functional purposes should be kept to the lowest output needed. Shielding or otherwise diffusing the light can also be effective in minimizing potential injuries. Consumer products using functional light sources need to consider foreseeable uses and likely consumers and design the strength of the light accordingly.

Light can have other effects that may not cause direct damage to the eye or skin, but may interfere with the normal activity of the consumer. These effects include flash-blindness, afterimage effects, glare and photosensitive epilepsy. These hazards are more common with electric light sources, but could be associated with lasers and LEDs depending on uses. Flash blindness can cause a temporary vision impairment that interferes with the ability to detect or resolve a visual target following exposure to bright light. This is similar to the effect produced by flashbulbs and can occur at exposure levels below those that cause eye damage. The impairment is transitory, lasting seconds to minutes depending on exposure level and time, the visual task, the ambient lighting and the brightness of the visual target. Afterimage effects are the perception of light, dark or colored spots after exposure to a bright light that may be distracting or disruptive. Afterimages typically wear off quickly; however, brighter lights can cause longer lasting afterimages. Glare creates a reduction or total loss of visibility, such as that produced by an intense light source in the central field of vision. The effect lasts only as long as the light is actually present affecting the individual's field of vision. Visual laser light can produce glare and can interfere with vision even at low energies well below those that produce eye damage. Photosensitive epilepsy is a form of epilepsy in which seizures are provoked by flickering light encountered in everyday life. 50% of photosensitive people are sensitive to 50Hz, but 75% are sensitive from 5 Hz to 25Hz. A strobe light at 10,13 or 15 [cycles per second] can induce seizures in people with a certain genetic makeup. This type of hazard is most common with electric light sources, but could be associated with LEDs depending on applications. Any light sources being considered for products should be evaluated against these potential concerns.

Other radiation hazards can be caused by ultraviolet light, infrared radiation, microwave radiation and ionizing radiation. Ultraviolet light can be created by the sun or man-made sources (e.g. plasma torches, UV lamps). Intense ultraviolet radiation can cause blindness and superficial skin burns in high doses over a short period of time, while skin cancer and cataracts of the eye are possible from lower doses over long periods of time. Infrared radiation is used in a variety of wireless communications, monitoring, and control applications; however, infrared radiation can cause destructive heating of biological tissue. Microwave radiation is used in communication systems and other applications (e.g. microwave ovens) and can also cause destructive heating of biological tissue. There is debate as to whether long-term exposure to moderate-to-intense radio-frequency (RF) fields and EMF fields is harmful to human beings (e.g. cell phones). Ionizing radiation is caused by x-rays or other nuclear particles being exposed to the body. Ionizing radiation is dangerous because it damages the internal structures of living cells. In high doses this can cause cell death over a short period of time and errors in the reproductive process (mutations) in lower doses over longer periods of time. These types of hazards are not frequently found in every day consumer products, but they are still hazards that must be considered depending on the characteristics of the product being developed.

2.4.20 Chemical

Over the past 5-10 years, there has been ever increasing scrutiny over the chemicals being used in consumer products. Many of these chemicals are already under a steady stream of attack even though there are conflicting reports about their relative toxicity (e.g. phthalates). This paper cannot go into the various specific chemical hazards that exist as there are thousands of chemicals used in products. The most challenging part of this area right now is how quickly it is

evolving, but also the knee jerk reactions taken by local, state and federal authorities before any detailed understanding of the issue is considered. To manage chemical risks, the only advice is to develop a network of resources that will keep you abreast of any changes in this area relative to consumer products. This network could include lab services that send out regulatory updates, news article services that send out updates on article found online, or other research organizations that could give advanced warnings of pending concerns. There are many regulations already in existence in the U.S. and Europe that should be considered regardless of the product's distribution.

