

HAZARD IDENTIFICATION IN THE PRODUCT LIFE CYCLE

Presented By:



Susan DeRagon, *AsiaInspection*

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Agenda

I. INTRODUCTION

II. HAZARD IDENTIFICATION

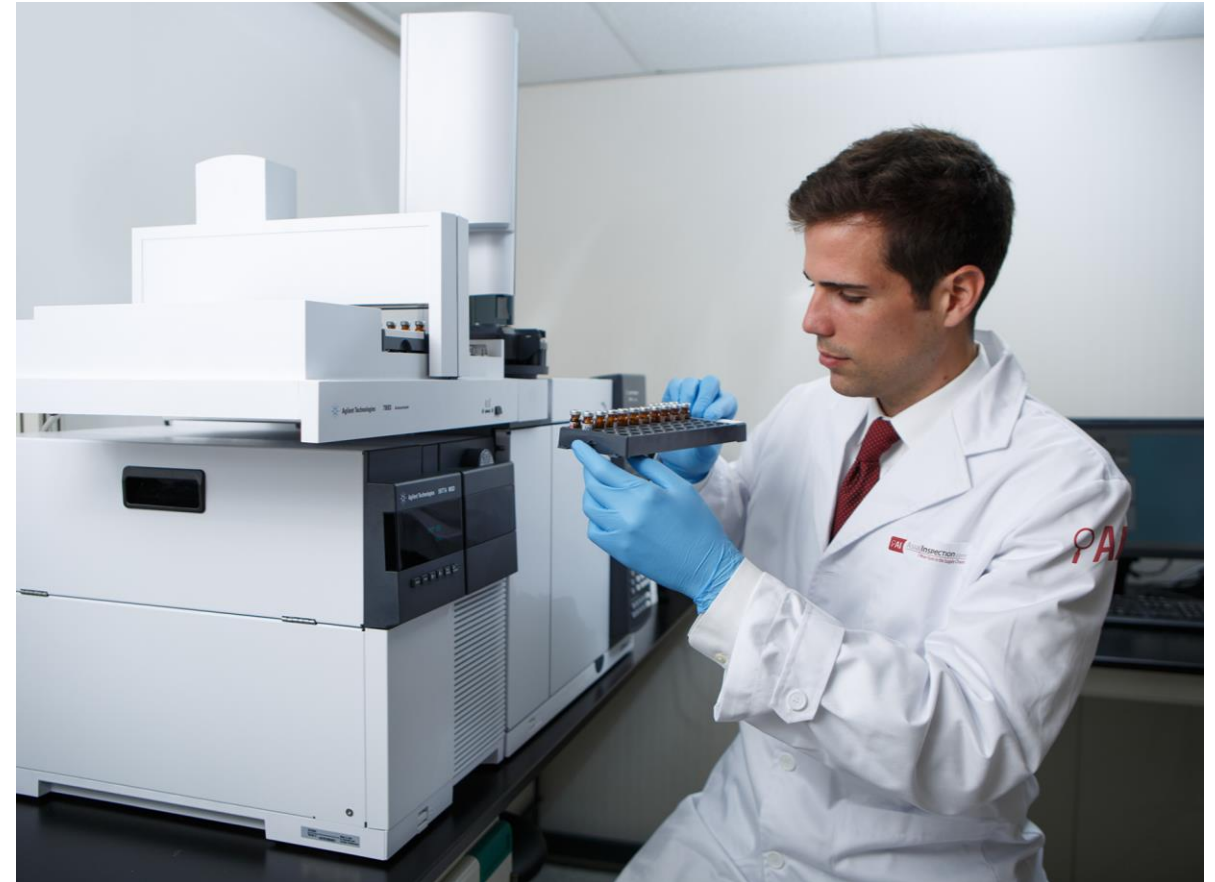
III. RISK MANAGEMENT

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Introduction

- Regulatory compliance is a minimum requirement
- Hazard identification and risk management
- Ensure continued compliance
- Safety-related recalls are still occurring



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Industry Concerns

- Products are often intended for use by adults, given out at trade shows and workplaces, but end up in the hands of children.
- How to determine whether a product is a general consumer product or a children's product?
- Who bears the responsibility for determining if a product is a children's product?

