Best practice guide for the design of

safe infant sleeping environments

A GUIDE FOR INDUSTRY TO REDUCE THE RISK OF DEATH AND LIFE-THREATENING INJURIES IN INFANTS

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Acknowledgements

This guide is the result of collective input and feedback from various organisations and their representatives.

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Introduction

The safety of products that relate to an infant's sleep environment has been a cause of concern for many years. Whilst some progress has been made by industry, the public sector and consumer groups in terms of education, standards and regulations that relate to infant sleep products, a need has emerged for a more comprehensive, coordinated and evidence-based approach.

Standards and regulations rarely keep pace with product development. Further, many products (including some that claim to have health benefits or to reduce the risk factors associated with sleep-related deaths) have fallen between standards and regulatory 'cracks'. Some suppliers, particularly smaller suppliers and new entrants to the marketplace, often rely solely on safety information provided by the manufacturer and this has resulted in unsubstantiated health benefit claims being made about particular products. The Federal Drug Administration in the U.S.A. and the Therapeutic Goods Administration in Australia have both taken action against suppliers of certain sleep positioners in relation to unfounded health claims. Other products may be safe with prescribed use, but when used inappropriately paradoxically increase the risk of injury. This has resulted in mixed and frequently confused consumer messaging and a lack of consistency in terms of what constitutes a safe infant sleep product. Many infant sleep products are used in the absence of supervision in the home environment, so it is critical that these products meet the highest level of safety.

This guide provides industry with information, based on a combination of medical (anatomy, physiology), regulatory and epidemiological expertise, on what makes a sleeping environment unsafe for infants and highlights essential considerations for designing, marketing and supplying safe infant sleep products.

The guide's content is the result of collective input from an inter-sectoral working group of persons and organisations that have expertise in product safety, the safety of infants and safe sleeping (**see Acknowledgements**).

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What is an infant sleep product?

An infant sleep product is a product that is designed or marketed towards use by an infant (children under 12 months of age) to sleep with, on, or in, or designed to be an aid for infant sleeping.

Products include, but are not limited to: household cots, portable cots, bassinets, cradles, sling carriers, bedside sleepers, cot bumpers, sleep positioners, mattresses, pillows, cocoons, baby nests, in bed co-sleepers and other devices and associated accessories (e.g. apnoea and temperature monitors) that may be used in an infant's sleep environment.

It is also recognised that infants sleep on, or in, a broad array of products that are marketed for transport or seating. Many contemporary hybrid product designs perform dual functions; e.g. child car restraint to pram fixture. The likelihood of injury occurring in these devices depends on the design and marketing of the product, duration of use, and degree of direct supervision. Current health recommendations are that infants should not spend more than one hour in a child car restraint due to the risk of positional asphyxia. Comfortable and versatile product design and recommendations relating to infant safety for sleep need to be balanced against the additional protection provided to the infant in the event of a crash. Specific consideration should be given to the likelihood of an infant sleeping or napping in infant products that are not specifically designed for sleeping, such that hazards as described in this document are eliminated where possible.

Bunk beds are not included because they are not products intended for or marketed toward infants. However, bunk beds are recognised as an important sleep safety issue for children.

Whilst the focus is on sleep products supplied into the domestic market there is a flow on continuum effect for products used in hospitals, child health facilities, early learning and commercial childcare environments. It is, however, expected that medical facilities and maternal and child health programs will have established risk management criteria in place that would mean that sleep products in that setting are used under the close supervision of a health professional in a highly controlled or monitored (e.g. continuous physiological monitoring in a neonatal intensive care unit; contact support provided by health professionals in home-based community settings) environment. Notably, some products used relatively safely in a highly controlled environment such as a hospital may not be safe to use in a domestic setting.

Another example of this includes maternal and child health programs that use portable infant sleep spaces. Unlike commercially available baby boxes, these programs such as the Pēpi-Pod® and Wahakura programs in New Zealand and Queensland have recognised education, parent support and follow-up responses to reinforce ongoing safe use of the device as the infant develops, including a transition plan to a suitable infant sleep space when the baby outgrows the portable space.

Why are infants vulnerable during sleep?

In contrast to healthy older children and adults, healthy infants (children under the age of 12 months) are inherently vulnerable to sleep-related injury through a variety of mechanisms. This vulnerability evolves with age and fluctuates with other external factors, some of which are modifiable by the parent or caregiver.

This inherent vulnerability stems from the following differences between infants and older children and adults.

Compared with older children, an infant has:

- Smaller more easily compressed airways
- A large, heavy head relative to body size
- A protruding occiput (back of the head), such that the head tips forward even when lying on their back on a flat surface
- More easily compressed chest wall
- Less respiratory stamina
- Reduced temperature control
- Reduced sleep arousal to elevations in carbon dioxide
- If prone, a reduced ability to lift their face away from any obstruction (mattress/pillow)

These anatomical (structural) and physiological (functional) vulnerabilities are unique to an infant's chronological age and development stage.

In addition, infants may have as many as seven upper respiratory tract infections in their first year of life, especially if there are older siblings. Even mild illnesses result in a degree of respiratory compromise. There are a variety of factors that can further compound this vulnerability: prematurity, low birth weight (‹2500 g), exposure to cigarette smoke, drugs or alcohol both in utero and after delivery, medical conditions, other intercurrent illnesses and the immediate sleep environment.

What is Sudden Unexpected Death in Infancy?

Many (but not all) sudden unexpected deaths in infancy (SUDI) occur during sleep.

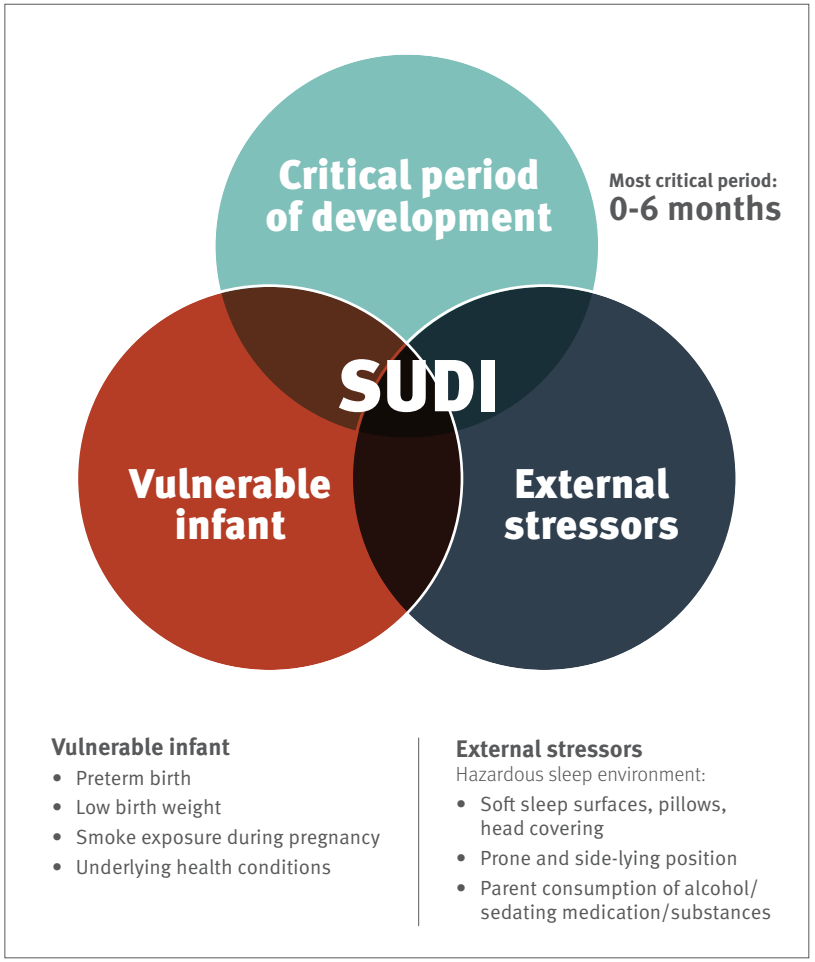
SUDI is a category of deaths in which an infant dies suddenly, usually during sleep, with no immediate obvious cause at the time of death. SUDI includes deaths that are later explained by natural (e.g. infection) or external causes (e.g. fatal sleep accidents) and deaths that remain unexplained after a thorough investigation (e.g. Sudden Infant Death Syndrome [SIDS], undetermined deaths).

