# Requirements Management An Overview

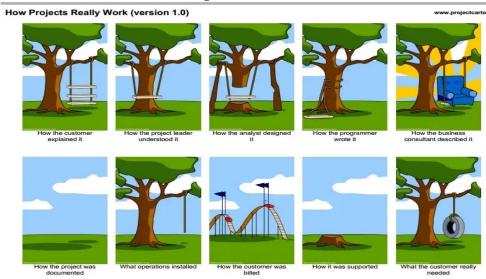
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#### **Requirements Management**

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#### **Group Exercise**

## **Need for Requirements** [1]



#### Requirements are needed -

- To get an in-depth understanding of the future product
- To identify hidden and assumed requirements
- To clearly define deliverables and build only relevant functionality
- Lay out predictable project timelines so we can plan accordingly

Requirement is a usable representation of a need.

- 1. A condition or capability needed by a stakeholder to solve a problem or achieve an objective.
- 2. A condition or capability that must be met or possessed by a solution or solution component to satisfy a contract, standard, specification, or other formally imposed documents.
- 3. A documented representation of a condition or capability as in 1. or 2.



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I MEAN WHAT ARE

YOU TRYING TO

ACCOMPLISH WITH

CAN YOU DESIGN

IT TO TELL YOU

MY REQUIREMENTS?

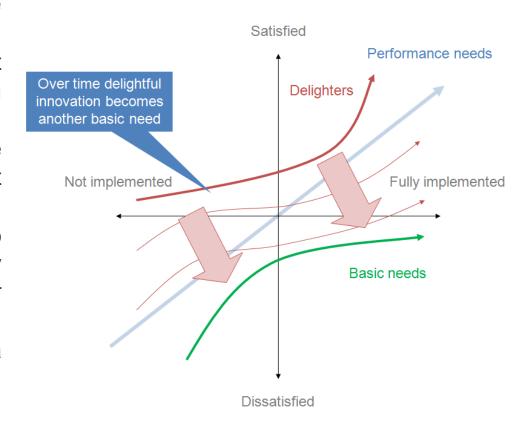
## Writing Good Requirements [2]



- Understand the user needs what, why, who, how
- Requirements should be unambiguous
- Requirements should be simple, specific, concise, and comprehensive
- Requirements should be testable
- Requirements should be separate from design and implementation
- Requirements should be attainable
- Requirements should be properly categorized
- Requirements should be prioritized
- Requirement should be traceable

#### Kano Model [3]

- *Must-be Quality:* The requirements that the customers expect and are taken for granted.
- Performance Quality: These attributes result in satisfaction when fulfilled and dissatisfaction when not fulfilled.
- Delighter Quality: These attributes provide satisfaction when achieved fully, but do not cause dissatisfaction when not fulfilled.
- Indifferent Quality: These attributes refer to aspects that are neither good nor bad, and they do not result in either customer satisfaction or customer dissatisfaction.
- Reverse Quality: These attributes refer to a high degree of achievement resulting in dissatisfaction and to the fact that not all customers are alike.



### Regulatory Bodies & Industry Standards

- Regulatory bodies, government or nongovernment, establishes laws control the way a business shall be operated.
- These practices ensure the protection of the public, environment and also upholds certain ethical standards for professional engineers.
- Industry standards are published documents created to ensure the reliability of the materials, products, methods, and/or services.
- Thev establishes baselines minimum level of performance and quality control to ensure that optimal conditions and procedures for the purpose of creating compatibility with products and services from different periods and a range of sources.







































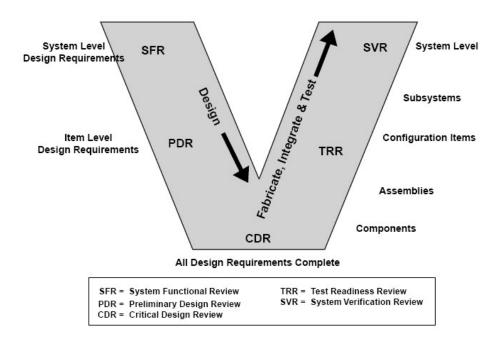


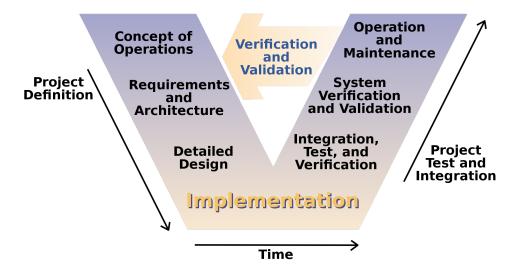
# **Requirements Classification** [4]

