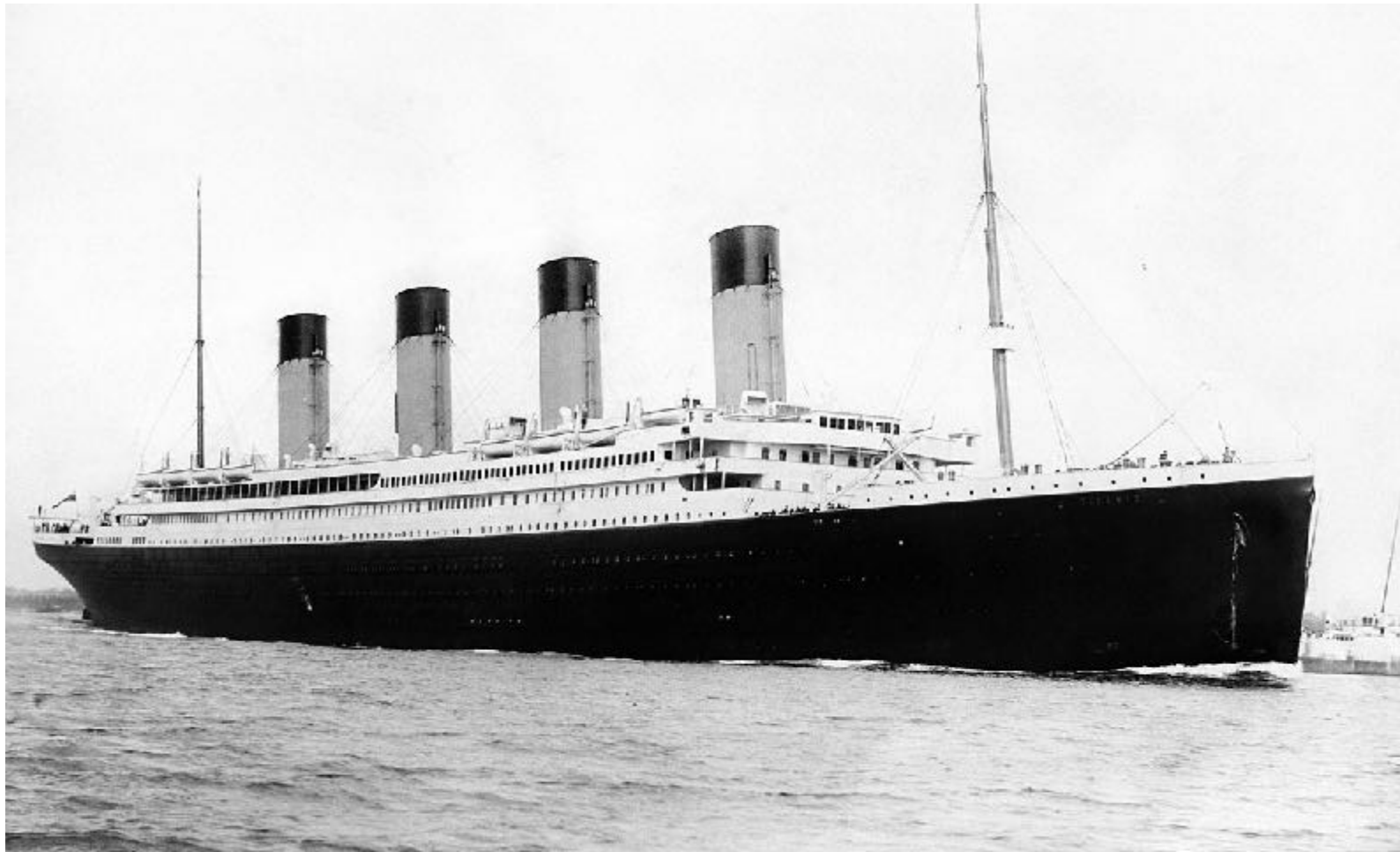




Assessment and Control of Risks for Achieving Safety

About the Teacher

- Safety by Design, MSc course, (course creator)
- Editorial board, System Safety Journal
- Member of standardisation committee for ISO/TC 199 “Safety of Machinery”
- See <https://safety productions>
- Contact
 - Tel: 053 489 3278
 - De Horst, W250
 - M.Rajabalinejad@utwente.nl



Overview

- Risk assessment and control (safety) by design
 - Scope and issues
 - History and current states
 - Why? When? Where? Who?
 - Ingredients and how to
 - Best practices
- Exercise

IS IT SAFE?

- Designed by IKEA
- Produced in large scale
- Available in many countries
- See it in action

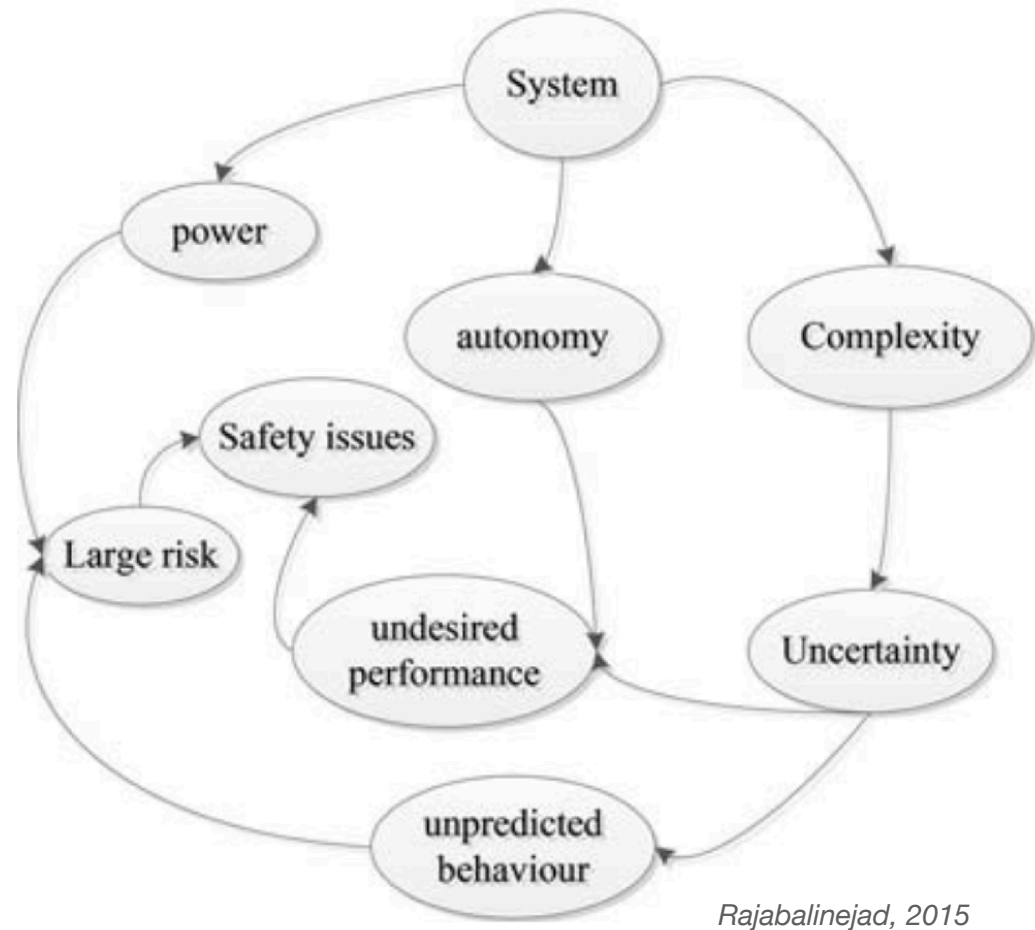


<https://safety productions/?p=85>



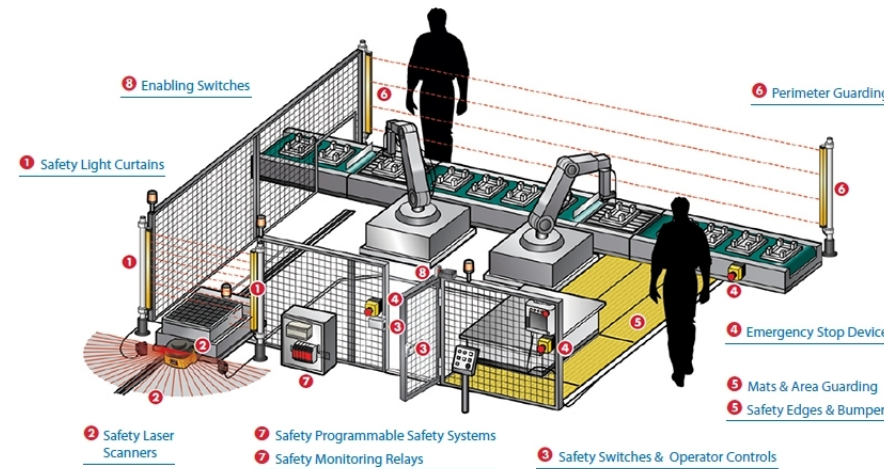
EXPERIENCE?

- New technologies
 - Autonomous
 - Complex
 - Uncertain
- Result in “large risks”



Ex Machina!

- Safe guarding is not an option
 - Robotes
 - Cobots
 - Exo-skeleton
 - Servant drones



Edmond De Belamy

- Trust and empathy?
- \$432,500 fortune for a student who used
 - $\min G \max D x[\log(D(x))] + z[\log(1-D(G(z)))]$.
- Isn't this about emotion too?



Friend or Enemy?



Code of Hammurabi

- As old as men exists
- Code of Hammurabi, 1750 BC, BabylonAs old as men exists
- Code of Hammurabi, 1750 BC, Babylon
 - a tooth for a tooth
 - liability rules
 - A house is built and collapses, killing the owner, the builder would be put to death



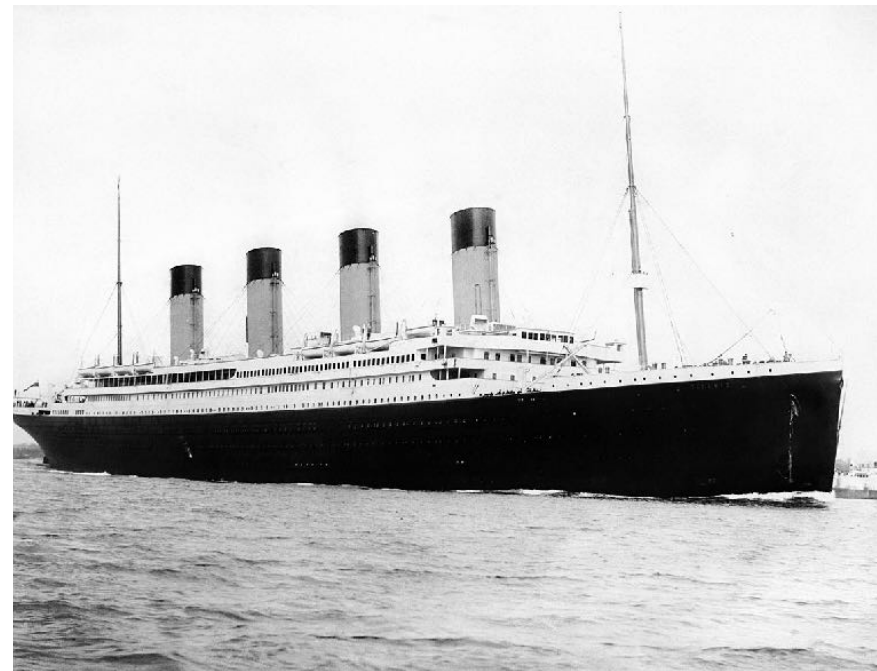
Ship Safety

- As old as men exists
 - Code of Hammurabi, 1750 BC, Babylon
 - Comité Maritime, 1897, Antwerp
-
- Maritime regulations
 - See <http://www.comitemaritime.org/A-Brief-History/0,27139,113932,00.html>



Insure Safety

- As old as men exists
- Code of Hammurabi, 1750 BC, Babylon
- Comité Maritime, 1897, Antwerp
- Safety of Life at Sea treaty, 1914 (after [RMS Titanic](#))
- Safety of Life at Sea treaty, 1914 (after [RMS Titanic](#))
- Safety equipment have to be in line with number of passengers



RMS Titanic - wikipedia

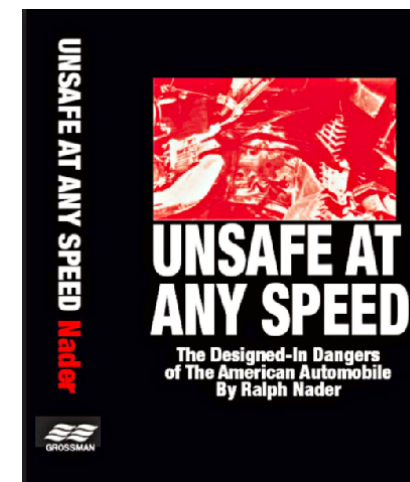
System Safety

- As old as men exists
- Code of Hammurabi, 1750 BC, Babylon
- Comité Maritime, 1897, Antwerp
- Safety of Life at Sea treaty, 1914 (after Titanic)
- System Safety 1950-1960
- “System Safety Engineering: Military Specification for the Development of Air Force Ballistic Missiles.”, 1962, US Air Force