Where an unexpected infant death occurs, the quality of the police, forensic and coronial investigation can vary according to jurisdiction, expertise and situation. Where death has occurred during sleep, an ideal investigation should collate information about the infant's health (recent, background and family history), drug/alcohol and cigarette exposure and sleeping environment. As with any death investigation, circumstances surrounding the death may be difficult to establish with any certainty.

Even with the most comprehensive investigation, it is difficult to attribute causality to any one factor and it is likely that infants succumb to a series of cumulative physical insults—one of which is a sleep environment that contains elements known to increase risk for an infant. This cumulative insult is described in the Triple Risk Hypothesis **www.rednose.org.au/article/the-triple-risk-model**

Application of the Triple Risk Model to SUDI emphasises interactions between predisposing factors, however acknowledges that one domain may contribute greater risk depending on infant vulnerability and stage of development.

Triple Risk Model for SUDI



Adapted from Filiano JJ, Kinney HC. A perspective on neuropathologic findings in victims of the sudden infant death syndrome: the triple-risk model. Biology of the Neonate 1994;65(3-4):194-7

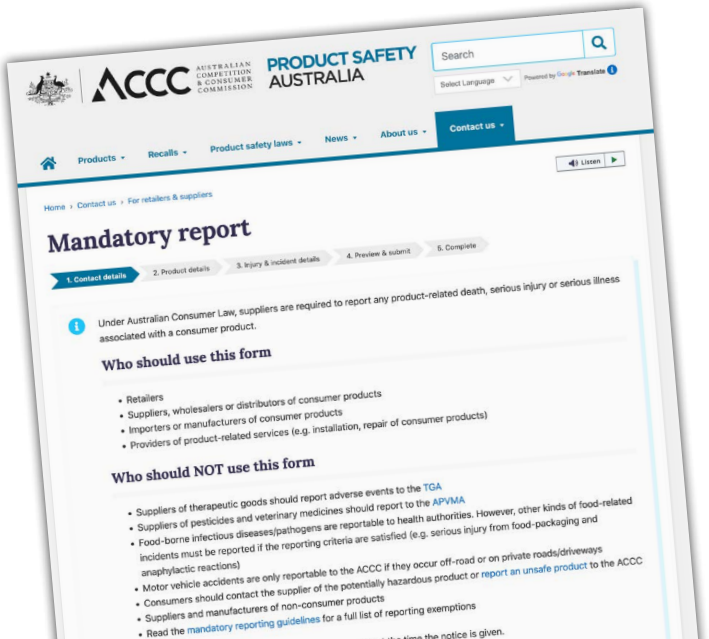
Sudden Unexpected Death in Infancy includes Sudden Infant Death Syndrome and fatal sleeping accidents.

Is there data linking sleep products to infant deaths?

Injury data can be useful for examining product-related risk and developing a plan for action to reduce that risk. However, data is most informative when:

- There is a broad range of outcomes; minor injury to death
- Witnesses/patients can describe events leading up to the injury
- There is a clear relationship between use of the product and the injury
- There is an obvious failure of the product

For sleep-product related infant injuries, there is usually no witness and the patient cannot describe events. The child usually either wakes without apparent ill-effect or does not wake at all. Only a small proportion of infants present to hospital with a 'near-miss' event (found blue/unresponsive in their sleep environment). As with coronial investigations, it is challenging (even with a live patient) to rule out all medical causes in 'near-miss' situations.



Reporting of unsafe infant sleep products

The Australian Consumer Law requires suppliers to report any death, serious injury or illness associated with their products to the Australian Competition and Consumer Commission (on behalf of the Commonwealth Minister) within two days of becoming aware that the product caused, or may have caused, the incident **Appendix A**. Suppliers can report to the Australian Competition and Consumer Commission using the **mandatory report form** on the Product Safety Australia website.

This obligation applies to all participants in the supply chain and requires a report be submitted where a supplier becomes aware that:

- the use or foreseeable misuse of a consumer product they have supplied has caused, or may have caused, a death or serious injury or illness (even when the death, serious injury or illness occurred outside of Australia), or
- another person (e.g. customer) considers the product caused the death, serious injury or illness, or
- the product was somehow related to, or involved with, a death, serious injury or illness irrespective of whether it was being used or misused at the time of the incident, so long as the misuse was foreseeable.

Suppliers must submit a mandatory report even where all the information may not be available (details can be updated after the initial report). A reportable serious injury or illness is one that is acute (sudden, brief and severe) and requires medical treatment from a nurse or medical practitioner.

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Even where suppliers assess they are not legally required to submit a mandatory report, such as for near misses, the Australian Competition and Consumer Commission strongly encourages adopting the best practice approach of **voluntary reporting**.

Sometimes suppliers will not be aware of an incident until made aware by a parent or health clinician, or the information is posted on social media or covered in mainstream media. There are numerous potential barriers to caregivers and clinicians reporting incidents to suppliers. For example, the shock of trauma, an unclear relationship between the product and incident, or confusion about the responsible supplier. Such barriers further highlight the importance of submitting a mandatory report where suppliers do become aware of a reportable incident.

The Australian Competition and Consumer Commission uses information from reports to identify emerging hazards and risks in consumer goods and product related services, and to take action to prevent similar injuries, illnesses or fatalities. More information about mandatory reporting is available on the Australian Competition and Consumer Commission's **Product Safety Australia website**.

Parents and clinicians are unlikely to report to suppliers or regulators for the following reasons:

- Parents are often too traumatised to report
- Injury may be the result of an interaction between one or more products
- It is often not clear who the responsible supplier is for many products
- It is often not clear who the responsible regulator is
- Most parents (and clinicians) are unaware of the reporting obligations of suppliers
- Most parents (and clinicians) are unaware of the regulatory reporting channels

Most importantly, however, one has to mentally attribute risk to the product in order to consider reporting. Sometimes this is more obvious, but in the case of sleep-related deaths/injury, unless the infant was found entangled/hanging, the attribution is not always clear.