Requirements	Descriptions
> Safety	Requirements for system-level functions include minimum performance constraints for both availability and integrity of the function.
Functional	Requirements necessary to obtain the desired performance of the system under the conditions specified.
Customer	Specific function or the type of system under consideration based on customer need.
Operational	Requirements defining the interfaces between humans and various related functions or systems or components or subcomponents. Actions, decisions, information requirements and timing constitute the bulk of the operational requirements.
Performance	Attributes of the function or system that make it useful to the aircraft and its operation; it includes function specifics such as: accuracy, fidelity, range, resolution, speed, and response times.
Physical and Installation	Physical attributes of the system to the environment; includes: size, mounting provisions, power, cooling, environmental restrictions, visibility, access, adjustment, handling, storage and production constraints.
Maintainability	Includes scheduled and unscheduled maintenance requirements and any links to specific safety-related functions.
Interface	Includes the requirement for physical system or component or subcomponents interconnections with the other physical system or component or subcomponents based on relevant specific characteristics.
> Certification	Additional functions, functional attributes, or implementations required by regulatory body or necessary to show compliance with regulations.
> Derived	Decisions from previous phases on how to meet particular requirements of that phase results in derived requirements for the next phase which are not uniquely related to higher-level requirements.
<ul><li>Re-use Existing Certified Systems and Items</li></ul>	Systems and items previously used can be reused in new or derivative products as their maturity would be better in comparison to a totally new product.

#### System Development Process [4][5][6]

- V-model is a graphical representation of a systems development lifecycle.
- V-model summarizes the main steps to be taken in conjunction with the corresponding deliverables within project life cycle development.





 The left side of the "V" represents the decomposition of requirements, and creation of system specifications. The right side of the "V" represents integration of parts, their validation and verification.

## Validation and Verification of Requirements [4]

- Validation of requirements is the process of ensuring that the specified requirements are sufficiently correct and complete so that the product will meet the needs of customers, users, suppliers, maintainers and certification authorities, as well as aircraft, system and item developers.
- Validation should consider both intended and unintended functions

- Verification is the evaluation of an implementation of requirements to determine that they have been met.
- The verification process ensures that the system implementation satisfies the validated requirements.

#### Validations methods include:

- Traceability
- Analysis
- Modeling
- > Test
- Similarity
- Engineering review

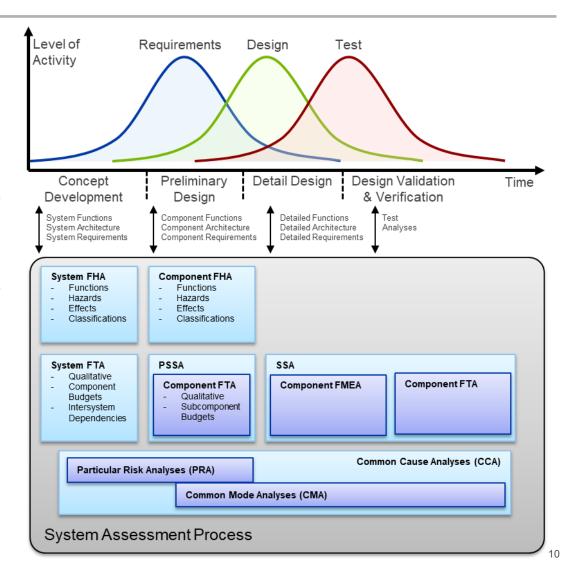
#### Verification can be achieved by -

- Inspections
- Reviews
- Analyses
- > Tests
- Service Experience

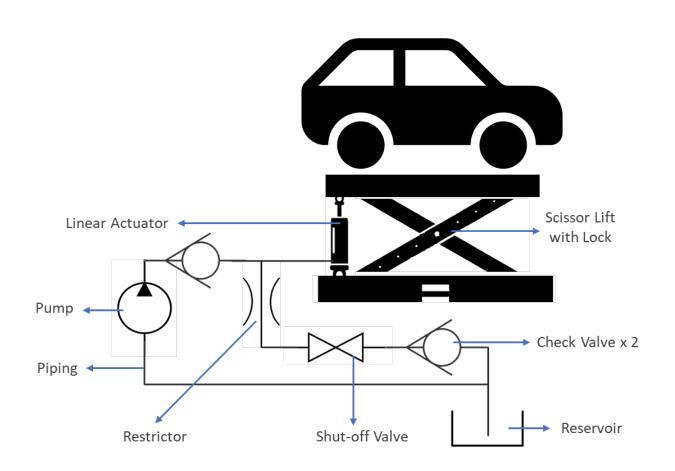
## System Safety Overview [7]

