Safety Requirements

Definitions of Safety

- Informally
  - "Nothing bad will happen"
- N. Leveson, Safeware
  - "Freedom from accidents or losses"
  - But no system can be completely safe in absolute sense…
  - Focus is on making systems safe enough, given limited resources
  - Emphasis on accidents, rather than risk
- N. Storey, Safety-Critical Computer Systems:
  - "System will not endanger human life or environment"
  - More emphasis on removing hazards than actual accidents…
- Safety-critical system
  - System that has the potential to cause accidents

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Safety requirements

- In order to determine safety requirements:
  - Identification of the hazards associated with the system
  - Classification of these hazards
  - Determination of methods for dealing with the hazards
  - Assignment of appropriate reliability and availability requirements
  - Determination of an appropriate safety integrity level
  - Specification of development methods appropriate to this integrity level

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The Role of Standards

- Helping staff to ensure that a product meets a certain level of quality
- Helping to establish that a product has been developed using methods of known effectiveness
- Promoting a uniformity of approach between different teams
- Providing guidance on design and development techniques
- Providing some legal basis in the case of a dispute

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Conflicting requirements

- High performance v low cost
- Reliability ≠ safety

BUT

- System must be reliable AND safe
- Hazard analysis and risk analysis to identify acceptable levels of safety and reliability

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Hazard Analysis

Hazards & Risk Definitions

Definitions

- Hazard
  - Situation with actual or potential danger to people, environment or material, of a certain severity
  - e.g. lock that prevents elevator door from opening is not activated
- Incident (near miss)
  - Unplanned event that involves no damage or loss, but has the potential to be an accident in different circumstances
  - e.g. elevator door opens while the elevator is missing but nobody is leaning against it

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Definitions (cont.)

- Accident
  - Unplanned event that results in a certain level of damage or loss to human life or the environment
  - e.g. elevator door opens and someone falls to the shaft
- Risk
  - Combination of the severity of a specified hazardous event with its probability of occurrence over a specified duration

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Risk Assessment

- Risk = penalty x likelihood
  - Penalty can be measured in money, lives, injuries, amount of deadline…
  - Likelihood is the probability that a particular hazard will be activated and result in an undesirable outcome
  - Pareto ranking: 80% of problems are from 20% of the risks…

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Risk Assessment (cont.)

- Example of risk calculation
  - Failure of a particular component results in chemical leak that could kill 500 people
  - Estimate that component will fail once every 10,000 years

    risk = penalty x (probability per year)
    = 500 x (0.0001)
    = 0.05 deaths per year
- But rare and costly events are a problem
  - E.g. infinite penalty multiplied by near-zero probability?
  - Must guard against catastrophic penalties event for near-zero probability

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Acceptability of Risk

- ALARP (As Low As is Reasonably Possible)
  - If risk can be easily reduced, it should be
  - Conversely, a system with significant risk may be acceptable if it offers sufficient benefit and if further reduction of risk is impractical
- Ethical considerations
  - Determining risk and its acceptability involves moral judgement
  - Society's view not determined by logical rules
  - Perception that accidents involving large numbers of deaths are perceived as more serious than smaller accidents, though they may occur less frequently

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Conflicting Requirements – Safety and Reliability

- A system can be unreliable but safe
  - If it does not behave according to specification but still does not cause an accident
- A system can be unsafe but reliable
  - If it can cause harm but faults occur with very low probability
- Fail Safe
  - System designed to fail in a safe state
    e.g. trains stop in case of signal failure
  - affects availability – 100% safe but 0% available..
- Fail Operational
  - System designed to keep working even if something fails
  - usually using redundancy
- Fail-over to reduced capability system
  - Mechanical backup

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Hazards

Hazards Overview

Hazards

- A Hazard is a system state that could lead to:
  - Loss of life
  - Loss of property
  - Release of energy
  - Release of dangerous materials
- Hazards are the *states* we have to avoid
- An accident is a loss event:
  - System in hazard state, ***and***
  - Change in the operating environment
- Classification
  - Severity
  - Nature

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Hazard Categories for Civil Aircraft

DESCRIPTION	CATEGORY	DEFINITION	PROBABILITY
CATASTROPHIC	I	Loss of Lives, Loss of Aircraft	10^{-9} / hr
HAZARDOUS	II	Severe Injuries, Major aircraft Damage	10^{-7} / hr
MAJOR	III	Minor injury, minor aircraft or system damage	10^{-5} / hr
MINOR	IV	Less than minor injury, less than minor aircraft or system damage	10^{-3} / hr
NO EFFECT	V	No change to operational capability	10^{-2} / hr

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Hazard Categories for Civil Aircraft

Frequency of Occurrence	Level	Specific Item	Fleet or Inventory	Failure Probability per Flight Hour
Frequent	A	Likely to occur frequently	Continuously experienced	$\geq 1 \times 10^{-3}$
Reasonably Probable	B	Will occur several times in the life of each item	Will occur frequently	$< 1 \times 10^{-3}$ to $\geq 1 \times 10^{-5}$
Remote	C	Unlikely but possible to occur in the life of an item	Unlikely but can reasonably be expected to occur	$< 1 \times 10^{-5}$ to $\geq 1 \times 10^{-7}$
Extremely Remote	D	So unlikely it can be assumed that the occurrence may not be experienced	Unlikely to occur, but possible	$< 10^{-7}$ to $\geq 1 \times 10^{-9}$
Extremely Improbable	E	Should never happen in the life of all the items in the fleet	Not expected to occur during life of all aircraft of this type	$<1 \times 10^{-9}$

Risk from lightning is 5×10^{-7} deaths per person year

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Hazard Risk Index

Probability	Severity Classification			
	Catastrophic	Hazardous	Major	Minor
Frequent	1	3	7	13
Reasonably Probable	2	5	9	16
Remote	4	6	11	18
Extremely Remote	8	10	14	19
Extremely Improbable	12	15	17	20

- Acceptable - only ALARP actions considered
- Acceptable - use ALARP principle and consider further investigations
- Not acceptable - risk reducing measures required