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Product Recalls - Children

- Regulatory compliance does not always equal product safety



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Product Recalls - Adult

- Design hazards cause recalls of adult or general use items as well



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CPSC Recommendation

“The safety of a product depends upon many factors. One factor is building safety into the product design. The circumstances under which products are used or misused by consumers is another factor. The ability of manufacturers to recognize and anticipate these factors is central to the effective design and production of safe products.”

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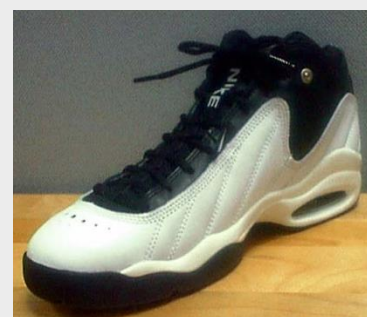


II. Hazard Identification

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Every Consumer Product Has Risk



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How Can You Identify Potential Hazards and Risks?

- Human Factors Review - Goes Beyond the Standards
- Try To Anticipate Foreseeable Use & Unintended Use Scenarios
- Understand & Enhance Interaction Between Users & Products



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What is Human Factors?

An area of psychology that studies the relationship between people and their environments



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Goals of Human Factors

Maximize performance

- Enhance user experience
- Comfort and fit

Minimize errors

- Foreseeable use and misuse

Safety

- Injury prevention



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Foreseeable Use and Misuse

- Instructions
- Product look and function
- Similarity to other products



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Who Can Conduct?

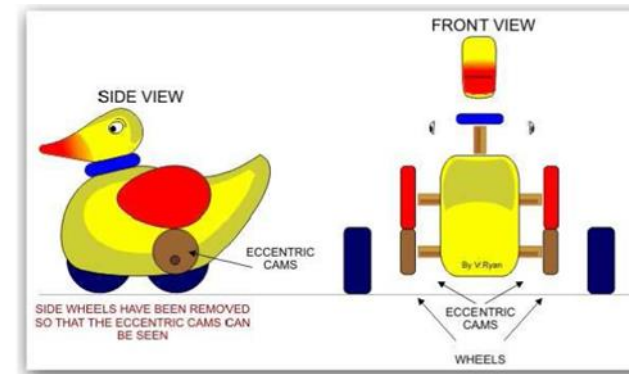
- Personnel with specialized skills (i.e. human factors, industrial design, child development)
- Internal or external team
- Independent from the product designer

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When to Conduct?

- Concept stage
- Sculpt or working model
- Engineering pilots
- Early production samples



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Components of Human Factors Review

Evaluate concept or product for:

- Intended and unintended users
- Function – foreseeable use and misuse
- Design – fit, comfort and size



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Determine if Item is a Children's Product or General Use/Adult Item

Children's Product vs General Use/Adult Items

- Children's products are highly regulated
- Theme can be a major factor



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Determine if Item is a Children's Product or General Use/Adult Item

Definition of Children's Product

- A children's product is defined as a consumer product primarily intended for children 12 years of age or younger
- **Factors to Consider:**
 - A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable
 - Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger
 - Whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger
 - The Age Determination Guidelines issued by CPSC staff



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Determine if Item is a Children's Product or General Use/Adult Item

Other Factors to Consider

- Size and Shape
- Materials Used
- Number of Parts
- Motor Skills Required
- Classic Product
- Colors
- Cause & Effect
- Sensory Elements
- Level of Realism/Detail
- Licensing/Theme



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Hazard Identification Resources

- Global & Voluntary Standards
- Existing Data
- Behavioral Task Analysis
- Research



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Review Global & Voluntary Standards

- Mandatory regulations and standards are minimum requirements
- *Over half of all products recalled complied with mandatory standards!*
- Voluntary standards address additional issues, including safety, quality and performance
- International standards vary

