



Risk Assessment and Hazard Reduction Methodology

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Overview

- Primary goals of consumer product design reviews.**
- Risk assessment and hazard reduction methodology.**
- Failure mode and effect analysis (FMEA).**



Primary Goals of Consumer Product Design Reviews

- To identify and eliminate by design potential hazards as early as possible during the design phase.**
- To identify critical components and manufacturing processes and, hence, provide recommendations to the factory quality control (QC) systems.**

Goals of Risk Assessment Methodology

- Create a systematic risk-based approach to evaluating potential hazards and their consequences.**

- Enhance the communication process among participants when evaluating risks.**

- Allow all participants to share information and expertise in a timely and interactive manner.**

- Demonstrate effectiveness of recommendations made to eliminate/reduce risks.**

- Reduce paperwork and provide a comprehensive program history.**



Risk Assessment Methodology



Components of Risk Assessment

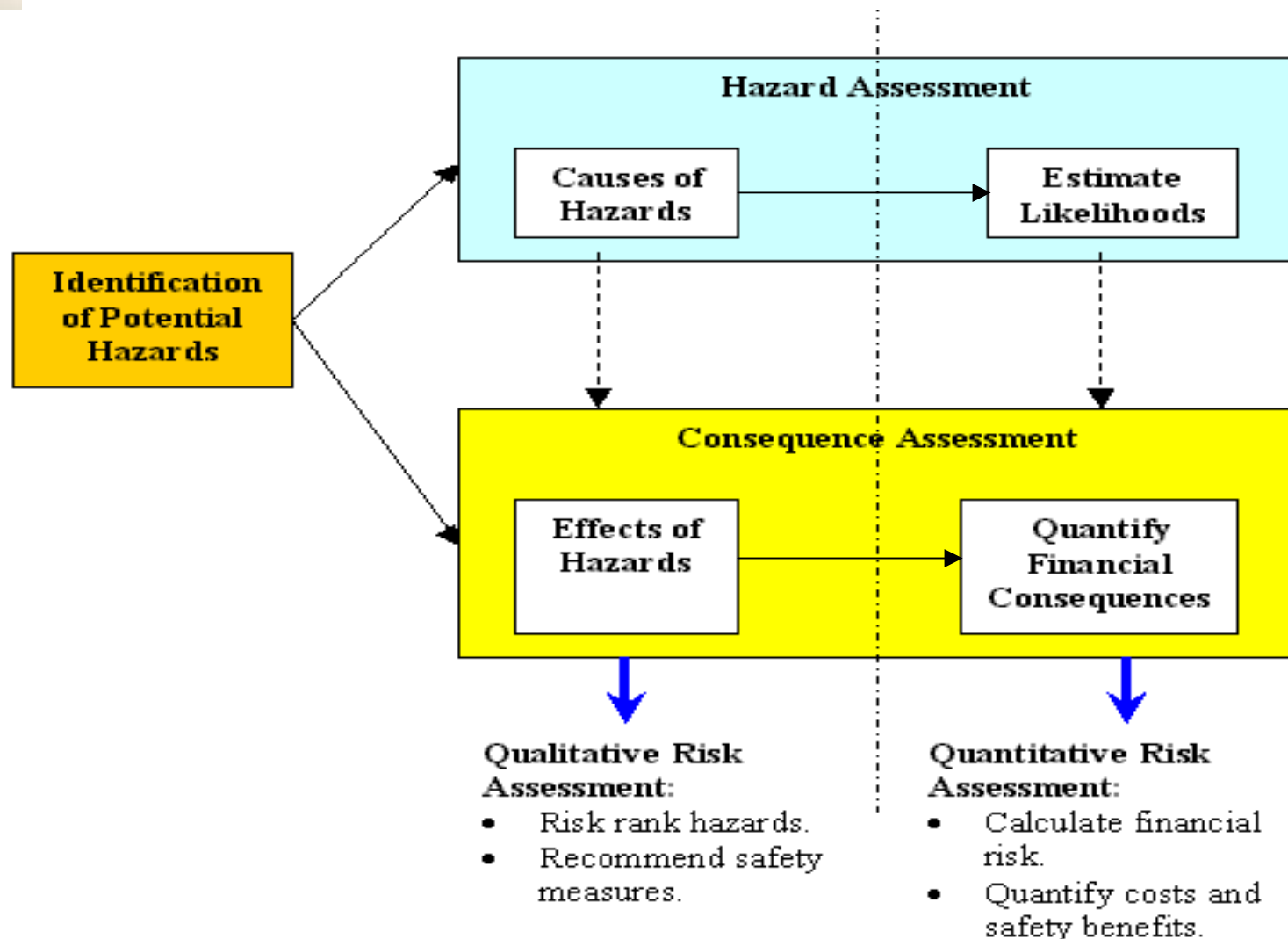
There are three components of risk assessment:

- ❑ **Hazard**: What could go wrong?