For products that contain larger amounts of accessible chemicals, or chemical substances that a consumer could be exposed to if the product breaks, it is critical to have a toxicity review done by a board certified toxicologist. This review must pay close attention to the consumer of interest (i.e. if the product is attractive to children, then the toxicologist should conduct a review specifically for children). Once the formula has been evaluated, an initial raw sample should be analyzed and recorded using an FTIR or similar process. This provides a "fingerprint" of the formulation based on the intended composition. Once production has started, random spot checks should be performed on every batch to verify the composition has not changed. FTIR scans can be compared against the original to determine if the formulation is the same. A new toxicologist review should be performed if the formulation or composition changes, or every 3 years even if composition has not changed since there is continuous new research in this field that may need to be considered.

2.4.21 Microbiological

Microbiological contaminants are capable of growing in certain media. Contaminants include e. coli, salmonella and other bacteria or molds. These contaminants can cause serious illnesses or other health concerns if contacted. A contaminated media is only hazardous if accessible to the consumer, but contamination can occur at manufacture and bacteria can breed during transportation. Any products that have a medium that could promote microbiological growth (e.g. arts and crafts, gels, pastes, liquid filled items, etc.) should have no medium present that allows for pathogenic bacteria growth. Preservatives may be used to minimize growth or sterilization of the product immediately before pack out could minimize contamination.

2.4.22 Other Hazards

The hazards discussed in the preceding sections are the most common hazards that exist in consumer products, but the list is in no way comprehensive. For a given industry, there may be specific hazards or even patterns of usage that exist that should be built in to any risk assessment process. In the early phase of building a risk assessment process into a company, it is always better to begin with DFMEA for all products over a period of time to get a handle on the specific nuances of the product types and industry related hazards. In some cases, products requiring a high degree of assembly by the consumer may need detailed DFMEAs on the assembly and instruction processes themselves just to determine how the product could be hazardous if assembled incorrectly. This may require a change to the instructions, or in some cases a redesign of the product. This is why it is especially important to begin these risk assessment processes as early in the design process as possible, and to have them frequently during the develop cycle to better prevent resources being wasted on a faulty design.

2.5) Risk Determination

The most challenging aspect of the risk assessment process, and the part that requires the highest degree of experience and knowledge, is how to classify the actual risk of a specific hazard once identified. There are ways to calculate these risk numbers using advanced probability calculations combined with research of each specific factor, but analyses like these tend to beyond the capabilities of the vast majority of companies. Instead, a subjective decision must be made by a person or a group of people who have the knowledge and experience to make an educated decision. In some cases, a single hazard may have multiple risk levels (a minor incident could happen frequently, while a critical issue could have a remote chance of

happening). In these cases, both risk levels need to be evaluated to determine if a change is needed.

There are several tools available that can assist in defining the criticality of a specific hazard. Figure 3 shows a simple matrix chart used to help classify the risk of a given hazard based on the probability of occurrence and severity of injury. Each color represents a level of risk. Figure 4 shows a tool called a Risk Assessment Nomograph that was developed as a more comprehensive way of calculating the risk of a specific hazard. All of these tools still require someone to make subjective inputs into the tool to get an output though, so the person using it must be properly trained.

The additional challenge to implementing tools like these is the company must decide what risk level they are willing to assume with their products. Most children's product companies will not tolerate any risk, especially in light of the increased scrutiny of children's products these days. However, a manufacturer of adult products may actually accept a low to moderate level of risk depending on the specific issue. This general level of acceptance is important to get defined early on in the implementation of this type of process and must be continuously reviewed.

		Severity				
		Catastrophic	Critical	Moderate	Slight	Minimal
Probability	Improbable					
	Remote					
	Occassional					
	Frequent					