What makes a sleep environment unsafe?

Whilst data on sleep-product associated injuries is problematic, there is research that identifies what an infant's anatomical and physiologic vulnerabilities are and what factors might exacerbate these.

To understand the risk, you need to understand how infants are designed!

How an infant's respiration and circulation works:

Respiration is initiated by the downward movement of the diaphragm. This movement generates negative pressure inside the chest. As air is drawn in, the ribs expand passively. Infants can suffocate if there is an obstruction (partial or complete) to diaphragmatic movement, air inflow or chest wall expansion. This is better explained, with examples below.

Respiration is controlled by biofeedback loops that respond primarily to a rise in carbon dioxide levels. In some children who have chronic lung disease and elevated carbon dioxide levels (ex-premature infants) low oxygen levels may be the driver for respiration. Respiratory drive is reduced in sleeping infants and this can be further impacted if the infant is sick or exposed to sedative medication (prescription drugs, illicit drugs, alcohol) either directly or through the breast milk.

Circulation of blood requires squeezing and refilling of the heart and unimpeded flow to all organs but especially the brain (which controls vital body functions). Blood circulation can be impaired due to rises in intrathoracic (chest cavity) or abdominal pressure or occlusion of arteries that feed organs (high pressure) or veins that drain organs (low pressure). Occlusion of cerebral blood flow (through direct occlusion of neck arteries) results in rapid unconsciousness and cessation of vital functions.

Suffocation refers to deprivation of oxygen entering the body whereas asphyxia refers to deprivation of oxygen being delivered to the tissues. The causes of suffocation and asphyxia are largely the same, except that asphyxia can be caused by stopping blood flow (which delivers oxygen) independently of respiration (which replenishes oxygen supply).

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Hazards that can be avoided in the sleep environment

Some of these hazards are already described in *ISO/IEC Guide 50: 2014; Safety Aspects-guidelines for child safety on standards and other specifications* (**www.iso.org/standard/63937.html**), with part 6.4 providing specific reference to hazards in the sleep environment. ISO references are highlighted in red in the relevant sections below.

Suffocation

Rebreathing of exhaled carbon dioxide (CO_2)

People (at any age) can suffocate from rebreathing the CO_2 that they naturally exhale. This sometimes happens to adults who are working at the bottom of pits or in other enclosed spaces. More recently, during the Covid-19 pandemic, people have experienced the effects of face masks causing a mild CO_2 rebreathing effect. An infant sleep arrangement that prevents free dissipation of CO_2 (clothing or bedding covering the face, overly soft mattresses), can result in CO_2 rebreathing. This may cause an initial rise in respiratory rate but will (as CO_2 levels rise) subsequently result in raised brain pressure through increased cerebral blood flow and CO_2 narcosis (sedation and decreased respiratory drive). An infant can suffocate due to rebreathing of CO_2 in situations where there is direct (e.g. a baby lying face down on a pillow or soft mattress) or indirect covering of the infant's face/head (e.g. a doona or heavy blanket being used to cover a cot or pram bassinet etc).

Although some products may be marketed as 'breathable', there is currently no way of reliably quantifying and testing for CO_2 pooling risk. Many claims are also unrelated to the safety of the item and confuse the consumer. See 'Misinformation' below.

Face occlusion

Different infants develop the ability to roll at different ages. Infants learn to roll from back to front before they are able to roll from front onto their back. Therefore, an infant who rolls onto their stomach may not be able to roll back. If sleeping face down (prone), they are more likely to occlude their mouth and nose if the surface is soft and compressible and does not allow the free movement of inhaled and exhaled air (including dissipation of exhaled carbon dioxide) or they are unable to use their arms to push away from the surface (e.g. some swaddling products restrain arms).

Loose items placed within (pillows, bedding, sleep positioners, decorations or toys), or pulled into the sleep environment (nappy bags), can also cause face occlusion.

Sides of bassinet and portacots made of loose or non-taut fabric, or padded material can also cause face occlusion.

ISO 7.5.2 **Face occlusion is described in ISO Guide 50; 7.5.2 Suffocation Hazards; materials.**

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Airway occlusion

Airway occlusion can occur through internal obstruction (foreign body) or external compression (chin to chest position or neck entrapment).

ISO 7.7.1

Airway obstruction due to foreign bodies is described in ISO Guide 50; 7.7.1, Small objects and suction hazards; small objects.

Chin to chest: Even when lying on a flat, horizontal surface, an infant's head tends to tip forward because of their protruding occiput (back of the head). A surface that is curved (C-sling, soft-based hammock), has padding behind the head (child car restraint) or one where the infant can settle into the surface (waterbed, bean bag) creates a situation where the infant's chin can be pushed towards the chest. This can cause relative airway compression that subtly increases the work required for an infant to breathe. Inclined surfaces further exacerbate this risk due to gravity tipping the head forward, potentially occluding an infant's compressible airway.

Chest/abdominal compression

Infants can suffocate if exposed to products (weighted blankets, tight swaddling/wrapping) that restrict their chest wall/abdominal movement or if caught in a device that inadvertently closes (collapsed portacot, wedging of baby between mattress and wall) around the infant's chest or abdomen.

Risk associated with chest/abdominal compression/ entrapment is not specifically described in ISO Guide 50.

Airway occlusion with chest/abdominal compression

Tucked position: In addition to the hazard of chin to chest positioning, products with a curved surface (C-slings, soft-based hammocks) or one in which the child can settle (bean bags, waterbeds) also cause the child to be in a tucked position with a curved back. This compounds the effect of airway compression by further compromising respiratory efforts through increasing intra-abdominal pressure and reducing the downward diaphragm movement required for breathing.

Seated/inclined devices: Products where the infant sleeps inclined (inclined sleepers, rockers) promote external airway occlusion and respiratory compromise through the head falling forwards (even where the head is not pushed forward by the structure) and the infant slouching in the device. Such devices also promote premature rolling and therefore increase the risk of suffocation where the infant may end up prone.

ISO 7.5.5

Chin to chest, tucked and seated/inclined positioning are described in ISO Guide 50; 7.5.5 as Suffocation hazards; positional asphyxia.

Asphyxia (suffocation with reduced cerebral blood flow)

Strangulation

Strangulation occurs when a product tightens or wraps around an infant's neck and causes both airway obstruction and reduced blood flow to the brain. The reduced blood flow rapidly causes unconsciousness. Items that cause strangulation can either be worn (necklaces, clothing pulls/ties/cuffs) or be inherent to (straps), placed within (mosquito netting, monitor cords) or pulled into (blind cords) the sleep environment.

Strangulation can occur either because the infant's movement results in the product wrapping around the neck (necklace or clothing drawstring), or because the product tightens or retracts (elastic/flexible strings, retractable drawstrings) or because the product snags on a fixture (cuffs/hoodies). Sometimes a combination of these events may occur.

Head entrapment

An infant's head diameter is wider than their body (measured chest to back). Therefore, it is possible for an infant to pass their body through a gap but be caught at the head. Moreover, an infant's head diameter front to back is greater that the diameter side to side. Therefore, it is possible for them to pass their head through a gap (sideways) and not work out how to extract themselves. Where the infant is unable to support their weight other than by the head, this can cause respiratory compromise even where there is no direct airway or vascular compression.

