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Content

Background information

- What are we talking about ?
- Origin of the method
- Link with GPSD
- Principles of the RAG
 - Basic principles
 - Example



What is risk ?

- Risk is generally understood as a possibility to loose something
 - Losing money
 - Losing credibility
 - Losing health or your life
- Risk assessment is one of our daily activities
 - Crossing the street
 - Climbing on a chair or use a ladder ?



Which risk is assessed by the RAG?

- The risk, linked to physical hazards, presented to consumer(s) by a single product
- NOT: risk for the population
- NOT: risk for authorities
- NOT: cost of material damage
- NOT: conformity assessment



Kinney method

- Professional environment
- Risk = Severity x Exposure x Probability
- Severity of injury linked to hazard
- Exposure to the hazard
- Probability of the hazard to occur when exposed
- Numerical method



Differences between Kinney and RAG

- Severity scale change of scale
- Integrate Exposure into Probability
- Probability = probability that the hazard occurs with the foreseen severity during the foreseeable lifetime of the product
- Non numerical method (but all classifications are based on the figures behind the method)



Link between risk categories and the GPSD

GPSD	GPSD	RAG			
Rapex Notification (GPSD art.12)					
Dangerous	Unacceptable but non	Moderate risk			
	serious risk	Low risk			
Safe	Acceptable risk	Acceptable risk			



Basic principles of the RAG

- Products present hazards.
- A hazard can lead to different injuries, each with there own severity, each with their own probability.
- Severity of injury
- Probability
- Risk = $S \times P$



STEP 1: Determine the Severity of Injury

- Identify the hazards.
- Imagine accident scenarios to determine the injuries to which the hazards can lead.
- Determine the severity of these injuries (Slight, Moderate, Serious, Very Serious)
- Tables exist to help the risk assessors



Table 1. Hazards, typical injury scenario and typical injury

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
Size, shape and surface	Product is obstacle	Person trips over product, falls and hits the floor; or person bumps into product	Bruising; fracture
	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child)	Suffocation
	Product is or contains small part	Person (child) swallows small part; the part gets stuck in larynx and blocks airways	Internal airway obstruction
	Sharp corner or point	Person hits sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury	Puncture; blinding, foreign body in eye; hearing, foreign body in ear
	Sharp edge	Person touches sharp edge; this lacerates skin or cuts through tissues	Laceration, cut; amputation
	Slippery surface	Person walks on surface, slips and falls hitting the floor	Bruising; fracture
	Rough surface	Person slides along rough surface; this causes friction and/or abrasion	Abrasion
	Gap or opening between elements	Person puts a limb or body in opening and is trapped with finger, arm, neck, head, body or clothing; injury occurs due to gravity or movement	Crushing, fracture, amputation, strangulation
Potential energy	Low mechanical stability	Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; sprain; fracture; crushing; electric shock; burns
	Low mechanical strength	Product collapses by overloading; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; fracture; crushing; electric shock; burns
	High position of user	Person at high position on the product loses balance, has no	Bruising; dislocation; fracture; crushing



Example: bicycle – broken fork









Table 1. Hazards, typical injury scenario and typical injury

Hazard grou	ıp	Hazard	Typical injury	scenario	Typical injury	
Hazard	Injury scenario					
Rotating p	Pers with	on on the	e bicycle lose eed	s balance and	t falls	
Rotating p					re; crushing re; crushing re: crushing ng; cuts (see also	
Acceleratio	on			Possible	e injuries	
Flying obje	ects			Dislocation concussion	; fracture; bruisin	
Vibration						



Table 3. Severity of injury

Type of injury	Severity of injury					
	Slight	Moderate	Serious	Very serious		
Laceration, Cut	Superficial	External (deep) (>10cm long on body)	Optic nerve	Bronchial tube		
		(>5cm long on face)	Thyroid gland	Oesophagus		
		Tendon or into joint	Bladder	Aorta		
		White of eye	Nerve root cut	Spinal cord (low)		
		Tongue (deep)	Brain	Deep lung laceration		
		Cornea	Larynx	Deep laceration of intestines, kidney, liver,		
		Abdomen (deep but no organ damage)	Neck artery	spleen		
			Trachea	Severed throat, high spinal cord		
			Intestines	Completely severed aorta		
			Kidney	Brain (severe lesion/dysfunction)		
			Liver			
			Spleen			
			Lungs (superficial)			
			Penis			
Bruising (abrasion/	Superficial	Major	Trachea	Brain stem		
contusion)	≤25 cm² on face	>25 cm² on face	Bladder, colon, kidney, liver, spinal	Spinal cord causing paralysis		
	≤50 cm² on body	>50 cm² on body	cord (minor)			
		oesophagus	Lung (minor)			
		larynx	Heart			
			Brain			
			Lung, with blood or air in chest			
Concussion		Under 1 hour	Over 1 hour	Coma		
Sprain, strain,	Extremities	Knee ligaments (sprain)	Ankle ligament rupture/ tear	-		
musculoskeletal	Joints		Achilles tendon rupture/ tear			
disorder	Spine (no dislocation or fracture)		Knee ligament rupture/ tear			
			Ripped muscle/ tear			