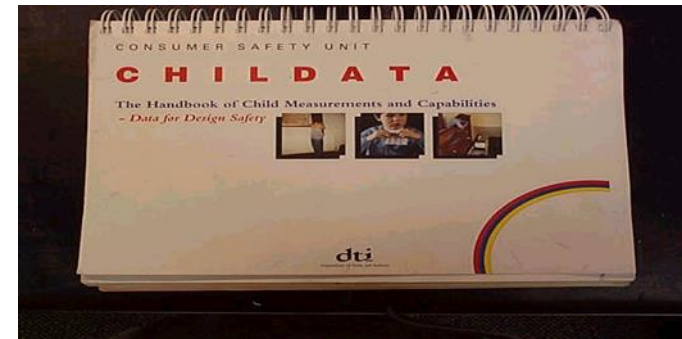
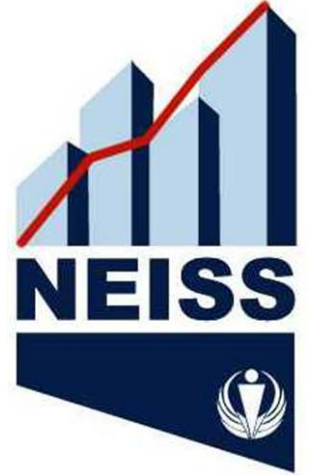


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Analyze Existing Data - external

- Incident / Injury Data, including NEISS Data
- Government and NGO Publications and Reports
- CPSC & International Recalls
- Medical / Social sciences publications – NIH, HFES
- Anthropometric data – Chidata, Adultdata, Older Adultdata, Strength Data for Design Safety
- SaferProducts.gov

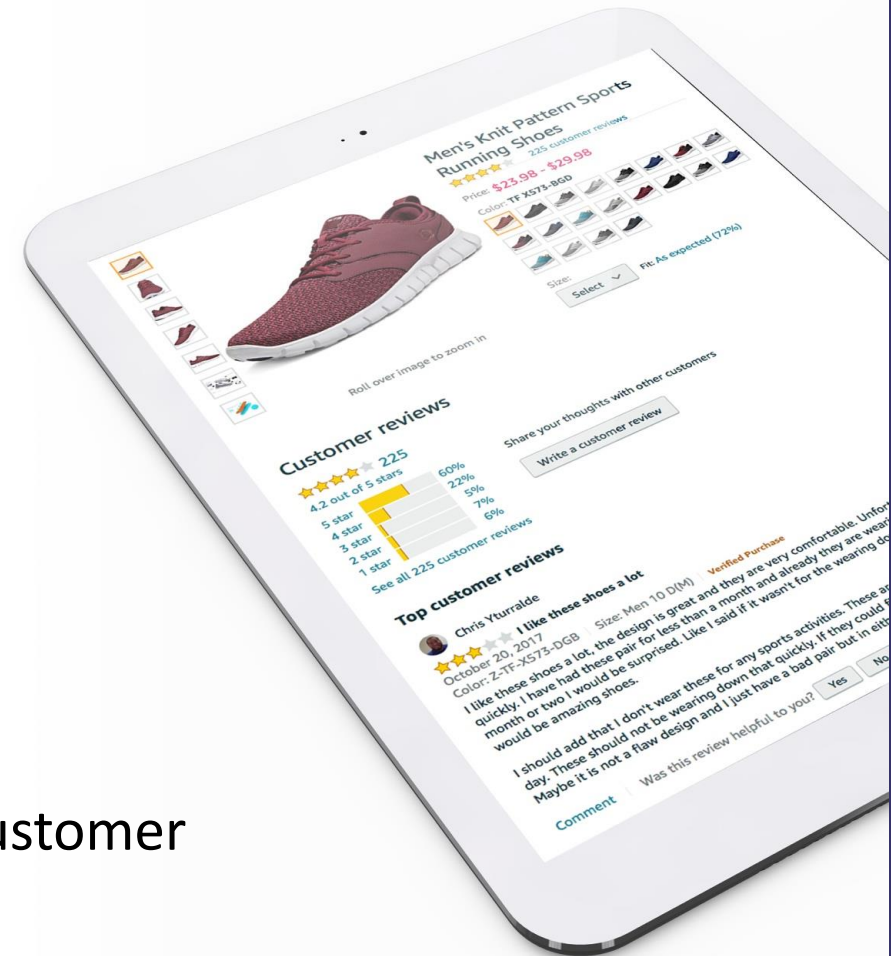


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Analyze Existing Data - internal