Head entrapment can also result from a device that inadvertently closes (collapsed portacot) around the infant's neck.

Hanging

Hanging involves either strangulation from a suspended fixture (mosquito netting, blind cord) or snagging/entrapment (hoodie or cuff caught on a fixture, toggle on hat cord wedged in a small opening or infant's head caught in a gap) and usually occurs when an infant is old enough to pull themselves to standing and/or attempt to climb out of the sleep environment.

ISO 7.6 **Strangulation hazards are described in ISO Guide 50; 7.6; Strangulation hazards**

ISO 7.2.1 **Entrapment hazards are described in ISO Guide 50; 7.2.1; Gaps and openings**

ISO 7.2.2 **Snagging hazards are described in ISO Guide 50; 7.2.2; Protrusions and projections**

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Environmental hazards

Temperature regulation

Infants have a reduced capacity to self-regulate temperature. Infants have a relatively large head surface area compared to adults and can lose significant heat if not covered. There are many infant sleep products that seek to assist with temperature regulation (head coverings, onesies, sleep bags). Design of these products needs to avoid overheating in addition to the risks identified above; strangulation, restriction of arms (infant's ability to push up) and chest movement.

Rebreathing of exhaled CO_2

As above, suffocation can occur in environmental situations that cause inadequate airflow and allow CO_2 accumulation and rebreathing (e.g. sleeping in a confined/enclosed space).

Carbon monoxide

Carbon monoxide (CO) causes asphyxia (at any age) through blocking oxygen delivery to the tissues. CO binds with haemoglobin and reduces its ability to release oxygen to organs. Carbon monoxide poisoning can result from use of burners/heaters in enclosed spaces.

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Addressing parental concerns and misinformation

Despite many years of safe sleep messaging, misconceptions persist amongst parents and the health community.

Infant comfort

Many parents are of the view that for the infant to be comfortable they need a softer sleep surface or cosier 'nest'. There are many industry claims appealing to this belief, marketing products as creating a 'womb-like environment' and referring to an infant's early life as 'the 4th trimester'. Close parent contact and nurturing caregiving that characterises this 4th trimester is supported by evidence to enhance infant neurodevelopment; it is quality of caregiving that is important, not specific product use. Many of the products marketed in this fashion create inherent hazards in the form of:

- Chin to chest positioning (e.g. 'snuggle' beds or nests, baby cot hammocks, some slings)
- Direct suffocation by face occlusion and CO_2 rebreathing (e.g. padded mattress toppers, nests/cocoons with padded sides)
- Encourage sleep in inclined devices which increase likelihood of chin to chest positioning (e.g. smart bassinets)

Sleep positioners

Parents concerned with keeping infants on their backs for longer (in order to reduce the risk of SUDI) often resort to sleep positioners/ restraints that may be marketed as 'reducing the risk of SUDI or SIDS'. The design of these devices varies but ones that require the use of additional rolls/padding and/or straps in the infant sleep environment may also pose a risk of:

- Direct suffocation through face occlusion and CO_2 rebreathing
- Strangulation in the restraint

Sleep positioners are not recommended for infants.

Plagiocephaly

Infants are born with skull bones that are not yet fused, allowing for the head to mould and pass through the birth canal. The bony plates of the skull are connected by 'suture lines' that allow expansion and overlapping of the bony plates as needed. As such, the shape of the skull is malleable before the bones fuse. Plagiocephaly is a misshapen or asymmetrical head shape. The most common is positional plagiocephaly, where infants have a preference for lying on one side or their back, and gravity influences the development of small flat spots on the baby's head. In rare circumstances, a misshapen/asymmetrical head shape may arise from premature closure of one or more suture lines. Positional plagiocephaly (due to any cause) does not cause brain damage or developmental delay; the infant's head shape changes as the infant gains greater head control and becomes more mobile, with the majority resolving by two years of age. An infant with a neurological impairment or brain injury may be at greater risk of developing plagiocephaly if they experience reduced movement and head control.

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Inclined sleep and reflux

Reflux is the passive regurgitation of milk from the stomach into the oesophagus (food pipe) and mouth. For many years, health workers recommended body positioning, prone sleeping and cot tilting—'propping' an infant by elevating the head end of the sleep surface such that the infant slept on a slight incline. Research has demonstrated that prone positioning, cot tilting and propping are ineffective in reducing reflux frequency and the discomfort and potential airway obstruction associated with regurgitation of milk.

Furthermore, in the wake of a cluster of reported infant deaths associated with inclined sleep products, recent investigations by the US Consumer Product Safety Commission has shown that inclined sleeping increases the risk of:

- Premature rolling of the infant onto the tummy
- Chin to chest positioning (gravity)
- Abdominal compression (semi seated position)

Therefore, inclined sleeping increases the risk of infant suffocation (even if an infant does not inadvertently end up prone). Current US recommendations which will be mandated from June 2022 and Canadian regulations limit the incline of infant sleep devices to a maximum of 10 degrees and 7 degrees from horizontal respectively.

Despite the research, the recommendation from health professionals to prop an infant persists and this needs to be addressed through better health communication and with reinforcement through industry and product design and marketing. Collaboratively, promoting 'Flat on the back' to sleep may reduce the incidence of infants being inappropriately left to sleep in prams, bouncers, infant bean bags as well as on improvised propped sleeping arrangements (e.g. boomerang or nursing pillows). It should be borne in mind that flat on the back means a level/horizontal surface.

'...Research has demonstrated that prone positioning, cot tilting and propping are ineffective in reducing reflux frequency and the discomfort and potential airway obstruction associated with regurgitation of milk'

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Misleading/unsubstantiated claims and mixed messaging

Standards misuse

The use of standards and images in marketing claims, though clear to the supplier, is often misleading to the consumer.

There is a common misconception that there are standards for all products, or that when a product is said to meet a standard, that all relevant hazards will have been considered or that the product meets all elements of the standard.

An example of this is infant beanbags. These devices are marketed as a seating device and are required under the **Mandatory standards** to carry a warning label saying that they are not suitable as a sleeping surface for infants. Marketing may correctly state that these infant beanbags comply with the general Australian Standard for beanbag safety. However, this standard specifically addresses accessibility of the beans to prevent choking/inhalation injury, but does not address by design or constructional requirements the inherent risk of suffocation (due to chin to chest positioning) by an infant sleeping on the product.

It is also common to see visual marketing messaging in direct conflict with textual safety messaging or standards. Again, an example of this is infant bean bags which often use marketing images of sleeping infants in contradiction to the mandatory safety standard warning that a bean bag is not a safe sleeping surface for an infant under 12 months of age.

Sometimes standards that are irrelevant to the product's use are displayed in marketing material, presumably intended (incorrectly) as a marker of credibility.

See appendix A: Australian Consumer Law

'Breathability'

Many suppliers are making claims about 'breathability' of their infant products, implying that the suffocation risk has been designed out of the product.