Figure 3: Risk Matrix

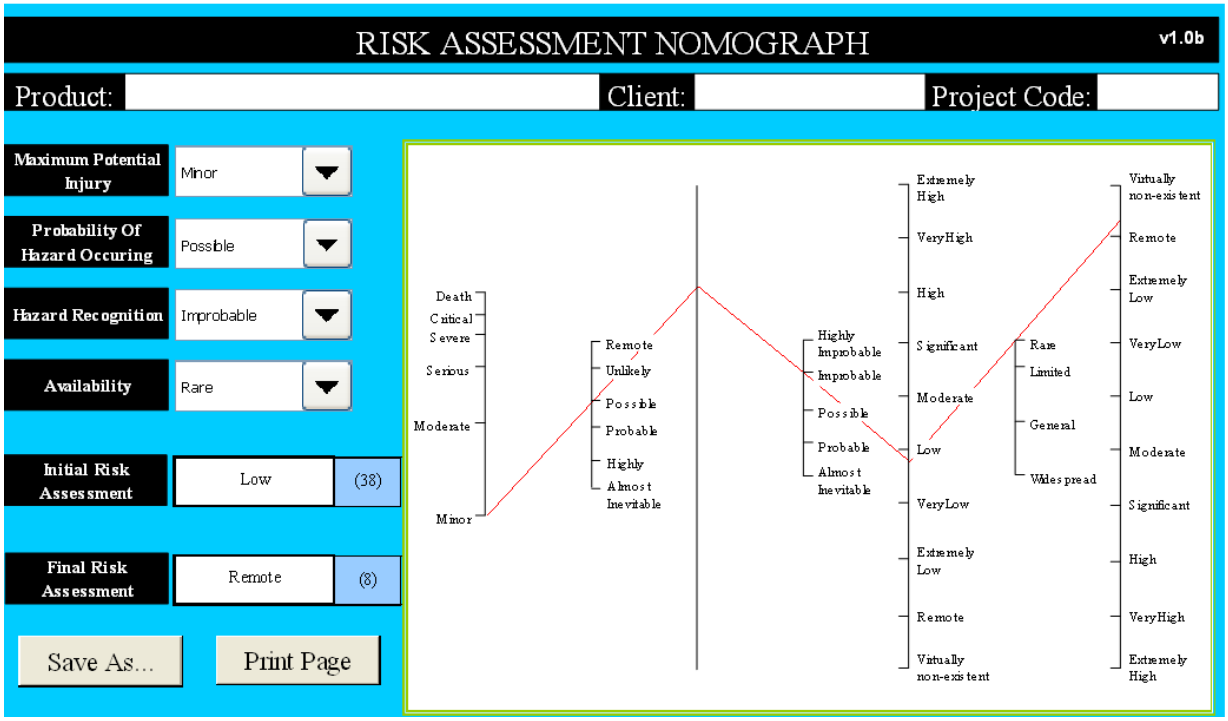

Figure 4: Risk Assessment Nomograph

Once the risk level has been assigned for a given hazard, the company has to decide what to do. The first choice should always be to design the hazard out of the product. This is the only effective way to eliminate the risk of injury. However, in many instances, the hazard may be an

inherent hazard or it may be too expensive to design out (note, product cost should never be a factor for safety, but increasing the cost of a product by 200% to design out a minor hazard is not a reasonable business model – court rulings have even vetted this out so long as there were no reasonable alternatives). Keep in mind, any changes to a design requires another risk assessment to be performed to determine if the new design has introduced new foreseeable uses or additional hazards. If the hazard cannot be designed out, the next solution should be to protect or safeguard against the hazard (i.e. make it difficult to access the hazard). For example, drain cleaner is a caustic chemical that needs to be caustic to work properly, but placing it in a bottle with a childproof cap reduces the risk of poisoning to children. If the hazard cannot be designed out or safeguarded against, warnings and instructions might be able to be considered. However, this should be the last option considered since this does not do anything to change the hazard. Lastly, in some cases, a company may be willing to accept a given hazard based on the overall risk, exposure in the marketplace or other factors. Not addressing an identified hazard must be done carefully considering documentation will show that the hazard was found during the design process. Knowingly producing a product with a hazard can result in massive punitive damages unless there is a sound scientific basis to allow the product to be manufactured.