- Functional architecture shall be created by allocation of functions logically to subcomponents focusing on safety.
- Preliminary System Safety Assessment (PSSA) is a systematic evaluation of a proposed system architecture and implementation based on the FHA and failure condition classification to determine safety requirements for all items.
- System Safety Assessment (SSA) is a systematic, comprehensive evaluation of the implemented system to show that the relevant requirements are met.
- System Safety Assessment Process (SSAP) is the complete process applied during the design of the system to establish safety objectives and to demonstrate compliance with regulatory and other safety related requirements.
- Popular tools used in SSAP are:
  - Functional Hazard Analysis (FHA)
  - Fault Tree Analysis (FTA)
  - Failure Modes and Effects Analysis (FMEA)
  - Particular Risks Analysis (PRA)
  - Common Mode Analysis (CMA)

There are other tools available too and use of these tools can differ from project to project. Bottomline is to ensure regulatory requirements are met appropriately.



# **System Architecture Overview**



#### **Design & Develop**

- 1 Scissor Lift with Lock
- 2 Restrictor
- 3 Linear Actuator
- 4 Shut-off Valve
- 5 Check Valve

#### **COTS Selection**

- 1 Pump
- 2 Piping
- 3 Reservoir
- 4 Hydraulic Fluid

Integrate all components per workshop lift schematic & layout

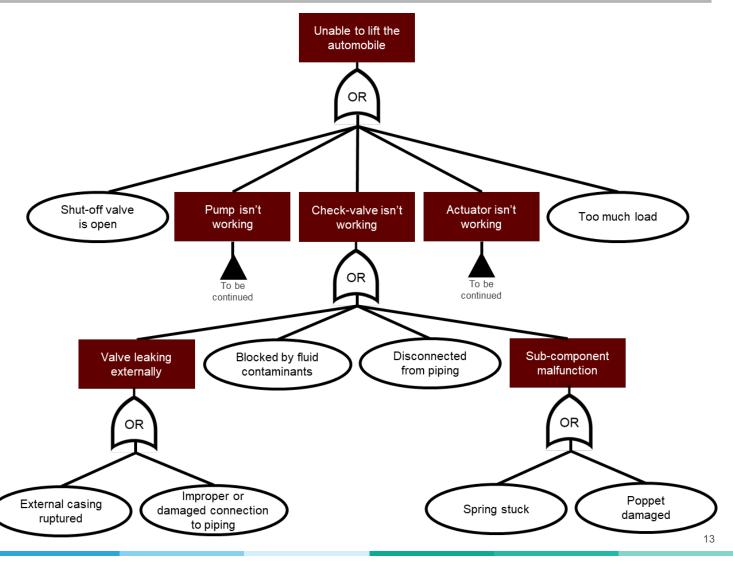
# System Safety Overview - FHA [7]

Functional Hazard Analysis (FHA) is a systematic, comprehensive examination of functions to identify and classify failure conditions of those functions according to their severity.

Effect on Hydraulic Lift System	No effect on operational capability or safety	Slight reduction in functional capabilities or safety margin	Significant reduction in functional capabilities or safety margin	Large reduction in functional capabilities or safety margins	Normally complete loss of the system
Effect on Mechanic	No effect on mechanic	Slight increase in workload	Physical discomfort or significant increase in workload	Physical distress or excessive workload, impairs ability to perform tasks	Fatalities or incapacitation
Effect on Car	No effect on car	Slight amount of damage to the car, minor repair needed	Significant amount of damage to the car, major repair needed	Large amount of damage to the car, extensive repair needed	Total loss of car, not repairable
Effect on Workshop/Owner	Inconvenience	Slight loss of money, minor repair needed	Significant loss of money, major repair needed	Large loss of money, extensive repair needed	Complete loss of systems, replace with new, complete reinvestment needed.
Classification of Failure Condition	No safety effect	Minor	Major	Hazardous	Catastrophic
Allowable Qualitative Probability	No probability requirement	Probable	Remote	Extremely Remote	Extremely Improbable
Allowable Quantitative Probability		10 <sup>-3</sup>	10 <sup>-5</sup>	10 <sup>-7</sup>	10 <sup>-9</sup>
System Development Assurance Level (DAL)	Level E	Level D	Level C	Level B	Level A
System Compliance Method	Design Review, FHA	Design Review, DAL Verification Methods, FHA	Design Review, DAL Verification Methods, FHA, FMEA	Design Review, DAL Verification Methods, FHA, FMEA, FTA	Design Review, DAL Verification Methods, FHA, FMEA, FTA, CMA

# System Safety Overview – FTA [7]

Fault Tree Analysis (FTA) is a top-down analysis techniques, that proceed down through successively more detailed (i.e., lower) levels of the design to determine what single failures or combinations of failures can exist (if any) at the lower levels that might cause each failure condition.