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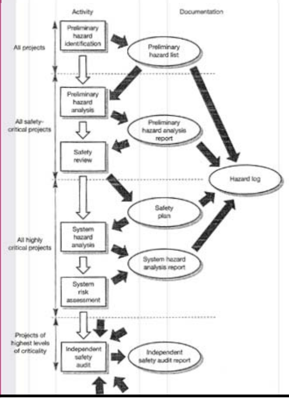
Hazards

Hazard Analysis

Hazard analysis lifecycle



- Preliminary hazard identification: is the system safety related?
- Preliminary hazard analysis: determine the integrity levels of each major function
- Safety plan: how will the safety be achieved and who is responsible (staff names!)
- System hazard analysis: FMEA, HAZOP, event trees, fault trees, reliability block diagrams, Markov modeling

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Hazard Analysis

- The purpose
  - Identify events that may lead to accidents
  - Determine impact on system
  - Performed throughout the life cycle
- Analytical Techniques
  - Failure modes and effects analysis (FMEA)
  - FMECA: Failure modes, effects and criticality analysis (FMECA)
  - ETA: Event tree analysis (ETA)
  - FTA: Fault tree analysis (FTA)
  - HAZOP: Hazard and operability studies (HAZOP)
- Standards

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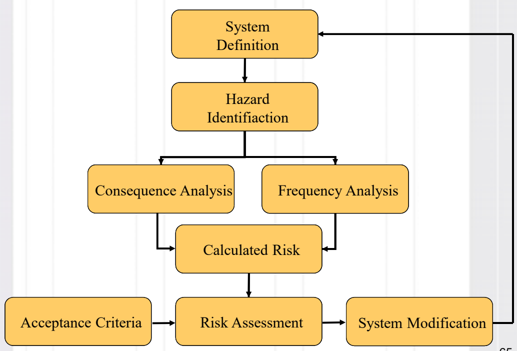
Hazard and Risk Analysis Process



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Preliminary Hazard Identification

- First activity in safety process, performed during early requirements analysis (concept definition)
- Identifies potential hazard sources and accidents
- Sources of information include
  - system concept and operational environment
  - incident data of previous in-service operation and similar systems
  - technology and domain specific analyses and checklists
- Method is group-based and dependent on experience
- Process is largely informal
- Output is Preliminary Hazard List

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Preliminary Hazard Analysis

- Refines hazards and accidents based on design proposal
- Performed using a system model that defines
  - scope and boundary of system
  - operating modes
  - system inputs, outputs and functions
  - preliminary internal structure
- Techniques for Preliminary Hazard Analysis include
  - Hazard and Operability Studies
  - Functional Failure Analysis
- Output is initial Hazard Log

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Hazard Analysis

Failure Mode and Effects Analysis (FMEA)

Failure Modes, Effects and Criticality Analysis (FMECA)

Failure Mode and Effects Analysis

- **Failure modes and effects analysis** (FEMA) considers the failure of any component within a system and tracks the effects of this failure to determine its ultimate consequences.
  - Probably the most commonly used technique
  - Looks for consequences of component failures (forward chaining technique)

FMEA

- Manual analysis
  - Identify component, module or system failures
  - Determine consequences
  - Performed bottom-up
- Outputs
  - Spreadsheet noting each
    - failure mode
    - possible causes
    - consequences
    - possible remedies
  - Usually computer records kept
- Standardised by IEC (International Electrotechnical Commission)

FMEA

- Notes
  - Can be applied at any stage of the design process and at any level within the system
  - Teams of four to eight engineers
- Limitations:
  - Lot of unnecessary work, it considers all components/failure modes
  - Requires expert knowledge to decide what to analyze
  - Usually do not consider multiple failures

FMEA Example

FMEA for a microswitch

Ref No.	*Unit*	*Failure mode*	*Possible cause*	*Local effects*	*System effects*	*Remedial action*
1	Tool guard switch	Open-circuit contacts	(a) faulty component (b) excessive current (c) extreme temperature	Failure to detect tool guard in place	Prevents use of machine – system fails safe	Select switch for high reliability and low probability of dangerous failure Rigid quality control on switch procurement
2		Short-circuit contacts	(a) faulty component (b) excessive current	System incorrectly senses guard to be closed	Allows machine to be used when guard is absent – dangerous failure	Modify software to detect switch failure and take appropriate action
3		Excessive switch-bounce	(a) ageing effects (b) prolonged high currents	Slight delay in sensing state of guard	Negligible	Ensure hardware design prevents excessive current through switch

Failure Modes, Effects and Criticality Analysis

- FMECA:
  - Extension to FMEA
  - Takes into account importance of each component
  - Determines probability/frequency of occurrence of failures
- Problems
  - Measuring reliability of components difficult
  - Models often too simplistic
  - Tool support needed
- Used as input to fault tree analysis
  - Standardised

Background

- FMECA was one of the first systematic techniques for failure analysis
- FMECA was developed by the U.S. Military. The first guideline was Military Procedure MIL-P-1629 “Procedures for performing a failure mode, effects and criticality analysis” dated November 9, 1949
- FMECA is the most widely used reliability analysis technique in the initial stages of product/system development
- FMECA is usually performed during the conceptual and initial design phases of the system in order to assure that all potential failure modes have been considered and the proper provisions have been made to eliminate these failures

What can FMECA be used for?

- Assist in selecting design alternatives with high reliability and high safety potential during the early design phases
- Ensure that all conceivable failure modes and their effects on operational success of the system have been considered
- List potential failures and identify the severity of their effects
- Develop early criteria for test planning and requirements for test equipment
- Provide historical documentation for future reference to aid in analysis of field failures and consideration of design changes
- Provide a basis for maintenance planning
- Provide a basis for quantitative reliability and availability analyses.

