

System FMEA / DFMEA / DVP&R

AIAG-VDA FMEA Handbook for
Practitioners and Facilitators

QUALITY

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Course Objectives

- Explain the difference between DFMEA and SFMEA.
 - Demonstrate an ability to properly construct a Boundary (Block) Diagram.
- Explain the use of an inter-relationship matrix to identify relationships between components and higher level systems.
- Demonstrate an ability to properly and effectively complete all items in the DFMEA process.
 - Identify Functions, Requirements, Failure Modes, Causes and Controls and properly enter the information in a DFMEA.
- Explain how a DFMEA can help identify effects and severity for a process failure mode.
- Explain how to prioritize continual improvements.

Agenda

- Course Overview and Introductions
- Chapter 1 – Introduction to Failure Modes and Effects Analysis (FMEA)
- Chapter 2 – Developing an FMEA
- Chapter 3 – Design FMEA Prerequisites
 - **Breakout Exercise 1: Boundary Diagram**
 - **Breakout Exercise 2: Structure Analysis**
 - **Breakout Exercise 3: Function Analysis**
- Chapter 4 – Developing the Design FMEA
 - **Breakout Exercise 4: Potential Design Failure Modes**
 - **Breakout Exercise 5: Failure Net (Effects ← Failure Mode ← Cause)**
 - **Breakout Exercise 6: Design Controls**
 - **Breakout Exercise 7: Risk Analysis (Indices and Action Plan)**
- Chapter 5 – Test Planning and Reporting
- Chapter 6 – Effectively Using the AIAG-VDA FMEA Approach
- Summary

Course Overview

- Focus of the course is on the AIAG-VDA FMEA Handbook 1st Edition method for the development of Failure Modes and Effects Analysis.
 - Published by AIAG and VDA.
- All learning objectives relate to the AIAG-VDA FMEA method.
- Breakouts will be conducted using the AIAG-VDA FMEA method.
 - There are two views of FMEA examples shown in the manual. The Software View depicts what the user sees when developing a FMEA using specialized software that utilizes system element structure, function net, failure net, etc. The Form View depicts what the user sees when developing an FMEA in a spreadsheet.
 - This class will use the Form View during the breakout exercise development, but will demonstrate the results using the Software View.

A BRIEF INTRODUCTION TO OMNEX

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Omnex Introduction

- International consulting, training and software development organization founded in 1985.
- Specialties:
 - Integrated management system solutions.
 - Elevating the performance of client organizations.
 - Consulting and training services in:
 - Quality Management Systems, e.g. ISO 9001, IATF 16949, AS9100, QOS
 - Environmental Management Systems, e.g. ISO 14001
 - Health and Safety Management Systems, e.g. ISO 45001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
 - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.



About Omnex

- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 400 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for ISO/TS 16949.
- Served on committees that wrote QOS, ISO 9001, QS-9000, ISO/TS 16949 and its Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Former member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).

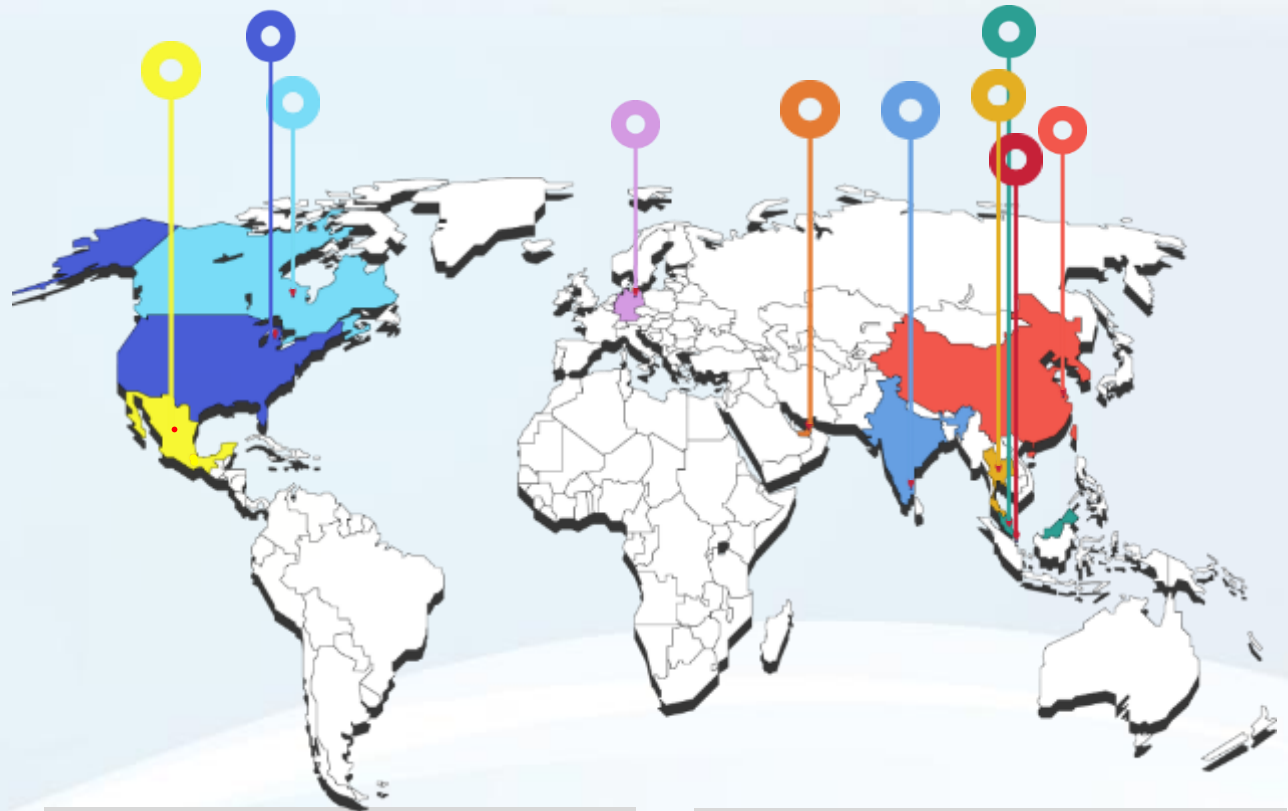





Omnex is headquartered and operates from the United States through offices in Michigan.


The company maintains international operations in many countries to provide comprehensive services to clients throughout Western Europe, Latin America and the Pacific Rim.


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 Canada (Mississauga)


 Europe (Berlin, Germany)

 Middle East (Dubai, Saudi Arabia, Bahrain)

 Thailand (Bangkok)

 Mexico (Monterrey)

 Singapore

 Malaysia (Kuala Lumpur)



Rules of the Classroom

- ✓ Start and end on time
- ✓ Return from breaks and lunch on time
- ✓ All questions welcome
- ✓ Your input is valuable and is encouraged
- ✓ Don't interrupt others
- ✓ One meeting at a time
- ✓ Listen – and respect others' ideas
- ✓ No “buts” – keep an open mind
- ✓ Phones in Do Not Disturb (silent) mode
- ✓ No e-mails, texting or tweeting during class

If you must take a phone call or answer a text please leave the room for as short a period as possible

Icebreaker

- Instructor Information:
 - Name
 - Background
- Student Introductions:
 - Name
 - Position / Responsibilities
 - What is your involvement in the new product development process?
 - What are your experiences with DFMEA?
 - What are your expectations of this course?
 - Please share something unique and/or interesting about yourself.



Chapter 1

Introduction to Failure Mode and Effects Analysis

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Chapter 1: Introduction to FMEA – What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe an FMEA
- Describe the benefits of an FMEA
- Describe the types of FMEAs
- Compare a System FMEA to a Design FMEA