# System Safety Overview – FMEA [8]

Failure Modes and Effects Analysis (FMEA) is a systematic, bottom-up method of identifying the failure modes of a system, item, or function and determining the effects on the next higher level; it is used to address failure effects resulting from single failures.

properly to the actuator    Fluid   process to   clean filter   design   before the engineer & pump and clean it periodically, write a manual   process to   clean filter   design   before the engineer & pump and clean it periodically, write a manual   process to   clean filter   design   before the engineer & pump and clean it   periodically, write a manual   process to   clean filter   design   before the engineer & pump and clean it   periodically, write a manual   process to   clean filter   design   before the engineer & pump and clean it   periodically, write a manual   process to   clean filter   design   before the engineer & pump and clean it   periodically, write a manual   process to   clean filter   design   before the engineer & pump and clean it   periodically, write a manual   process to   clean filter   design   before the engineer & pump and clean it   periodically, write a manual   process to   clean filter   design   pump and clean it   periodically, write a manual   process to   clean filter   design   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write a manual   process to   pump and clean it   periodically, write   periodically   process to   pump and clean it   periodically   pump and clean it   periodically   pump and		What is the item or function step?	What is the ideal condition?	In what ways can the ideal condition go wrong? (chance of not meeting requirements)	What is the impact on the Key Output Variables (customer requirements) or internal requirements?	How Severe is the effect? Check References	What causes the Key Input to go wrong? (How could the failure mode occur?)	How frequent is cause likely	that either prevent	How probable is Detection of cause?	Risk Priority # to rank order	What are the actions for reducing the Occurrence of the cause, or improving Detection? Should have actions on high RPN's or Severity of 9 or 10.	Who's Responsible for the recommended action? What date?	What were the actions implemented? Include completion month/year. (Then recalculate resulting RPN.)	Future Severity	Future Occurrence	Future Detection	Future RPN
1 Check Valve Deliver hydraulic fluid properly to the actuator    Minor   6 Disconnected from piping   Minor   Minor   6 Disconnected from piping   Minor   M					Potential	s			Current		R	Decemmended		Acti	on Re	esult	s	
properly to the actuator    Fluid   Contaminants   Fluid   Contaminants   Contami	SI. #	Item / Function	Requirement	Potential Failure Mode			Mechanism(s) of	1	Controls	е			Completion		е	С		R P N
from piping process to to inspect the piping before issue starting.	1	Check Valve	properly to the		Minor	6	fluid	6	process to identify the	6	216	clean filter before the pump and clean it periodically,	design engineer &	In work	6	2		36
Poppet moves properly					Minor	6	1	3	process to identify the	6	108	to inspect the piping before		Completed	6	3	2	36
				Excessive fluid supply														
Spring moves properly																		
No external leakages																		

# System Safety Overview – FMEA [8]

Effect	SEVERITY of Effect	Ranking
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe system operation without warning	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe system operation with warning	9
Very High	System inoperable with destructive failure without compromising safety	8
High	System inoperable with equipment damage	7
<b>Moderate</b>	System inoperable with minor damage	6
Low	System inoperable without damage	5
Very Low	System operable with significant degradation of performance	4
Minor	System operable with some degradation of performance	3
Very Minor	System operable with minimal interference	2
None	No effect	1

PROBABILITY of Failure	Failure Prob	Ranking
Very High: Failure is almost inevitable	>1 in 2	10
	1 in 3	9
High: Repeated failures	1 in 8	8
	1 in 20	7
Moderate: Occasional failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively few failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure is unlikely	<1 in 1,500,000	1

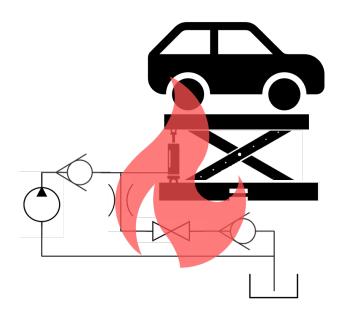
Detection	Likelihood of DETECTION by Design Control	Ranking
Absolute Uncertainty	Design control <b>cannot</b> detect potential cause/mechanism and subsequent failure mode	10
Very Remote	Very remote chance the design control will detect potential cause/mechanism and subsequent failure mode	9
Remote	Remote chance the design control will detect potential cause/mechanism and subsequent failure mode	8
Very Low	Very low chance the design control will detect potential cause/mechanism and subsequent failure mode	7
Low	Low chance the design control will detect potential cause/mechanism and subsequent failure mode	6
Moderate	Moderate chance the design control will detect potential cause/mechanism and subsequent failure mode	5
Moderately High	Moderately High chance the design control will detect potential cause/mechanism and subsequent failure mode	4
High	High chance the design control will detect potential cause/mechanism and subsequent failure mode	3
Very High	Very high chance the design control will detect potential cause/mechanism and subsequent failure mode	2
Almost Certain	Design control will detect potential cause/mechanism and subsequent failure mode	1