System Safety

- As old as men exists
- Code of Hammurabi, 1750 BC, Babylon
- Comité Maritime, 1897, Antwerp
- Safety of Life at Sea treaty, 1914 (after Titanic)
- System Safety 1950-1960
- “System Safety Engineering: Military Specification for the Development of Air Force Ballistic Missiles.”, 1962, US Air Force
- [Unsafe at any speed](#), 1965, Ralph Nader
 - Volvo, 3 point seat belts - GM, airbags

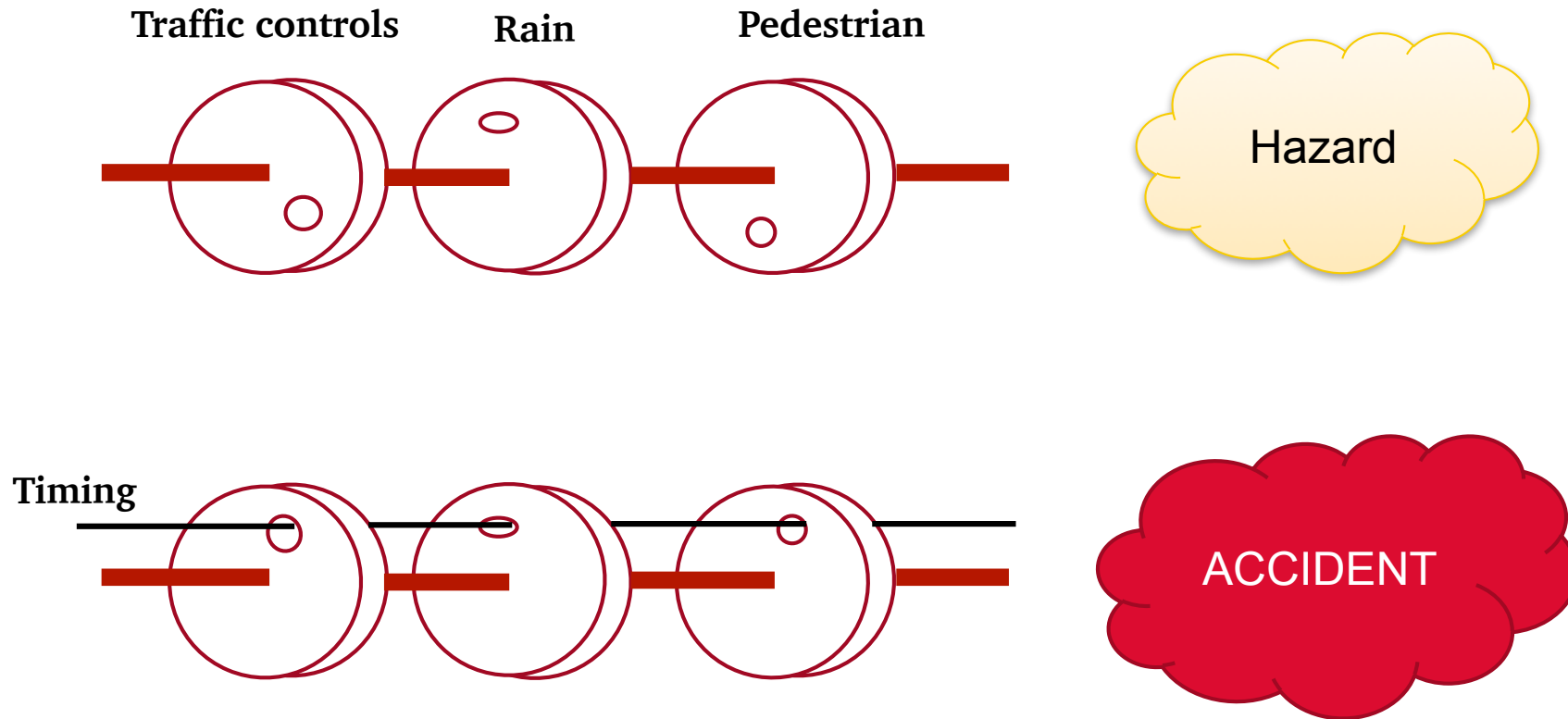


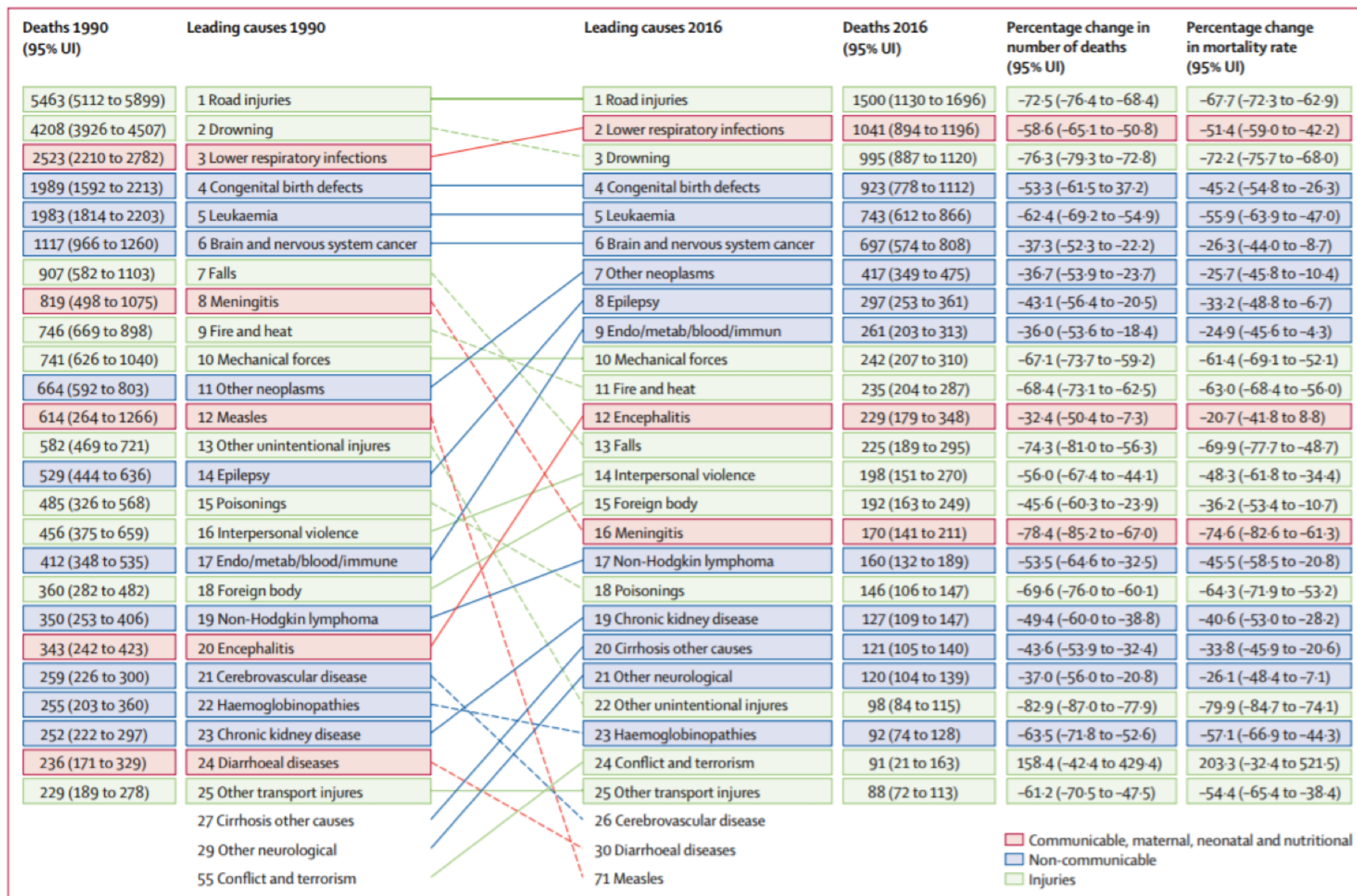
Accidents

- They are often suddenly, unexpected, unwanted
- Have multiple causes leading to injuries, damage
- Are counted by number of accidents, victims, injuries,...
- Counted by ER (Emergency Rooms), CBS, Eurostat,...



Hazard-To-Accident





Top 25 causes of death in the WHO European Region, age 5–9 years, both sexes, 1990 and 2016

Accidents on Road

- Are under the influence off quality of road vehicles, safety functions,...
- Traffic management system, more controls,...
- Regulations well enforced and applied
- Driving culture

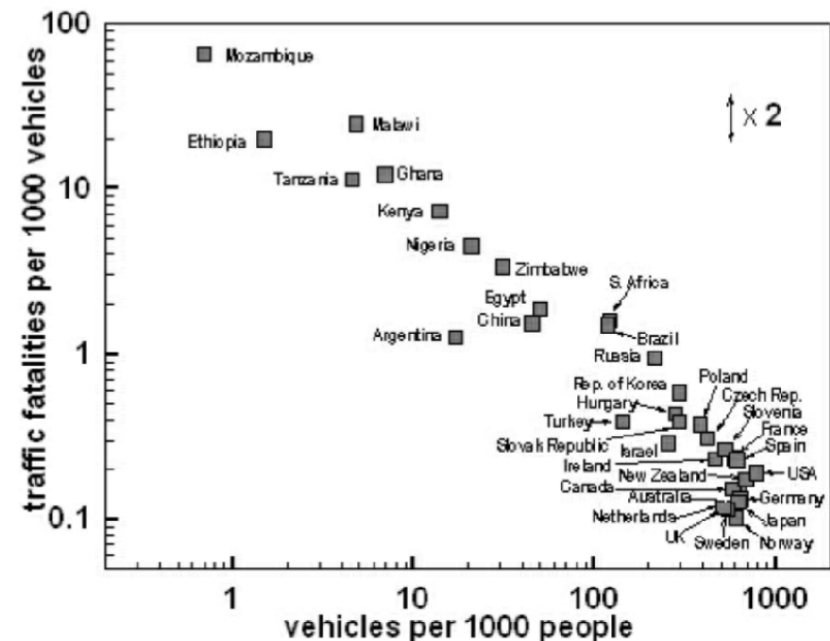


Figure 4.1. Traffic fatalities for selected countries (Evans, 2004). Reproduced with permission from Evans L., Traffic Safety (2004), Bloomfield, MI: Science Serving Society. © Leonard Evans.

Accidents in Elderly

Injury Mechanism	ER	Average costs €	Total Costs (M€)	Products involved (cause of accident, cause of injury, otherwise involved)
Fall, among which	89.000	5400	510	
- trip over	17.000	4200	75	Threshold, furniture
- fall from stairs/ladder	10.000	3900	42	Ladders and steps
- fall from height	7.200	5900	45	Bed, Chair
- slip	6.600	4300	30	Paving, Floor
- sprain	6.400	2600	17	Kerb, Tile
- by disease	3.600	6400	25	
Cut to object	6.400	1000	6,7	Tools, knife
Hit to object	4.500	1200	5,2	Door, furniture
Hit by object	3.700	1300	4,7	Car door, tools
Unusual object	2.800	1000	2,8	Splinter, fish bone
Entrapment	2.200	1300	3,0	(Car)Door

Source: Letsel Informatie System 2002-2006 (jaarlijks gemiddelde), Consument en veiligheid ism Erasmus Medisch Centrum Rotterdam. *Directe medische kosten van een ongeval waarna een SEH-behandeling of Ziekenhuisopname is gevolgd.

Accidents Young Children (0-4)

	ER	Average costs, €	Total costs, x 1000 €
Table	1.900	450	880
Bed	1.400	730	1.000
Couch	1.400	680	1.000
Chair	1.300	610	800
Slide, playground	1.200	840	1.000
Climbing frame	800	1.200	1.100
Closet	570	550	310
Swing	460	1.000	480
Kommode / changing unit	400	870	350
Car Door	350	430	150

Source: Letsel Informatie System 2002-2006 (jaarlijks gemiddelde), Consument en veiligheid ism Erasmus Medisch Centrum Rotterdam. *Directe medische kosten van een ongeval waarna een SEH-behandeling of Ziekenhuisopname is gevolgd.

Accidents in Home

- Kitchen is often the most risky place @home
 - 12.000 accidents a year
 - 41% Cuts (knives, kitchen tools, glass)
 - 27% Falls (kitchen steps, tripping)
 - 16% Burns (hot liquid, cooking)



Just a prank

Source: Letsel Informatie System 2002-2006 (jaarlijks gemiddelde), Consument en veiligheid ism Erasmus Medisch Centrum Rotterdam. *Directe medische kosten van een ongeval waarna een SEH-behandeling of Ziekenhuisopname is gevolgd.