- Customer Service Feedback
- Complaints, associated follow-up
- Returns / Replacement parts / Repairs
- On-line product reviews
- Feed back safety-related issues to product designers and engineers
- Maintain central repository for incident reports and other customer feedback



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Perform Behavioral Task Analysis

Identify steps associated with product use

- Assembly
- Intended use
- Foreseeable unintended use (misuse)
- Cleaning
- Troubleshooting
- Disassembly
- Storage



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Conduct Research

- Behavioral observations
- Sensory panels
- Focus groups
- Survey research



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Use Standardized Checklist

- ISO Guide 50, ISO Guide 51
- EU Guidelines for Non-food Consumer Products
- ISO 13077
- Internal Hazard Pattern Checklist

Hazards - Based on ISO Guide 60	Is the Hazard Present	Has the Hazard Been Addressed
<u>Mechanical Hazards</u>		
Gaps and openings		
Protrusions	✓	
Corners, edges and points		
Projectiles		
Hazards from small objects		
Non-permeable enclosures	✓	✓
Inadequate stability		
Inadequate structural integrity		
Hazardous heights		
Moving and rotating objects		
Noise	✓	✓
Drowning hazards		
Hazards from suction		
<u>Thermal Hazards</u>		
Flammability and burning characteristics		
Hazards from hot and cold surfaces		
Hazards from hot and cold fluids		

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Hazard Pattern Checklist (not all-inclusive)

- Burns/Fires
- Eye Injuries
- Facial Suction
- Suffocation
- Impalement
- Puncture/Projection
- Choking/Aspiration
- Throat Impaction
- Lacerations
- Contusions
- Finger/Wrist
- Entanglement
- Ear Impaction
- Finger Entrapment
- Hair Entanglement



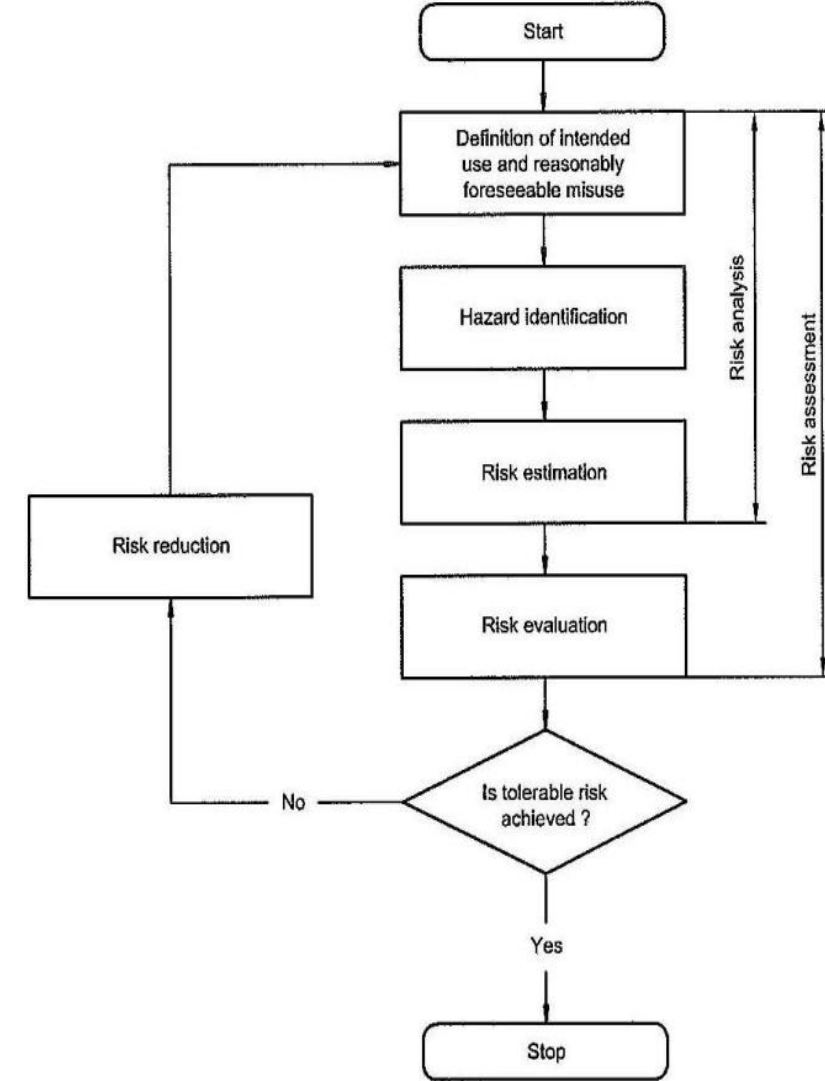
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Use Decision Tree