- The risk priority number (RPN) is a numeric assessment of risk assigned to a process, or steps in a process, as part of failure modes and effects analysis (FMEA).
- The product of these three scores is RPN for that failure mode.
- The sum of the RPNs for the failure modes is the overall RPN for the process.
- If RPN falls within a pre-determined range, corrective action may be recommended or required to reduce the risk
- RPN ratings are relative to a particular analysis

# System Safety Overview – PRA & CMA [7]

Particular Risks Analysis (PRA) is the analysis of risks that are defined as events or influences which are outside the system(s)/item(s) concerned, but which may violate failure independence claims.

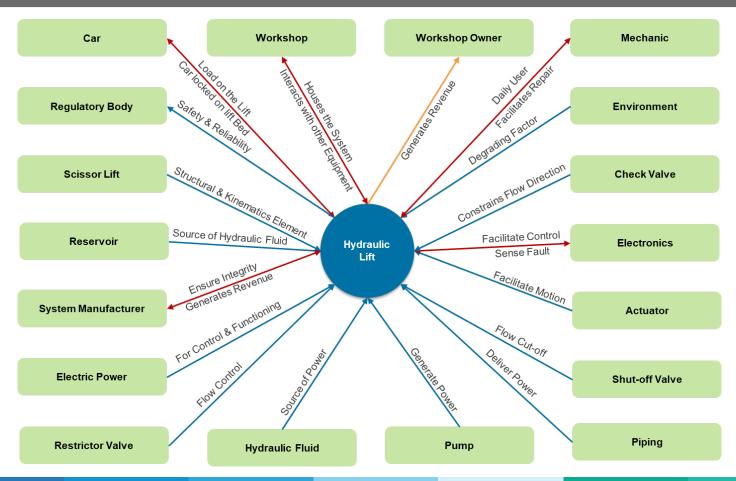
Common Mode Analysis (CMA) is performed to verify that common failure events identified in the FTA is independent in the actual implementation.



Failure Event	Component	CMA Failure Case	CMA Failure Case Result & Effect	CMA Failure Case Mitigation
Loss off	Actuator	Actuator powered by hydraulics fails	Scissor lift collapses	Scissor lift lock shall be
hydraulic power	Scissor Lift Lock	Scissor lift lock powered by hydraulics fail	suddenly • Effect can be catastrophic	automated mechanical mechanism

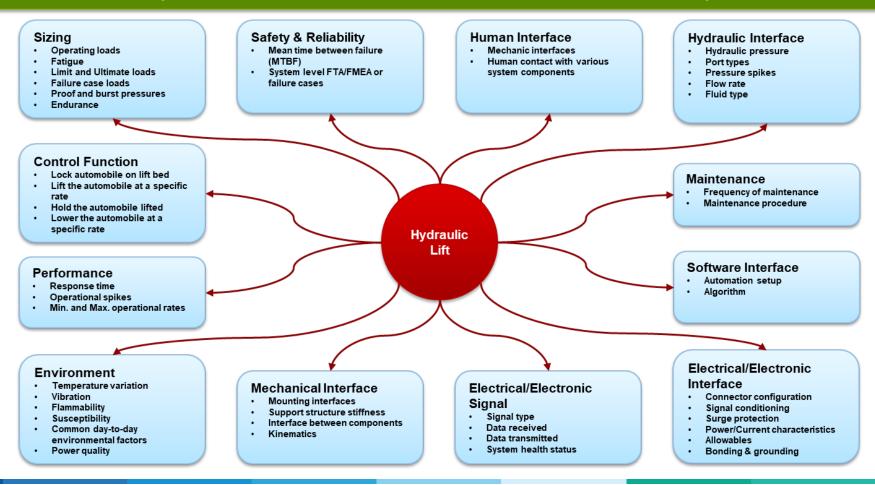
## **Context Diagram**

Defines the boundary between the system, or part of a system, and its environment, showing the entities that interact with it. Show a system, as a whole and its inputs and outputs from/to external factors, i.e. all the entities and their relationships between each other with respect to the central system.