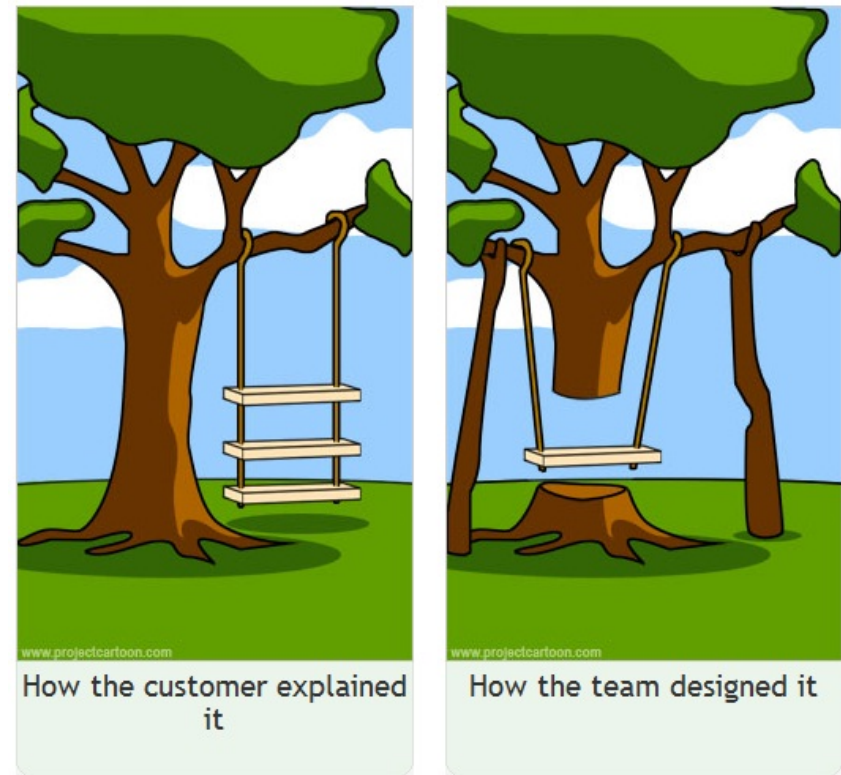
Safety in Product Lifecycle

- Safety in full product life-cycle
 - Needs (requirements)
 - Design (functions)
 - Test (acceptance)
 - Implement (assembly)
 - Operation (use)
 - Disposal (disassembly)



Safety in Engineering Requirements

- Public become less tolerant to failures
- Big consequences for safety failure
 - Cost
 - Reputation
 - Customers
 - Market-share
 - Less tolerant public



Safety in Product Design

Toy Example

- Safety in full product life-cycle
 - Needs
 - The toy breaks easily, generating small parts. Small children could put the small parts in the mouth and choke
 - The product does not comply with the requirements of the Toy Safety Directive



Safety in Engineering (Assembly)



Ondezoekraad

Alphen aan den Rijn

Safety in Engineering Use

- Safety in full product life-cycle
 - Needs (requirements)
 - Design (functions)
 - Test (acceptance)
 - Implement (assembly)
 - Operation (use)



www.safety.fail

Safety in Engineering (Disposal)



Danish Silo

Red Faces for Being Too Late

- Get informed of regulations
- Be aware of hazards in a system
- Determine the causes of those hazards
- Develop/ verify controls
- Monitor the system

Not a coat of paint!

Not after detail design!

French red faces over trains that are 'too wide'

21 May 2014



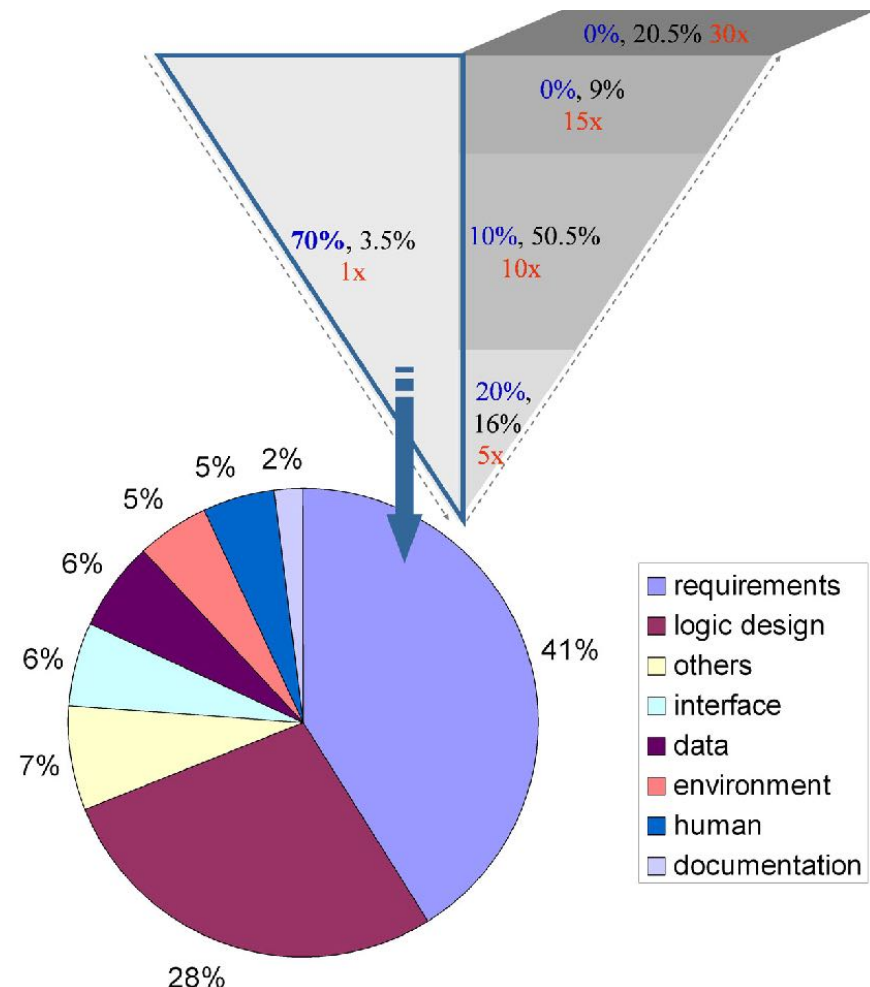
Share



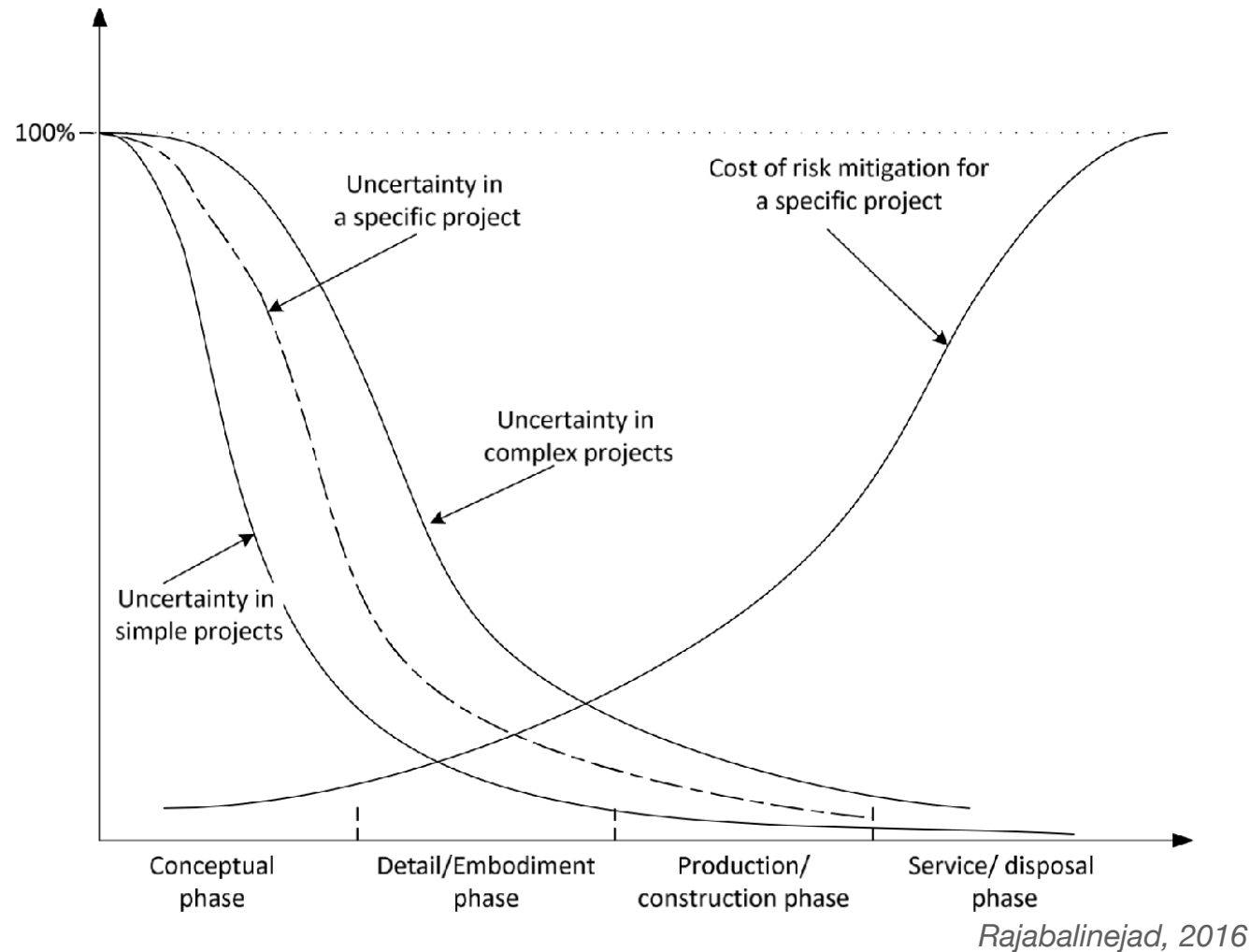
<https://www.bbc.com/news/world-europe-27497727>

Easy To Fix in the Beginning

- Share of faults per category
 - Primarily for IT projects
 - Based on research of Standish Group (1995), Scientific American (1994), NDIA (2003, 2006), DoD, ..
 - Easy to fix in the beginning, very costly to fix at the implementation phase

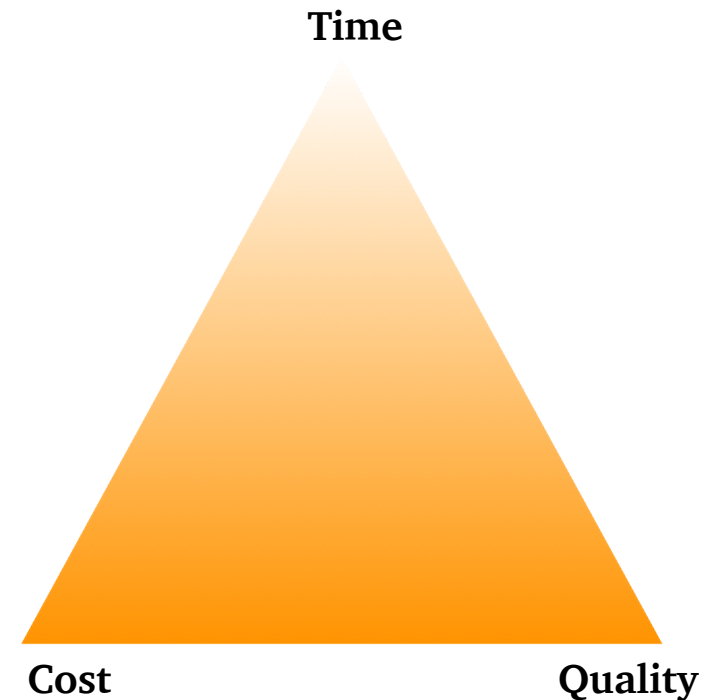


Early Design Decisions



Metrics for Designers

- Designers or Engineers
 - focus on functions and use
 - may overlook malfunction or misuse



