Risk Management in Consumer Products

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Risk Management

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Risk Management

- Overview of Risk Management Process
- History / Case Study
- RAHR Process
- Tools
- Take Away
- Credits

Risk Management

Risk Management Program is a comprehensive and systematic prevention based process which:

- Targets known high probability risk characteristics;
- Eliminates or controls identified risks;
- Enables attention to be focused on the inherent undefined risks.

  - Target the known to enable the discovery of the unknown

Risk Management

- Sensitive dependence on initial conditions

  (AKA "Chaos Theory")

- Small change in initial conditions causes a chain of events leading to a large scale phenomena

  (product defect (loose screw; foreign material) → injuries → investigation → withdrawal → perceived issues by consumers → legal actions → additional withdrawals → brand damage → ∞)

- Initial conditions of both Product and Process critical

Risk Management

- Case Study: Toys for Children "Under Three"
  - Numerous issues:
    - Breakage
    - Not functional
    - As received
    - Paint peeling
    - Appropriate Age Grade
    - Play value
    - Exposure to dried solvents
    - Foreign Materials

Risk Management

- Case Study:
  - Root Causes:
    - Supplier Approval Process
    - Design Review Process
    - Design Process
    - Material Selection
    - Assembly Methods
    - Reliability Testing
    - Product Sampling Program
    - Testing Program
  - In- Process Monitoring
  - “Pre-Shipment” Inspections
  - Redundant Assemblies
  - Consumer sensitivity
  - Feedback Loops
  - Inspection Mentality
  - Accountability

Risk Management

- Case Study:
  - Corrective Actions:
    - Design Guidelines
    - Product Specifications: Bill of Materials, Assembly Details, Functional Expectations, Color Callouts
    - Statistically valid Sampling Program
    - Supplier Capability Review
    - Risk Analysis and Hazard Reduction Program (RAHR)

Risk Management

- RAHR
  - Combination of Failure Mode Effect Analysis (FMEA); Hazard Analysis and Critical Control Point (HACCP) and Active Prevention Monitoring
  - Utilizes: Hazard Pattern Checklists, RAHR Worksheets, Risk Matrix, Auditor Sampling

Risk Management

- Risk Analysis and Hazard Reduction Process
  - Process Steps:
    - Pre-concept
    - Concept
    - Design
    - Pre-production
    - Production
    - Distribution
    - Consumer
    - Post Consumer

Risk Management

- RAHR Process Key Elements
  - Total product lifecycle
  - Every attribute of product is reviewed and assessed
  - Detail definition of Hazards
  - Defines levels of acceptable risks
  - Communicates clearly design and production concerns/action items
  - Provides for historical “clearing” of issues
  - Knowledge transfer

Risk Management

- RAHR Process Key Elements:
  - "OTHER"
    - Process enables **time** to find the inherent safety concerns with the design
  - Validation
    - Product testing serves as a validation step of process

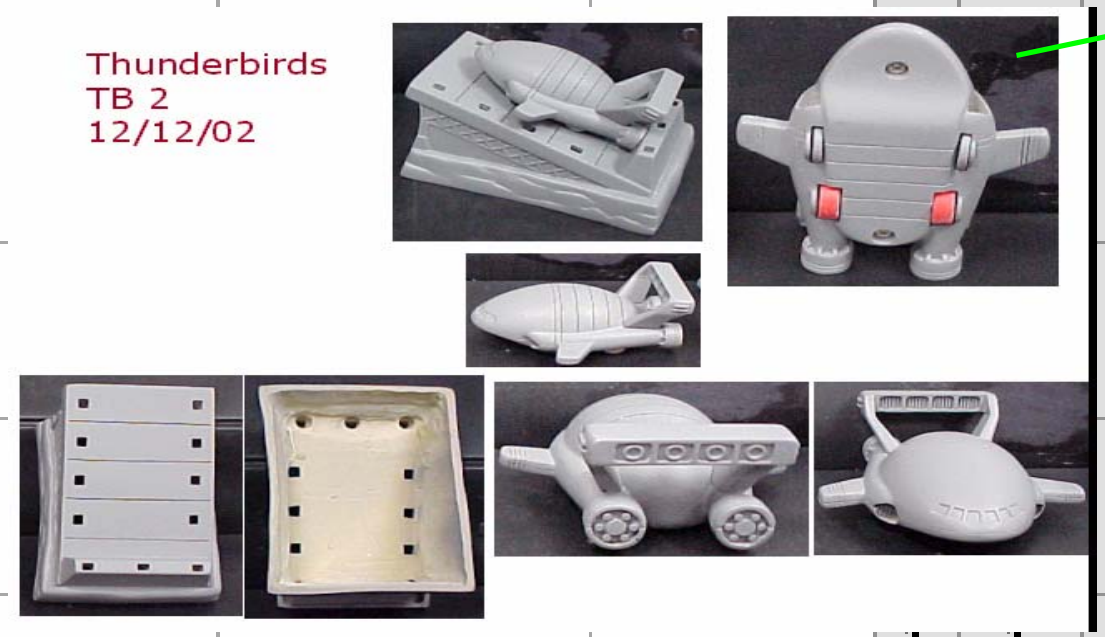
Risk Management

- Tools:

Risk Management

Potential Hazards	Potential Causes of Hazard	Potential Effects of Hazard	Sev	Occ	RPN	STR Recommend-ations	Agency Response	Implementation Phase	STR Response to Resolution	CCP	MCP	Critical Limits	Monitoring and Operational Control Methods or HACCP Number *	Risk After Design Modification or Process Controls			Pictures & Related Documents
														Sev	Occ	RPN	
1.a Burns and fires (based on artwork).																	
1.b Burns and fires (based on sculpt).																	
1.c Burns and fires (based on WL/LL)																	
2.a Eye injury (based on artwork).																	
2.b Eye injury (based on sculpt).																	
2.c Eye injury (based on WL/LL)																	
3.a Facial suction suffocation (based on artwork).																	
3.b Facial suction suffocation (based on sculpt).																	
3.c Facial suction suffocation (based on WL/LL).																	
4.a Impalement (based on artwork).																	
4.b Impalement (based on sculpt).																	
4.c Impalement (based on WL/LL).																	
5.a Puncture/Projection hazards (based on artwork).																	
5.b Puncture/Projection hazards (based on sculpt).																	
5.c Puncture/Projection hazards (based on WL/LL).																	
6.a Choking/Aspiaration on small parts (based on artwork).																	
6.b Choking/Aspiration on small parts (based on sculpt).																	
6.c Choking/Aspiration on small parts (based on WL/LL).																	

Implementation Phase	STR Response to Resolution	MCCP	Risk After Corrective Actions are Taken				Pictures
			Sev	Occ	RPN	% Reduction	
N/A	N/A	N/A	1	1	1	0.0	TB2.ppt
N/A					1	0.0	Hazard_Types.doc
N/A					1	0.0	
Sculpt					1	75.0	
					1	0.0	



Agency Action(s) to be Taken	Implementation Phase	STR Response to Resolution	MCCP	Risk After Corrective Actions are Taken				Pictures
				Sev	Occ	RPN	% Reduction	
None	**N/A**	**N/A**	**N/A**	**1**	**1**	**1**	**0.0**	

Hazard Types and Definitions

Hazard Type	Definition				
1. Ear Impaction	Laceration to outer & inner ear canal.	**1**	**1**	**0.0**	
2. Choking	Throat impaction causing asphyxia due to airway obstruction.				
3. Impalement	Child accidentally sat, fell, or jumped buttocks-first into shallow water and landed on dive stick. As a result, the child could suffer rectal or vaginal impalement.	**1**	**1**	**0.0**	
4. Facial Suction Suffocation	Object "cupped" the face, simultaneously covering nose and mouth.	**1**	**1**	**75.0**	
5. Strangulation on Strings (neck)	Strangulation can result from toys containing ropes such as the squidgy water balls (known as water yo-yos). Incidents of infants strangulation occurred when the rope of the ball became entangled around their necks. In this specific toy, the rope is made of such stretchy material that tightens around the neck.	**1**	**1**	**0.0**	
6. Finger/Wrist Entanglement in Strings	String from a toy tangled on Finger or wrist. Also, a wrist tangled in a loop on toy				

Agency Action(s) to be Taken	Implementation Phase	STR Response to Resolution	MCCP	Risk After Corrective Actions are Taken				Pictures
				Sev	Occ	RPN	% Reduction	
None	**N/A**	**N/A**	**N/A**	**1**	**1**	**1**	**0.0**	TB2.ppt
Non						**1**	**0.0**	Hazard_Types.doc
Non						**1**	**0.0**	STR Two Factor Risk Model.doc
Roo rou						**1**	**75.0**	

STR Two-Factor Risk Model [4x5]

Probability of Occurrence	Severity Ranking				
	Catastrophic (5)	Critical/Serious (4)	Moderate (3)	Slight (2)	Minimal (1)
Improbable (1)	5	4	3	2	1
Remote (2)	10	8	6	4	2
Occasional (3)	15	12	9	6	3
Frequent (4)	20	16	12	8	4

Color-Coded Risk Levels:

- Green = signifies an acceptable risk level (also known as "*base-line risk*")
- Yellow, Orange, and Red = each signifies an elevated risk level with "Red" being the highest risk level.
- All "Non-Green" risk levels require corrective actions to eliminate the cause(s) of hazard.
- Examples of corrective actions include: "eliminate by design," "warning labels", … etc.

Risk Management

- RAHR Process accepts risks under certain defined conditions
- RAHR Process communicates to manufacturing the critical characteristics, processes and steps necessary to enable product to be manufactured:
  - Mushroom plugs, redundant assemblies (HACCP on sonic welding and glue process), vacuum testing, etc.
- RAHR Process requires third party auditing of production processes

Risk Management

- **Take Away:**
  - **Design Guidelines**:
    - Create Design Guidelines which inform designers of your company's "hot buttons" and restricts their designs
  - **Risk Matrix**:
    - Define your organizations risk tolerance through the creation of a Risk Matrix
  - **Critical Characteristics**:
    - For the type or family of products your are producing or distributing define the critical attributes/hazards of those products
  - **Hazard Pattern Checklist**:
    - For the Critical Characteristics defined above list the type of injuries or negative outcomes which correspond and define corollary levels of acceptability (you will be surprised)
  - **Design Review**:
    - Perform a design review and if risks cannot be eliminated determine if they can be controlled in manufacturing; if controllable in manufacturing develop a process to communicate these controls to the manufacturer
    - Don't be afraid to "JUST SAY NO"
  - **Product Testing**:
    - Use product testing to validate your process, NOT as the acceptance method……request the manufacturer to perform sufficient testing to accept product

Risk Management

- According to Albert Einstein:

"We can't solve problems
by using the same kind of thinking
we used
when we created them."

- A Risk Analysis approach may enable you to approach your products with a different point of view……

Risk Management

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