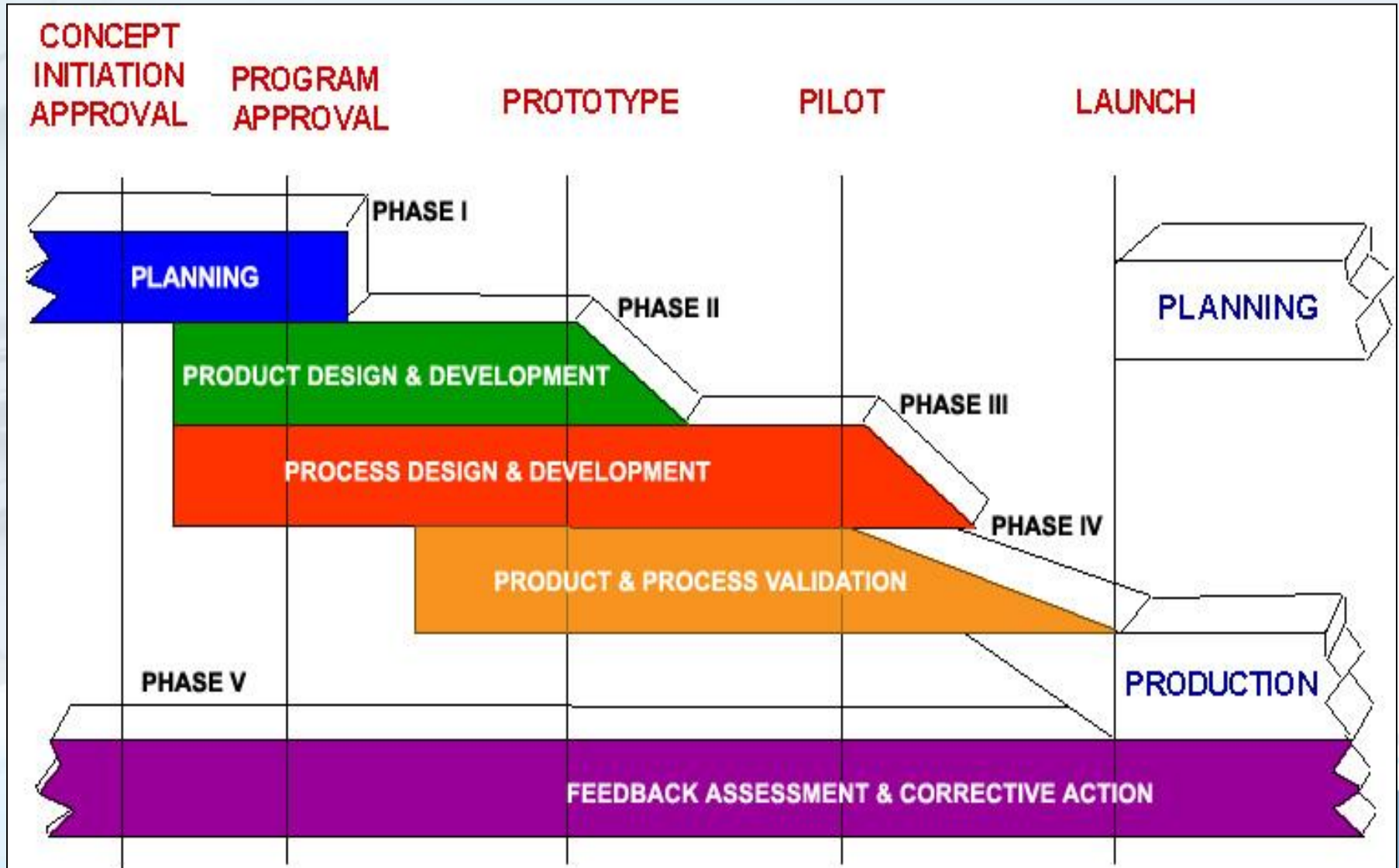
Chapter Agenda

- What is an FMEA?
- Maintaining FMEAs
- System vs Design FMEAs
- Types of FMEAs

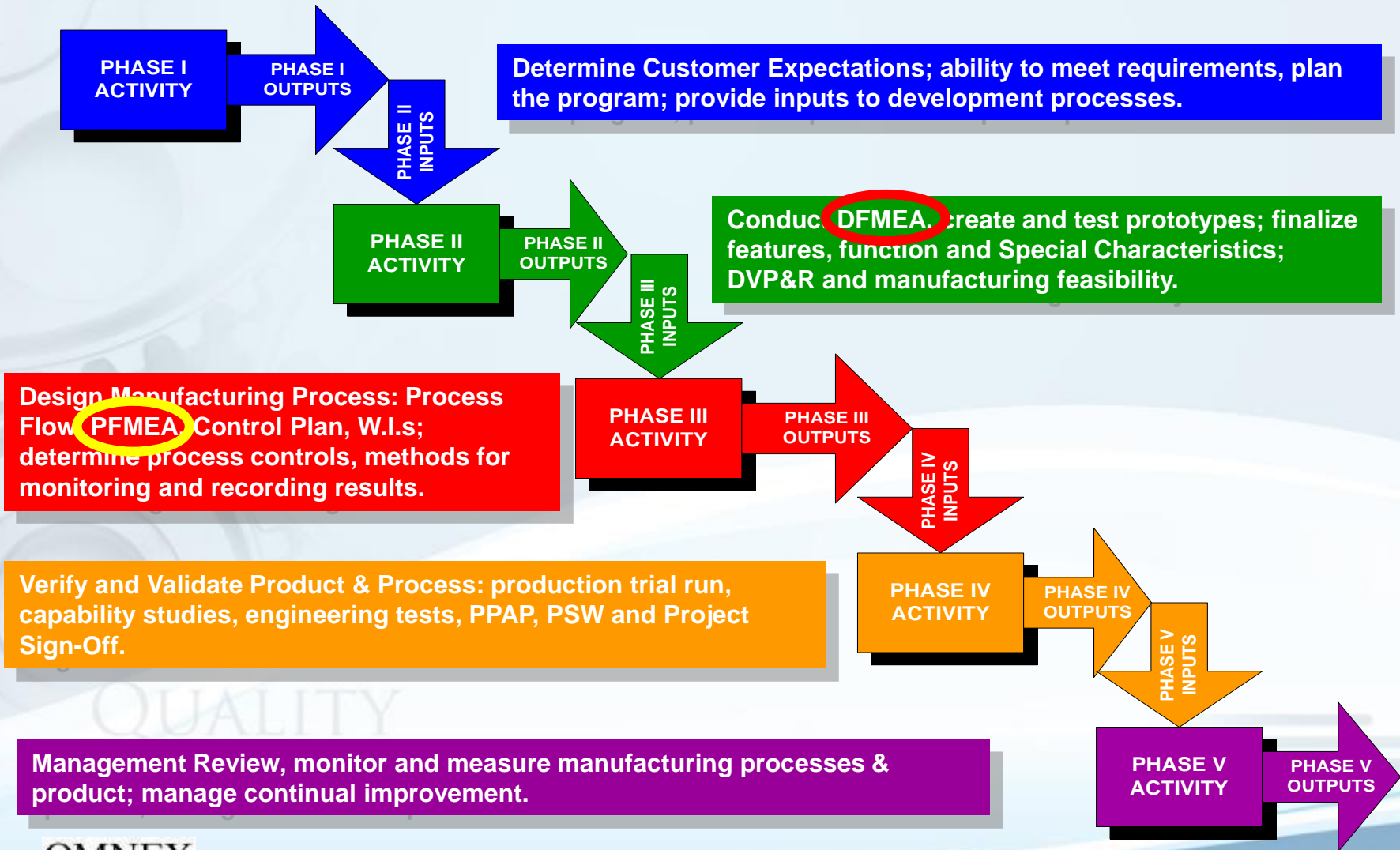
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Alignment of APQP Processes



FMEAs are Deliverables of APQP



FMEAs are also PPAP Requirements

Product Definition

- 1 Design Record
- 2 Engineering Change Documents
- 3 Customer Engineering Approval

PPAP Core Elements

- 4 **DFMEA**
- 5 Process Flow
- 6 **PFMEA**
- 7 Process Control Plan (Prototype)
- 8 Measurement Systems Analysis
- 9 Dimensional Results
- 10 Material Performance Tests

PPAP Core Elements

- 11 Initial Process Studies
- 12 Qualified Laboratory Documentation
- 13 Appearance Approval Report
- 14 Sample Production Parts
- 15 Master Sample
- 16 Checking Aids
- 17 Customer Specific Requirements
- 18 Part Submission Warrant

PPAP Approval

- 19 PPAP Review and Sign-Off

WHAT IS AN FMEA?

Purpose and Benefits



FMEA: Process Definition

- The FMEA process is a disciplined analytical process that allows the design team to anticipate potential failures and prevent their occurrence early in product design, and manufacturing process development.
- The FMEA is integrated into the work of the design and development teams (departments) and aimed at system optimization and risk mitigation.

**Risk Assessment and
Knowledge Management**

Why Perform FMEA?

- Prevention is the only effective way to achieve zero defect launch goals.
- S/D/P FMEA are used extensively in the automotive industry to effectively reduce defect levels:
 - Many automotive manufacturers are at <20 ppm
 - Automotive industry average is 0.23% defects
 - Aerospace industry average is 2% defects
- FMEA enables building an engineering knowledge base providing shorter lead times and fewer delays.
- FMEAs are integral in Problem Solving.

We Need a Paradigm Shift from Detection to Prevention

Considerations of the FMEA

When an FMEA is performed, the following norms are observed:

- **Clear:**
Potential failure modes are described in technically precise, specific terms; enabling a specialist to assess failure causes and possible effects.
Descriptions are free from possible misunderstanding. “Elastic” or emotionally laden terms (dangerous, intolerable, irresponsible, etc.) are not appropriate.
- **True:**
The consequences of potential failures are described accurately, even if they may sometimes be disagreeable (re-development, delivery backlog, etc.).
- **Realistic:**
Failure causes are reasonable. Extreme events are not considered.
- **Complete:**
Foreseeable potential failures are not concealed. Concern about revealing too much know-how by creating a correct and competent FMEA does not lead to restricted representations.

Purposes and Benefits of FMEA

- The FMEA process is a structured approach to...
 - Improve the quality, reliability, and safety of products, processes, and services.
 - Increase customer satisfaction.
 - Reduce development timing and cost.
 - Document and track actions taken to reduce risk.
 - Enable knowledge management.