#### **Mind Map**

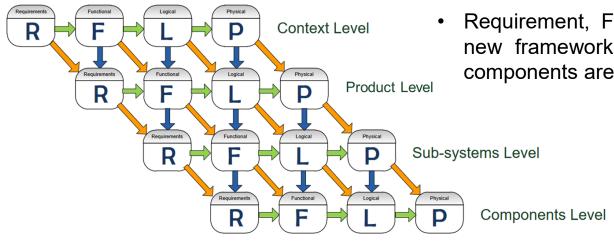
Visually organize information into hierarchy, showing relationships among pieces of the whole. Single page view of requirements and their categorization. A good exercise to understand the whole picture. Pre-requisite is functional architecture and allocation of functions to subcomponents.



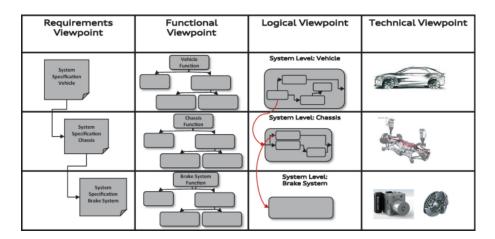
#### Overview of Functional Flow [9]

- Identification of the functions of a system provides a better understanding of the system itself and its capabilities, and a more efficient definition of interfaces.
- Functional architecture is a set of functions and their sub-functions that defines the transformations of input into output performed by the system to achieve its mission.
- Functional analysis is the process of identifying, describing, and relating the functions a system must perform in order to fulfill its goals and objectives. Functional analysis is logically structured as a top-down hierarchical decomposition of those functions.
- Functional decomposition is the process of defining a system in functional terms, then defining lower level functions and sequencing relationships from these higher level systems functions.
- Functional derivation from requirements, essentially are functions originating from requirements, which are not necessarily associated with the decomposition of the top-level function, like functions that implemented due to certification requirements.
- Functions are used for safety assessment activities. The possibility of a safety assessment at conceptual level would improve product maturity and minimize risk at later development phases.
- At the highest level (context level) requirements are more abstractly defined as customer needs, marketing and program requirements and objectives, and are then decomposed to lower levels.
- Similarly, the defined top-level functions are decomposed towards implementation-level functions.

#### RFLP Approach [9][10][11]



- Requirement, Functional, Logical and Physical (RFLP) is a new framework. The requirements and the physical (part) components are commonly seen in the industry.
  - The functional objects and relationships help us to understand "what" we are developing, and the logical structure helps us define "how" we are going to accomplish our goals.
- A multi-level RFLP relationship that is aligned with the ubiquitous V-model of the Systems Engineering Process is shown here.
- The green horizontal arrows represent the conventional RFLP interactions between its elements of the same level.
- The orange diagonal arrows represent decompositions of elements of the same nature into the next level.
- The blue vertical arrows represent implications to lower level elements of a different nature, like functions that drive requirements at a lower level



# **System Requirement Tiers**

#### Tier 1

- Automobile maintenance requirement
- Human safety
- Automobile safety

#### Tier 2

- Workshop requirements
- System requirements
- Human & system safety
- System reliability requirement

#### Tier 3

- Component level requirements
- Safety requirements
- Reliability requirement

### **Requirements Tiers**

#### Tier 1

Final product level requirement.

Government & industry regulations.

Product safety and reliability requirements.

#### Tier 3

Component level general requirement.

Component functional requirement.

Component performance requirement.

Drill down of government and industry regulations into actionable requirement

Drill down of safety and reliability requirement into actionable requirement

Component maintenance and replacement requirement.

#### Tier 2

System level general requirement.

System functional requirement.

System performance requirement.

Drill down of government and industry regulations into actionable requirement

Drill down of safety and reliability requirement into actionable requirement

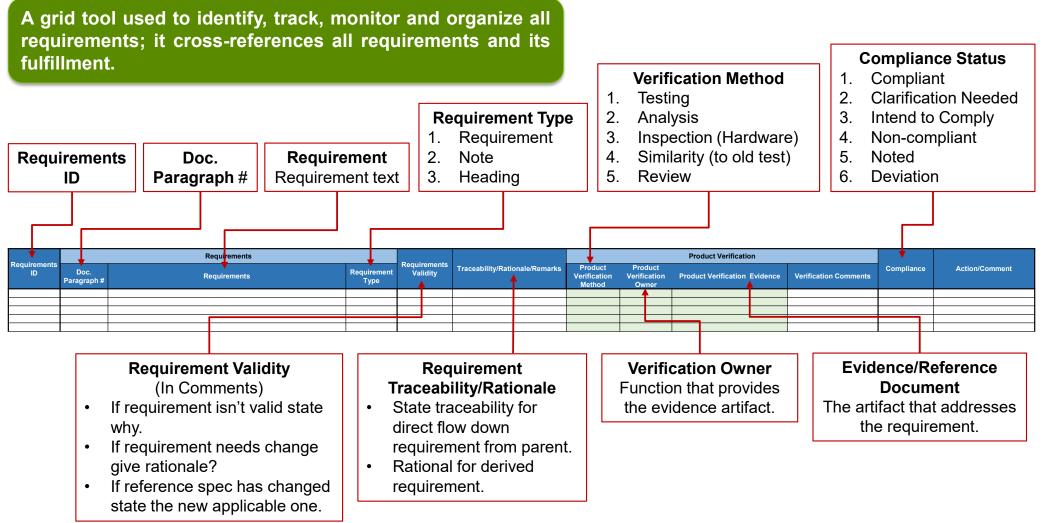
System maintenance requirement.