- ❑ **Probability of Occurrence**: What is the probability that an injury will occur as a result of exposure to the hazard?

- ❑ **Severity**: Should an injury occur as a result of the hazard, how severe will the outcome be?

Risk Assessment Methodology





Risk Quantification

Risk Priority Number (RPN) =

Occurrence x Severity

- ❑ Occurrence refers to the probability of occurrence of incidents caused by a specific hazard.
- ❑ Severity refers to the effect (or seriousness) of the incident/injury caused by a specific hazard.



Example of Occurrence Levels



General FMEA

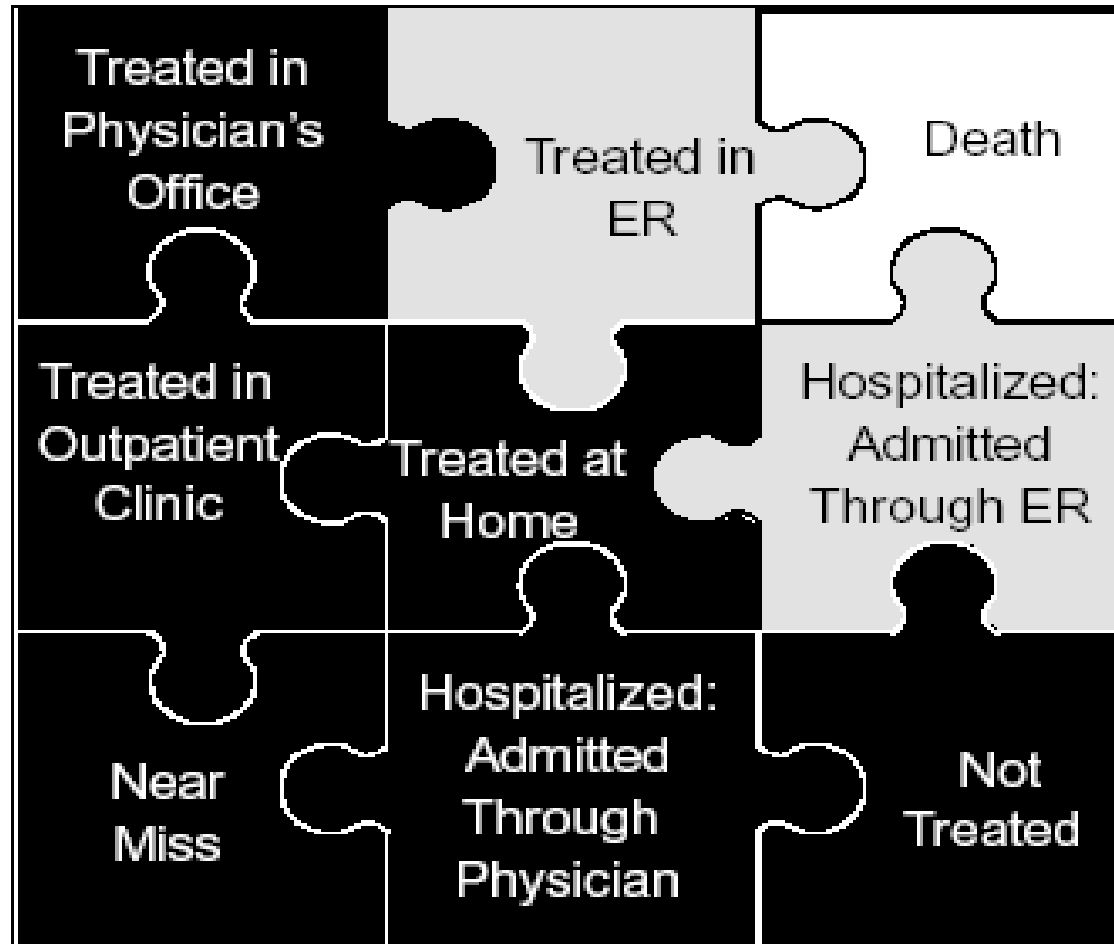
General	Severity	Occurrence	Detectability	Usage	Statistics
Low ↑	Ranking	Occurrence	Likelihood of Hazard Occurring		
	1	Improbable	Rare event. Frequency of hazard equals 1.0E-7 or less (that is, 1:10,000,000 or less).		
	2	Remote	Not likely to occur, but could possibly occur. Frequency of hazard equals 1.0E-6 (that is, 1:1,000,000).		
	3	Occasional	Occurs sporadically, likely to occur sometime (less than monthly). Frequency of hazard equals 1.0E-5 (that is, 1:100,000).		
	4	Frequently	Likely to occur repeatedly (e.g., daily). Frequency equals 1.0E-3 or greater (that is 1:1000 or greater).		