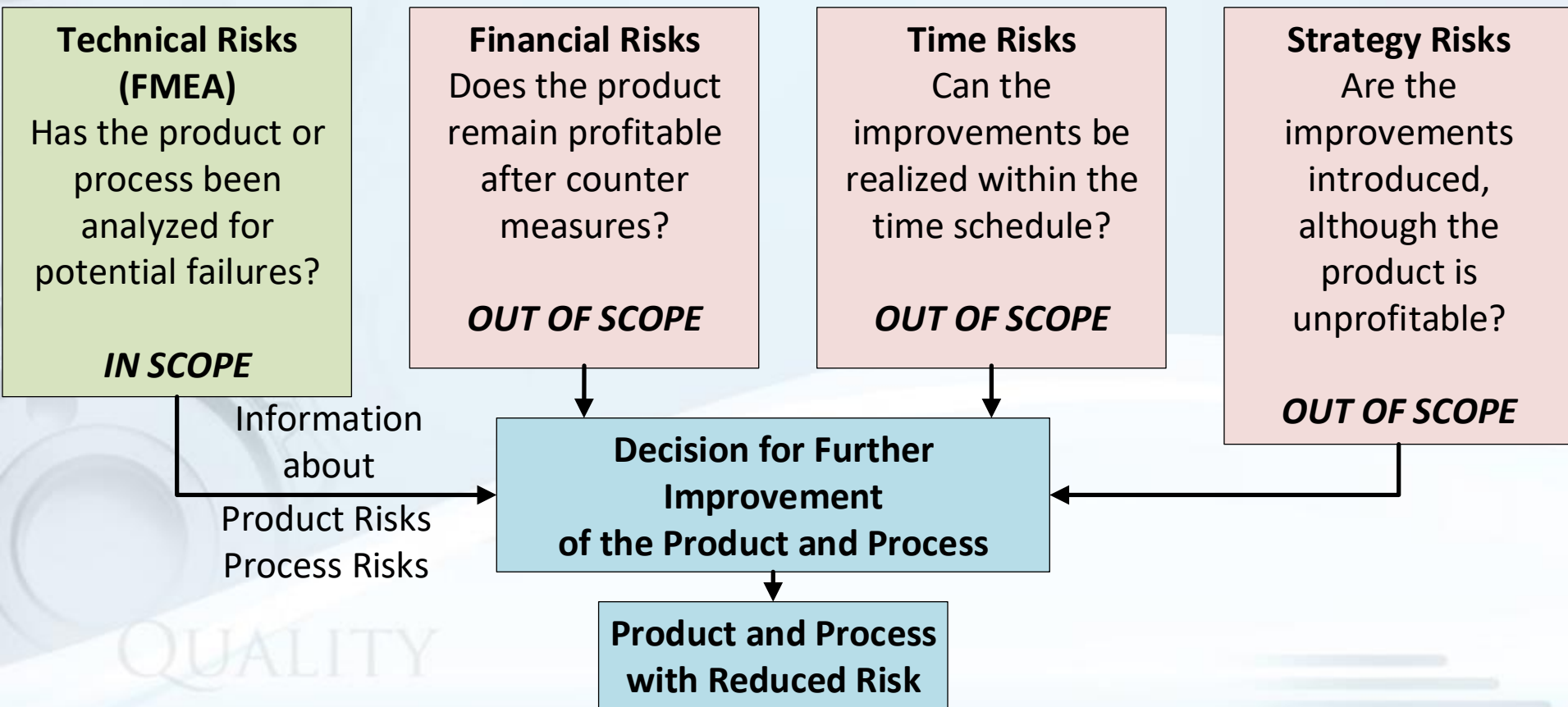
Concept

Identify ways the product or process can fail

Then plan to prevent those failures

Purposes and Benefits of FMEA

Feasibility / Risk Analysis

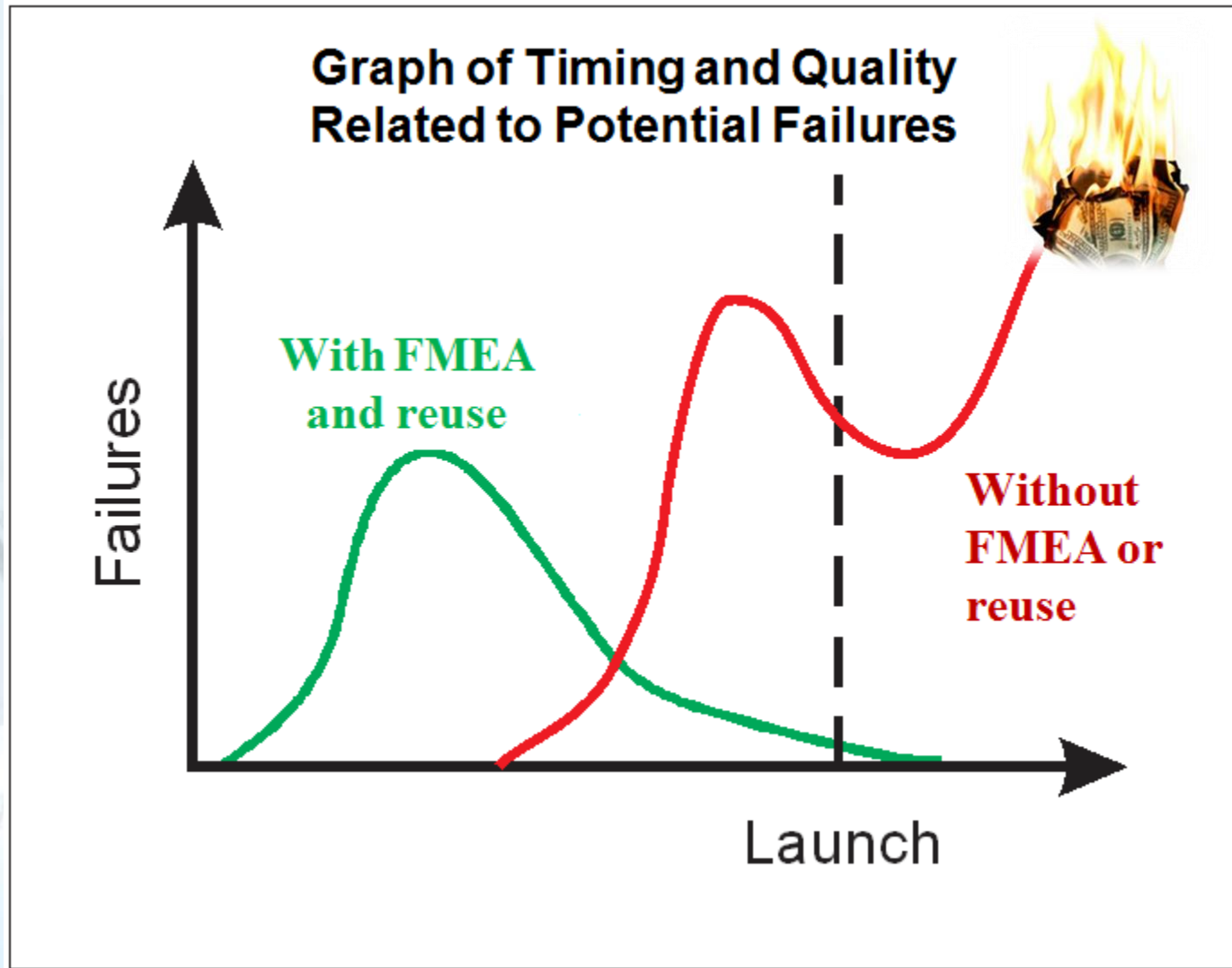


source: AIAG-VDA FMEA Handbook 1st Edition

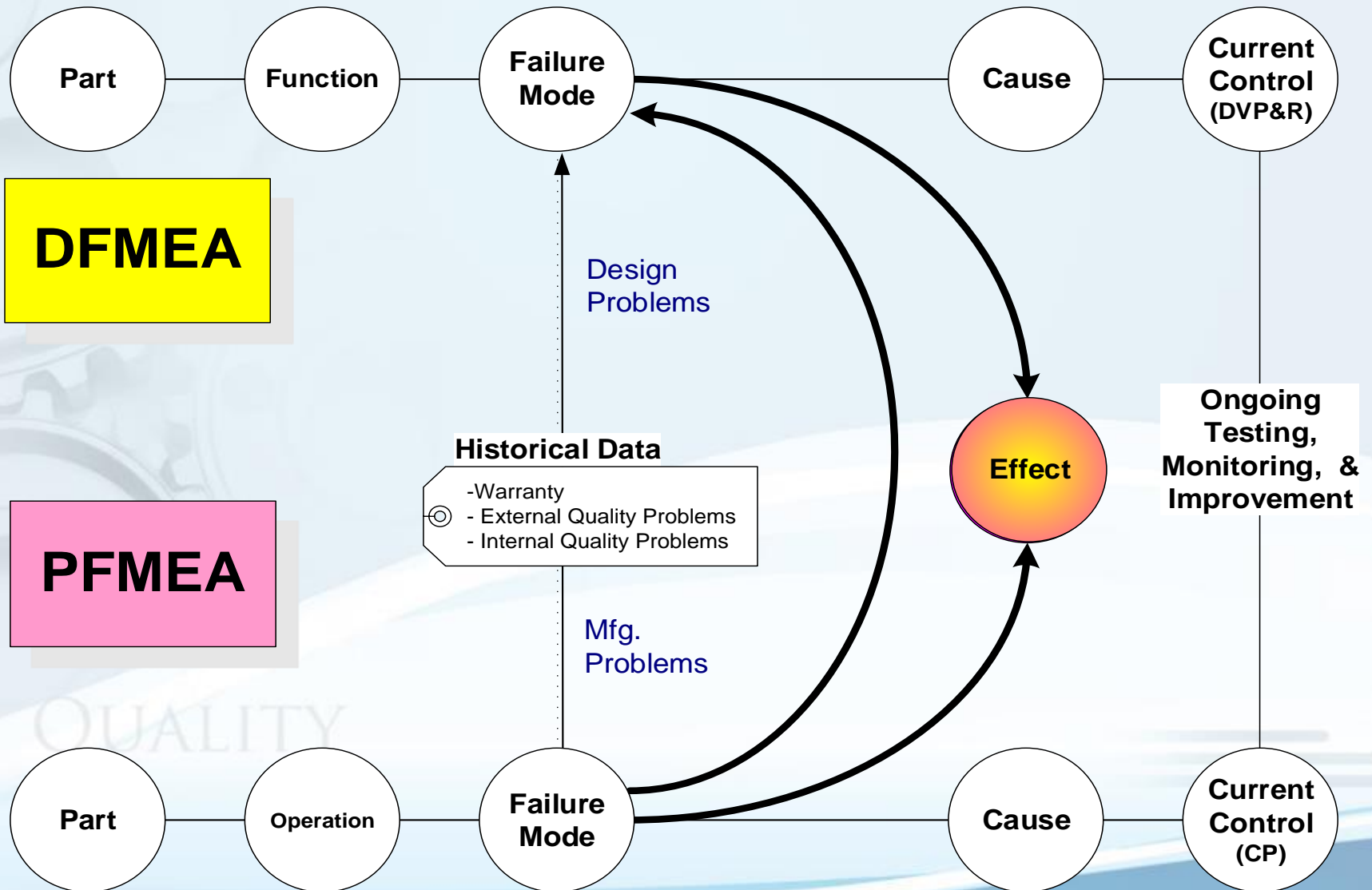
Risk Reduction and FMEA

- FMEA distinguishes between System, Subsystem, and Component design risk.
- Prevention is built into the FMEA format for S/DFMEA and PFMEA.
- FMEA links with controls and strives for better and earlier controls in design; e.g. DFMEA with DVP&R and PFMEA with Control Plans.
- Links PFMEA with Control Plans to shop floor controls.
- FMEA focus is on improvement actions to reduce risk.

FMEA Advantage



Design and Process FMEA Links



FMEA Relation to Other Standards

- FMEA is part of APQP
- PPAP requires many components of FMEA:
 - DFMEA (if design responsible)
 - PFD (Process Flow Diagram showing special characteristics)
 - PFMEA (Process FMEA)
 - Control Plan (Showing special characteristics)
 - Work Instructions (Special Characteristics)
- One of the tools for prevention of failures and continuous improvement highlighted in 8D Problem Solving
- ISO 26262 requires FMEA
- IATF 16949 requires FMEA
- ... and many others

MAINTAINING FMEAS

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Maintaining FMEAs

The FMEA documents living information and should be reviewed whenever there is a product design change, and should be updated as required.

- To have value, FMEA updates must occur at these change points:
 - New design or process is planned
 - Modification to a component, system or process is planned
 - Component or system is used in a new environment, location or application
 - **Important** – Update FMEA to capture continual improvement and problem solving analyses and results (like 8D Problem Solving)

Knowledge Management

TYPES OF FMEAS

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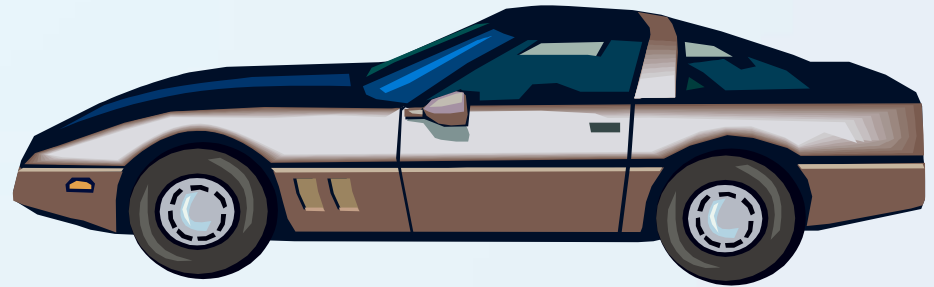
Primary Types of FMEAs

- **System FMEA:** Used to analyze systems and subsystems in the early concept and design stages.
 - Focuses on potential failure modes associated with the functions and interfaces of a system inherent in the design.
- **Design FMEA:** Used to analyze products before they are released to production.
 - Focuses on potential failure modes associated with the functions of a product inherent in the design.
 - NOTE: VDA uses the term **Product FMEA** instead of Design FMEA
- **Process FMEA:** Used to analyze processes before they are released for use in serial production.
 - Focuses on potential failure modes associated with the deliverables of a process due to design and operation.

SFMEA vs. DFMEA

A system is a complete “product”; e.g.