# **Requirements Tiers - Example**

ID	Requirement	Parent							
	Tier 1								
T1-R-1	Car shall undergo periodic maintenance as recommended by manufacturer.	-							
T1-R-2	For maintenance, shall have easy access to the underside of the car.	T1-R-1							
T1-R-3	Maintenance shall ensure safety and reliability standards.	T1-R-1							
T1-R-4	During maintenance the car shall not be damaged	T1-R-1							
	Tier 2								
T2-R-1	The workshop shall have the capability to service the underside of the car.	T1-R-2							
T2-R-2	The workshop shall capability to lift the car to a height of 2.15m.	T1-R-2 T2-R-1							
T2-R-3	The lift shall ensure clear access to the underside of the car.	T1-R-2 T2-R-1 T2-R-2							
T2-R-4	The tires of the car shall interface with the lift bed.	T1-R-2 T2-R-1 T2-R-2							
T2-R-5	The lift shall have mechanism to arrest the motion of the car on top of the lift bed.	T1-R-4 T2-R-4							
T2-R-6	The lifting time shall be less than 30sec.	T1-R-2 T2-R-1							
T2-R-7	The lowering time shall be more than 1min but less than 2.	T1-R-3 T1-R-4							
T2-R-8	The lift shall be designed to fail safe.	T1-R-3 T1-R-4							
T2-R-9	The overall envelope of the lift shall be as shown in figure ************************************	T2-R-1 T2-R-2							
T2-R-10	Lift shall be capable of lifting a 2800 kg car, with 50% additional allowance.	T2-R-1 T2-R-2							

ID	Requirement	Parent
	Tier 3	
	Check Valve	
T3-R-CV1	The function of the unit shall be to allow Hydraulic System Fluid to free flow/minimum resistance in one direction only, and prevent flow in the opposite direction.	T2-R-1 T2-R-10
T3-R-CV2	It shall contain a minimum number of individual parts, consistent with the stated functional requirements.	T3-R-CV1
T3-R-CV3	The product shall be manufactured using material and process as per industry standard.	T1-R-3
T3-R-CV4	The unit shall meet all applicable environmental requirements without degradation during and after exposure to the following conditions.	T1-R-3
T3-R-CV5	The weight of the unit shall not exceed 500g.	T2-R-9
T3-R-CV6	Reseating of the valve shall occur between the limits of 55.16 kpa forward pressure and zero pressure	T2-R-6/7/8
T3-R-CV7	Cracking pressure of the valve shall be not less than 13.8 kpa nor greater than 55.16 kpa.	T2-R-6/7/8
T3-R-CV8	The unit shall be designed for rated flow of 0.1136 m^3/min.	T2-R-6/7/8
T3-R-CV9	The pressure drop shall not exceed 344.738 kpa at 0.1136 m^3/min flow at a temperature of 40 deg.C +/-30 deg.C.	T2-R-6/7/8
T3-R-CV10	Internal leakage in the reverse flow direction, measured after a two minute seating period shall be zero when subjected to pressure of 13790 kpa and 34.5 kpa consecutively.	T2-R-6/7/8
T3-R-CV11	No external leakage shall be seen when subjected to proof pressure of 1.5 times the max operating pressure.	T2-R-6/7/8