Designers' View

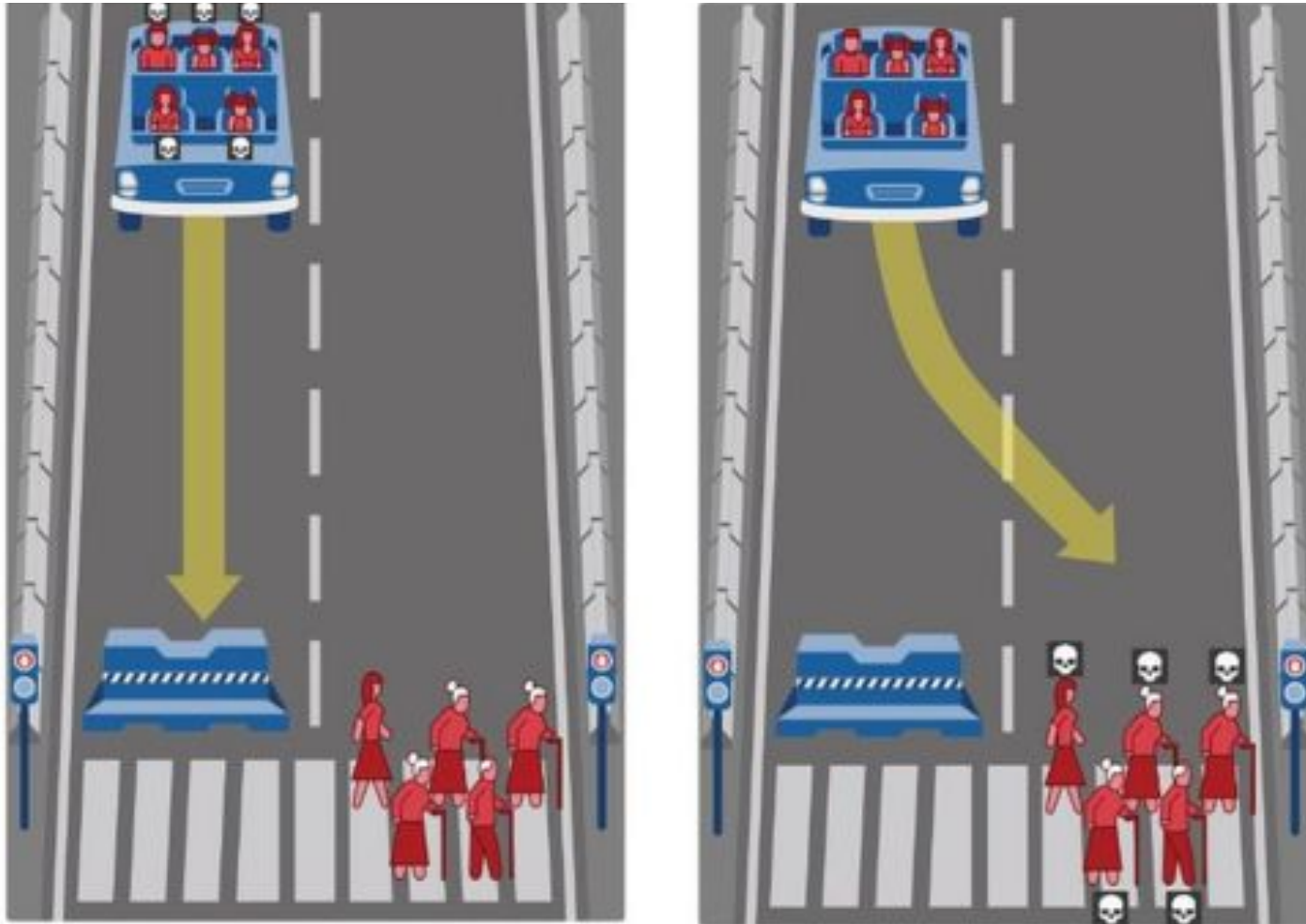


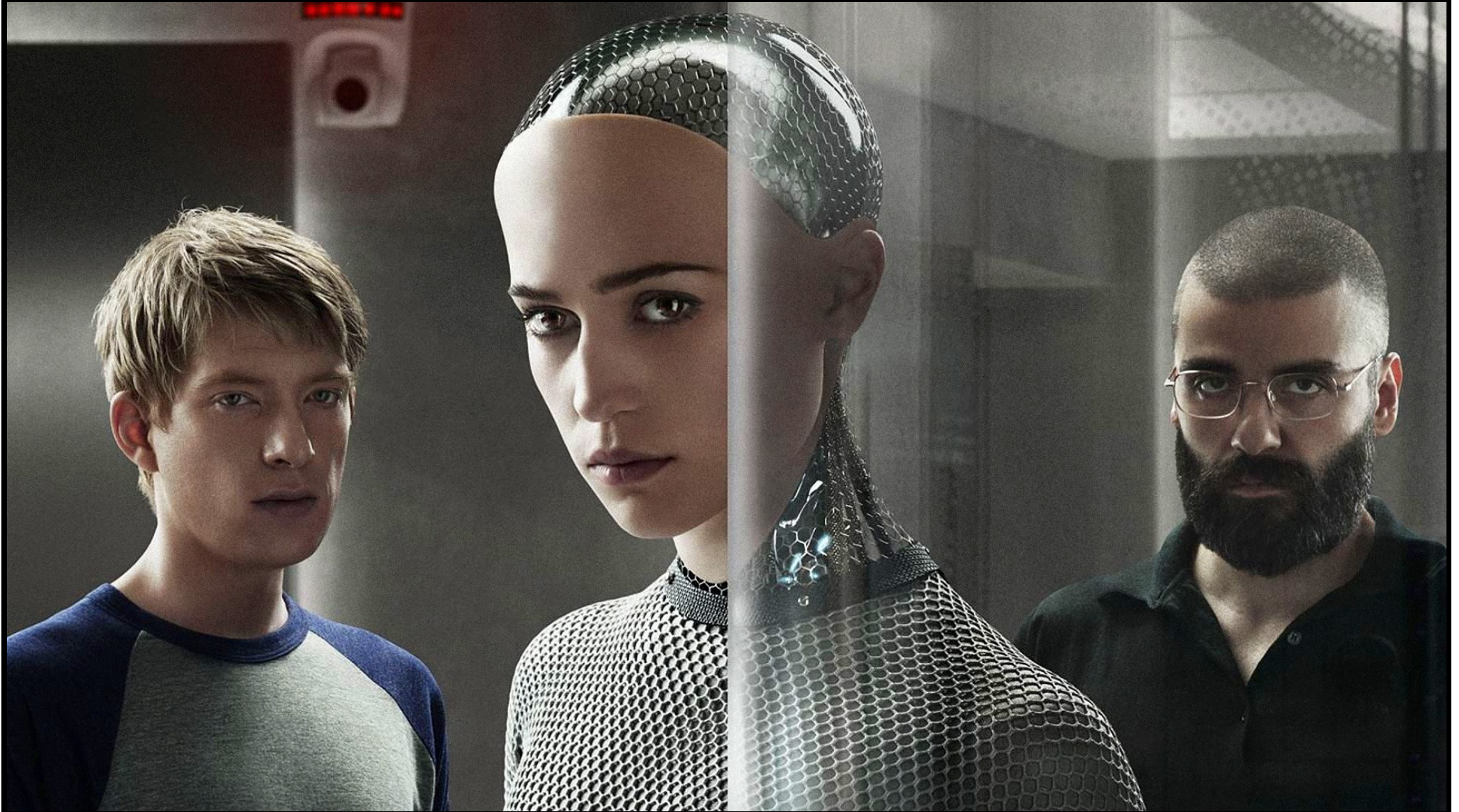
Safety in Engineering (Design)



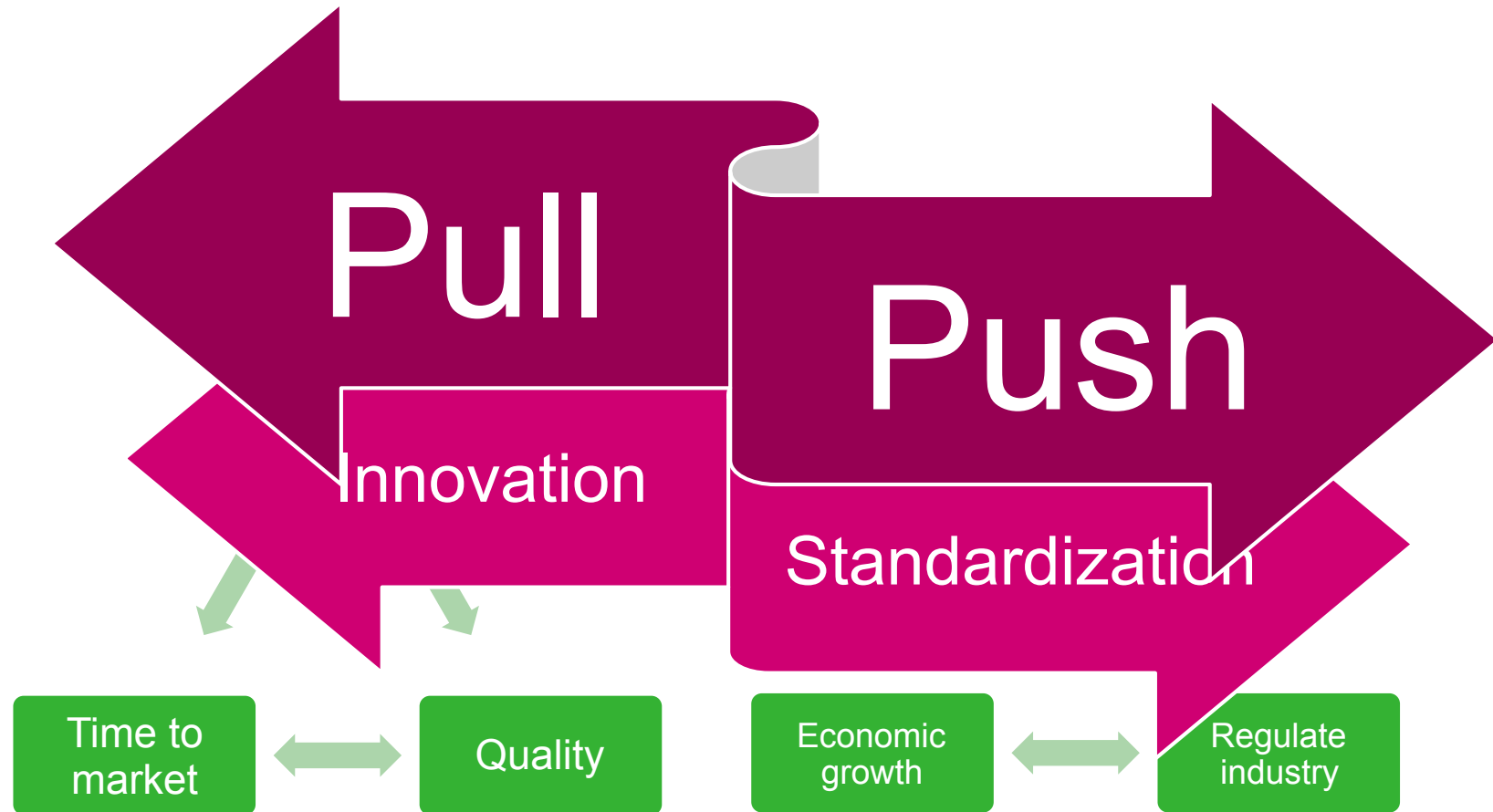
Ikea pet water dispenser, 2018

Who Dies First?





Technology or Safety?

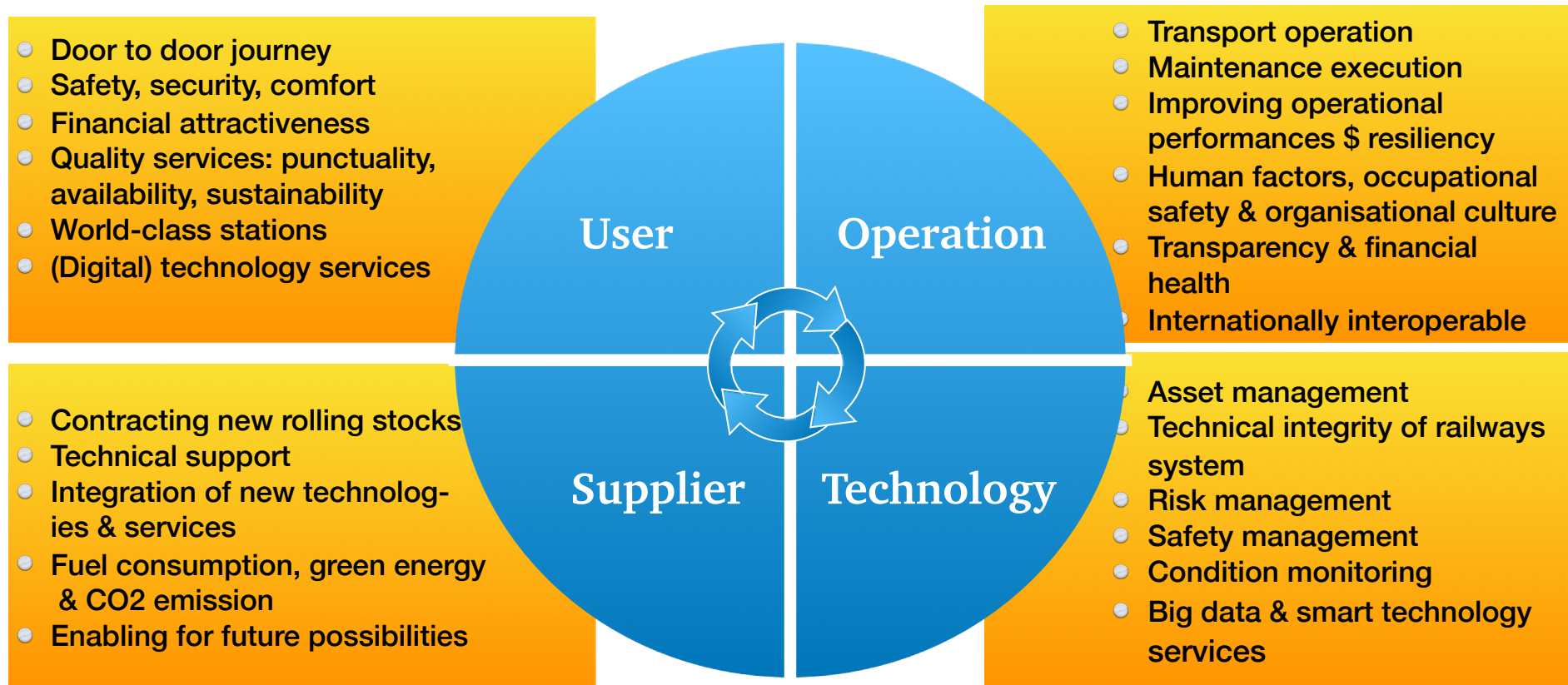


Dutch Design Week 2018

- Beyond non-stop workers
- Already started developing feeling for them
- Humiliation?!