- At the top level system = Automobile



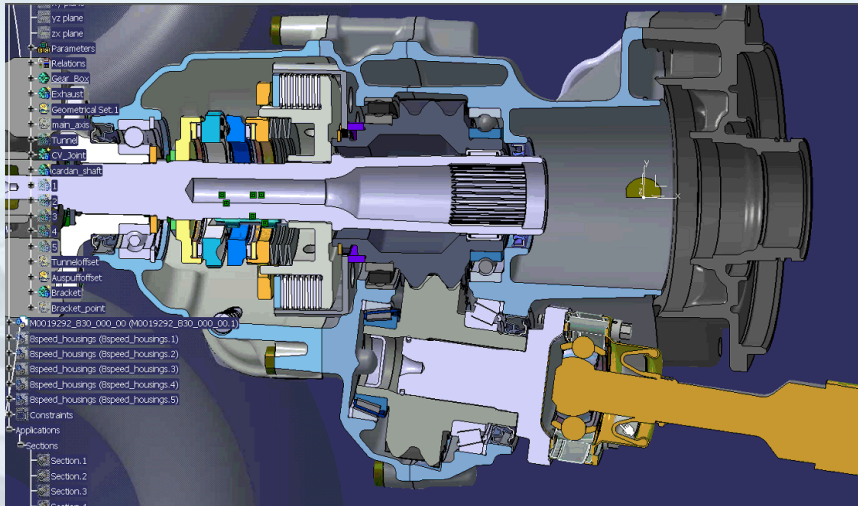
- At the WP (work product) level system = “System” or Structure



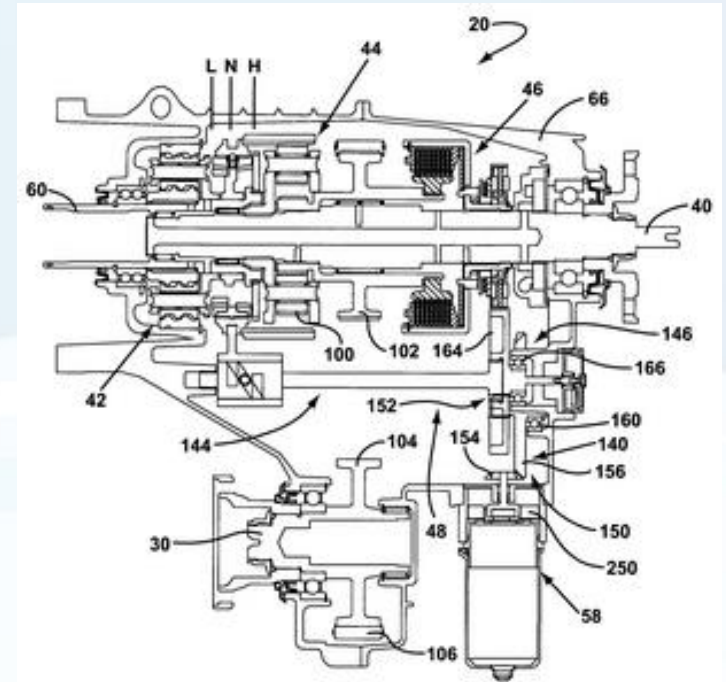
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SFMEA vs. DFMEA

An SFMEA includes the analysis of the interfaces **among** the related subsystems / components.



A DFMEA focuses on the analysis of the requirements and interfaces **within** a subsystem / component.



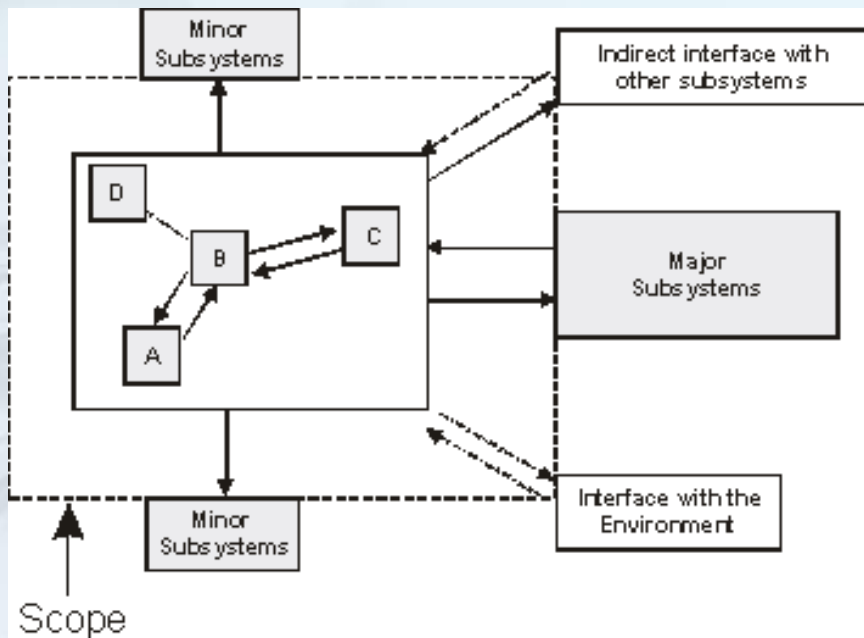
SFMEA vs. DFMEA

The process for a System FMEA is generally the same as the development of other FMEAs.

- **Major Differences:**

- The System Level FMEA focuses on functions and relationships that are unique to the system as a whole (i.e. do not exist at lower levels).
- The System level FMEA includes failure modes associated with *interfaces and interactions* in addition to considering single-point failures, which is the primary focus of Product Level FMEAs.
- The DFMEA is at the Item/Feature Level and is an effective design input tool; design output should have characteristics that address all the critical items or features.

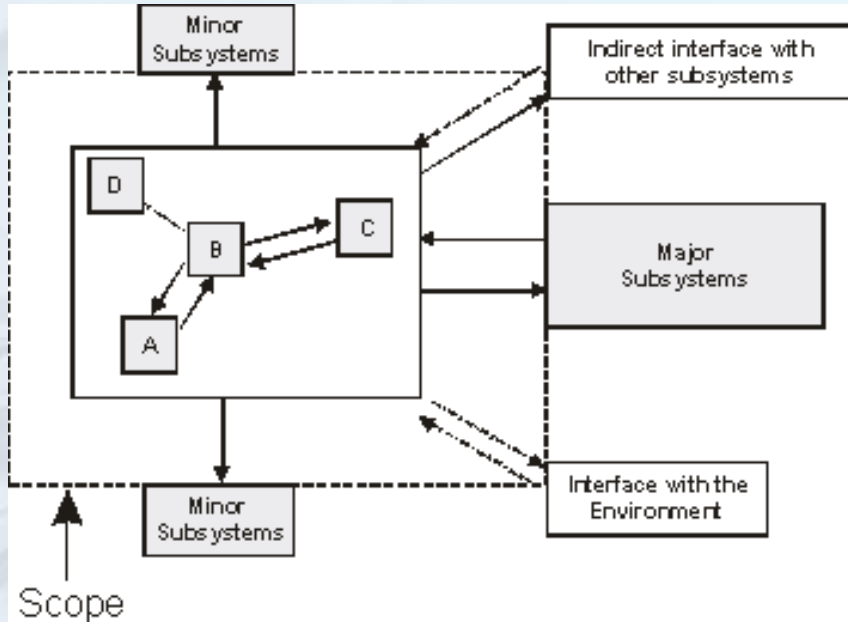
SFMEA vs. DFMEA



Interfaces

- Interfaces within the product are shown by solid and dashed lines.
- The Environment also touches each of the subsystems which requires the “**Environmental Interfaces**” to be considered when completing the FMEA.
- Also, the interfaces to major and minor subsystems, whether direct or indirect, should be included.
- The interfaces which are identified in the System FMEA should be included in the respective Subsystem DFMEA.

SFMEA vs. DFMEA



Interactions

- Interactions between subsystems and components can occur among any of the interfacing systems; i.e. a change in one subsystem or component may cause a change in another subsystem or component.

Example 1: Subsystem A heats up, resulting in Subsystem B and D gaining heat through their respective interfaces, as well as Subsystem A giving off heat to the environment.

Example 2: if the environment is composed of high humidity and Subsystems A and C are dissimilar metals separated by a non-metal composing Subsystem B, Subsystem A and C can still have an electrolytic reaction due to the moisture from the environment. Thus, interactions among non-contacting subsystems can be relatively difficult to predict but may be important.

Other Scopes of FMEAs

Design and Process FMEA may take on different names depending on the application

- **Process Design FMEA:** Used to improve process design; capability, efficiency, productivity, reliability.
- **Maintenance FMEA:** Used to improve maintenance process and Overall Equipment Effectiveness (OEE).
- **Machinery FMEA:** Used to improve the design of plan machines and equipment.
- **EHS FMEA:** Used to reduce risk of accident and injury experience to those operating the process, as well as reduce damage to the process, facilities and equipment.
- **Inspection Process FMEA:** Used to analyze and improve the inspection process.
- **Logistics / Shipping FMEA:** Used to improve the logistics / shipping process.

Chapter 1: Introduction to FMEA – What We Covered

Learning Objectives

You should now be able to:

- Describe an FMEA
- Describe the benefits of an FMEA
- Describe the types of FMEAs
- Compare a System FMEA to a Design FMEA
- Describe the different cases for when to use an FMEA

Chapter Agenda

- What is an FMEA?
- Maintaining FMEAs
- System vs Design FMEAs
- Types of FMEAs

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Chapter 2

Developing an FMEA

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Process Applicable to Any Type of FMEA



Chapter 2: Developing an FMEA – What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe the structure of an FMEA
- Describe the steps to conduct an FMEA

Chapter Agenda

- Conducting an FMEA
- Basic Structure of an FMEA

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CONDUCTING AN FMEA

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The intent is to provide a common foundation for FMEA across the sectors of the automotive industry represented by these organizations.

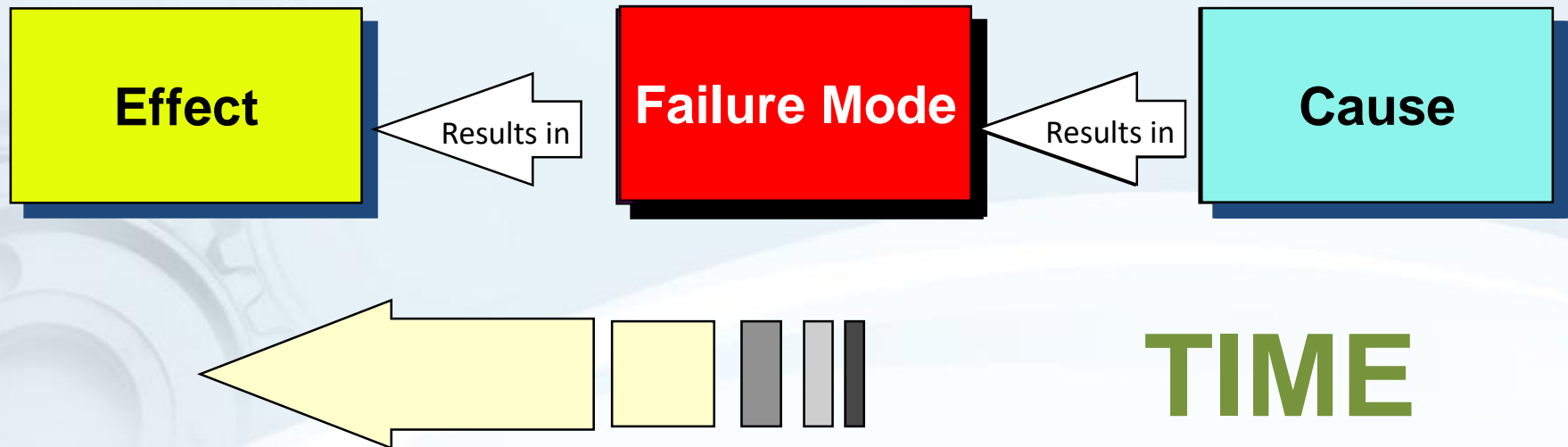
Not a “Blue Book”

- The VDA-AIAG Handbook is not part of the “Core Tools” set, but may be required by the major OEMs as per their CSRs.
- The core tools belong to GM-Ford-FCA....
the “Handbook” is co-owned by VDA and AIAG.