Example of Severity Levels



CPSC Classification of Severity of Injury





UK Classification of Product-Related Injuries







UK classifies product-related injuries based on the “**outcome**” and “**number of days of hospitalization.**”

- 1) **Trivial**: “patient didn’t wait” or “examined but no treatment given.”
- 2) **Minor**: treated, no more treatment required, referred to a general practitioner (GP), referred to an outpatient clinic (OP), referred to OP or GP, or admitted for < 1 day.
- 3) **Serious**: admitted for one, two, or three days.
- 4) **Very Serious**: admitted for more than three days or transferred to a specialized hospital.
- 5) **Fatal**: death.

Source: UK Government Consumer Safety

Severity Levels of Product-Related Injuries

General FMEA

General	Severity	Occurrence	Detectability	Usage	Statistics
Low 	Ranking	Severity	Severity of Effect		
	1	Minimal	Negligible adverse effects - see attached comments 		
	2	Slight	Slight adverse effects - see attached comments. 		
	3	Moderate	Moderate adverse effects - see attached comments. 		
	4	Critical/Serious	High severity of adverse effects - see attached comments. 		
	5	Catastrophic	Maximum severity - see attached comments. 		



General

Severity



Occurrence

Detectability

Usage

Statistics

Low

Ranking	Severity	Severity of Effect
1	Minimal	Negligible adverse effects - see attached comments 
2	Slight	Slight adverse effects - see attached comments. 

Note

Minimal (mostly negligible adverse effects, no injury):

Incident doesn't require treatment. Examples include, red mark around the child's arm, soreness, and short periods of discomfort.

Notes:







1. The "Green" risk code refers to the baseline risk which reflects the fact that achieving "zero risk" is both non-physical and unrealistic.
2. The baseline risk is an "acceptable" risk level.

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Ranking	Severity	Severity of Effect
1	Minimal	Negligible adverse Effects - see attached comments 
2	Slight	Slight adverse effects - see attached comments.  
3	Moderate	Moderate adverse effects - see attached comments. 
4		...ments. 
5		...ments. 





Note

Hazard may cause slight injury or illness to the child:


1. Injury treatment can be easily done at home. Examples include contusions, abrasions, bruising, or slight (1st degree) burns (these are superficial burns).
2. Incident may not require medical treatment, but may cause some level discomfort.



General | Severity | Occurrence | Detectability | Usage | Statistics



Ranking	Severity	Severity of Effect
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Low ↑

Note 

Hazard may cause moderate injury or illness to the child:

1. Injury occurred and outpatient medical attention required -- treated & released (T & R).
2. Injury treatment in outpatient clinic.
3. Injury treatment in physician's office.
4. Physician office visits and follow up maybe required.





Severity	Occurrence	Detectability	Usage	Statistics
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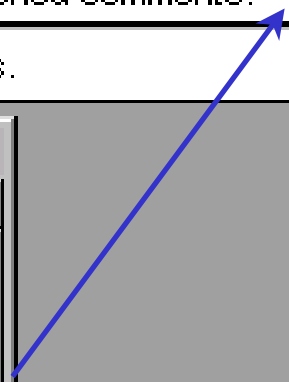
Note

Hazard may cause critical/serious injury, illness, or severe damage:






Examples:

1. An injury which causes an irreversible physical damage such as a permanent scar.
2. An injury which results in admission to ER and hospitalization.
3. An injury which results in treatment by a Physician and includes hospitalization for a day or more.

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General					Severity	Occurrence	Detectability	Usage	Statistics	
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5	Catastrophic	Maximum severity - see attached comments.								

Note ✕

Catastrophic: Injury results in catastrophe (i.e., child death).

Examples:

1. Death.
2. Physical or mental disability.
3. Loss of sight or hearing.
4. Violation of legal safety standards creating a hazardous product.

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Risk Priority Number (RPN)

- Injury severity x Probability of Occurrence.
- An aid for ranking potential hazards.
- High RPNs require immediate attention/corrective actions.
- Use relative severity ranking to prioritize hazards with the same RPN.



Why Calculate the Risk Priority Number?

- Prioritize potential hazards.
- Optimize resources by focusing on eliminating hazards with largest RPNs.
- Monitor risk reduction throughout product design phases.
- Demonstrate effectiveness of recommended corrective actions.
- Communicate potential product risks.