### **Compliance Matrix**



# **Example Compliance Matrix**

		Requirements					Produc	t Verification			
Requirements ID	Doc. Paragraph #	Requirements	Requirement Type	Requirements Validity	Traceability / Rationale / Remarks	Product Verification Method	Product Verification Owner	Product Verification Evidence	Verification Comments	Compliance	Action / Comment
T3-R-CV1	-	The function of the unit shall be to allow Hydraulic System Fluid to free flow/minimum resistance in one direction only, and prevent flow in the opposite direction.	Requirement	Valid	T2-R-1 T2-R-10	Test	Design / Analysis	Test Report		Intend to Compliant	
T3-R-CV2	-	It shall contain a minimum number of individual parts, consistent with the stated functional requirements.	Requirement	Valid	T3-R-CV1	Review	Design	Drawings, BoM		Intend to Compliant	
T3-R-CV3	-	The product shall be manufacture using material and process as per industry standard.	Requirement	Valid	T1-R-3	Review/Inspect	Design / Analysis / Manufacturing	Drawings, BoM, Analysis Report		Intend to Compliant	
T3-R-CV4	-	The unit shall meet all applicable environmental requirements without degradation during and after exposure to the following conditions.	Requirement	Valid	T1-R-3	Test / Analysis / Similarity	Design / Analysis	Report, Similarity Report		Intend to Compliant	
T3-R-CV5	-	The weight of the unit shall not exceed 500g.	Requirement	Valid	T2-R-9	Test / Analysis / Similarity	Design / Analysis	Test Report, Analysis Report, Similarity Report		Intend to Compliant	
T3-R-CV6	-	Reseating of the valve shall occur between the limits of 55.16 kpa forward pressure and zero pressure	Requirement	Valid	T2-R-6/7/8	Test / Analysis / Similarity	Design / Analysis	Test Report, Analysis Report, Similarity Report		Intend to Compliant	
T3-R-CV7	-	Cracking pressure of the valve shall be not less than 13.8 kpa nor greater than 55.16 kpa.	Requirement	Valid	T2-R-6/7/8	Test / Analysis / Similarity	Design / Analysis	Test Report, Analysis Report, Similarity Report		Intend to Compliant	
T3-R-CV8	-	The unit shall be designed for rated flow of 0.1136 m^3/min.	Requirement	Valid	T2-R-6/7/8	Test / Analysis / Similarity	Design / Analysis	Test Report, Analysis Report, Similarity Report		Intend to Compliant	
T3-R-CV9	-	The pressure drop shall not exceed 344.738 kpa at 0.1136 m^3/min flow at a temperature of 40 deg.C +/-30 deg.C.	Requirement	Valid	T2-R-6/7/8	Test / Analysis / Similarity	Design / Analysis	Test Report, Analysis Report, Similarity Report		Intend to Compliant	
T3-R-CV10	-	Internal leakage in the reverse flow direction, measured after a two minute seating period shall be zero when subjected to pressure of 13790 kpa and 34.5 kpa consecutively.	Requirement	Valid	T2-R-6/7/8	Test / Analysis / Similarity	Design / Analysis	Test Report, Analysis Report, Similarity Report		Intend to Compliant	
T3-R-CV11	-	No external leakage shall be seen when subjected to proof pressure of 1.5 times the max operating pressure.	Requirement	Valid	T2-R-6/7/8	Test / Analysis / Similarity	Design / Analysis	Test Report, Analysis Report, Similarity Report		Intend to Compliant	

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## **Group Exercise**

- Setting up the exercise and convey the expectation 10mins
  - Make groups of 3
  - Distribute exercise sheet
  - Explain the exercise
  - Stress on the expectation
- Exercise Execution 30mins
  - Fill in the Compliance Matrix for a component from the hydraulic lift system 20mins
    - Min. 5 functional requirements
  - Fill in FMEA sheet for the component 10mins
    - Min. 1 failure mode completed
- Group Discussion 20mins
  - Discuss 2 components
    - Invite 3 per component and compare exercise notes

#### Exercise Compliance Matrix | Component Selected: Scissor Lift with Lock / Actuator / Restrictor Valve / Shut-off Valve

Requirements		Requirements		Requirements	Traceability /		Produc	ct Verification		Compliance	1.0
. ID	Doc. Paragraph #	Requirements	Requirement Type	Requirements Validity	Traceability / Rationale / Remarks	Product Verification Method	Product Verification Owner	Product Verification Evidence	Verification Comments	Compliance	Action / Comment

#### **Exercise FMEA**

	What is the item or function step?	What is the ideal condition?	In what ways can the ideal condition go wrong? (chance of not meeting requirements)	What is the impact on the Key Output Variables (customer requirements) or internal requirements?	How Severe is the effect? Check References.	What causes the Key Input to go wrong? (How could the failure mode occur?)	How frequent is cause likely to Occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is Detection of cause?	Risk Priority # to rank order concerns	What are the actions for reducing the Occurrence of the cause, or improving Detection? Should have actions on high RPN's or Severity of 9 or 10.	Who's Responsible for the recommended action? What date?	What were the actions implemented? Include completion month/year. (Then recalculate resulting RPN.)	Future Severity	Future Occurrence	Future Detection	Future RPN
SI. #	Item / Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure		Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Process Controls	D e t e c	R P N	Recommended Action(s)	Responsibility and Target Completion Date	Acti Actions Taken	S e v	sults O c c	D e t	R P N

# **Thank You**