Top down method of analyzing a series of foreseeable events

- ISO Guide 51
- ISO 13077
- EU Guidelines for Non-Food Consumer Products



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FMEA Can Quantify Risks

Process of systematically identifying hazards to determine outcome and level of risk

■ EU Guidelines for Non-Food Consumer Products

Probability of damage during the foreseeable lifetime of the product		Severity of Injury			
		4	3	2	1
Almost certain, might well be expected	> 50 %	S	S	S	H
Quite possible	> 1/10	S	S	S	Sig
Unusual but possible	> 1/100	S	S	S	Sig
Only remotely possible	> 1/1,000	S	S	H	L
Conceivable, but highly unlikely	> 1/10,000	S	H	Sig	L
Practically impossible	> 1/100,000	H	Sig	L	L
Impossible unless aided	> 1/1,000,000	Sig	L	L	L
(Virtually) Impossible	< 1/1,000,000	L	L	L	L

Severity of injury	
1	Injury or consequence that after a basic treatment (first aid, normally not by a doctor) does not substantially hamper the functioning or cause excessive pain; usually the consequences are completely reversible.
2	Injury or consequence for which a visit to the Emergency Room may be necessary, but in general hospitalisation is not required. The functioning may be affected for a limited time, not more than about 6 months, and recovery is more or less complete.
3	Injury or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.
4	Injury or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe/grievous loss of limbs and/or function, leading to more than about 10% of disability.

S –	Serious Risk
H –	High risk
Sig –	Significant risk
L –	Low risk

Probability of damage during the foreseeable lifetime of the product	
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