Current Industry's Risk Models

- ❑ Designsafe Two-Factor Risk Model [4 x 4]
- ❑ Designsafe Three-Factor Risk Model [4 x 4 x 4]
- ❑ MIL-STD 882B Two-Factor Risk Model [4 x 5]
- ❑ AFP 91-215 Two-Factor Risk Model [4x5]
- ❑ Fred Manuele Three-Factor Risk Model [4 x 4 x 5]
- ❑ Simple Two-Factor Risk Model [3 x 3]
- ❑ Simple Three-Factor Risk Model [3 x 3 x 3]
- ❑ ANSI B11 TR3 Two-Factor Risk Model [4 x 4]

Severity: Catastrophic, Serious, Slight, and Minimal.

Exposure: Frequent, Occasional, Remote, and Seldom.

Probability: Probable, Possible, Unlikely, and Negligible.



Example: A Two-Factor Risk Model [4 x 5]

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

Treatment of Frequent Consumer Complaints and Concerns about Product Safety Hazards

- Voice of the customer (VOC): dissatisfaction with the product, perceived safety hazards, . . . etc.**

- A low risk priority number (RPN = 2) has been assigned to the VOC.**

- RPN = 2 is assumed to be a “Green Risk.”**

- The goal is to bring the RPN value from 2 to 1.**



Financial Risk Assessment

- **Financial Risk (\$/year) = Frequency of Occurrence x Consequences (\$)**

- **Consequences (\$) = Tangibles (\$) + Intangibles (\$)**



Failure Mode and Effects Analysis (FMEA)

- Can be applied to a system, subsystem, or component/part of a system.
- Looks into the cause(s) and effect(s) of each failure mode or hazard.
- Excellent tool for root cause investigations.



FMEA Worksheet (continued)

System: Subsystem: Component:

Item Selected: **1.**

Item Function Selected: **1.**

Recommendations			Action Results						
Recommendation	Responsibility	Target Completion Date	Actions Taken	Effective Date	Sev	Occur	Detec	R.P.N.	% Reduction



Populating the Worksheet

- ❑ Start with a worksheet template that includes all recognized hazard types, for each product category.

- ❑ Each hazard is reviewed during 3 design phases: conceptual, prototype, final product.

- ❑ Each worksheet maintains complete design review history in a single document, including engineering drawings.

Populating the Worksheet

- ❑ **UL Lab completes the design review worksheet worksheet up to “Recommended Action(s)”**
- ❑ **UL Lab posts the worksheet, and automatic email notifier is sent to all stakeholders (manufacturer, agency, ... etc)**
- ❑ **Stakeholders review and complete “*Corrective Action(s) to be Taken*” and “*Implementation Phase*” where necessary**
- ❑ **Stakeholders post the modified worksheet**



Populating the Worksheet

- ❑ **UL Lab reviews stakeholders' additions and completes the worksheet as follows:**
 - **“UL Lab response to resolution”**
 - **Recalculate risk and % reduction in RPN after remedial actions are taken**
- ❑ **Completed worksheet is posted.**



Integrating dFMEA and HACCP

- 1) The design FMEA (dFMEA) phase generates MCPs and other design information.**
- 2) The factory process flow charts provide inspection checkpoints and other control points (CPs).**
- 3) The factory QC plan provides check points and control & monitoring processes.**
- 4) The approach includes a systematic process to determine which control points (from steps 1, 2, and 3 above) are truly critical control points (CCPs)**



CPs and CCPs

- Identification of the critical control points (CCPs) constitutes Principle #2 of the factory HACCP plan.

- The control points (CPs) can be used to create factory work instructions.



Features of the Risk Assessment Methodology

- ❑ Integrates FMEA and HACCP

- ❑ Includes two phases I and II:
 - Phase-I:
 - Involves “design-related” tasks for identifying hazards, quantifying risks, and eliminating or reducing risks

 - Focuses on the concept of design for safety (*i.e., risk elimination by design*) using FMEA



Features of the Risk Assessment Methodology

➤ Phase-II involves:

- **Using the residual risks (from Phase-I) to guide the development of a manufacturing QC plan**
- **Ensuring that these residual risks are carefully controlled and maintained at pre-determined acceptable risk levels**



Features of the Risk Assessment Methodology

- ❑ **A systematic risk-based approach to product design reviews.**
- ❑ **Allows all participants to contribute to the decision process by sharing information and expertise.**
- ❑ **Encourages “buying into” recommended corrective actions since the process runs interactively.**
- ❑ **Traceability of file versions.**