However, 'breathability' of fabric or surfaces is a confusing term for parents and suppliers and requires further definition and restriction. It is often used to refer to wicking/moisture removing capacity for material used in sports clothing—and does not directly relate to the safety of the item.

Breathing requires BOTH the passive indrawing of fresh oxygenated air as well as unimpeded expiration and clearance of CO_2.

There is currently no testing standard to determine whether a fabric/surface/item is 'breathable' in terms of infant respiration. Therefore, the term 'breathability' has deliberately not been used here.

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Use and foreseeable ‘misuse’

An infant’s sleep environment results from a COMBINATION of products that interact due to (largely) predictable human (parent and infant) factors and product design factors.

Whilst it is not possible to consider every product and behavioural interaction there are predictable issues that need to be considered when designing and marketing infant products.

Infant development

Infant development, though predictable, occurs at an individual pace. Therefore, the timing of an infant reaching a given developmental milestone (rolling, sitting, pulling to stand, climbing) is hard to predict. Parents usually only discover what an infant can do, once they have done it. Product directions suggesting that parents modify or stop using a product prior to an infant attaining a given milestone may be reassuring for the designer, but are hard for parents to implement.

Static and dynamic design features

Design and use of any given product may have both static and dynamic components. Frequently the static elements of the design may function well, but the behavioural interface coupled with the dynamic components introduce new hazards. This is particularly challenging to control where there are multiple or infrequent users of the device.

Dynamic design features can be used:

- Everyday (e.g. clipping and unclipping a harness)
- Occasionally (e.g. moving a child car restraint to a second vehicle)
- As the infant develops (e.g. reconfiguring a bassinet to a cot by dropping the base)

In addition, infant carers may or may not be the original purchaser, and they may be frequent or occasional users of the product.

For example, child car restraint carriers that can be lifted out of the restraint base and clicked into a pram base pose a fall hazard for infants. Users need to understand how the carry handle locks into place and how the carrier clicks into the pram base. Although designers might assume that an infant would be clicked into the harness, this often does not occur until the infant is in the car/pram as there is a perception that it is not necessary until ‘travel’ occurs. Injuries have occurred where failure to lock the handle or device into the pram base has resulted in the baby falling from the carrier.

A product may have multiple configurations that allow safe use through infancy and beyond or accommodate an expanding family. Reconfiguration can be instant or involved. Dynamic cot drop sides are an example of an instant configuration change that can occur without a tool. When an infant shows signs that they are able to climb from the cot (bearing in mind that the first sign might be a fall from the cot), that parent can drop the cot side allowing for a safer descent (a lowered cot side may still prevent the infant from rolling out during sleep). However, some products require dismantling and reassembling and this may delay modification or introduce new risk if the product can be inadvertently misassembled.

Finally, dynamic features that are intended to address an issue for the intended users (parent and infant) may create a hazard where other unintended ‘users’ are present. For example, change tables that attach to the side of a cot create a tipping hazard where toddlers might swing on the end of the change table. Similarly, a collapsible side on a bedside co-sleeper that facilitates removal of the infant by a parent may create an infant fall hazard if a toddler is trying to access the infant.

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A safe sleeping environment

The following provides an overview of what a safe sleeping environment looks like:

The infant

- Should be lying on a firm, flat, horizontal (level) surface with their face up and uncovered (face free)
- An exception would be for infants who are being carried/'worn' in a sling device; they should be supported vertically with a straight back, face free and visible to wearer with chin off the chest.
- Should be able to get hands to mouth and, in the event that they roll over, be able to push up with their forearms (arms and hands should be free).
- Clothing or wrapping should allow easy chest movements/ breathing, and not be weighted such that it would restrict respiration or circulation.
- Clothing should be and remain (after anticipated wear and washing) closely fitted around the neck, such that fabric does not occlude the face if the baby lifts their arms above their head.
- There should be no cords/leads/toggles or hoodies that can wrap around the infant or snag on protrusions.

The sleep product

- The product should comply with current Australian Standards or equivalent if applicable (See 'Safety Standards' below).
- There should be no products or devices within the sleep product that could cause:
  - Suffocation: 'soft or padded nests', pillows/supports, bumpers, padded sides/edges, sleep or positioning aids or additional mattresses or items which may create a trough in which baby can become trapped.
  - Strangulation: cords, leads, harnesses/restraints.
  - Choking: small parts/batteries
- Mattresses should comply with the **Australian standard for firmness**.
- The mattress/sleeping surface should remain firm and horizontal (level) over the expected lifetime and not allow the infant to settle into the surface.
- The mattress should be well fitted to the device with the gap between the mattress and the device sides being no more than 20 mm when centred in the cot.
- Sheets/mattress protectors should be able to be firmly tucked under the mattress to prevent bunching and facilitate cleaning/ maintenance.
- The device/product should be secure and stable; though it may rock, oscillate or move, it should not tip/collapse in any configuration.
- Moving/moveable elements within the device should not pose a hazard of entrapment, hanging, strangulation, choking or fall.

Around the sleep product

There should be no protrusions/snags such that a mobile/climbing infant (even one exiting the device) could be caught.

The sleep product should be placed away from surrounding hazards such as windows, blind cords, electrical cords.

There should be no access to items that could be pulled into the sleep environment such as mosquito netting, nappy bags or small parts.

The sleep product should not be placed in a position where it potentially creates an entrapment space; i.e. there should be either a <5 cm gap, or a clear space of 20 cm around the product.

Heaters should be thermostatically controlled on low and at least 1 metre away from the infant sleep product. It is not advisable to leave a heater in an infant's room overnight.

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Key considerations for designing, marketing and supplying infant sleep products

Safety Standards

The Government mandates standards and Australian Consumer Law regulators monitor for compliance a number of mandatory safety standards relevant to infant products (e.g. baby bean bags—which are not to be used as an infant sleep device—folding cots, household cots) and designers, manufacturers and suppliers need to ensure that products supplied into the Australian market comply with the safety requirements (**Appendix B**). For a comprehensive list of mandatory standards see: **Mandatory standards**.

In addition to mandatory standards, there are a number of voluntary standards that set out specifications, procedures and guidelines that aim to ensure products are safe, consistent and reliable. Designers and manufacturers of infant sleep products should contact standards organisations (e.g. **Standards Australia**) to search for relevant voluntary standards. The ISO/IEC Guide 50:2014 also provides useful information on potential sources of harm to children from products that they use or come into contact with.

Risk assessment

The risk assessment process is intended to steer product designers and manufacturers through a series of safety-gateways to ensure safety is engineered into new products at the earliest possible stage of a product's lifecycle. By identifying and substantially eliminating potential safety hazards during the design and sample/prototype approval procedures, the risks of safety incidents arising through poor design can be minimised. The information above on sleep environment hazards and a safe sleep environment should inform the assessment process. Further information on risk assessments is provided in **Appendix B**.

Determining how an infant sleep product will be used, or could potentially be misused, is an important component of risk assessments to identify all events or event chains that could result in an infant injury. This should include consideration of how the product will be used when the infant is asleep, and also how an infant may use the product while awake and unsupervised. Parental/carer behaviour should also be considered including how the product could be used in conjunction with other products, its placement near other products, how it can be cleaned and the potential for it to be adjusted or assembled and disassembled numerous times.