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Types of FMECA

- **Design FMECA** is carried out to eliminate failures during equipment design, taking into account all types of failures during the whole life-span of the equipment
- **Process FMECA** is focused on problems stemming from how the equipment is manufactured, maintained or operated
- **System FMECA** looks for potential problems and bottlenecks in larger processes, such as entire production lines

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FME(C)A Chart

Failure Modes and Effect Analysis								
Product Name: DeWalt Tradesman Drill				Part name: Rear Vent				
Function	Failure Mode	Effects of Failure	Causes of Failure	Current Controls	S	O	D	RPN
Allow Additional Air Flow	Filter Blocked	Overheated Motor	User Error	Visual Inspection	4	1	5	20
Prevent Dangerous Usage	Filter Not In Place	Larger Opening to Motor	User Error	Visual Inspection	8	4	1	32
Filter dust	Defective Filter	Additional dust flows into shell	Poor Materials	Visual Inspection	1	1	7	7

S = Severity rating (1 to 10)
O = Occurrence frequency (1 to 10)
D = Detection Rating (1 to 10)
RPN = Risk Priority Number (1 to 1000)

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Severity Rating

Rank	*Severity class*	*Description*
10	Catastrophic	Failure results in major injury or death of personnel.
7-9	Critical	Failure results in minor injury to personnel, personnel exposure to harmful chemicals or radiation, or fire or a release of chemical to the environment.
4-6	Major	Failure results in a low level of exposure to personnel, or activates facility alarm system.
1-3	Minor	Failure results in minor system damage but does not cause injury to personnel, allow any kind of exposure to operational or service personnel or allow any release of chemicals into the environment

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Detection Rating

Rank	*Description*
1-2	Very high probability that the defect will be detected. Verification and/or controls will almost certainly detect the existence of a deficiency or defect.
3-4	High probability that the defect will be detected. Verification and/or controls have a good chance of detecting the existence of a deficiency/defect.
5-7	Moderate probability that the defect will be detected. Verification and/or controls are likely to detect the existence of a deficiency or defect.
8-9	Low probability that the defect will be detected. Verification and/or control not likely to detect the existence of a deficiency or defect.
10	Very low (or zero) probability that the defect will be detected. Verification and/or controls will not or cannot detect the existence of a deficiency/defect.

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Risk Ranking

- Risk Matrix
- Risk Ranking:
  - O = the rank of the occurrence of the failure mode
  - S = the rank of the severity of the failure mode
  - D = the rank of the likelihood the the failure will be detected before the system reaches the end-user/customer.
  - All ranks are given on a scale from 1 to 10. The risk priority
  - number (RPN) is defined as
    $$RPN = S \times O \times D$$
  - The smaller the RPN the better – and – the larger the worse.

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Hazard Analysis

Hazard & Operability Analysis (HAZOP)

Hazard & Operability Analysis

- HAZOP:
  - Developed in Chemical industry
  - Applied successfully in other domains
  - "What if" analysis for system parameters
  - E.g., suppose "temperature" of "reactor" "rises", what happens to system?
  - System realization of perturbation or sensitivity analysis
  - Requires flow model of operating plant

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Hazard & Operability Analysis

- Flowing items are "entities"
- Entities have characteristic properties known as "attributes"
- Analysis based on possible deviations of attribute values
- "Guide words" used to guide the analysis— designed to capture dimensions of variation
- Supplementary adjectives add temporal element
- Different word sets for different applications

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HAZOP examples

- Guide words:
  - no, more, less, early, late, before, ...

  Interpretation examples:
  - Signal arrives too late
  - Incomplete data transmitted / only part of the intended activity occurs

- Attributes:
  - Data flow, data rate, response time, ...

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HAZOP guide word interpretations

Guide word	*Chemical plant*	*Computer-based system*
No	No part of the intended result is achieved	No data or control signal exchanged
More	A quantitative increase in the physical quantity	A signal magnitude or a data rate is too high
Less	A quantitative decrease in the physical quantity	A signal magnitude or a data rate is too low
As well as	The intended activity occurs, but with additional results	Redundant data sent in addition to intended value
Part of	Only part of the intended activity occurs	Incomplete data transmitted
Reverse	The opposite of what was intended occurs, for example reverse flow within a pipe	Polarity of magnitude changes reversed
Other than	No part of the intended activity occurs, and something else happens instead	Data complete but incorrect
Early	Not used	Signal arrives too early with reference to clock time
Late	Not used	Signal arrives too late with reference to clock time
Before	Not used	Signal arrives earlier than intended within a sequence
After	Not used	Signal arrives later than intended within a sequence

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HAZOP attributes

Attribute	*Guide word*	*Possible meaning*
Data flow	More Less	More data is passed than expected Less data is passed than expected
Data rate	More Less	The data rate is too high The data rate is too low
Data value	More Less	The data value is too high The data value is too low
Repetition time	More Less	The time between output updates is too high The time between output updates is too low
Response time	More Less	The response time is longer than required The response time is shorter than required

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HAZOP Example

Item	Inter-connection	Attribute	Guide word	Cause	Consequence	Recommendation
1	Sensor supply line	Supply voltage	No	PSU, regulator or cable fault	Lack of sensor signal detected and system shuts down	
2			More	Regulator fault	Possible damage to sensor	Consider overvoltage protection
3			Less	PSU or regulator fault	Incorrect temperature reading	Include voltage monitoring
4		Sensor current	More	Sensor fault	Incorrect temperature reading, possible loading of supply	Monitor supply current
5			Less	Sensor fault	Incorrect temperature reading	As above
6	Sensor output	Voltage	No	PSU, sensor or cable fault	Lack of sensor signal detected and system shuts down	
7			More	Sensor fault	Temperature reading too high – results in decrease in plant efficiency	Consider use of duplicate sensor
8			Less	Sensor mounted incorrectly or sensor failure	Temperature reading too low – could result in overheating and possible plant failure	As above

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Hazard Analysis

Fault Tree Analysis (FTA)

Fault Tree Analysis

- Fault tree analysis (FTA) is a top-down approach to failure analysis, starting with a potential undesirable event (accident) called a TOP event, and then determining all the ways it can happen.
- The analysis proceeds by determining how the TOP event can be caused by individual or combined lower level failures or events.
- The causes of the TOP event are “connected” through logic gates
- FTA is the most commonly used technique for causal analysis in risk and reliability studies.