Success Framework For Netherlands Railways



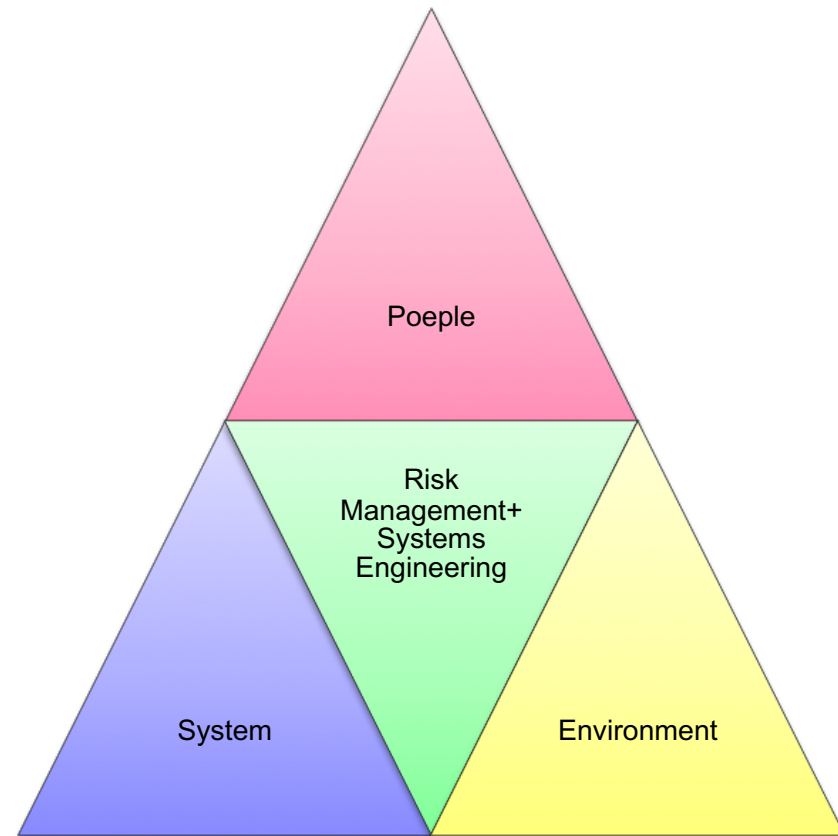
Rajabalinejad, van Dongen, 2018, Framing Success: the Netherlands Railways Experience

Success Framework For Netherlands Railways (NS)



Design Components for Safety

- Needs three basics elements of
 - people/humans
 - product/system
 - environment
- And three domains of
 - design
 - engineering
 - risk assessment
- Across the full product life-cycle



Rajabalinejad, 2017

Product/ System

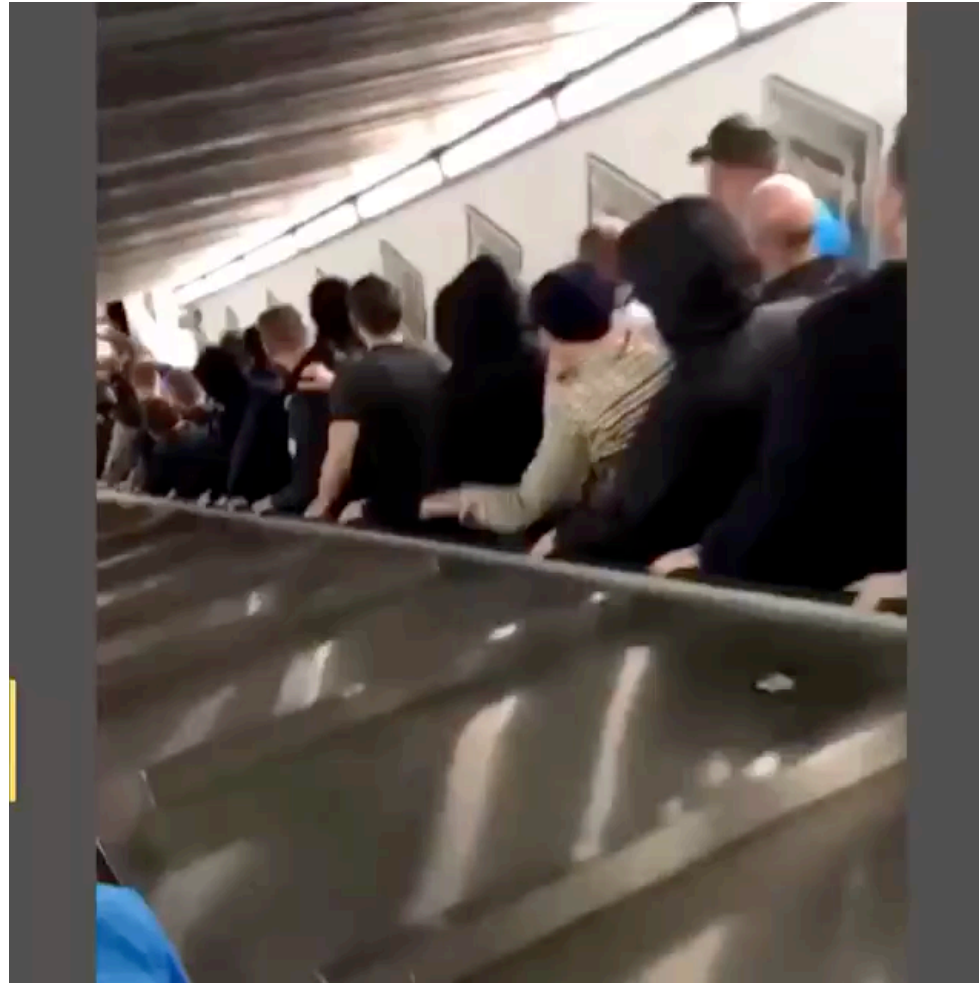
- System/ product
- combination of components, internal interfaces



Safety Gate: Rapid Alert System for dangerous non-food products

Alert number	A12/0134/19
Category	Hobby/sports equipment
Risk level	Serious risk
Product user	Consumer
Product	Bicycle
Brand	B'TWIN
Name	B'TWIN City bike
Type / number of model	B'TWIN B' Original 900 Full Suspension Hybrid Touring, B'TWIN B' Original 500, B'TWIN B' Original 500 Hybrid Touring, B'TWIN B' Original 900 Hybrid Touring, B'TWIN VTC B' Original 700 Customable Hybrid
Batch number / Barcode	Bicycles sold between 01.01.2016 and 31.08.2018
OECD Portal Category	71000000 - Sports Equipment
Description	City bicycle.
Country of origin	Unknown
Alert submitted by	Romania
Risk type	Injuries
Technical defect	There is a defect in the front mudguard that may block the wheel during use.
Risk	This could cause the cyclist to fall off the bicycle and suffer injuries.
Measures adopted by notifying country	Recall of the product from end users
Company recall page:	http://
	

System



Rome, Italy, 2018

System+Human

- System
 - combination of components, internal interfaces
- System + human
 - human system interaction, user/ external interfaces



Safety Gate: Rapid Alert System for dangerous non-food products

Alert number	A11/0066/17
Category	Childcare articles and children's equipment
Risk level	
Product user	Consumer
Product	Children's bicycle
Brand	Romet
Name	Unknown
Type / number of model	1.) Diana 16Y (distributed: 18.09.2014 - 09.06.2016), 2.) Salto 16B (distributed: 18.09.2014 - 10.06.2016), 3.) Diana 16S (distributed: 24.08.2012 - 24.08.2016), 4.) Diana 12 (distributed: 24.08.2012 - 24.08.2016), 5.) Salto 16 (distributed: 01.09.2014 - 15.07.2016), 6.) Salto 12 (distributed: 26.08.2012 - 26.08.2016)
Batch number / Barcode	1.) 5907782765447, 2.) 5907782765507, 3.) 5907782765453, 4.) 5907782765413, 5.) 5907782765491, 6.) 5907782765439 & 5907782765422
OECD Portal Category	71000000 - Sports Equipment
Description	Children's bicycles equipped with 12" or 16" wheels and additional side wheels (stabilisers), depending on the model.
Country of origin	China
Alert submitted by	Poland
Risk type	Cuts, injuries
Risk	The nuts on the cranks have sharp edges. During riding or maintenance of the bicycle, these sharp edges may cut the user's leg or fingers. The bicycle seat posts have a quick-release mechanism which may cause the seat to become unstable during the ride and the child may lose its balance and fall. The product does not comply with the relevant European standard EN 8098.
Measures adopted by notifying country	Recall of the product from end users
	

People

- Users assume that available products
 - have expected qualities and
 - are safe to use.
- These assumptions are
 - legally supported by authorities e.g. EU Commission



System+ Environment

- System
 - combination of components, internal interfaces
- System + human
 - human system interaction, user/ external interfaces
- System+environment
 - system environment interactions



Safety Gate: Rapid Alert System for dangerous non-food products

Alert number	A12/0497/15
Category	Machinery
Risk level	Serious risk
Product user	Consumer
Product	Electric bicycles
Brand	Baltik Vairas
Name	Unknown
Type / number of model	Ruhrwerk, Panther, Göricke, Böttcher, Crosswave, D-Cycle, Ebsen, Kristall, EBIKE Ultrasport, Spezi, MSA. The bicycle frame number is from 00022543 to 00049980 (frame numbering is not chronological);
Batch number / Barcode	Unknown
OECD Portal Category	71000000 - Sports Equipment
Description	Electric bicycles produced during the period 2012 - 2014, equipped with "REVA" rechargeable batteries.
Country of origin	Lithuania
Alert submitted by	Lithuania
Risk type	Burns, Fire
Risk	The batteries of the e-bikes can present defective sealing, which could result in the accumulation of humidity inside the battery and cause overheating and self-ignition.
Measures adopted by notifying country	Recall of the product from end users
Products were found and measures were taken also in	Denmark, Germany
Images	

Environment



Schiphol, Netherlands, 2018

System+Human+Environment

- System
 - combination of components, internal interfaces
- System + human
 - human system interaction, user/external interfaces
- System+environment
 - system environment interactions
- System+human+environment
 - technical and non-technical matters



Safety Gate: Rapid Alert System for dangerous non-food products

Alert number	A12/0497/15
Category	Machinery
Risk level	Serious risk
Product user	Consumer
Product	Electric bicycles
Brand	Baltik Vairas
Name	Unknown
Type / number of model	Ruhrwerk, Panther, Göricke, Böttcher, Crosswave, D-Cycle, Ebsen, Kristall, EBIKE Ultrasport, Spezi, MSA. The bicycle frame number is from 00022543 to 00049980 (frame numbering is not chronological);
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System + Environment

Extreme Modes of Operation

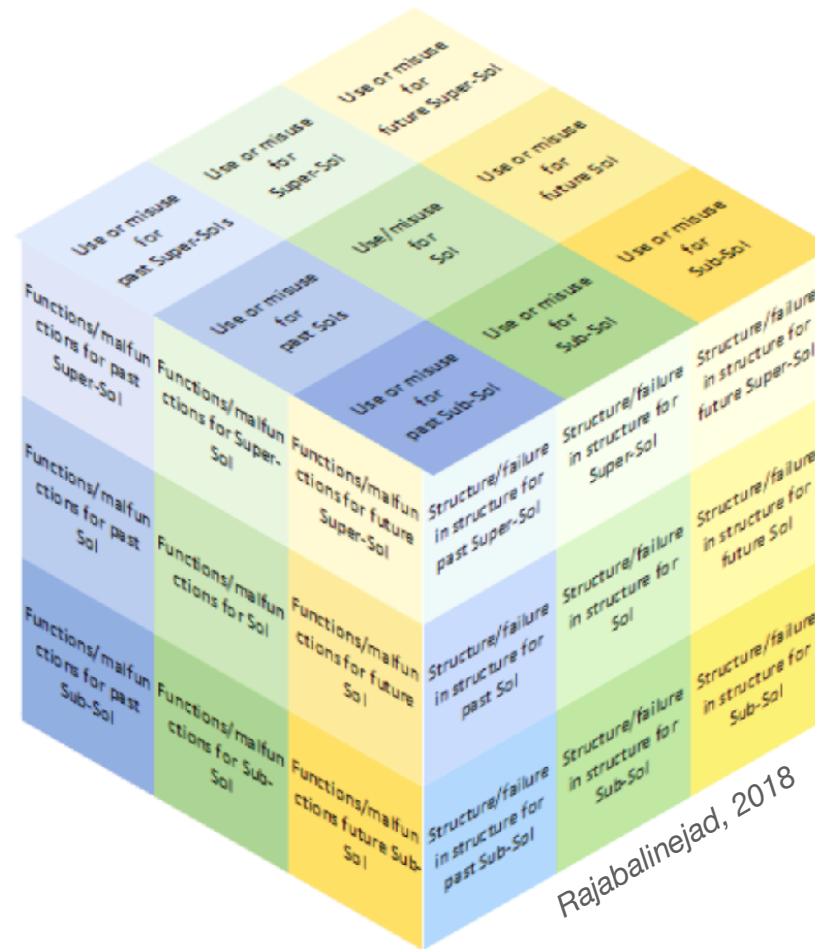
- Safe in normal mode of operation
- Safe in foreseeable (not normal) modes of operation
- Safe (perhaps not functional) in extreme mode of operation
- See <https://safety productions>



USE SCENARIOS

- A product can be used by a user who
 - has not studied in engineering
 - is not a safety expert
 - has not her full attention while using the product
 - uses her (temporal) mental model





Safety Cube

Hazard Assessment for System of Interest

	<i>System requirements, functions, and behavior</i>	<i>Physical system (system-SoS/ environment relation)</i>	<i>Use/misuse scenarios (human-system relation)</i>
<i>Environment and super systems</i>			
<i>System</i>		a two-wheels personal vehicle powered & steered by human	
<i>sub-systems</i>			

Hazard Assessment for

	<i>System requirements, functions, and behavior</i>	<i>Physical system (system-SoS/ environment relation)</i>	<i>Use/misuse scenarios (human-system relation)</i>
<i>Environment and super systems</i>		bicycle path, roads, crossing, traffic lights, infrastructure, and natural environment	
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Hazard Assessment for

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<i>sub-systems</i>		two wheels, frame, pedals chain, tires may go flat	