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Example

Portacot design with a standalone fabric base, with no mattress provided. There is no ability to fit a protective sheet in the bottom of the portacot which creates the behavioural risk of parents adding ad hoc padding/mattresses to the portacot in order to keep the base clean and for perceived comfort, which creates a suffocation risk.

Novel product design often crosses existing standards and creates novel patterns of use and hazard. The resulting product use should be carefully assessed to determine the level of risk.

Example:

Hybrid child car restraints/pram devices: the evolution of such products means that infants are seated in the restraint for longer periods of time than would occur were they transferred from a child car restraint to a pram. This increases the likelihood that the infant will be sleeping in an inclined position, which creates a suffocation risk.

Sometimes safer product design can generate a new hazard.

Example

Sleep bags have attempted to design out the risk of infants suffocating under blankets. However, they have been used in older age groups, delaying climbing activity and delaying dropping of the cot side, with falls resulting from unanticipated climbing when the child is older and sleeps without the suit. Sleep bags have also been implicated in vehicle crash fatalities where the infant's arms and/or legs were swaddled and not restrained by the 5-point harness.

Another important consideration is to ensure all marketing, packaging and point of sale displays demonstrate safe use of the infant sleep product. Parents/carers can take cues from visual displays which can influence product use.

Example

An advertisement for a product with an image of a sleeping infant, using a pillow or surrounded by soft toys, which creates a suffocation risk.

Image showing young infant sleeping on side, on an inclined surface, with a toy that can cause suffocation **should be avoided**.

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The following checklist can be used as a guide to identify product use and hazards:

Unpackaging

- [ ] Are all the small parts secure within the packaging?
- [ ] Are plastic bags perforated?

Instructions

- [ ] Are instructions written in simple English with images to assist?
- [ ] Do images demonstrate safe sleeping environments for infants?
- [ ] Is it clear to the consumer when the infant should transition from the device; i.e. when rolling, sitting, pulling to stand, climbing?
- [ ] Are warnings about incorrect use or adaptation of the device clear and easy to understand?

Assembling

- [ ] Is there a right way and a wrong way that your product can be assembled?
- [ ] What happens if it is assembled the wrong way?
- [ ] If the product is battery powered, can it be charged without removing the battery?
- [ ] Can it use an alternative to button batteries?
- [ ] Is the battery compartment durable and child resistant?

Positioning

- [ ] Is there communication about where/how to position the sleep device, avoiding fall, entrapment and strangulation hazards as well as trip hazards due to the device footprint?

Stability

- [ ] Has the design considered stability and inadvertent collapse in the event of anticipated loads (attachments, bags, climbing siblings)?

Maintenance

- [ ] Can the bedding platform be easily adjusted in anticipation of the child sitting and pulling to stand?
- [ ] Can the side be lowered or removed when the infant starts to climb?

Cleaning

- [ ] Can the product be washed/wiped to maintain hygiene?

Durability

- [ ] Will the product withstand assembly, disassembly and reassembly as families grow and move?
- [ ] Will any moving parts withstand an appropriate number of adjustments?

Sleeping requirements (sheet/blanket)

- [ ] Will the product accommodate the necessary bedding required to safely sleep the infant?
- [ ] Can sheeting and mattress protectors be tucked in under the provided mattress?
- [ ] Is it clear what size bedding should be used with the device?

Second-hand infant sleep products

With the growing popularity of second-hand products, it is possible that an infant sleep product may be used by a number of families. Although suppliers have little control over a private resale process, it is important that product user guides and assembly instructions are easily accessible to new owners e.g. online; where possible, sewn into product.

Businesses supplying second-hand infant sleep products subject to national mandatory standards must ensure that the products either comply with the relevant standard or are subject to an exemption prior to offering a product for sale. Regardless of these exceptions, it is strongly recommended that all second-hand products come with full instructions for safe assembly and use and that all necessary parts are in good working order.

'...point of sale is the ideal time to alert customers, guide them toward effective product choice and emphasise the importance of safety messages and safe/intended use instructions including correct assembly if required.'

Retailers

Retailers can play a key role in improving purchasing choices, raising consumer awareness about safe sleeping and providing meaningful specific product instructions for safe and intended use and potential foreseeable misuse.

As consumers are often unaware of all the potential infant safe sleep hazards, point of sale is the ideal time to alert customers, guide them toward effective product choice and emphasise the importance of safety messages and safe/intended use instructions including correct assembly if required.

To do so it is essential that sales team members have an understanding of the relevant products they offer and the simple message and measures required to address the potential hazards. It is recommended any team member selling baby nursery items to the public that relate to safe sleeping environments should be made aware of:

- This guide and any of their retailer's policy regarding the safe supply of products for infants
- Australian Consumer Law obligations, including the product safety provisions
- Which products types, categories and ranges are covered by this guide or policy, and which are not
- Why safe sleeping is important for safety and how this helps protect vulnerable infants
- Safety tips related to safe sleeping guidance
- How to explain this information and provide in a simple understandable message to customers

This information should be easily available to sales team and form part of any specific training related to infant safe sleeping or specific product safety training. And refreshed from time to time as deemed appropriate (i.e. retraining, on boarding of new team members, etc.)

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Risk surveillance

The supply chain between initial design and consumer is complex and often disconnected. To reduce the risk of supplying unsafe products, suppliers should develop and implement a product safety compliance program. The program can be tailored to meet the needs of the supplier depending on its size and risk profile. Key elements include:

- Clear identification of the officer(s) responsible for administering the compliance program.
- Ensure the responsible officer(s) is aware of, or attends training on, the product safety provisions of the Australian Consumer Law (**Appendix A**).
- Develop compliance checklists for all products supplied, including any mandatory requirements for regulated products (i.e. labelling).
- Inspect each shipment of products received and ensure compliance checklists are completed and filed.
- Obtain and retain appropriate laboratory test reports to ensure products have been (removed regularly) tested to any claims made or the mandatory standards required.
- Develop procedures for recording, storing and responding to product safety complaints.

There are many benefits of implementing a product safety compliance program including demonstrating a commitment to compliance, rapidly identifying compliance failure before products are supplied to market, identifying injury from consumer complaints to ensure any mandatory reporting obligations can be met and providing records of controls and business systems. Further information on developing a compliance program can be found at the **Product Safety Australia website**.

'...suppliers should develop and implement a product safety compliance program. The program can be tailored to meet the needs of the supplier depending on its size and risk profile.'

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Appendix A: Australian Consumer Law

Suppliers of infant sleep products are legally bound by the **Australian Consumer Law** (ACL) and it is important that suppliers are fully aware of their legal obligations in terms of supplying safe products. Ignorance of the law is not an excuse and serious penalties exist for contraventions of the law. Failure to comply with the law may also have a negative impact on suppliers in terms of reputation and consumer perception and is unlikely to help should a product liability claim be made against a supplier either as an individual or company.

Key safety features of the ACL

Mandatory standards and banned products

Mandatory standards specify minimum safety requirements or information features that products must meet before they can be legally sold in Australia. A list of current mandatory standards can be found at the **Product Safety Australia website**.