FMEA Model – AIAG-VDA FMEA Handbook

Linking Failure Mode to Cause and Effect



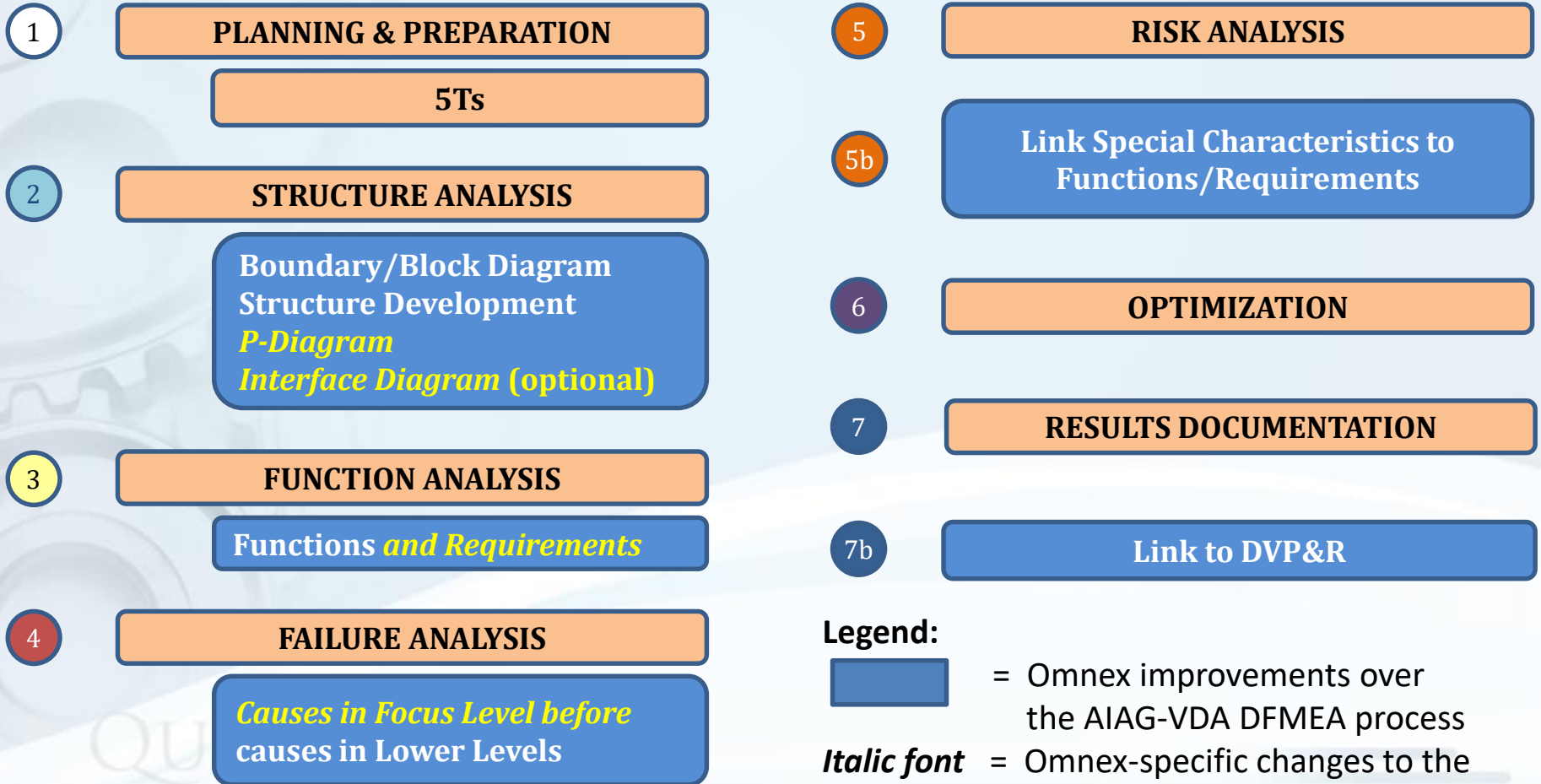
We must understand the risks involved in these linkages

Conducting an FMEA – General Approach

- Complete necessary prerequisites
 - Define the scope of the analysis
 - Identify and list all the requirements
- For each requirement
 - Identify potential failure modes
- For each failure mode
 - Assess potential effects of failures
 - Identify the cause(s)
- For each cause
 - Identify what control(s) are/will be in place to prevent or detect the cause or failure mode
 - Identify and implement continual improvement actions










Omnex 7-Step DFMEA Process



7-Step Process – AIAG-VDA FMEA Handbook

Seven Step Approach

System Analysis			Failure Analysis and Risk Mitigation			Risk Communication
1st Step Planning & Preparation	2nd Step Structure Analysis	3rd Step Function Analysis	4th Step Failure Analysis	5th Step Risk Analysis	6th Step Optimization	7th Step Results Documentation
						
Project identification	Visualization of the analysis scope	Visualization of product or process functions	Establishment of the failure chain	Assignment of existing and/or planned controls and rating of failures	Identification of the actions necessary to reduce risks	Communication of actions taken to reduce risks
Project plan: Intent, Timing, Team, Tasks, Tools (5T)	DFMEA: Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts PFMEA: Structure tree or equivalent: process flow diagram	DFMEA: Function tree/net, function matrix parameter diagram (P-diagram) PFMEA: Function tree/net or equivalent process flow diagram	DFMEA: Potential Failure Effects, Failure Modes, Failure Causes for each product function PFMEA: Potential Failure Effects, Failure Modes, Failure Causes for each process function	DFMEA & PFMEA: Assignment of Prevention Controls to the Failure Causes DFMEA & PFMEA: Assignment of Detection Controls to the Failure Causes and/or Failure Modes FMEA-MSR: Analysis of provisions for functional safety and regulatory compliance	Assignment of responsibilities and deadlines for action implementation	The layout of the document may be company specific. The content may include the following: • Executive summary • Scope of the FMEA • A reference to the specific S/O/D Rating Tables used in the analysis • Action Priority • Results and conclusions of the analysis
Analysis boundaries: What is included and excluded from the analysis	DFMEA: Identification of design interfaces, interactions, close clearances PFMEA: Identification of process steps and sub-steps	DFMEA: Cascade of customer (external and internal) functions with associated requirements DFMEA & PFMEA: Association of requirements or characteristics to functions	DFMEA: Identification of product failure causes using a parameter diagram or failure network PFMEA: Identification of process failure causes using a fishbone diagram (4M) or failure network	DFMEA & PFMEA: Rating of Severity, Occurrence and Detection for each failure chain FMEA-MSR: Rating of Severity, Frequency and Monitoring for each failure chain	Implementation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken	Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
Identification of baseline FMEA with lessons learned	Collaboration between customer and supplier engineer teams (interface responsibilities)	Collaboration between customer and supplier engineering teams (systems, safety, and components)	Collaboration between customer and supplier (Failure Effects)	Collaboration between customer and supplier (Severity)	Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures	The content of the documentation fulfills the requirements of the intended reader, and relevant stakeholders, and details may be agreed between the relevant parties.
Basis for the Structure Analysis step	Basis for the Function Analysis step	Basis for the Failure Analysis step	Basis for the documentation of failures in the FMEA form and the Risk Analysis step	Basis for the product or process Optimization step	Basis for refinement of the product and/or process requirements and prevention and detection controls	Record of risk analysis and reduction to acceptable levels.

Transition Strategy

- Existing FMEAs conducted with an earlier version of the FMEA handbook may remain in their original form for subsequent revisions.
- When practical, existing FMEAs used as a starting point for new programs should be converted to comply with the new format. However, if the team determines that the new program is considered a minor change to the existing product, they may decide to leave the FMEA in the existing format.
- New projects can follow the FMEA method presented in this guidebook **unless company procedure defines a different approach. The transition date and project milestone after which new projects follow this method should be defined by the company taking into consideration any customer specific requirements and standards.**

AIAG-VDA FMEA Handbook 1st Edition

Optimizing the FMEA Process

- Communicate effectively
- Utilize / build upon existing product information
 - Requires an acceptable DFMEA of the referenced product
 - Focus is on the “new” stuff in the product; i.e. differences and changes in the product requirements and use
 - Can utilize design and process segments
- Acquire and deploy needed information before meetings
 - Historical information on the same or surrogate products; this can impact effects, causes, occurrence, etc.

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FMEA STRUCTURE

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AIAG-VDA FMEA Handbook Form

This process requires the identification / analysis for at least three levels of product flow-down

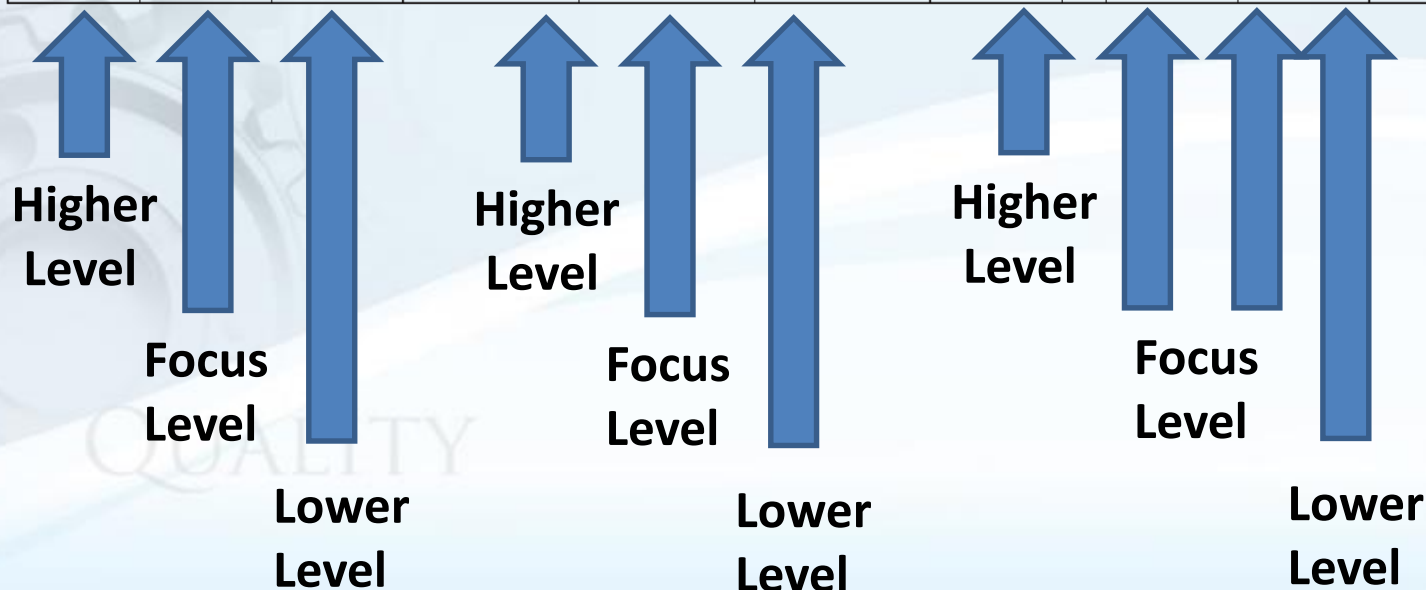
STRUCTURE ANALYSIS			FUNCTION ANALYSIS			FAILURE ANALYSIS			RISK ANALYSIS						
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic	1 Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Control (DC) of FC or FM	Detection (D) of FCFM	AP	Filter Code (Optional)

OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	AP

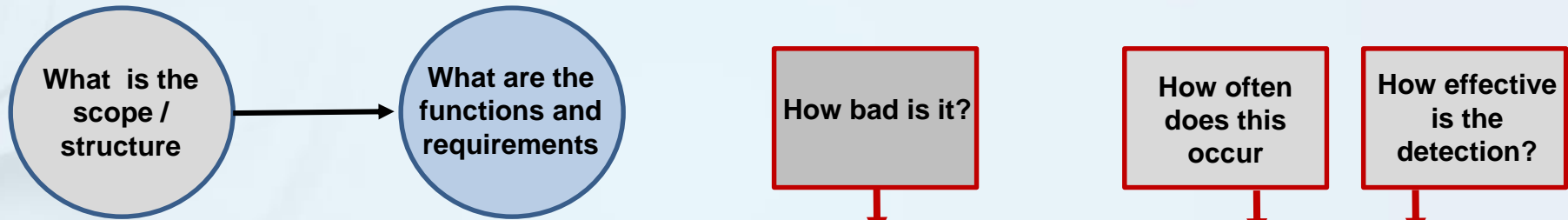
AIAG-VDA FMEA Handbook Form

This process requires the identification / analysis for at least three levels of product flow-down

STRUCTURE ANALYSIS			FUNCTION ANALYSIS			FAILURE ANALYSIS			RISK ANALYSIS						
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic	1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Control (DC) of FC or FM	Detection (D) of FCFM	AP	Filter Code (Optional)



Sequence – AIAG-VDA FMEA Handbook



STRUCTURE ANALYSIS			FUNCTION ANALYSIS			FAILURE ANALYSIS			RISK ANALYSIS						
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic	1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Control (DC) of FC or FM	Detection (D) of FC or FM	AP	Filter Code (Optional)

How does this impact the customers?

What can go wrong?

How can this be prevented?

What is the risk?

What are the causes?

How can this be detected?

OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	AP

How can this be improved?



7-Steps and the Form

1st Step

Planning and Preparation



DESIGN FAILURE AND EFFECTS ANALYSIS (DFMEA)

Company Name: _____	Subject: _____	DFMEA Number: _____
Engineering Division: _____	Product Unit: _____	Date of Birth: _____
Customer Name: _____	DFMEA Study Team: _____	Security Classification: _____
Internal Code / Revision: _____	Project Code: _____	Final Date: _____
File Name: _____		File Path: _____

System Analysis

2nd Step

Structure Analysis



3rd Step

Function Analysis



and Risk Mitigation

4th Step

Failure Analysis



5th Step

Risk Analysis



STRUCTURE ANALYSIS			FUNCTION ANALYSIS		
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic

6th Step Optimization



FAILURE ANALYSIS			RISK ANALYSIS			
1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Control (DC) of FC or FM
					Detection (D) of FCFM	AP
						Filter Code (Optional)

OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	AP

7th Step Results

Documentation



Layout of document may be company-specific



Chapter 2: Developing an FMEA – What We Covered

Learning Objectives

You should now be able to:

- Describe the structure of an FMEA
- Describe the steps to conduct an FMEA

Chapter Agenda

- Conducting an FMEA
- Basic Structure of an FMEA

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Chapter 3: Design FMEA Prerequisites – What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe who the customer is for FMEAs
- Explain design functions
- Complete a Function Analysis
- Describe Planning and Preparation
- Describe the scope of analysis
- Complete a Boundary Diagram
- Describe the purpose of a P-Diagram and Interface Matrix

Chapter Agenda

- Step 1: Planning and Preparation
 - Scope of Analysis
 - **Breakout Exercise 1**
- Step 2: Structure Analysis
 - Boundary Diagrams
 - **Breakout Exercise 2**
- Robust Designs
 - P-Diagram
 - Interface Matrix
- Step 3: Function Analysis – Product Design
 - **Breakout Exercise 3**

FMEA Prerequisites

“If I had six hours to cut down a tree, I would spend four hours sharpening the axe.”

– Abraham Lincoln



The Design is Your Friend




Get to Know it Well



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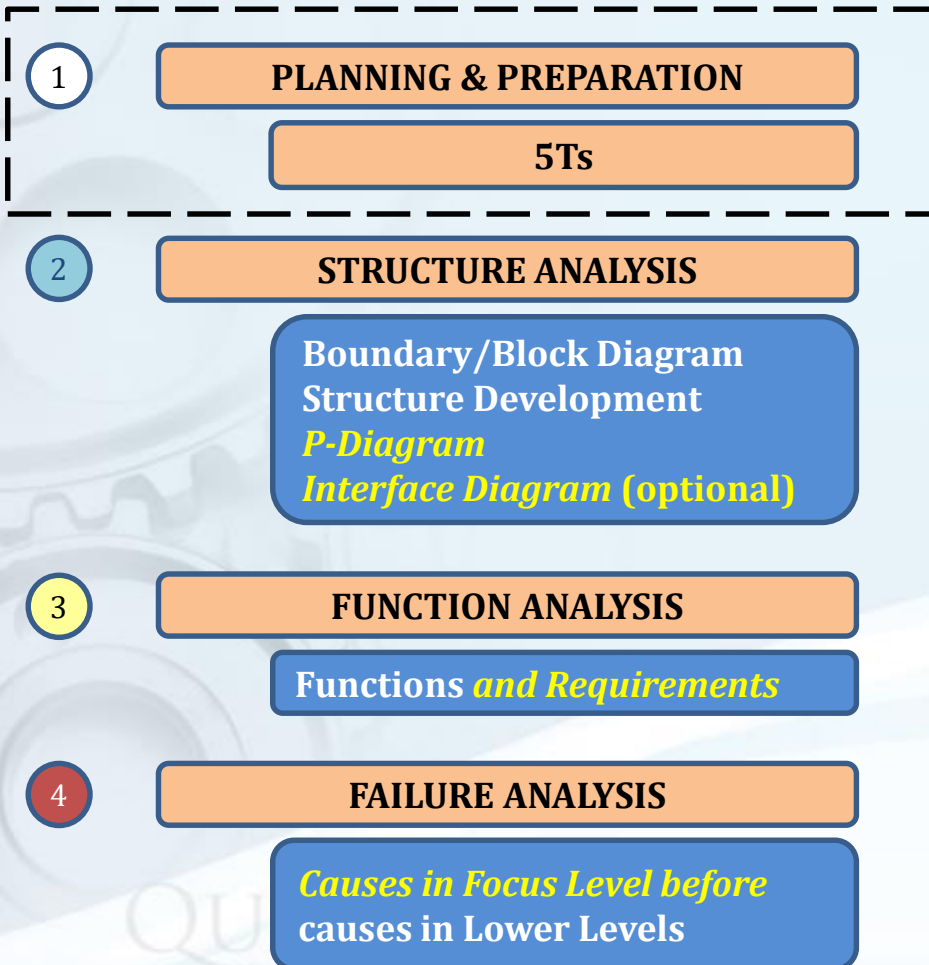


Steps 1-3 – AIAG-VDA FMEA Handbook

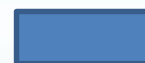
System Analysis (Prerequisites)		
1 st Step Planning & Preparation	2 nd Step Structure Analysis	3 rd Step Function Analysis
		
Project identification	Visualization of the Analysis Scope	Visualization of Product or Process Functions
Project Plan: InTent, Timing, Team, Tasks, Tools (5Ts)	Structure Tree or equivalent Process Flow Diagram	Function Tree/Net or equivalent Process Flow Diagram
Analysis boundaries: What is included and excluded from analysis	Identify structural relationships, interfaces and interactions among the levels	Identify functions and requirements at all levels
Identification of baseline FMEA with lessons learned	Collaboration between customer and supplier engineering teams (interface responsibilities)	Collaboration between engineering teams (systems, safety, and components)
Basis for the Structure Analysis step	Basis for the Function Analysis step	Basis for the Failure Analysis step



PROJECT PLANNING



Legend:



= Omnex improvements over the AIAG-VDA DFMEA process

Italic font

= Omnex-specific changes to the AIAG-VDA DFMEA process



Step 1: Project Planning and Preparation

The purpose of the Design FMEA Preparation Step is to define what is included and excluded in the FMEA based on the type of analysis being developed, i.e. system, subsystem or component.

The main objectives of Design FMEA Preparation are:

- Project identification and boundaries
- Project plan: InTent, Timing, Team, Tasks, Tools (5T)
- Analysis boundaries: What is included and excluded from the analysis
- Identification of baseline FMEA with lessons learned
- Basis for the Structure Analysis step





Step 1: Project Planning and Preparation

Project Identification and Boundaries

- As part of FMEA preparation, a clear understanding of what is to be evaluated is to be determined. What to exclude can be just as important as what to include in the analysis.
- The scope of analysis is established at the start of the project to assure consistent direction and focus.

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Step 1: Project Planning and Preparation

The following criteria which may be considered in defining the scope of a single FMEA include, but are not limited to:

- Novelty of Technology/ Degree of Innovation
- Quality / Reliability History (In-house, zero mileage, field failures, warranty and policy claims for similar products)
- Complexity of Design
- Safety of People and Systems
- Cyber-Physical System (including cyber-security)
- Legal Compliance
- Catalog and Standard Parts



Understanding the Scope of the Analysis

1st Step: Planning and Preparation

5Ts

- FMEA inTent
 - Why are we here?
- FMEA Team
 - Who needs to be on the team?
- FMEA Timing
 - When is this due?
- FMEA Task
 - What work needs to be done?
- FMEA Tool
 - How do we conduct the analysis?

Key Aspects:

- What to include and what to exclude in FMEA
- FMEA project plan including important dates, responsible persons, potential team members, timelines...
- Boundaries of the analysis



5Ts — 1. FMEA InTent

- It is recommended that members of the FMEA team are competent in the method, based on their role on the team.
- When members of the team understand the purpose and intent of the FMEA, they will be more prepared to contribute to the goals and objectives of the project.

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5Ts — 2. FMEA Timing

- One of the most important factors for the successful implementation of an FMEA program is timeliness.
- Up-front time spent properly completing an FMEA, when product/process changes can be most easily and inexpensively implemented, will minimize late change crises.
- The FMEA should be carried out according to the project plan (APQP) and be evaluated at the project milestones according to the state of the analysis.
- The FMEA as a method for system analysis and failure prevention is best initiated at an early stage of the product development process.



5Ts — 2. FMEA Timing

- It is used to evaluate the risks, valid at that time, in order to initiate actions to minimize them. In addition, the FMEA can support the compilation of requirements.
- The FMEA should be carried out according to the project plan and evaluated at the project milestones according to the state of the analysis.
- It is recommended that a company define desired maturity levels for their FMEAs according to overall company-specific development project milestones, etc.