Bike example

Table 3. Severity of injury

Type of	Severity of injury				
injury	Slight	nt Moderate Serious		Very Serious	
Bruising (abrasion/ contusion)	Superficial	Major			
Dislocation	Nose	Skull	Нір	Neck	
Fracture	Finger	Wrist	Thigh	Spinal column	
	Teeth	Forearm	Jaw (severe)		
	Rib	Jaw and teeth	Multiple rib		
	Тое	Upper arm	fractures		
			Severe skull fracture		
Concussion		Under 1 hour	Over 1 hour	Coma	



STEP 2: Determine the Probability of the injury to occur during the products lifetime

- Determine for each injury in each scenario the steps that are necessary for the injury to occur with the foreseen severity
- Estimate the probabilities of each of these steps.
- The overall probability is the multiplication of each of these sub-probabilities
- Is this probability realistic ?
- Choose the probability class out of the table



Table 4. Probability of injury (to occur within the products lifetime)

Description of the probability	Indicative statistical value of the probability		
Almost certain, might well be expected	> 50 %		
Quite possible	> 1/10		
Unusual but possible	> 1/100		
Only remotely possible	> 1/1.000		
Conceivable, but highly unlikely	> 1/10.000		
Practically impossible	> 1/100.000		
Impossible unless aided	> 1/1.000.000		
(Virtually) Impossible	< 1/1.000.000		



Which factors influence the probability ?

- Product properties including the presentation and the presence of warnings
- Intended users and foreseeable users
 - Children, elderly, disabled, professional
- Intended use and foreseeable (mis)use
- Frequency and duration of use
- Hazard recognition and ensuing protective behaviour and equipment
- Consumer behaviour in case of an incident
- Consumer's cultural background



How to deal with information, (accident) statistics or the lack of such information to determine the probability ?

- Manufacturers with a quality system should be able to give a lot of usefull statistics.
- When accident statistics for specific products exist, they can directly be used to determine the probability.
- A search in newspapers or on the internet might help to find some useful information
- Even finding nothing might help to estimate the probability.



Bike example

Probability of the injury to occur - superficial bruising

- Conditions for superficial bruising (severity = slight)
 - 1. a leg of the fork breaks;
 - 2. the user looses balance and falls;
 - 3. the fall results in superficial bruising.
- Sub-probabilities
 - 1. 1/100;
 - 2. 1/20;
 - 3. 1/1.
- Overall probability = P1 x P2 x P3 = 1/2.000



Bike example

Probability of the injury to occur – hip fracture

- Conditions for hip fracture (or other injuries with the same severity) (severity = serious)
 - 1. a leg of the fork breaks;
 - 2. the user looses balance and falls;
 - 3. the fall results in serious injury.
- Sub-probabilities
 - 1. 1/100;
 - 2. 1/20;
 - 3. 1/50.
- Overall probability = P1 x P2 x P3 = 1/100.000



STEP 3: Determine the risk by combining Severity and Probability for each scenario and severity.

Probability of damage during the foreseeable		Severity of Hazard			
		Very			
lifetime of the product		Serious	Serious	Moderate	Slight
Almost certain, might well be expected	> 50 %	S		S	
Quite possible	> 1/10	S		S	
Unusual but possible	> 1/100	S		S	
Only remotely possible	> 1/1.000	S		М	
Conceivable, but highly unlikely	> 1/10.000	3			A
Practically impossible	> 1/100.000			А	A
Impossible unless aided	> 1/1.000.000	L	A	А	А
(Virtually) Impossible	< 1/1.000.000	Α	A	A	A

The highest risk found, is the risk of the product.



Tips and Techniques

- Work in groups different inputs lead to more realistic results
- Let experts participate to the risk assessment
- Use all available (statistical) information
- Split the probability up into sub-probabilities discussions often only focus on a sub-probability
- In case of doubt, make a sensitivity analysis to see if the result you found is stable or if a more detailed examination is needed



Sensitivity analysis

		Severity of Hazard			
Probability of damage during the fore	Very				
lifetime of the product		Serious	Serious	Moderate	Slight
Almost certain, might well be expected	> 50 %		8		М
Quite possible	> 1/10				L
Unusual but possible	> 1/100		C.		L
Only remotely possible	> 1/1.000			M	А
Conceivable, but highly unlikely	> 1/10.000	5.2 5.2	M		
Practically impossible	> 1/100.000	М		A	
Impossible unless aided	> 1/1.000.000	L	A	A	
(Virtually) Impossible	< 1/1.000.000	А	А	А	



Test results

- First tests show that the RAG
 - are rather easy to use
 - result in less difference between risk assessors than other methods
 - permit to focus on specific aspects in case of different risk assessment results
 - can result in realistic risk classifications



Conclusions

- The RAG give good results if you
 - work in group
 - use your imagination
 - but ... stay realistic



Thanks for your attention !