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History

- FTA was first used by Bell Telephone Laboratories in connection with the safety analysis of the Minuteman missile launch control system in 1962
- Technique improved by Boeing Company
- Extensively used and extended during the Reactor safety study (WASH 1400)

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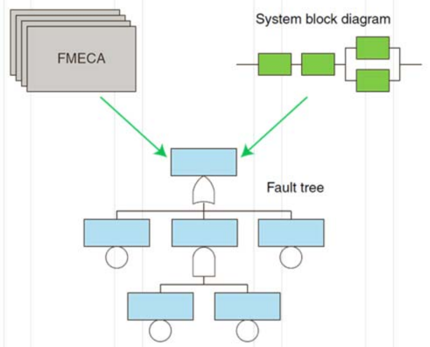
Preparations for FTA



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Boundary Conditions

- The physical boundaries of the system (Which parts of the system are included in the analysis, and which parts are not?)
- The initial conditions (What is the operational stat of the system when the TOP event is occurring?)
- Boundary conditions with respect to external stresses (What type of external stresses should be included in the analysis – war, sabotage, earthquake, lightning, etc?)
- The level of resolution (How detailed should the analysis be?)

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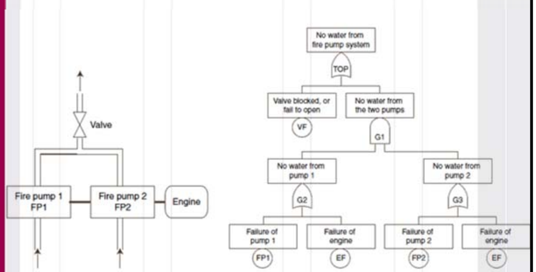
Fault Tree Construction

- Define the TOP event in a clear and unambiguous way.
  Should always answer:
  What e.g., "Fire"
  Where e.g., "in the process oxidation reactor"
  When e.g., "during normal operation"
- What are the immediate, necessary, and sufficient events and conditions causing the TOP event?
- Connect via a logic gate
- Proceed in this way to an appropriate level (= basic events)
- Appropriate level:
  - Independent basic events
  - Events for which we have failure data

Fault Tree Symbols

Logic gates	OR-gate	The OR-gate indicates that the output event occurs if any of the input events occur
	AND-gate	The AND-gate indicates that the output event occurs only if all the input events occur at the same time
Input events (states)		The basic event represents a basic equipment failure that requires no further development of failure causes
		The undeveloped event represents an event that is not examined further because information is unavailable or because its consequences are insignificant
Description of state		The comment rectangle is for supplementary information
Transfer symbols	Transfer out Transfer in	The transfer-out symbol indicates that the fault tree is developed further at the occurrence of the corresponding transfer-in symbol

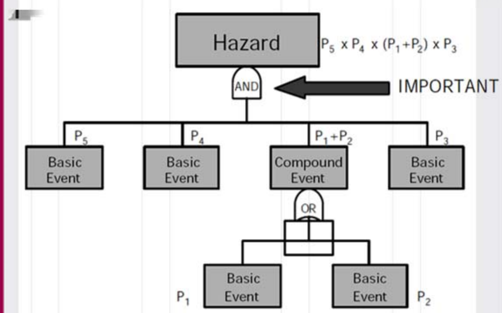
Fault Tree Example



Elementary Fault Tree Analysis

- Assignment of probabilities to specific events
- Computation of probabilities for compound events
- Sophisticated dependability analysis possible
- Extensive, elaborate, established technique
- Provides:
  - Mechanism for showing that design will meet dependability requirements

Fault Trees and Probabilities



Practical Fault Trees

- Developed by human analysis
- Tend to be *very* large for real systems
- Evolve as insight is gained
- Many analysis techniques possible:
  - Hazard probability can be calculated if probabilities associated with all basic events
  - Tables of probabilities available for degradation faults for common components
  - Recall, infeasible for design faults

Hazard Analysis

Event Tree Analysis (ETA)

Event Trees

- Event sequences that follow from some initial event of interest, usually a component failure
- Downstream events follow from original event and subsequent events of other components
- E.g. Chemical plant pressure sensor sounds siren when pressure drops to unsafe level

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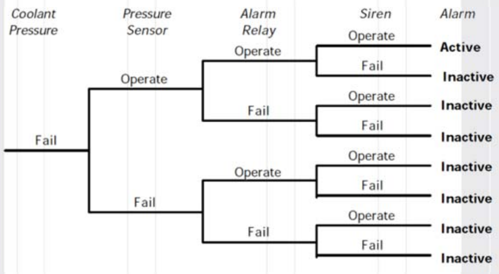
Event Tree



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Barriers

- Most well designed systems have one or more barriers that are implemented to stop or reduce the consequences of potential accidental events. The probability that an accidental event will lead to unwanted consequences will therefore depend on whether these barriers are functioning or not.
- The consequences may also depend on additional events and factors. Examples include:
  - Whether a gas release is ignited or not
  - Whether or not there are people present when the accidental event occurs
  - The wind direction when the accidental event occurs
- Barriers may be technical and/or administrative (organizational).

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Event Tree Analysis

- An event tree analysis (ETA) is an inductive procedure that shows all possible outcomes resulting from an accidental (initiating) event, taking into account whether installed safety barriers are functioning or not, and additional events and factors.
- By studying all relevant accidental events (that have been identified by a preliminary hazard analysis, a HAZOP, or some other technique), the ETA can be used to identify all potential accident scenarios and sequences in a complex system.
- Design and procedural weaknesses can be identified, and probabilities of the various outcomes from an accidental event can be determined.

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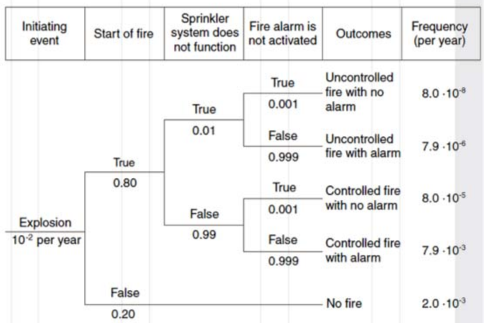
ETA Example



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ETA Pros and Cons

- Positive
  - Visualize event chains following an accidental event
  - Visualize barriers and sequence of activation
  - Good basis for evaluating the need for new / improved procedures and safety functions
- Negative
  - No standard for the graphical representation of the event tree
  - Only one initiating event can be studied in each analysis
  - Easy to overlook subtle system dependencies
  - Not well suited for handling common cause failures in the quantitative analyses
  - The event tree does not show acts of omission

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Risk

- A combination of the likelihood af an accident and the severity of the potential consequences
- The harm that can result if a threat is actualised
- Acceptable/tolerable risk: The Ford Pinto case (1968)

BENEFITS
Savings: 180 burn deaths, 180 serious burn injuries, 2,100 burned vehicles.
Unit Cost: $200,000 per death, $67,000 per injury, $700 per vehicle.
Total Benefit: 180 X ($200,000) + 180 X ($67,000) + $2,100 X ($700) = $49.5 million.