NOTE: Exceptions to this FMEA timing include non-traditional development flows such as where development of a "standard" process precedes the development of products that will be manufactured using the process.



5Ts — 2. FMEA Timing

Senior Management Commitment to Timing:

- The FMEA workshop needs to start on time and should be part of the Design Timing Schedule.
- Companies have more success with FMEAs when allotted time is built into the schedule.
- Engineers need to have FMEA activities built into the schedule and have interest shown by senior management.
- Senior Management interest is shown by:
 - Regular FMEA gate reviews
 - Being educated in FMEA
 - Supporting FMEA education
 - Supplying any resources required



5Ts — 3. FMEA Team

- The FMEA team consists of multi-disciplinary (cross-functional) members who encompass the necessary subject matter knowledge.
- This should include facilitation expertise and knowledge of the FMEA process.
- The success of the FMEA depends on active participation of the cross-functional team as necessary to focus on the topics of discussion.

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THE FMEA TEAM

Purpose and Benefits

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Team Approach

- Conducting an FMEA is a “*creative*” process involving a cross-functional team.
- A large portion of the benefit of the FMEA process comes from the increase in knowledge generated by team discussions and related activities.

This, in itself, is sufficient justification for using the FMEA process.

FMEA 4th Edition

Without a team, very little analysis is likely to occur and the associated risks may be either underestimated or missed entirely



The FMEA Team

- Why?
 - Shared experience
 - Shared level of understanding
 - Capture knowledge base
 - Assist in problem solving
 - Consensus decision-making



Without a team, very little analysis is likely to occur and the associated risks may be either underestimated or missed entirely



FMEA Team

The Core Team may consist of the following people:

- Facilitator
- Design Engineer
- System Engineer
- Component Engineers
- Test Engineer
- Quality/Reliability Engineer
- Others responsible for the development of the product

The Extended Team may consist of others that may have specialized knowledge that will help the core team analyze specific aspects of the product.



Roles on the FMEA Team

- **Team Leader**
 - Typically the responsible engineer
- **Facilitator / Moderator**
 - Is an FMEA process expert
 - Skilled in the FMEA methodology and facilitation methods
 - Not a requirement for every team
 - May not need a full-time facilitator
 - Applicable for novice teams
- **Team Members**
 - Core Team
 - Expanded Team
- **Scribe or Recorder**
 - Skilled in the use of the appropriate software
 - Role should be rotated, if possible



FMEA Meetings

- Acquire and deploy needed information before the meeting
- Book meetings in advance
- Prepare an agenda with objectives
- Assign roles
- Communicate effectively
- Define, assign and track tasks





Keys to FMEA Team Success

Support by Management

- Ensure competency of team members
- Team sized for the task
- Scope not too large
- Objectives well-defined
- Follow a well-defined process
- Objectives considered relevant and significant
- A measurable for success identified
- Time is allotted for analysis and improvement
- Activity integrated with organization's development process
- Input information and data are available





Management Responsibility

“Ultimately, management has the responsibility and ownership for development and maintenance of the FMEAs”

FMEA 4th Edition

“Management carries the responsibility for the application of FMEA. Ultimately, management is responsible for acceptance of the risks and risk minimization actions identified in the FMEA”

AIAG-VDA FMEA Handbook 1st Edition



Senior Management Commitment

The FMEA process can take considerable time to complete! Important to FMEA development are the active participation of the product and process owners and commitment from senior management. Senior Management carries the responsibility for the application of FMEA:

- Ultimately, senior management is responsible for acceptance of the risks and risk minimization actions identified in the FMEA.
- Senior management needs to make FMEAs a critical topic during Design Reviews.
- Senior management needs to take an active interest in the results of an FMEA and support the mitigation of the risk, whatever time and resources are required
- Senior management is responsible for the “FMEA” culture in the company.



Senior Management Commitment

- Senior Management interest is shown by:
 - Regular FMEA reviews
 - Being educated in FMEA
 - Supporting FMEA education
 - Supplying any resources required
- Companies have more success with FMEAs when allotted time is built into the schedule.
- Engineers need to have built FMEA activities into the schedule and have interest shown by senior management.

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5Ts — 4. FMEA Tasks

- The 7-Step Overview provides the framework for the tasks and deliverables of the FMEA. In addition, the FMEA team should be prepared to review the results of their analysis with management and the customer, upon request.
- The FMEA may also be audited by an internal auditor, customer auditor, or third-party registrar to ensure each task has been fulfilled.

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5Ts — 4. FMEA Tasks

System Analysis			Seven Step Approach			Risk Communication
1st Step Planning & Preparation	2nd Step Structure Analysis	3rd Step Function Analysis	4th Step Failure Analysis	5th Step Risk Analysis	6th Step Optimization	7th Step Results Documentation
Project identification	Visualization of the analysis scope	Visualization of product or process functions	Establishment of the failure chain	Assignment of existing and/or planned controls and rating of failures	Identification of the actions necessary to reduce risks	Communication of actions taken to reduce risks
Project plan: Intent, Timing, Team, Tasks, Tools (5T)	DFMEA: Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts PFMEA: Structure tree or equivalent: process flow diagram	DFMEA: Function tree/net, function matrix parameter diagram (P-diagram) PFMEA: Function tree/net or equivalent process flow diagram	DFMEA: Potential Failure Effects, Failure Modes, Failure Causes for each product function PFMEA: Potential Failure Effects, Failure Modes, Failure Causes for each process function	DFMEA & PFMEA: Assignment of Prevention Controls to the Failure Causes DFMEA & PFMEA: Assignment of Detection Controls to the Failure Causes and/or Failure Modes FMEA-MSR: Analysis of provisions for functional safety and regulatory compliance	Assignment of responsibilities and deadlines for action implementation	The layout of the document may be company specific. The content may include the following: <ul style="list-style-type: none"> • Executive summary • Scope of the FMEA • A reference to the specific S/O/D Rating Tables used in the analysis • Action Priority • Results and conclusions of the analysis
Analysis boundaries: What is included and excluded from the analysis	DFMEA: Identification of design interfaces, interactions, close clearances PFMEA: Identification of process steps and sub-steps	DFMEA: Cascade of customer (external and internal) functions with associated requirements DFMEA & PFMEA: Association of requirements or characteristics to functions	DFMEA: Identification of product failure causes using a parameter diagram or failure network PFMEA: Identification of process failure causes using a fishbone diagram (4M) or failure network	DFMEA & PFMEA: Rating of Severity, Occurrence and Detection for each failure chain FMEA-MSR: Rating of Severity, Frequency and Monitoring for each failure chain	Implementation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken	Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
Identification of baseline FMEA with lessons learned	Collaboration between customer and supplier engineer teams (interface responsibilities)	Collaboration between customer and supplier engineering teams (systems, safety, and components)	Collaboration between customer and supplier (Failure Effects)	Collaboration between customer and supplier (Severity)	Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures	The content of the documentation fulfills the requirements of the intended reader, and relevant stakeholders, and details may be agreed between the relevant parties.
Basis for the Structure Analysis step	Basis for the Function Analysis step	Basis for the Failure Analysis step	Basis for the documentation of failures in the FMEA form and the Risk Analysis step	Basis for the product or process Optimization step	Basis for refinement of the product and/or process requirements and prevention and detection controls	Record of risk analysis and reduction to acceptable levels.



5Ts — 5. FMEA Tools

- There are numerous FMEA software packages that can be used to develop a DFMEA and PFMEA as well as follow up on actions.
- This software ranges from dedicated FMEA software to standard spreadsheets customized to develop the FMEA.
- Companies may develop their own in-house database solution or purchase commercial software.

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5Ts — 5. FMEA Tools

- In any case, the FMEA team needs to have knowledge of how to use the FMEA software selected for their project as required by the company.
- There are two views of FMEA examples shown in the manual.
- The Software View depicts what the user sees when developing a FMEA using specialized software that utilized e.g. system element structure, function net, failure net, etc.
- The Form (or Matrix) View depicts what the user sees when developing a FMEA in a spreadsheet.

Note: The development of the steps will be shown using the “Form” (manual) approach with Excel and the software approach using the web-based software from OnmexSystems EwQIMS.



Project Plan

The Project Plan is the output from the 5T process.

- The DFMEA Project Plan (subset of the APQP Plan) should be developed once the DFMEA project is known.
- The DFMEA activities (The 7-Step Process) should be incorporated into the plan.

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Identification of the Baseline or Foundation FMEA



Part of the preparation for conducting the DFMEA is knowing what information is already available.

- This includes the use of a baseline (foundation) DFMEA or product family DFMEA which allows for variances based on different customers buying similar product or systems.
- Like brake systems, in general they basically are the same, but have variances based on the customer.

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Identification of the Baseline or Foundation FMEA



A Family DFMEA is a specialized foundation design FMEA for products:

- Common Boundaries
- Related Functions
- A “New Product” in the family, the new specific components and functions would be added to the family

Note: This requires a subject matter expert design engineer to decide if the variance is unique or may drive a change to fundamental system.

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DFMEA HEADER INFORMATION

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Header Information

During Scope Definition, the header of the DFMEA document should be completed. The header includes some of the basic DFMEA scope information, as follows →

- The FMEA header should clearly identify the focus of the FMEA as well as information related to the document development and control process.
- This may include an FMEA number, identification of the scope, design responsibility, completion dates, etc.
- Needs to be consistent with the other Design and Process documentation information.



Header Information

- **Company Name:** Name of company of the DFMEA
- **Engineering Location:** Geographical Location
- **Customer Name:** Name of customer(s) for this document and System / Subsystem / Component / Part
- **Model Year / Platform:** Starting vehicle model year and/or vehicle program as applicable
- **Subject:** Name of DFMEA project
- **DFMEA Start Date:** The date the team initiates the DFMEA
- **DFMEA Revision Date:** The revision of the specific unique DFMEA document (latest date it was changed)
- **Cross-Functional Team:** DFMEA development team members
- **DFMEA ID Number:** A unique identification number for the DFMEA document
- **Design Responsibility:** Name of person who is responsible for the design; this person also accepts ownership of the content and findings of the DFMEA
- **Confidentiality Level:** The level of confidentiality determined by the DFMEA owner, e.g. Internal Business Use, Proprietary, Confidential