Voluntary Australian and overseas standards may exist for products not subject to mandatory standards. Whilst compliance with these standards is not mandatory, it is good business practice for suppliers to ensure their products meet an established safety benchmark such as an Australian or recognised overseas standard.

Product safety bans can be placed on products if there is risk that they may cause serious injury, illness or death. It is against the law to supply products that are banned. A list of current interim and permanent product safety bans can be found at the **Product Safety Australia website**.

Mandatory reporting

Suppliers are required by law to **report to the ACCC** within two days of becoming aware that the use or foreseeable misuse of a consumer product they have supplied caused or may have caused the death or serious injury or illness to any person. This obligation includes a reporting requirement if the supplier becomes aware that another person (e.g. a customer) considers the consumer product caused or may have caused the death or serious injury or illness of any person.

Product safety recalls

If a product is found to present a safety risk, it may need to be recalled. Many suppliers voluntarily initiate their own recalls and must **notify the ACCC** within two days of initiating the recall action. Suppliers should refer to the **ACCC Product Safety Recall Guidelines** prior to conducting the recall to ensure the recall runs smoothly and the marketplace is fully informed. Recall return rates are monitored by the ACCC to ensure suppliers are taking their obligations seriously.

In a situation where a product may cause injury to a person and the supplier has not taken satisfactory action to prevent an injury, the Commonwealth or State or territory Ministers can issue a compulsory recall notice. This can require the supplier to take certain action such as how to advertise the recall, or what remedy they must provide to consumers.

Consumer guarantees

Industry must ensure their products are **safe and of acceptable quality**. Whilst 'safety' is often left to interpretation, good business practice will reduce the risk of supplying a product that is 'unsafe'.

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Misrepresentation

Suppliers must not in connection with the supply of products make a false or misleading representation that products are of a particular standard or quality (including claims about safety or meeting certain standards).

Suppliers must not engage in conduct that is liable to mislead the public as to the nature, characteristics or suitability of the products for their purpose. This is especially true for products that are used by infants where parents and caregivers seek out products that make claims as to their safety.

Substantiating claims made about products

Under the ACL, suppliers must not suggest a product is safer (e.g. non-toxic), offers a medical or therapeutic benefit such as relieves flat head or '100% safe' for baby, or complies with a particular safety standard, unless **the claim can be substantiated**. Product safety regulators can issue a substantiation notice in order to assess the veracity of a claim made in promoting the supply of products.

TGA requirements when making claims of any health benefit and medical device registration

If claims are made about a product that indicates it may have a health or medical benefit these claims must be able to be substantiated. It may also mean the product is classified as a **medical device** under laws administered by the **Therapeutic Goods Administration** (TGA). This Australian government agency may require that products be registered under some circumstances. It is critical that suppliers consult with the TGA prior to manufacturing or importing a product that claims to have a medical or health benefit.

Online suppliers

Online suppliers who supply to businesses or consumers in Australia must comply with Australian product safety laws. Even if products meet overseas standards, it does not necessarily mean they will meet Australian safety requirements.

Safe disposal of unsafe products

If a product is found not to comply with a mandatory safety standard, be unsafe, subject to a mandatory or voluntary recall or banned, then safe disposal of stock on hand is vital. If the product safety problem cannot be rectified then the product must be disposed of in a way so as it cannot be resold or reused at any time, by anyone.

Irrespective of how an unsafe product is destroyed suppliers should ensure adequate records of the destruction are maintained, e.g. photographs and/or a destruction certificate.

Second-hand products

Under the ACL, suppliers must ensure the products they sell meet relevant mandatory standards whether the products are brand new or second-hand. However, there are some mandatory standards that contain exemptions for second-hand products, e.g. care labelling for clothing and textiles.

Businesses supplying second-hand products subject to mandatory standards must ensure that the products either comply with the relevant standard or are subject to an exemption prior to offering a product for sale.

Regardless of these exceptions, it is strongly recommended that all second-hand products, especially those used by infants, come with full instructions for safe assembly and use and that all necessary parts are in good working order.

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Appendix B: Risk Assessments

The theory

The risk assessment process is intended to steer product designers and manufacturers through a series of safety-gateways to ensure safety is engineered into new products at the earliest possible stage of a product's lifecycle. By identifying and substantially eliminating potential safety hazards during the design and sample/prototype approval procedures, the risks of safety incidents arising through poor design is appreciably minimised.

Before commencing the risk assessment, the "conditions of use" need to be defined. This includes an understanding of the expected conditions of use as well as the reasonably foreseeable conditions of misuse. Special considerations relating to infants include:

- Their development and behaviour
- Their likelihood of being injured
- Their vulnerability

The risk assessment involves consideration for three key criteria before determining whether a "tolerable level of risk" has been achieved:

- Identify the risk—What can happen
- Analyse the risk—How probable is it?
- Evaluate the risk—How severe could the resulting injury be?

If a position of tolerable risk has not been achieved, then the risks need to be treated (i.e. eliminated or reduced) before the risk assessment cycle starts again.

Assessor capabilities

The skills required to identify potential hazards are often acquired after many years of involvement with product development, in assessing and investigating problems, in implementing corrective action plans and in updating/creating product standards/specifications. For this reason, the safety-feature checklists have been created to assist those who have been less involved in assessments so they can identify hazards and conduct risk assessments to a high level of overall consistency and diligence.

For many organisations though, the concept of conducting detailed risk assessments may be daunting. Where an organisation feels that the skills required to conduct a thorough and accurate risk assessments do not exist within their organisation, it is recommended that the assistance of professional risk management services or product evaluation services are employed for these purposes.

Methodology

Risk assessment modelling has been extensively captured through a variety of Australian and International standards. The overall process of risk identification, risk analysis and risk evaluation is utilised to achieve a position of "tolerable risk", taking into consideration design, materials, components and construction. This is an iterative process requiring repeated application until a tolerable level of risk is achieved.