COSTS
Sales: 11 million cars, 1.5 million light trucks.
Unit Cost: $11 per car, $11 per truck.
Total Cost: 11,000,000 X ($11) + 1,500,000 X ($11) = $137 million.

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Hazard Analysis in the Life Cycle

- FME(C)A
  - Used to generate event trees and fault trees
- FME(C)A, FTA, ETA
  - Appropriate when functional design complete
- Preliminary HAZOP
  - Early in the life-cycle
  - Identify hazards, take account of them in the design
- Full HAZOP
  - Later in the life-cycle
  - Identify further hazards, feed back into design design

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Risk Analysis

- The purpose
  - Associate risk with given hazards
    - Consequence of malfunction - severity
    - Probability of malfunction – frequency
  - Ensure nature of risks is well understood
  - Ensure safety targets can be set and evaluated
- Techniques
  - Quantitative
  - Qualitative, risk classification
  - Integrity classification
  - Safety Integrity Levels (SILs)
  - ALARP
- Standards
  - IEC 1508, IEC 61508

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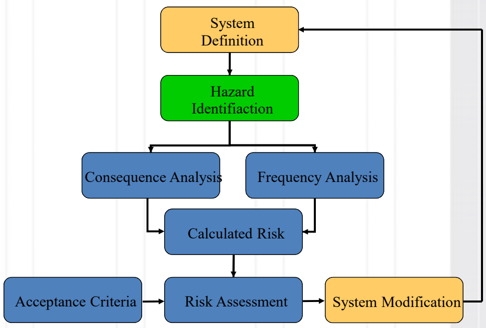
Risk Analysis

Hazard and Risk Analysis Process



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Flashback

- A Hazard is a system state that could lead to:
  - Loss of life
  - Loss of property
  - Release of energy
  - Release of dangerous materials
- Hazards are the states we have to avoid
- An accident is a loss event:
  - System in hazard state, and
  - Change in the operating environment
- Classification
  - Severity
  - Nature

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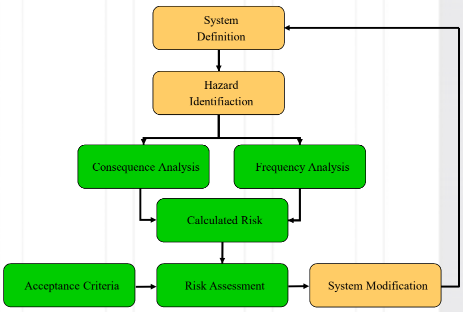
Hazard and Risk Analysis Process



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Introduction

- Risk is associated with every hazard
  - Hazard is a potential danger
    - i.e. possibility of being struck by lightning
  - Associated risk
- *Accident is an unintended event or sequence of events that causes death, injury, environmental or material damage*

Storey 1996

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Introduction

- Hazard analysis identifies accident scenarios: sequences of events that lead to an accident
- *Risk is a combination of the **severity** of a specified hazardous event with its **probability** of occurence over a specified **duration***
  - Qualitative or quantitative

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Risk Calculation

- Quantify probability/frequency of occurence:
  - number of events per hour/year of operation
  - number of events per lifetime
  - number of failures on demand
- Ex 1:
  - Failure of a particular component results in explosion that could kill 100 people. Estimate that component will fail once every 10,000 years

  1 failure per 10,000 years = 0.0001 failures per year

  Risk = penalty x (probability per year)
  = 100 x (0.0001)
  = 0.01 deaths per year

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Risk Calculation

- Ex 2:
  - Country with population of 50,000,000
  - Approx. 25 people are each year killed by lightning i.e. 25/50,000,000=$5x10^{-7}$
  - Risk:
    - every individual has proabability of $5x10^{-7}$ to be killed by lightning at any given year
    - Population is exposed to risk of $5x10^{-7}$ deaths per person year
- Qualitative:
  - intolerable, undesirable, tolerable

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Levels of Fatal Risk

Risk	Chance per million
Risk of being killed by a falling aircraft	0.02 cpm
Risk of death by lightening	0.1 cpm
Risk of being killed by an insect or snake bite	0.1 cpm
Risk of death in a fire caused by a cooking appliance in the home	1 cpm
Risk of death in an accident at work in the very safest parts of industry	10 cpm
General risk of death in a traffic accident	100 cpm
Risk of death in high risk groups within relatively risky industries such as mining	1,000 cpm
Risk of fatality from smoking 20 cigarettes per day	5,000 cpm
Risk of death from 5 hours of solo rock climbing every weekend	10,000 cpm

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The Need for Safety Targets

- Learning from mistakes is not longer acceptable
  - Disaster, review, recommendation
- Probability estimates
  - Are coarse
  - Meaning depends on duration, low/high demand, but often stated without units
- Need rigour and guidance for safety related systems
  - Standards (HSE, IEC)
  - Ensure risk reduction, not cost reduction
  - For risk assessment
  - For evaluation of designs

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Quantitative Risk Assessment

- How it works
  - Predict frequency of hardware failures
  - Compare with tolerable risk target
  - If not satisfied, modify the design
- Example
  - The probability that airbag fails when activated
  - The frequency of the interconnecting switch failing per lifetime
- Even if target met by random hardware failure
  - Hardware could have embedded software, potential for systemic failure
  - Engineer's judgment called for in IEC 61508
    - (IEC 61508 – Functional Safety – www.iec.ch)

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Quantitative risk assessment

- Quantify probability/frequency of occurence:
  - number of events per hour/year of operation
  - number of events per lifetime
  - number of failures on demand
- Example:
  - Failure of a particular component results in explosion that could kill 100 people. Estimate that component will fail once every 10,000 years
    1 failure per 10,000 years = 0.0001 failures per year