Another risk assessment strategy that can be used, especially for companies that produce a broad range of products, is the application of different guidelines depending on the overall risk of the product being evaluated. Adult items that are not attractive to children may not require the most stringent requirements to be applied since the overall risk of certain injuries is low. Systems like this are much more complicated to implement, but can be very useful in stratifying a product mix. It is important to note though that a system like this should still require an evaluation of every product to ensure there are not obvious hazards that need to be addressed, or hazards that can be easily addressed. Figures 5 and 6 show examples of how a stratified risk guideline approach could work.

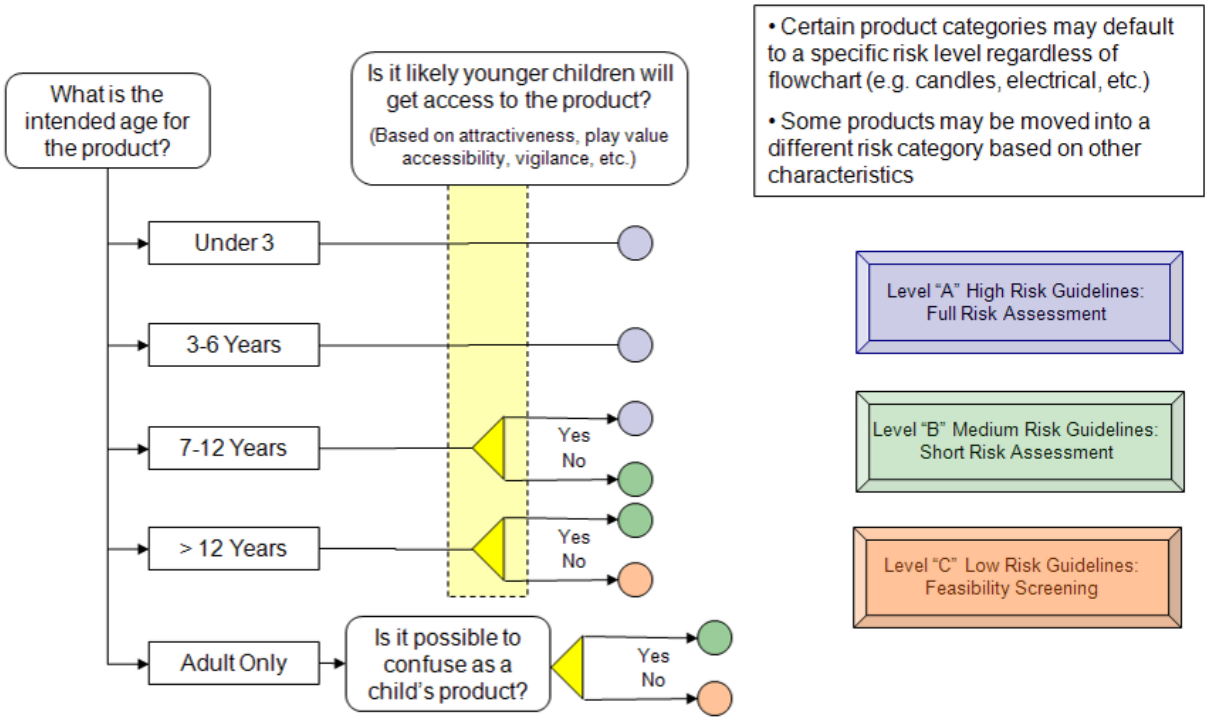

Figure 5: Application of Risk Guidelines – Flowchart

	Category A High Risk	Category B Medium Risk	Category C Low Risk
Product Evaluations			
Risk Assessment	X		
Feasibility Review		X	X
Compliance Review	X	X	X
Hazards Approach			
Airway Obstruction	No small parts allowed	No *critical* small parts allowed	Decided on case by case basis
	No small balls allowed	Small balls only if necessary for function	
	Products must comply with gauge	Products should comply with gauge	
	Most stringent requirements apply	and other requirements	
Suffocation	Most stringent requirements apply	Decided on case by case basis	Decided on case by case basis
Strangulation	Loops and cords requirements apply	Loops must have breakaways	Loops should have breakaways
		No long cords	Long cords decided case by case
Entrapment	No critical openings	No critical openings	Decided on case by case basis
	No nuisance openings	Nuisance openings decided case by case	
Electrical	Failure Analysis required	Failure Analysis required	Failure Analysis recommended
Toxicity	Full TRA required	Full TRA required	Legal requirements only
	In process verification should be used		TRA recommended
All Other Hazards	Follow Summary of Findings Approach using Essential Safety Guidelines		
Summary of Findings Approach			
Critical Concerns	Must be addressed	Must be addressed	Must be addressed
Major Concerns	Must be addressed	Decided on case by case basis	Decided on case by case basis
Minor Concerns	Decided on case by case basis	Decided on case by case basis	Decided on case by case basis