Hazard Assessment for

	<i>System requirements, functions, and behavior</i>	<i>Physical system (system-SoS/ environment relation)</i>	<i>Use/misuse scenarios (human-system relation)</i>
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<i>System</i>		a two-wheels personal vehicle powered & steered by human	cyclist cycles in a (non) specified path at night, rain, or cross roads, cyclist uses unassigned paths (shortcuts)
<i>sub-systems</i>		two wheels, frame, pedals chain, tires may go flat	

Hazard Assessment for

	<i>System requirements, functions, and behavior</i>	<i>Physical system (system-SoS/ environment relation)</i>	<i>Use/misuse scenarios (human-system relation)</i>
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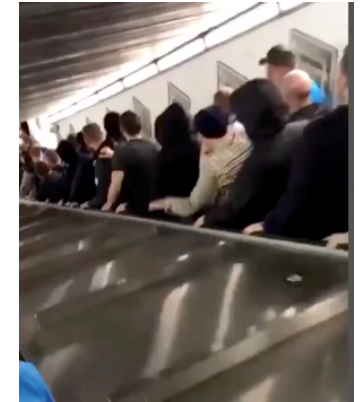
Hazard Assessment for

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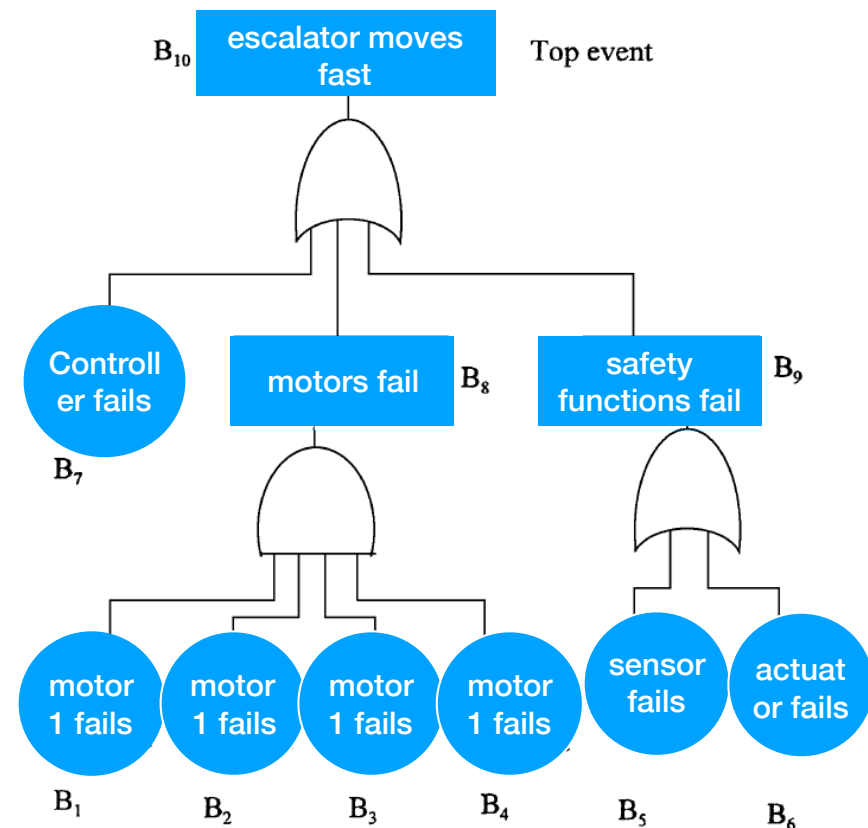
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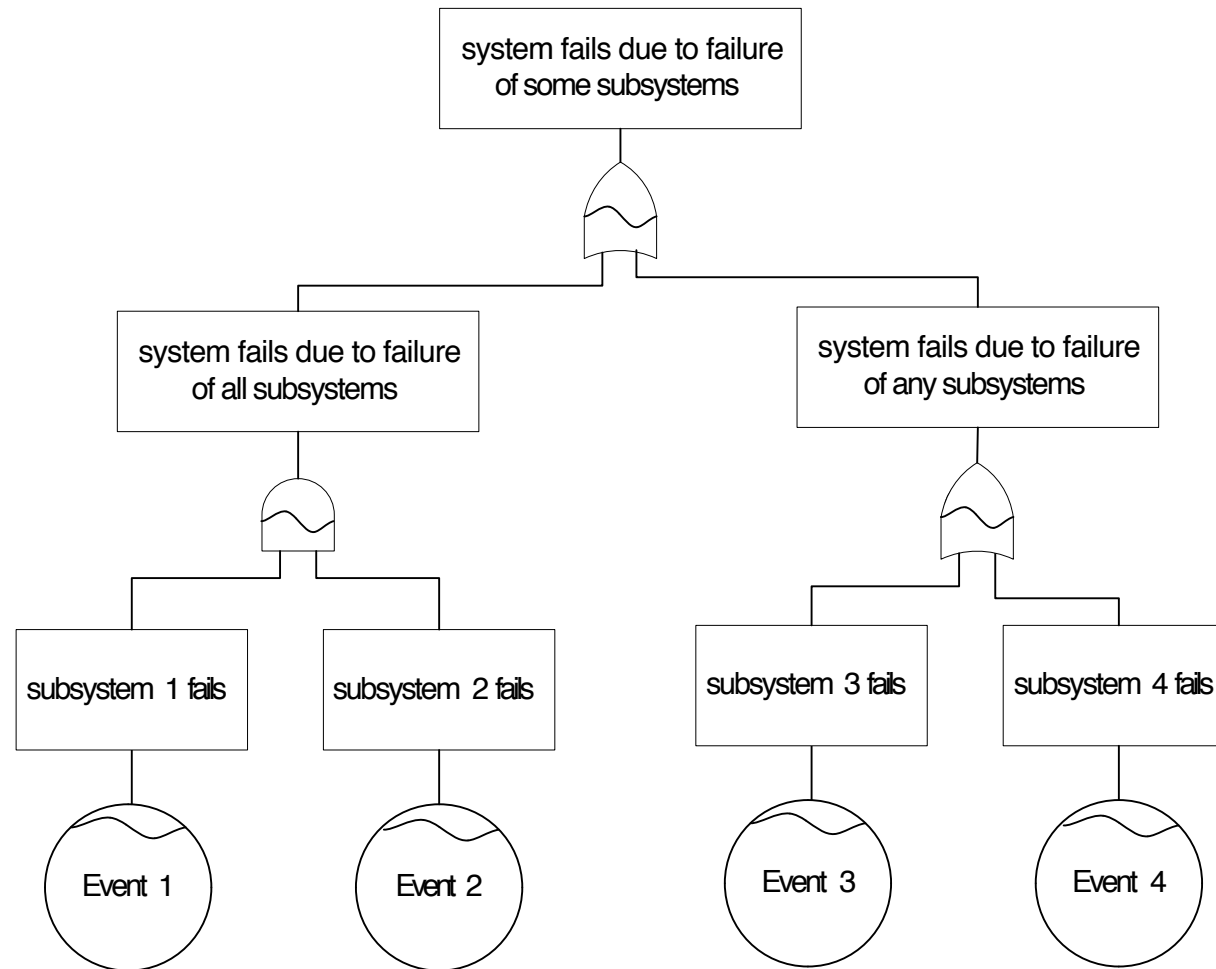
FAULT TREE



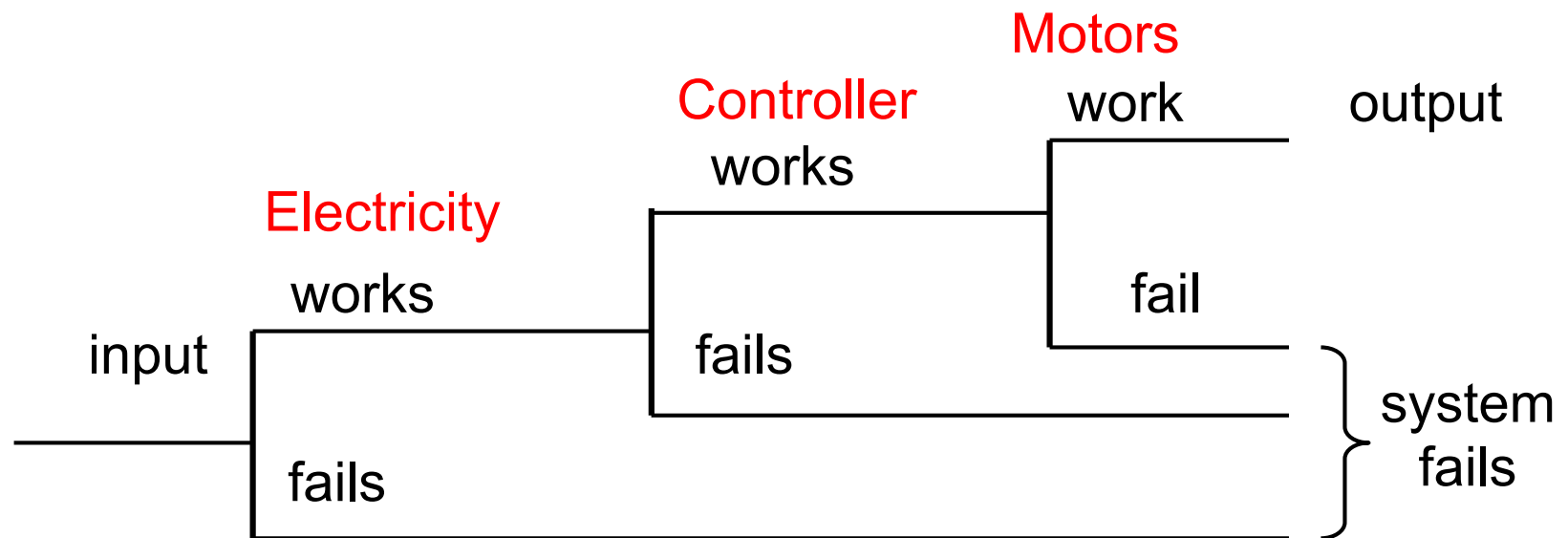
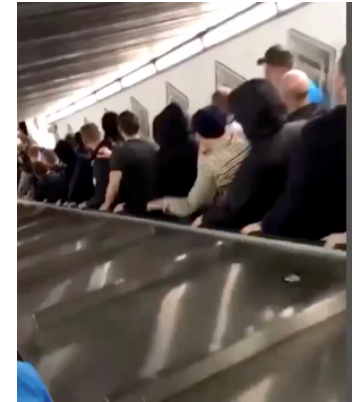
- For modelling system performances
 - safety, reliability, maintainability, etc.
- Qualitative/ quantitative
 - estimated probability
- FT enjoys logic
 - And/ OR
- FT and FMEA
 - top $\Leftrightarrow$ bottom