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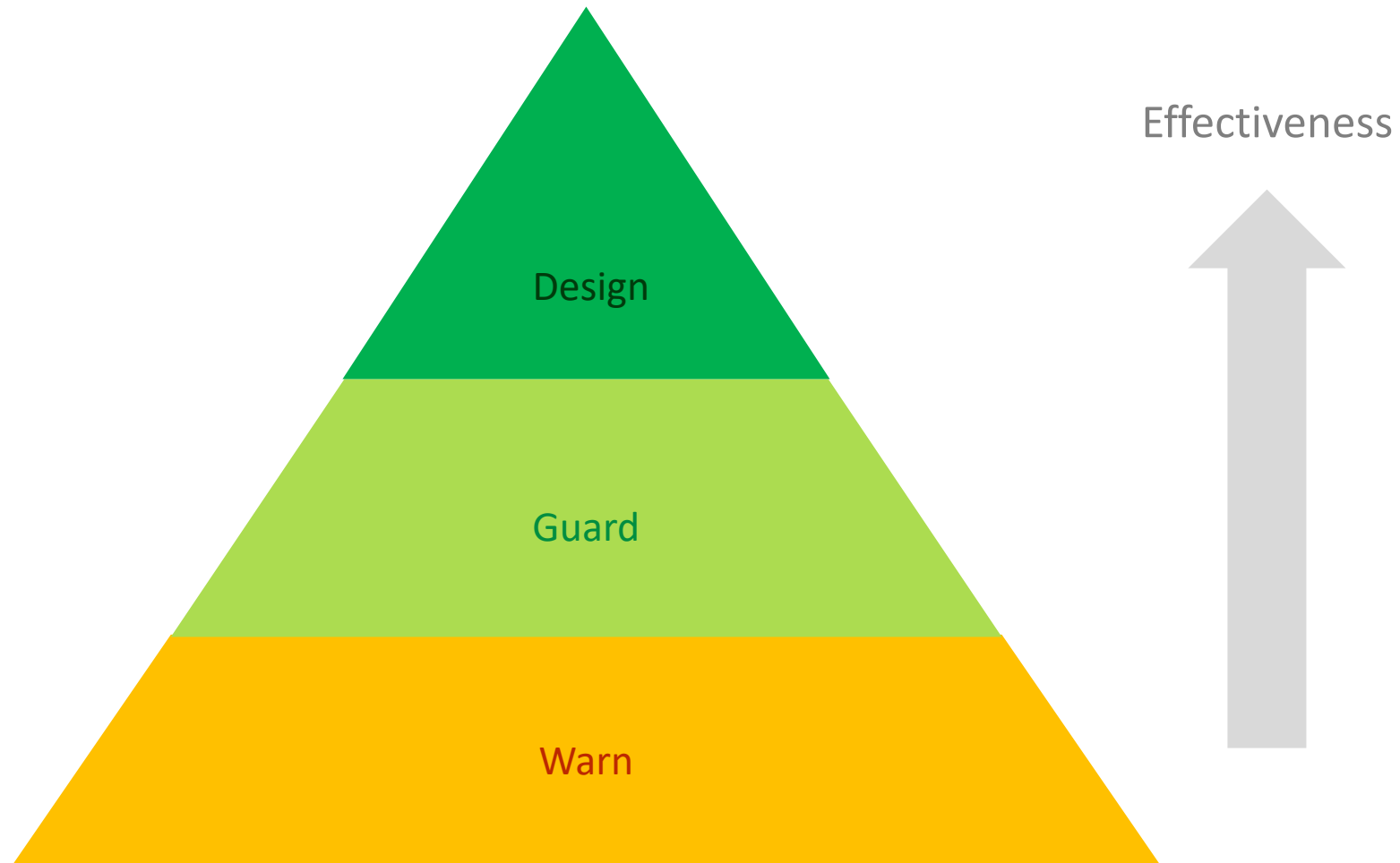


III. Risk Management

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Apply the Safety Hierarchy



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Design Hazard Out

- Likelihood of hazard occurring
- Severity of potential injury
- Technologically feasible
- Financially feasible
- High risk or high profile category



Probability of damage during the foreseeable lifetime of the product		Severity of Injury			
		4	3	2	1
Almost certain, might well be expected	> 50 %	S	S	S	H
Quite possible	> 1/10	S	S	S	Sig
Unusual but possible	> 1/100	S	S	S	Sig
Only remotely possible	> 1/1,000	S	S	H	L
Conceivable, but highly unlikely	> 1/10,000	S	H	Sig	L
Practically impossible	> 1/100,000	H	Sig	L	L
Impossible unless aided	> 1/1,000,000	Sig	L	L	L
(Virtually) Impossible	< 1/1,000,000	L	L	L	L

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Guard Against The Hazard

- Physical Guard
- Procedural Guard
- Proper Manufacturing Controls
- Select suitable vendor/factory
- Review factory flowchart and quality control (QC) plan
 - Critical processes
 - In-factory testing
- Start-up and In-process Monitoring



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Warn About The Hazard



WARNING:

CHOKING HAZARD--Small parts
Not for children under 3 yrs.



WARNING:

CHOKING HAZARD--Children under 8 yrs. can
choke or suffocate on uninflated or broken balloons.
Adult supervision required.

Keep uninflated balloons from children.
Discard broken balloons at once.



Traditional OSHA Design



Classic design – still
in common use.

ANSI Z535 Design



Shows how to avoid the
hazard, plus a symbol.
ANSI label designs
becoming prevalent.



Warning: Not intended for
children. Swallowing of
magnets may cause
serious injury and require
immediate medical care.