Risk = penalty x (probability per year)
= 100 x (0.0001)
= 0.01 deaths per year

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Qualitative Risk Assessment

- When cannot estimate the probability
- How it works
  - Classify risk into risk classes
  - Define tolerable/intolerable risks
  - Define tolerable/intolerable frequencies
  - Set standards and processes for evaluation and minimization of risks
- Example
  - Catastrophic, multiple deaths
  - Critical, single death
  - Marginal, single severe injury
  - Negligible, single minor injury
- Aims to deal with systemic failures

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Risk Management

Risk		Probability				
		Very High	High	Medium	Low	Very Low
Conse-quence	Very High	Very High	Very High	High	High	Medium
	High	Very High	High	Medium	Medium	Low
	Medium	High	Medium	Medium	Low	Low
	Low	High	Medium	Low	Low	Very Low
	Very Low	Medium	Low	Low	Very Low	Very Low

Risk Ranking table

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Hazard Severity Categories for Civil Aircraft

Category	*Definition*
Catastrophic	Failure condition which would prevent continued safe flight and landing
Hazardous	Failure conditions which would reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions, to the extent that there would be: (1) a large reduction in safety margins or functional capabilities (2) physical distress or higher workload such that the flight crew could not be relied on to perform their tasks accurately or completely (3) adverse effects on occupants, including serious or potentially fatal injuries to a small number of those occupants
Major	Failure conditions which would reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be, for example, a significant reduction in safety margins or functional capabilities, a significant increase in crew workload or in conditions impairing crew efficiency, or discomfort to occupants, possibly including injuries
Minor	Failure conditions which would not significantly reduce aircraft safety, and which would involve crew actions that are well within their capabilities. Minor failure conditions may include, for example, a slight reduction in safety margins or functional capabilities, a slight increase in crew workload, such as routine flight plan changes, or some inconvenience to occupants
No effect	Failure conditions which do not affect the operational capability of the aircraft or increase crew workload

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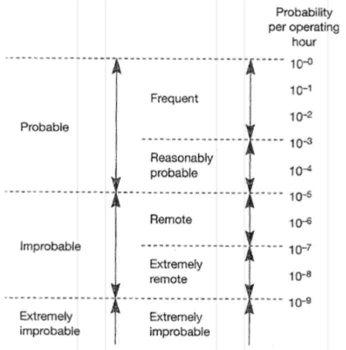
Hazard Probability Classes for Aircraft Systems



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Risk Management Advice

- Identify risks and track them
  - Avoid “unknown” risks at all costs!
- Approaches to risk
  - Mitigate, i.e. perform risk reduction
    - E.g. solve the problem, obtain insurance, etc
  - Avoid
    - Use a less risky approach - not always possible
  - Accept
    - Decide that expected cost is not worth reducing further
    - Often sensible choice
- Ignore
  - Proceed ahead blindly – uninformed acceptance

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Acceptability of Risk

- Acceptability of risk is a complex issue involving
  - social factors, e.g., value of life and limb
  - legal factors, e.g., responsibility of risk
  - economic factors, e.g., cost of risk reduction
- Ideally these tasks are performed by policy makers, not engineers!
- Engineers provide the information on which such complex decisions can be made
- At beginning of project, accurate estimates of risks and costs are difficult to achieve

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Acceptability of risk

- Ethical considerations
  - Determining risk and its acceptability involves moral judgement
  - Society’s view not determined by logical rules
  - Perception that accidents involving large numbers of deaths are perceived as more serious than smaller accidents, though they may occur less frequently

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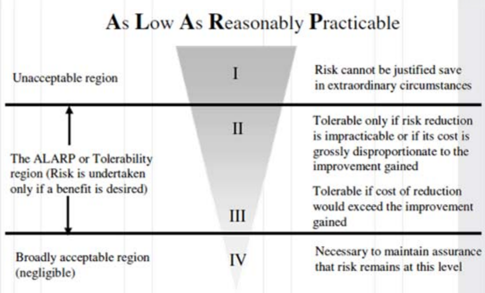
Risk Reduction - ALARP



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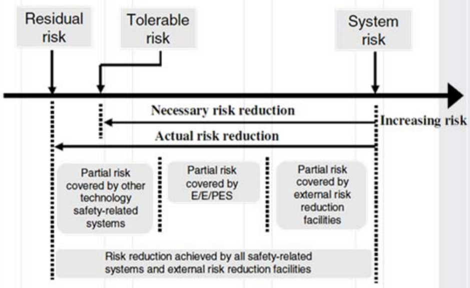
Risk Reduction



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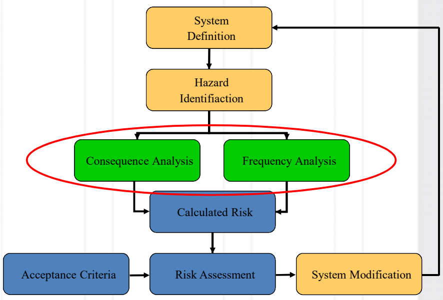
Hazard and Risk Analysis Process



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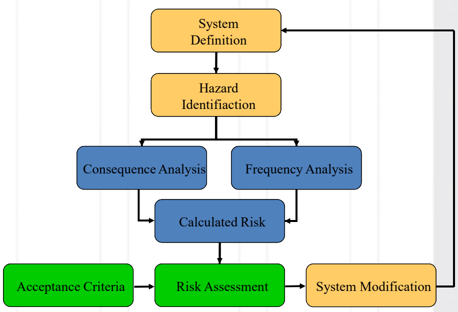
Hazard and Risk Analysis Process



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Safety Requirements

- Once hazards are identified and assessed, safety requirements are generated to mitigate the risk
- Requirements may be
  - primary: prevent initiation of hazard
    - eliminate hazard
    - reduce hazard
  - secondary: control initiation of hazard
    - detect and protect
    - warn
- Safety requirements form basis for subsequent development

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Safety Integrity

- Safety integrity, defined by
  - Likelihood of a safety-related system satisfactorily performing the required safety functions under all stated conditions within a stated period of time
  - Hardware integrity, relating to random faults
  - Systematic integrity, relating to dangerous systematic faults
- Expressed
  - Quantitatively, or
  - As Safety Integrity Levels (SILs)
- Standards, IEC 1508, 61508
  - Define target failure rates for each level
  - Define processes to manage design & development
- Aims to deal with systemic failures