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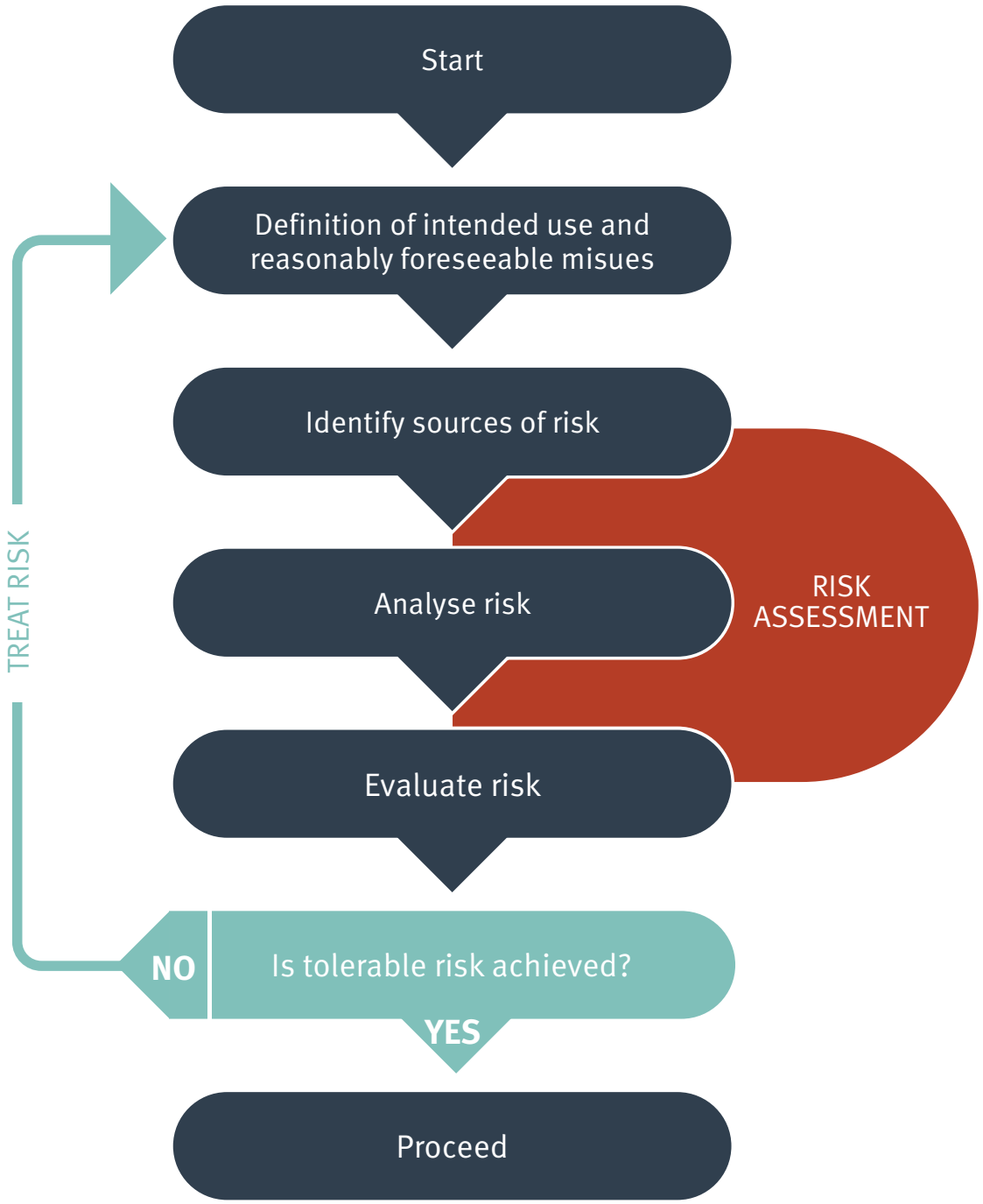
Start
Definition of intended use and reasonably foreseeable misues
Identify sources of risk
Analyse risk
Evaluate risk
RISK ASSESSMENT
TREAT RISK
NO
Is tolerable risk achieved?
YES
Proceed

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Risk assessment model

The risk assessment modelling contained within these guidelines has drawn upon the principles of "consequence" and "likelihood" used within existing standards. "**Consequence**" relates to the severity when an event causes injury or damage. For the purposes of these guidelines, "consequence" is categorised according to the following table.

Consequence for an injury	Injury outcome and treatment
Catastrophic	Permanent disability or death
Major	Extensive injuries requiring hospitalisation or substantial treatment by a registered physician
Moderate	Injuries requiring minor treatment by a registered physician but not requiring hospitalisation
Minor	First aid treatment
Insignificant	No injuries. Mild discomfort or irritation

"**Likelihood**" relates to the chances or probability of an event occurring. "Likelihood" within the design and development processes relates to the expected or anticipated rate of failure.

The "**risk rating**" is then determined based on the combination of consequence and likelihood according to the following table.

Likelihood	Consequence: Catastrophic	Major	Moderate	Minor	Insignificant
Almost certain	High	High	Medium	Medium	Low
Likely	High	High	Medium	Medium	Low
Possible	High	High	Medium	Medium	Low
Unlikely	High	Medium	Medium	Low	Low
Rare	High	Medium	Medium	Low	Low

The "**Recommended actions**" are then determined based upon the risk rating. The higher the risk rating, the greater the effort required to alter the design and to re-engineer the product to minimise or eliminate the identified risk.

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Recommended actions

High risk

To mitigate the known/anticipated HIGH risks and to achieve a position of "tolerable risk", actions should include:

- Eliminate/remove the identified hazard,
- Modify, re-design or re-engineer the product,
- Introduce cautionary labelling and warnings (if appropriate)
  Do not proceed with development of the product

Medium risk

To mitigate the known/anticipated MEDIUM risks and to achieve a position of "tolerable risk", actions should include:

- Eliminate/remove the identified hazard,
- Modify, re-design or re-engineer the product,
- Introduce cautionary labelling and warnings (if appropriate)

Low risk

To mitigate the known/anticipated LOW risks and to achieve a position of "tolerable risk", actions should include:

- Modify, re-design or re-engineer the product,
- Introduce cautionary labelling and warnings (if appropriate)

Minimising production risks

The primary purpose of conducting risk assessments during a product's design and development phases is to incorporate safety into the product from its origins. This is the single most effective strategy for eliminating product safety risks. It should also be noted that, regardless of design, safety hazards may also arise within the production process. Risk may arise through:

- Contamination from equipment (e.g. broken needles)
- Self-contamination (e.g. buttons, clasps loose)
- Deviation from specification
- Raw materials variability (e.g. fabric properties differ from approved fabric)

The use of production and post-production quality checks are required to ensure that quality and safety are not only engineered into products from the outset, but to ensure that safety transcends through the entire end-to-end process.

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Risk assessment model

CONSEQUENCE

LIKELIHOOD

RECOMMENDED ACTIONS

LIKELIHOOD \ CONSEQUENCE	Catastrophic Permanent disability or death	Major Extensive injuries requiring hospitalisation or substantial treatment by a registered physician	Moderate Injuries requiring minor treatment by a registered physician but not requiring hospitalisation	Minor First aid treatment	Insignificant No injuries. Mild discomfort or irritation
Almost certain	HIGH	HIGH	MEDIUM	MEDIUM	LOW
Likely	HIGH	HIGH	MEDIUM	MEDIUM	LOW
Possible	HIGH	HIGH	MEDIUM	MEDIUM	LOW
Unlikely	HIGH	MEDIUM	MEDIUM	LOW	LOW
Rare	HIGH	MEDIUM	MEDIUM	LOW	LOW

To mitigate the known/anticipated HIGH risks and to achieve a position of "**tolerable risk**", actions should include:

- Eliminate/remove the identified hazard
- Modify, re-design or re-engineer the product
- Introduce cautionary labelling and warnings (if appropriate) Do not proceed with development of the product

To mitigate the known/anticipated MEDIUM risks and to achieve a position of "**tolerable risk**", actions should include:

- Eliminate/remove the identified hazard
- Modify, re-design or re-engineer the product
- Introduce cautionary labelling and warnings (if appropriate)

To mitigate the known/anticipated LOW risks and to achieve a position of "**tolerable risk**", actions should include:

- Modify, re-design or re-engineer the product
- Introduce cautionary labelling and warnings (if appropriate)

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