Testing Approach	High Volume	Low Volume	High Volume	Low Volume	High Volume	Low Volume
Raw Material	Yes	Yes	Yes	Optional	Optional	Optional
Component	Yes	Optional	Optional	No	No	No
Pre-production	Yes	Yes	Yes	Optional	Yes	Optional
During Production	Yes	Optional	Optional	No	Optional	No
Final Product / Pre-shipment (France)	Yes	Yes	Yes	Yes	Yes	Yes

Inspection Approach	High Volume	Low Volume	High Volume	Low Volume	High Volume	Low Volume
Component	Yes	Optional	Optional	Optional	Optional	Optional
Pre-production	Yes	Yes	Yes	Optional	Optional	Optional
During Production	Yes	Optional	Optional	Optional	Optional	Optional
Final Product	Yes	Yes	Yes	Yes	Optional	Optional

Figure 6: Application of Risk Guidelines – Decision Matrix

3) Documentation

Any risk assessment process is only effective if extensive documentation is maintained. Many attorneys would argue against documenting the level of detail that goes into risk assessments due to the potential to have a “smoking gun”, but if the company has a robust system in place to address the hazards that are found and a product cannot be released for production until all items found in the risk assessment are addressed, the potential for legal problems get reduced significantly. In fact, a properly designed risk assessment process that is well documented can oftentimes be used in legal proceedings to show the company uses best practices in the design of products (and can sometimes reduce or eliminate punitive damages in case a product does cause an injury). However, any final determination on how documentation is done should be conducted under the advice of legal counsel for your industry.

To properly document a risk assessment, there are several key pieces of information that should be included. The first piece of information is to identify the unique product information for the product being evaluated. This should include a product/project name, a prototype or model number, the stage of development the product was in at the time of the review, and a detailed description of the actual product being evaluated. Detailed photos of the product being reviewed can also be helpful in identifying the product at a later time. In addition to the product information, the identity of the people involved in the review should also be documented in case specific questions arise later.

Detailed descriptions of the findings and the actions required to address any potential hazards should be included in the documentation. If a hazard is designed out at a later time, the process should document it in such a way that anyone reading the report would know a hazard was found,

what the hazard was, and exactly what was done to mitigate the hazard. Having a history in this manner allows for detailed understandings of how the risk assessment process works within the company. A date showing when a given issue was resolved can also be helpful later in tracing back resolutions or prototypes. Pictures of the specific hazard and actions taken can also be very useful from an archiving standpoint. If a specific department or individual has responsibility for resolving a specific hazard, this should be clearly indicated on the form. Additional reviews of the product at a later stage in development should be added to the previous review for continuity of information. This allows the evaluators to review past issues to ensure they remain closed, but also allows all information to be in one location.

4) Conclusion

Implementing a risk assessment process can be a daunting task for most companies. It is best to start slow and try different strategies on a small selection of products first before implementing a wide scale program. This allows adjustments to be made to the process very earlier based on what works or doesn't work without completely disrupting the business. The most important thing to remember as you embark on this process is to "know what you know, and know what you don't know". Your company will have lots of experience in many of the processes and hazards being reviewed and should utilize that experience to its fullest. However, you must also recognize and acknowledge when you do not have enough information, or don't have the right information, and seek help from outside experts at those times.

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Appendix A: Airway Obstruction Gauge Criteria Flowchart