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Safety Integrity Levels (SILs)

- Tolerable failure frequency are often characterised by Safety Integrity Levels rather than likelihoods
  - SILs are a qualitative measure of the required protection against failure
- SILs are assigned to the safety requirements in accordance with target risk reduction
- Once defined, SILs are used to determine what methods and techniques should be applied (or not applied) in order to achieve the required integrity level
- Point of translation from failure frequencies to SILs may vary

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Automotive SIL

- Uncontrollable (SIL 4), critical failure
  - No driver expected to recover (e.g. both brakes fail), extremely severe outcomes (multiple crash)
- Difficult to control (SIL 3), critical failure
  - Good driver can recover (e.g. one brake works, severe outcomes (fatal crash)
- Debilitating (SIL 2)
  - Ordinary driver can recover most of the time, usually no severe outcome
- Distracting (SIL 1)
  - Operational limitations, but minor problem
- Nuisance (SIL 0)
  - Safety is not an issue, customer satisfaction is

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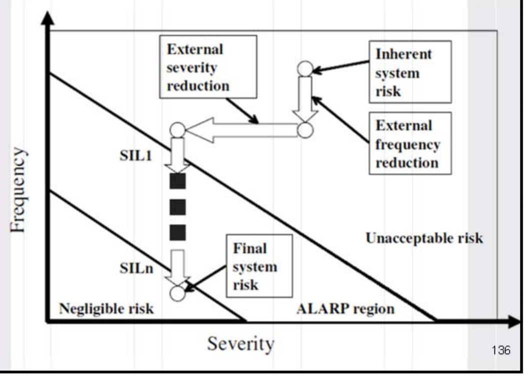
Risk & SILs



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IEC 61508 Standard

- Main standard for software safety
- Can be tailored to different domains (automotive, chemical, etc)
- Comprehensive
- Includes SILs, including failure rates
- Covers recommended techniques
- IEC = International Electrotechnical Commission
- E/E/PES = electrical/electronic/programmable electronic safety related systems

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Safety-Integrity Table of IEC 61508

Safety Integrity Level	Low demand mode of operation (Average probability of failure to perform its design function on demand)	
4	$\geq 10^{-5}$ to $< 10^{-4}$	(> 99.99 % reliable)
3	$\geq 10^{-4}$ to $< 10^{-3}$	(> 99.9 % reliable)
2	$\geq 10^{-3}$ to $< 10^{-2}$	(> 99% reliable)
1	$\geq 10^{-2}$ to $< 10^{-1}$	(> 90% reliable)

Safety Integrity Level	High demand mode or continuous mode of operation (Probability of dangerous failure per hour)
4	$\geq 10^{-9}$ to $< 10^{-8}$
3	$\geq 10^{-8}$ to $< 10^{-7}$
2	$\geq 10^{-7}$ to $< 10^{-6}$
1	$\geq 10^{-6}$ to $< 10^{-5}$

- The higher the SIL, the harder to meet the standard
- High demand for e.g. car brakes, critical boundary SIL 3
- Low demand for e.g. airbag, critical boundary is SIL 3, one failure in 1000 activations

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SILs

- SILs 3 and 4 are critical
- SIL activities at lower levels may be needed
- SIL 1
  - Relatively easy to achieve, if ISO 9001 practices apply,
- SIL 2
  - Not dramatically harder than SIL 1, but involves more review and test, and hence cost
- SIL 3
  - Substantial increment of effort and cost
- SIL 4
  - Includes state of the art practices such as formal methods and verification, cost extremely high

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Techniques and Measures

Clause 7.7 : Software Safety Validation						
TECHNIQUE/MEASURE	Ref	SIL1	SIL2	SIL3	SIL4
1. Probabilistic Testing	B.47	--	R	R	HR
2. Simulation/Modelling	D.6	R	R	HR	HR
3. Functional and Black-Box Testing	D.3	HR	HR	HR	HR
NOTE: One or more of these techniques shall be selected to satisfy the safety integrity level being used.					

Implementing the recommended techniques and measures should result in software of the associated integrity level.

For example, if the software was required to be validated to be of Integrity level 3, Simulation and Modelling are Highly Recommended Practices, as is Functional and Black-Box Testing.

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Detailed Techniques and Measures

- Related to certain entries in these tables are additional, more detailed sets of recommendations structured in the same manner. These address techniques and measures for:
  - Design and Coding Standards
  - Dynamic analysis and testing
  - Approaches to functional or black-box testing
  - Hazard Analysis
  - Choice of programming language
  - Modelling
  - Performance testing
  - Semi-formal methods
  - Static analysis
  - Modular approaches

Modeling

D.6 : Modelling Referenced by Clauses 7.6					
TECHNIQUE/MEASURE	Ref	SIL1	SIL2	SIL3	SIL4
1. Data Flow Diagrams	B.12	R	R	R	R
2. Finite State Machines	B.29	--	HR	HR	HR
3. Formal Methods	B.30	--	R	R	HR
4. Performance Modelling	B.45	R	R	R	HR
5. Time Petri Nets	B.64	--	HR	HR	HR
6. Prototyping/Animation	B.49	R	R	R	R
7. Structure Diagrams	B.59	R	R	R	HR
NOTE: One or more of the above techniques should be used.					