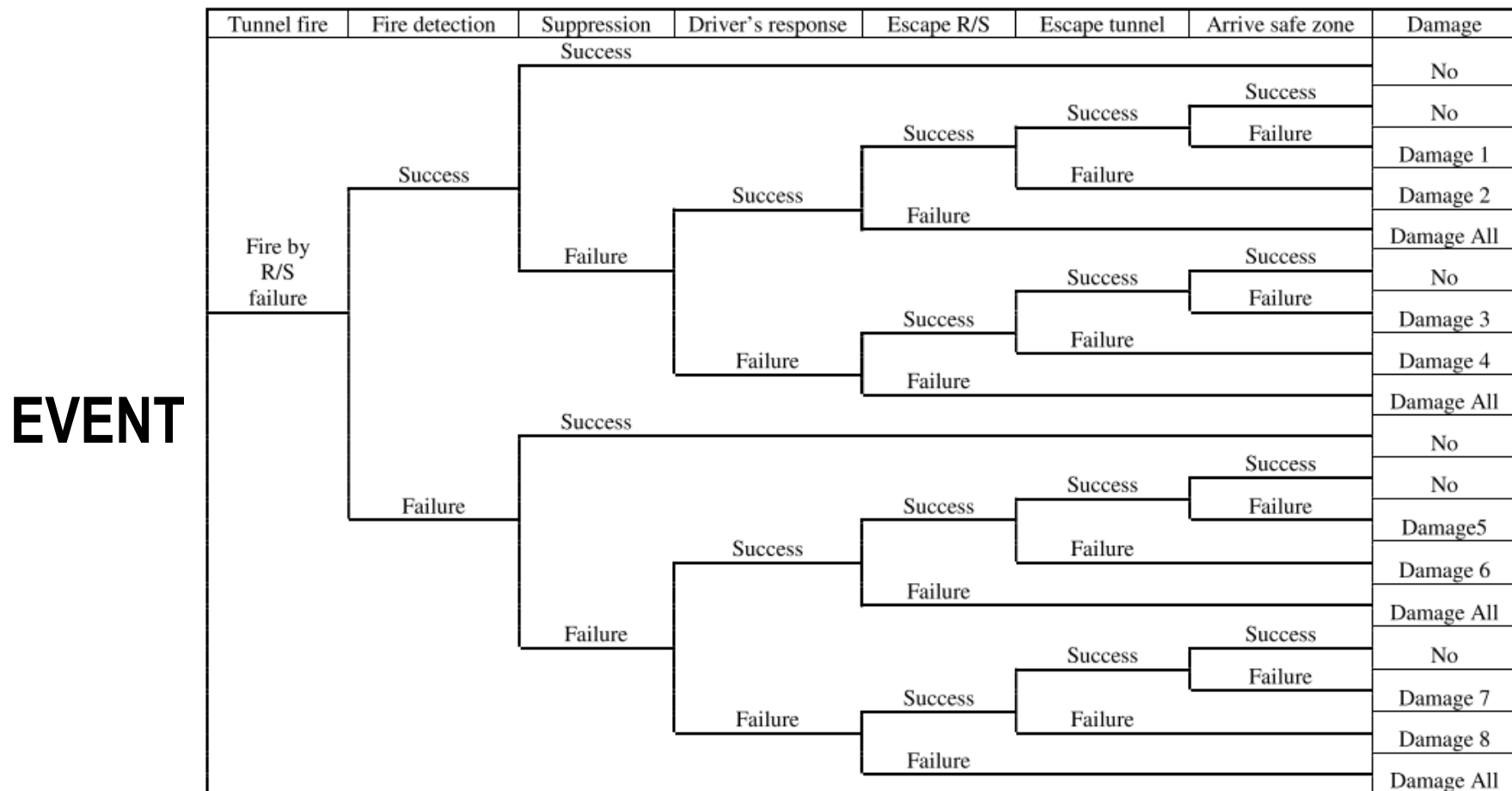
Naive Fault Trees



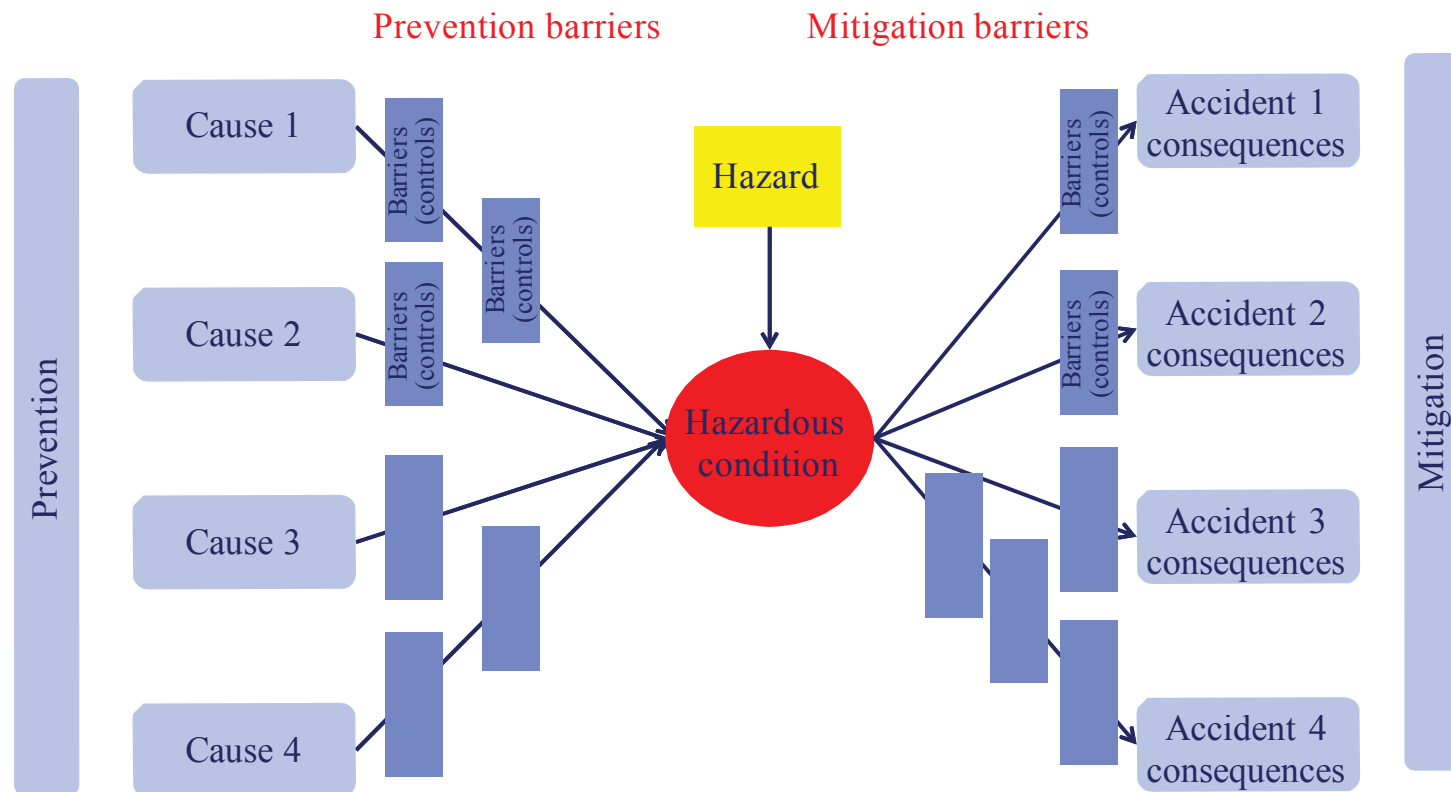
Event Tree



Example Event Tree for Tunnel Fire Scenario

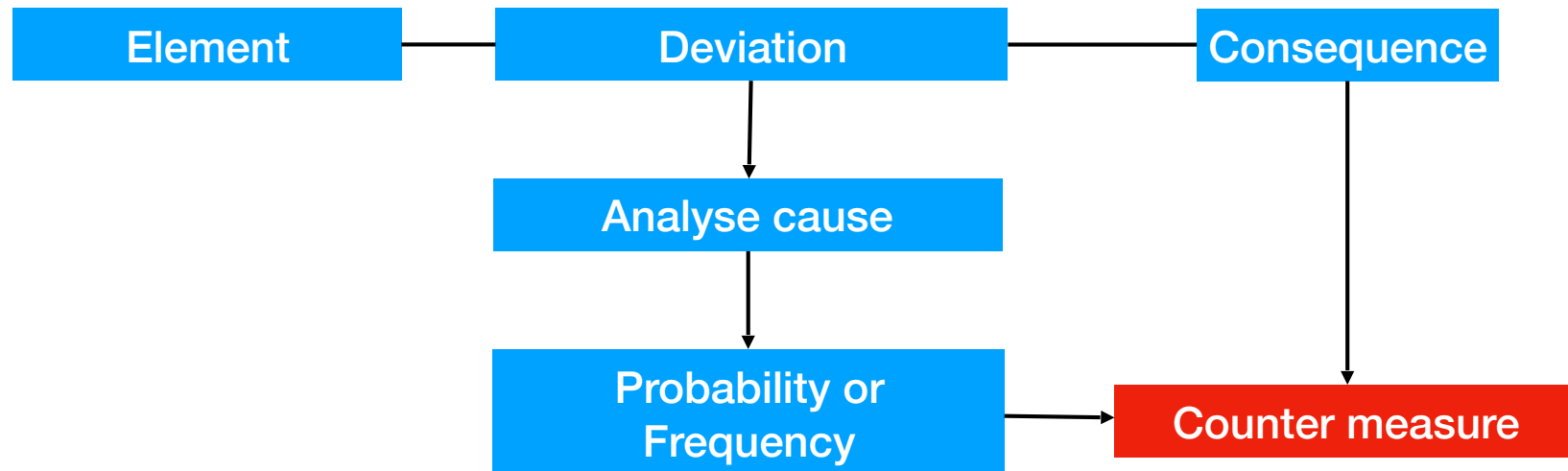


Bowtie



see www.bowtie.nl

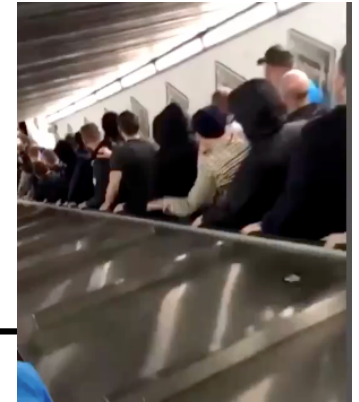
Failure Mode and Effect (FMEA) Analysis



FMEA Work Sheet

Element/function:				
function:				
deviation	cause	P	consequence	counter measure

FMEA Worksheet



Element/function: the escalator system				
function: provide vertical transportation				
deviation	cause	P	consequence	counter measure
escalator moves fast	controller malfunctions		unexpected behaviour	test different scenarios
	safety system failure		uncontrolled behaviour	use high reliability system
	motor error		failure to function as expected	maintain the motors

REFERENCES

Standard:

IEC 61025 Fault tree analysis (FTA), 2006.

Handbooks:

Fault Tree Handbook with Aerospace Applications, NASA, 2002

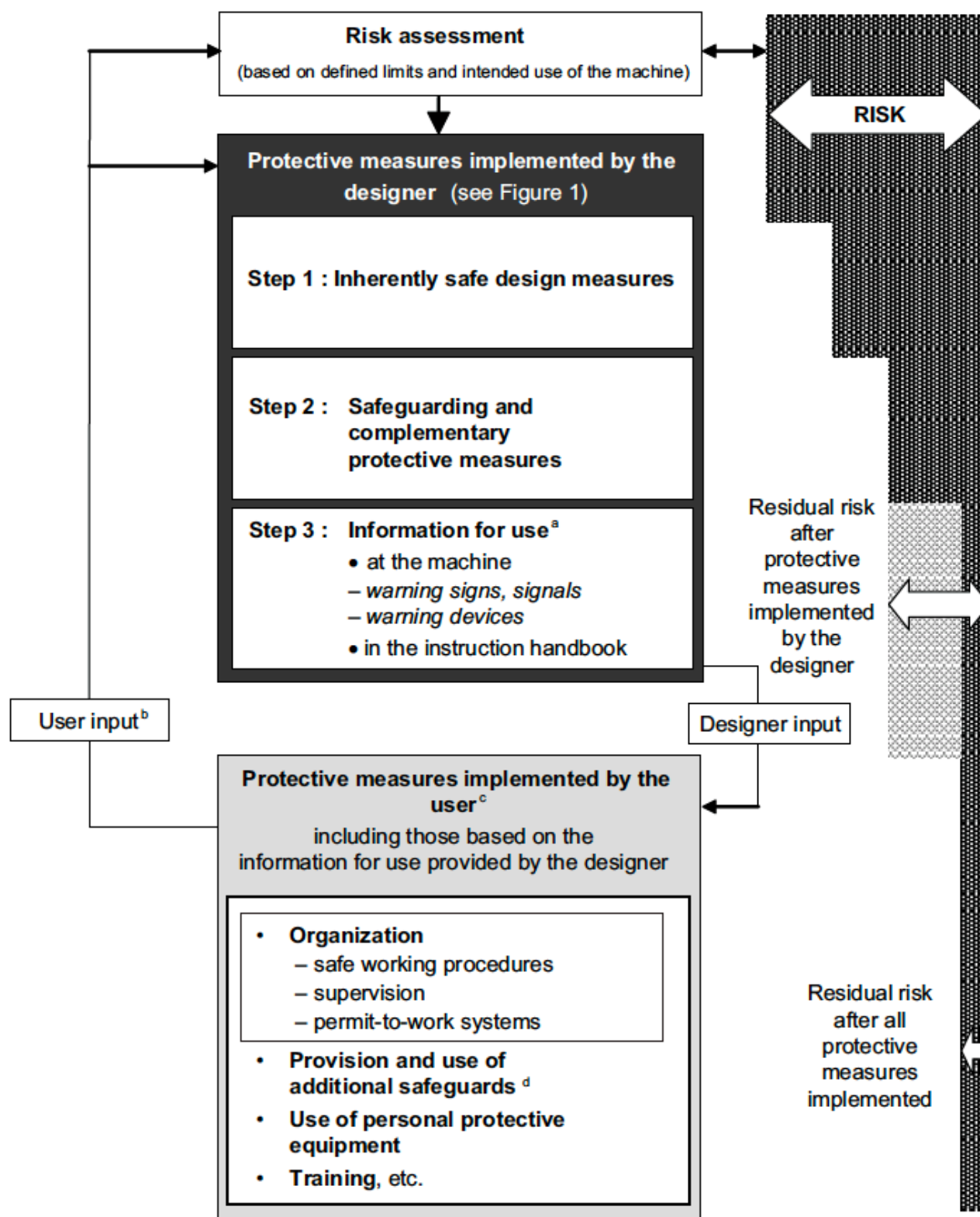
Fault Tree Handbook, NUREG-0492, 1981

System Safety Handbook, FAA, 2000

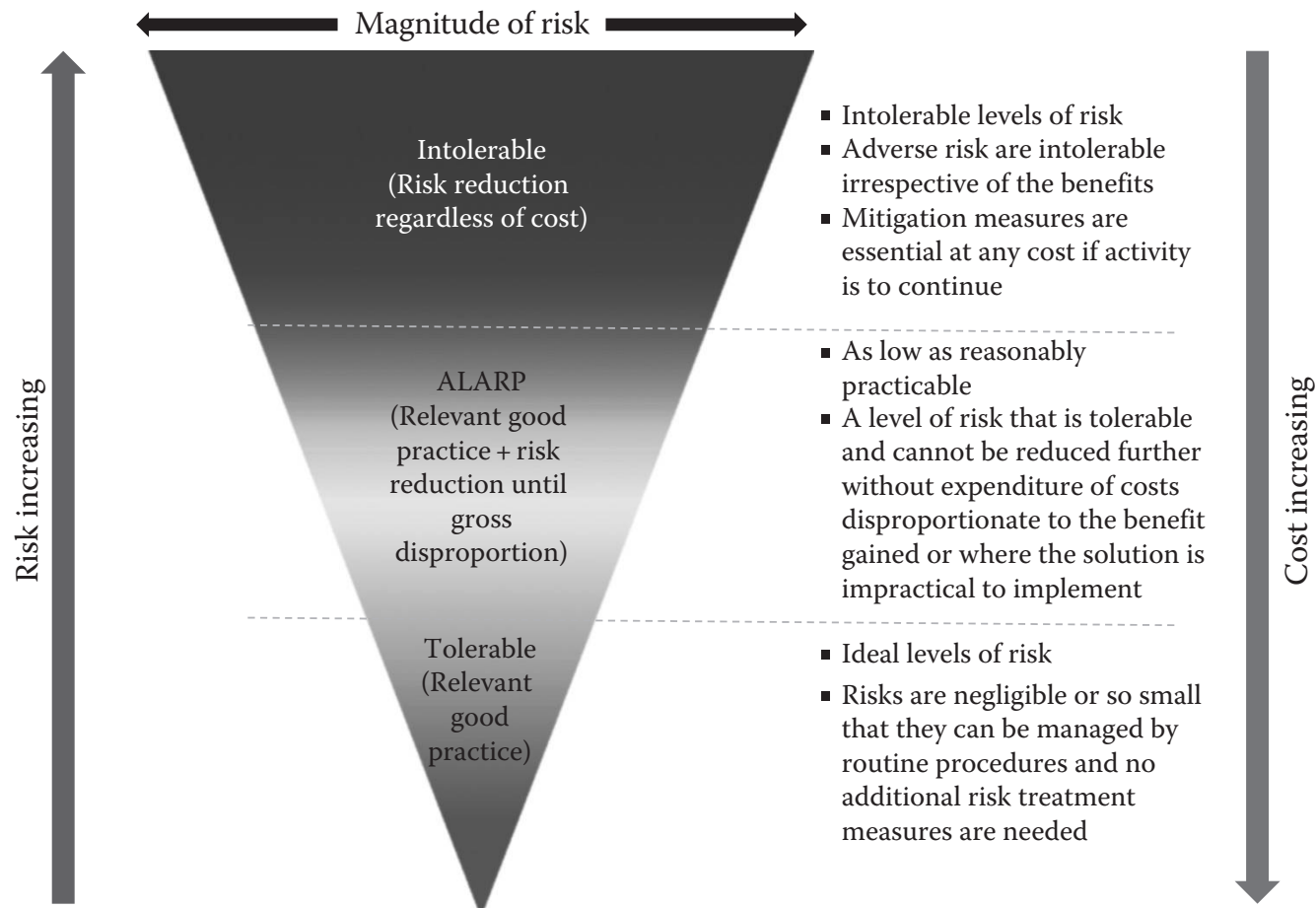
Electronic Reliability Design Handbook, Reliability Handbook, Engineering Design Handbook, etc

Paper:

Rajabalinejad, M. 2017. "[Naive Fault Tree: formulation of the approach](#)." In *International System Safety Conference*. Albuquerque, New Mexico USA.



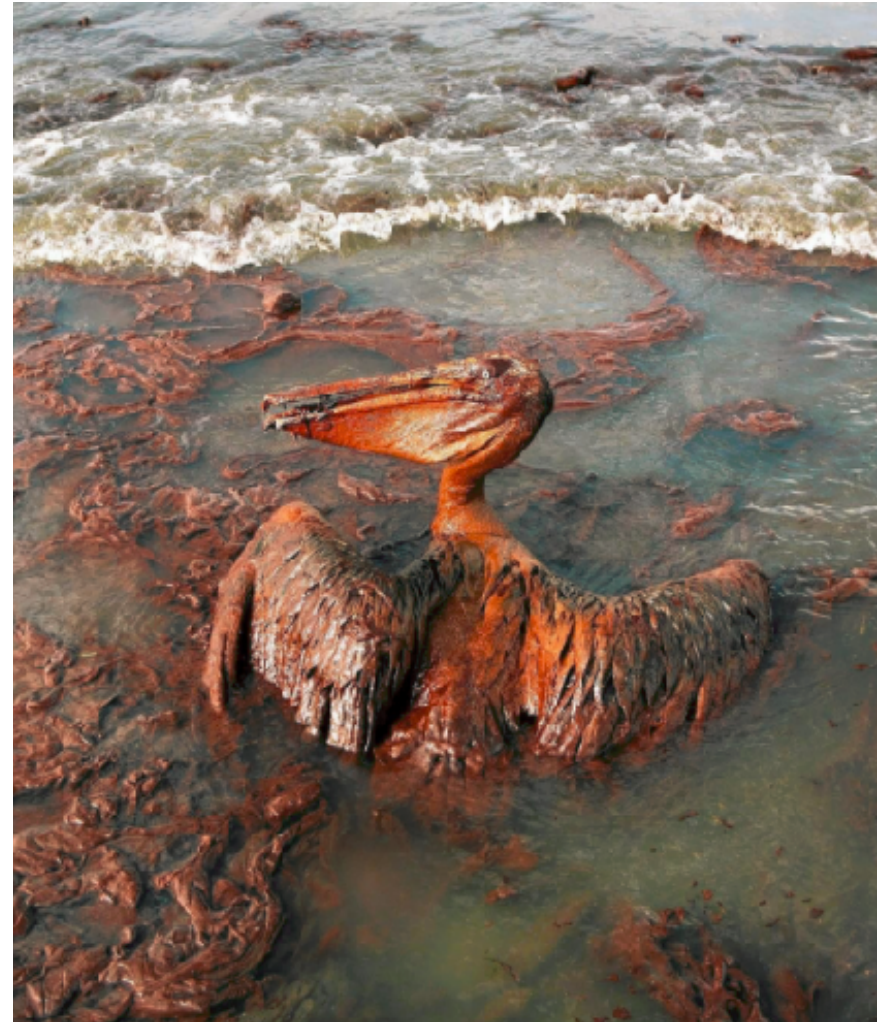
ALARP: AS LOW AS REASONABLY PRACTICABLE





HOW SAFE IS SAFE ENOUGH?

- How safe is safe enough?
 - Main driver for insurance industry
 - How much am I willing to spend to protect myself from accidents (including lawsuits and lost business revenue)?”
- An example of safety cost
 - After the 2010 BP [Deepwater Horizon](#) offshore oil platform explosion and oil spill in the Gulf of Mexico, BP has budgeted around \$40 billion for paying out of claims and compensation.



A Quick Recipe For Safety Engineering

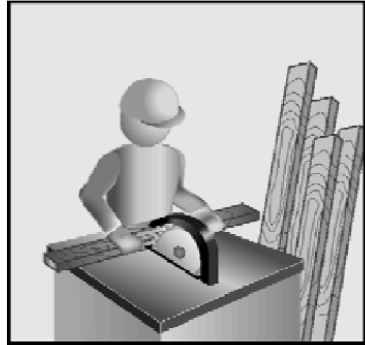
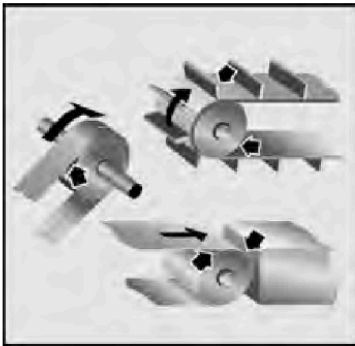
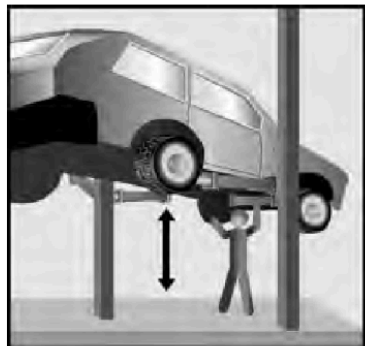
Modify the system if the risk is unacceptable

1. Design out the hazard
2. Use safety devices
3. Use warning devices
4. Special procedure and training



Example Hazards

See ISO 12100, ANNEX B

	Origin cutting parts Potential consequences – cutting – severing		Origin noisy manufacturing process Potential consequences – fatigue – hearing impairment – loss of awareness – stress
	Origin moving elements Potential consequences – crushing – impact – shearing		Origin moving elements (three examples) Potential consequences – drawing-in – friction, abrasion – impact
	Origin gravity, stability Potential consequences – crushing – trapping		Origin moving elements Potential consequences – crushing – friction, abrasion – impact – severing

Example Hazardous Situation

Phase of life cycle	Example situations	Phase of life cycle	Example situations
Transport	lifting, loading, packing, unloading, unpacking	Operation	Feeding, filling, loading/ unloading, removing waste, jams, supervision
Assembly	Assembly, connecting to power, fixing, running, testing	Cleaning	Housekeeping, lubrication, resetting,
Setting	Adjustment, feeding, loading, verification	Fault-finding	Removal of parts, fault-finding, recovering from jam, replacement of parts, resetting

Remove Hazards

Design

- Suitable choice of design, eliminate hazards by
 - hazards by gap safety, avoiding sharp edges & corners, limiting actuation force/noise/vibration, proper materials, appropriate technology, visible controls, isolation
 - hazardous behaviour such as failure to stop moving parts, start/stop mechanism, safety functions, high quality/ reliability

Protect User/Product

- If Step 2 is not possible, reduce hazard of moving parts by
- fixed guards, interlocking movable guards, adjustable guards, protective devices
- sensitive protective equipment e.g. laser scanners, trip bars...
- connecting guards properly to control system
- isolating the machine from all energy sources

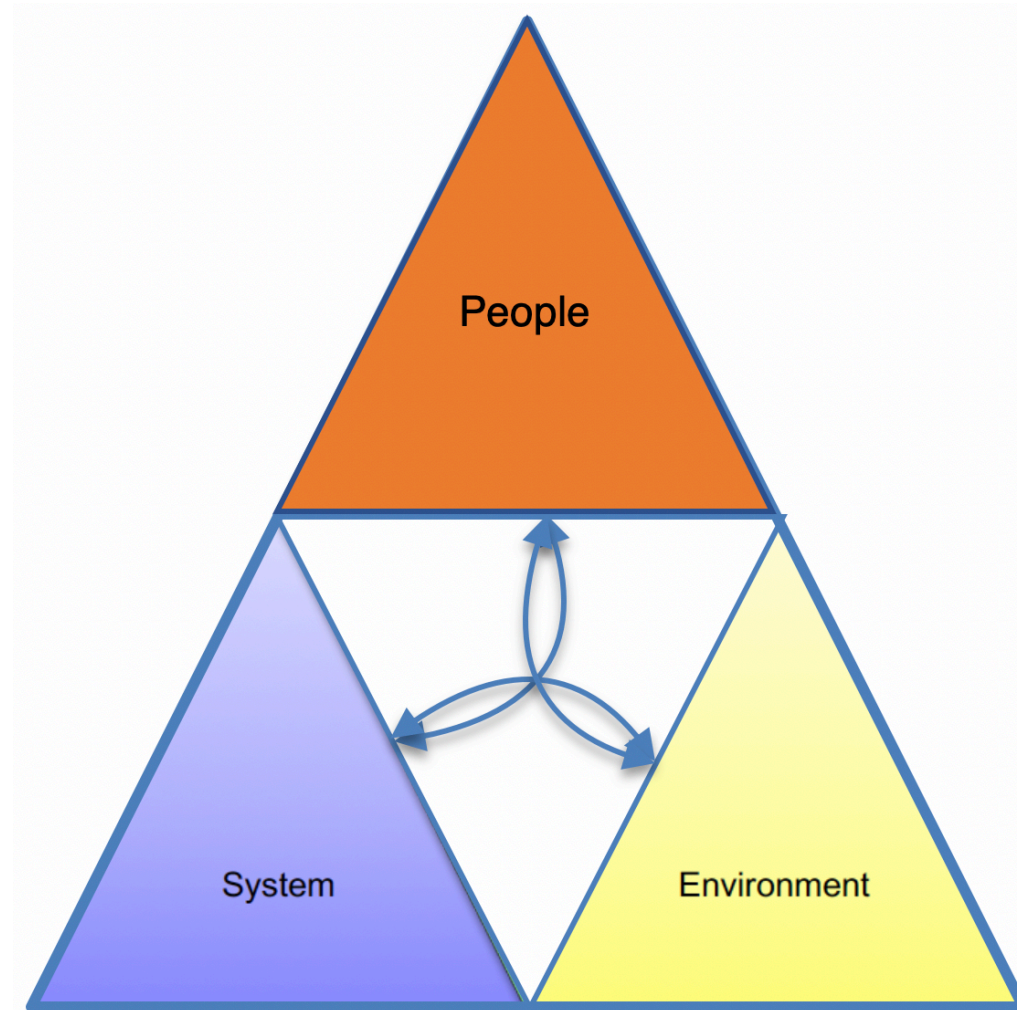


Inform Users 🙄

- If Steps 2 and 3 are not possible, inform the user about
 - operating procedure
 - safe working practices
 - sufficient information
 - protective equipments



Take Away



Rajabalinejad, 2019

References

- European Directive for General Product Safety, https://ec.europa.eu/info/general-product-safety-directive_en
- European Directive for Low Voltage Equipments, http://ec.europa.eu/growth/sectors/electrical-engineering/lvd-directive_en
- ISO 12100:2012, safety of machinery
- See: <https://safety productions>
- Rajabalinejad, M. (2018). *Incorporation of Safety into Design by Safety Cube*. *International Journal of Industrial and Manufacturing Engineering*, 12(3), 476-479. <https://doi.org/10.5281/zenodo.1317156>