Ages 13+

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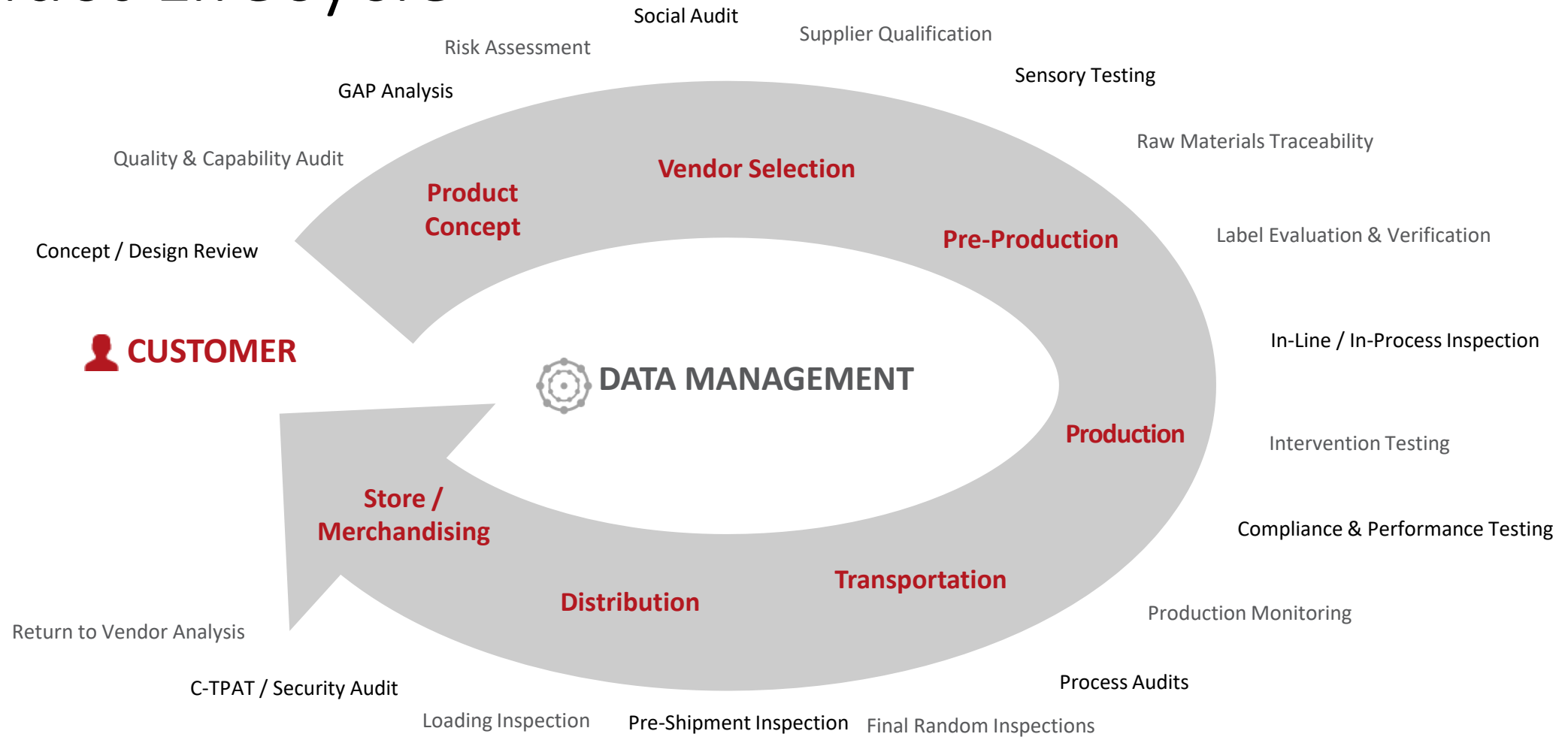
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Use Risk Management Techniques Throughout the Product Lifecycle



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Speaker's Contact Info

Susan E. DeRagon

Susan.deragon@asiainspection.com

860-416-5846

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Resources

- PPAI: www.ppai.org
- PPAI Product Responsibility: <http://www.ppai.org/inside-ppai/corporate-responsibility/product-responsibility/>
- Consumer Product Safety Commission: www.cpsc.gov , www.recalls.gov
- AsiaInspection: asiainspection.com
- Questions? AnneS@ppai.org

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