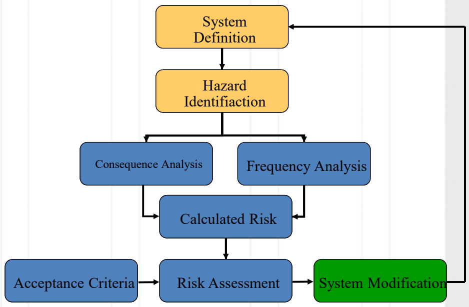
SILs

- What does it all mean?
  - SIL 4 system should have a duration of about 10-9 hours between critical failures
  - If established SIL 4 needed, used all the techniques…
  - But there is no measurement that the results actually achieves the target
  - Standard assumes that you are competent in all methods and apply everything possible
  - Except that these may be insufficient or not affordable

The Engineering Council's Code of Practice on Risk Issues

1	Professional responsibility	Exercise reasonable professional skill and care
2	Law	Know about and comply with the law
3	Conduct	Act in accordance with the codes of conduct
4	Approach	Take a systematic approach to risk issues
5	Judgement	Use professional judgement and experience
6	Communication	Communicate within your organization
7	Management	Contribute effectively to corporate risk management
8	Evaluation	Assess the risk implications of alternatives
9	Professional development	Keep up to date by seeking education and training
10	Public awareness	Encourage public understanding of risk issues

Hazard and Risk Analysis Process



Risk Reduction Procedures

- Four main categories of risk reduction strategies, given in the order that they should be applied:
  - Hazard Elimination
  - Hazard Reduction
  - Hazard Control
  - Damage Limitation
- Only an approximate categorisation, since many strategies belong in more than one category

Hazard Ellimination

- Before considering safety devices, attempt to eliminate hazards altogether
  - use of different materials, e.g., non-toxic
  - use of different process, e.g., endothermic reaction
  - use of simple design
  - reduction of inventory, e.g., stockpiles in Bhopal
  - segregation, e.g., no level crossings
  - eliminate human errors, e.g., for assembly of system use colour coded connections

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Design Principles

- Familiar
  - use tried and trusted technologies, materials techniques
- Simple
  - testable (including controllable and observable)
  - portable (no use of sole manufacturer components compiler dependent features)
  - understandable (behaviour can easily be from implementation)
  - deterministic (use of resources is not random)
  - predictable (use of resources can be predicted)
  - minimal (extra features not provided)

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Design Principles (cont.)

- Structured design techniques
  - defined notation for describing behaviour
  - identification of system boundary and environment
  - problem decomposition
  - ease of review
- Design standards
  - limit complexity
  - increase modularity
- Implementation standards
  - presentation and naming conventions
  - semantic and syntactic restrictions in software

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Classes of System Failure

- Random (physical) failures
  - due to physical faults
  - e.g., wear-out, aging, corrosion
  - can be assigned quantitative failure probabilities
- Systematic (design) failures
  - due to faults in design and/or requirements
  - inevitably due to human error
  - usually measured by integrity levels
- Operator failures
  - due to human error
  - mix of random and systematic failures

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Nature of Random Failures

- Arise from random events generated during operation or manufacture
- Governed by the laws of physics and cannot be eliminated
- Modes of failure are limited and can be anticipated
- Failures occur independently in different components
- Failure rates are often predictable by statistical methods
- Sometimes exhibit graceful degradation
- Treatment is well understood

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Treating Random Failures

- Random failures cannot be eliminated and must be reduced or controlled
- Random failures can be mitigated by:
  - predicting failure modes and rates of components
  - applying redundancy to achieve overall reliability
  - performing preventative maintenance to replace components before faults arise
  - executing on-line or off-line diagnostic checks

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Nature of Systematic Failures

- Ultimately caused by human error during development, installation or maintenance
- Appear transient and random since they are triggered under unusual, random circumstances
- Systematic and will occur again if the required circumstances arise
- Failures of different components are not independent
- Difficult to predict mode of failure since the possible deviations in behaviour are large
- Difficult to predict the likelihood of occurrence

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Treating Systematic Failures

- In theory, design failures can be eliminated
- In practice, perfect design may be too costly
- Focus the effort on critical areas
  - identify safety requirements using hazard analysis
  - assess risk in system and operational context
- Eliminate or reduce errors using quality development processes
  - verify compliance with safety requirements
  - integrate and test against safety requirements

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Hazard Reduction

- Reduce the likelihood of hazards
- Use of barriers, physical or logical
  - Lock-ins
  - Lock-outs
  - Interlocks
- Failure minimization
  - Redundancy
  - Recovery

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Redundancy

- Hardware redundancy
  - Static redundancy, e.g. triple modular redundancy
  - Dynamic redundancy, e.g. standby spare
- Software redundancy, e.g. N-version programming
- Information redundancy, e.g., checksums, cyclic redundancy codes, error correcting codes

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Recovery

- Can reduce failures by recovering after error detected but before component or system failure occurs
- Recovery can only take place after detection of error
  - Backward recovery
  - Forward recovery

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Error Detection

- Based on check that is independent of implementation of the system
  - coding - parity checks and checksums
  - reasonableness - range and invariants
  - reversal - calculate square of square root
  - diagnostic - hardware built-in tests
  - timing - timeouts or watchdogs

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Error Detection (cont.)

- Timing of error detection important
  - early error detection can be used to prevent propagation
  - late error detection requires a check of the entire activity of system
- Checking may be in several forms
  - monitor, acting after a system function, checking outputs after production but before use
  - kernel, encapsulating (safety-critical) functions in a subsystem that allows all inputs to and outputs from the kernel to be checked

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Backward Recovery

- Corrects errors through reversing previous operations
- Return system to a previous known safe state
- Allows retry
- Requires checkpoints or saved states (and the expenses involved with producing them)
- Rollback usually impossible with real-time system

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Forward Recovery

- Corrects errors without reversing previous operations, finding safe (but possibly degraded) state for system
  - data repair, use redundancy in data to perform repairs
  - reconfiguration, use redundancy such as backup or alternate systems
  - coasting, continue operations ignoring (hopefully transient) errors
  - exception processing, only continue with selection of (safetycritical) functions
  - failsafe, achieve safe state and cease processing
    - use passive devices (e.g., deadman switch) instead of active devices (e.g., motor holding weight up)

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Hazard Control

- Detect and control hazard before damage occurs
- Reduce the level or duration of the hazard
- Hazard control mechanisms include:
  - Limiting exposure: reduce the amount of time that a system is in an unsafe state (e.g. don't leave rocket in armed state)
  - Isolation and containment
  - Fail safe design

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Damage Limitation

- In addition to eliminating hazards or employing safety devices, consider
  - warning devices
  - procedures
  - training
  - emergency planning
  - maintenance scheduling
  - protective measures

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Architectural Design

- Suitable architectures may allow a high integrity system to be built from lower integrity components
  - combinations of components must implement a safety function independently
  - overall likelihood of failure should be the same or less
  - be wary of common failure causes
- Apportionment approaches can be quantitative and/or qualitative
  - quantitative: numerical calculations
  - qualitative: judgement or rules of thumb

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