AIAG VDA

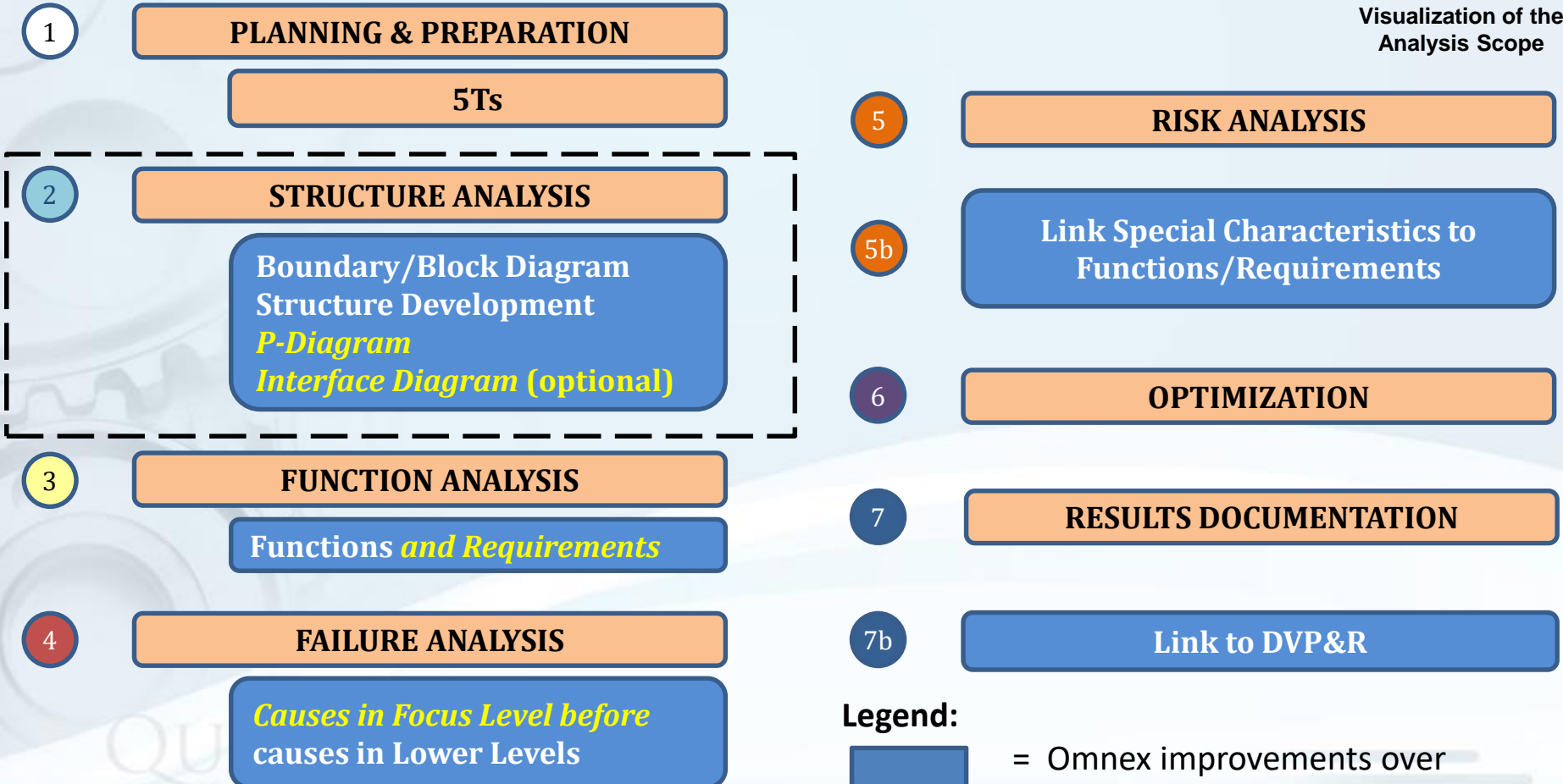
Interactive Example using EwQIMS Software

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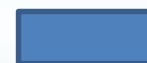


Visualization of the
Analysis Scope

STRUCTURE ANALYSIS



Legend:



= Omnex improvements over
the AIAG-VDA DFMEA process

Italic font

= Omnex-specific changes to the
AIAG-VDA DFMEA process



Step 2: Structure Analysis

Boundary or Extent of the DFMEA

Defines what is included and excluded from the analysis

Need to know:

- What is included
- What is not included
 - That is, what is the scope of the analysis?
 - Component
 - Assembly
 - Subsystem
 - System
- Common Tools Used
 - Boundary (Block) Diagram
 - Step 2 Activities
 - Structural (Tree) Analysis
 - Interface Matrix
 - Parameter (P) Diagram

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BOUNDARY DIAGRAMS

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Boundary Diagram

Graphical illustration of the relationships between the subsystems, assemblies, subassemblies, and components within the object as well as the interfaces with the neighboring systems and environments.

- Early in the design program, a Boundary Diagram may be no more than a few blocks representing major functions and their interrelationships at the system level.
- As the design matures, Boundary Diagrams may be revised, or additional ones developed to illustrate lower levels of detail – all the way down to the component level.

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Boundary Diagram

The Boundary or Block Diagram indicates the flow of information, energy, force, fluid, etc. within the scope of the design.

- The objective is to understand the deliverables (input) to the block, the process (function) performed in the block, and the deliverables (output) from the block.
- The Block Diagram of the product shows the physical and logical relationships between the components of the product.
- There are different approaches / formats to the construction of a Block Diagram.

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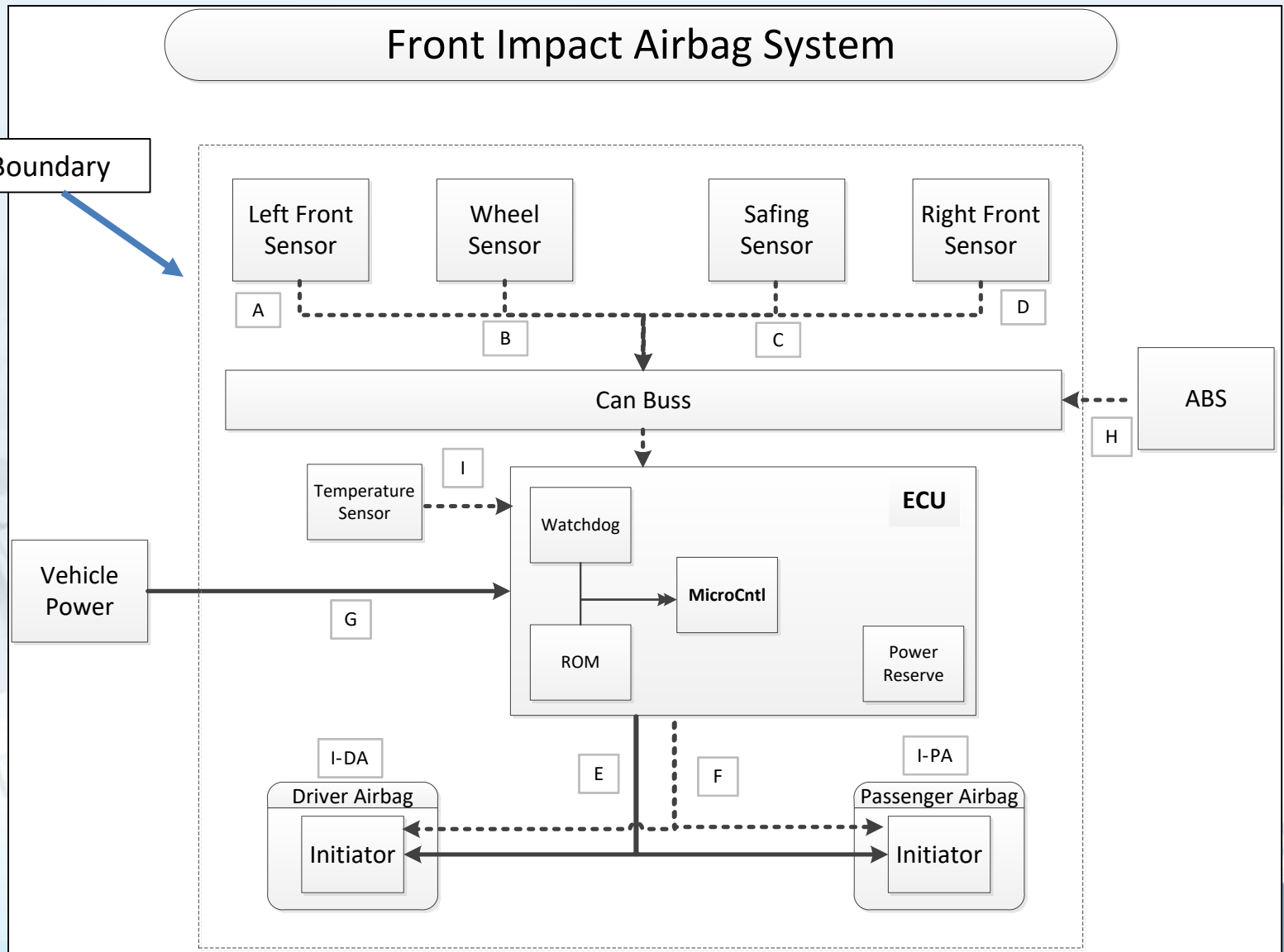
Boundary Diagram – Airbag

An airbag is a vehicle safety device. It is an occupant restraint consisting of a flexible envelope designed to inflate rapidly in an automobile frontal collision in excess of 14 mph (solid barrier) to prevent vehicle occupants (driver and front passenger) from striking interior objects such as the steering wheel, dashboard or window.

- The design is conceptually simple; a central "**Airbag Control Unit**" (ACU) (a specific type of ECU) monitors an impact sensor.
- When the requisite 'threshold' has been reached or exceeded by the collision detecting sensor, the Airbag Control Unit will trigger the ignition of a gas generator propellant to rapidly inflate a nylon fabric bag.



Boundary Diagram – Airbag System





Item Boundaries

Reference	Name	Type	In Scope of item?	Relationship to the item
<i><ID referring to the boundary diagram></i>	<i><name></i>	<i><ECU Bus Sensor Actuator></i>	<i>YES/NO</i>	<i><describe the relationship to the item></i>
FS	front sensor	Sensor	yes	senses front collision
ECU	control unit	ECU	yes	control unit
I-DA	initiator - driver airbag	Actuator	yes	provides sufficient volume of gas to deploy airbag
I-PA	initiator - passenger airbag	Actuator	yes	provides sufficient volume of gas to deploy airbag
VS	Vehicle speed	Sensor	no	provides speed information to the system
VP	vehicle power	Power Source	no	Provides vehicle power to the system

Breakout Exercise 1

Boundary Diagram

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Breakout Exercise 1: Boundary Diagram

Instructions

- Read the scenario for the **Wheelchair Brake Assembly**
- Develop a Boundary Diagram.

Identify Key Interfaces:

- _____ to _____
- _____ to _____
- _____ to _____
- _____ to _____

- Prepare to present and review as a class.

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Boundary Diagram



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AIAG VDA

Interactive Example using EwQIMS Software

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Appreciation of a System

Dr. W. Edwards Deming includes Appreciation of a System within his System of Profound Knowledge

- Synthesis – Explains the reason for the system and how the *system* works.
 - Take the thing you want to understand as part of a larger whole.
 - Explain the behavior of the containing whole.
 - Disaggregate the understanding of the containing whole into the role or function of the parts.
- Understanding of a system never lies inside the system; it always lies outside the system.
 - To manage a system effectively, focus on the interactions.
 - Improve the performance of a part only if it improves the performance of the whole.



Step 2: Structure Analysis

Information gathered in the Planning step is transferred to visualize the relationships and interactions between the design or process elements.



- **Goal of Structure Analysis**

- An overview of the system structure of the product
- Definition of the system boundaries/interface description
- Allows for the reuse of system elements

Note: the AIAG-VDA requires at least 3 levels in the structure:

Higher Level > Focus Level > Lower Level

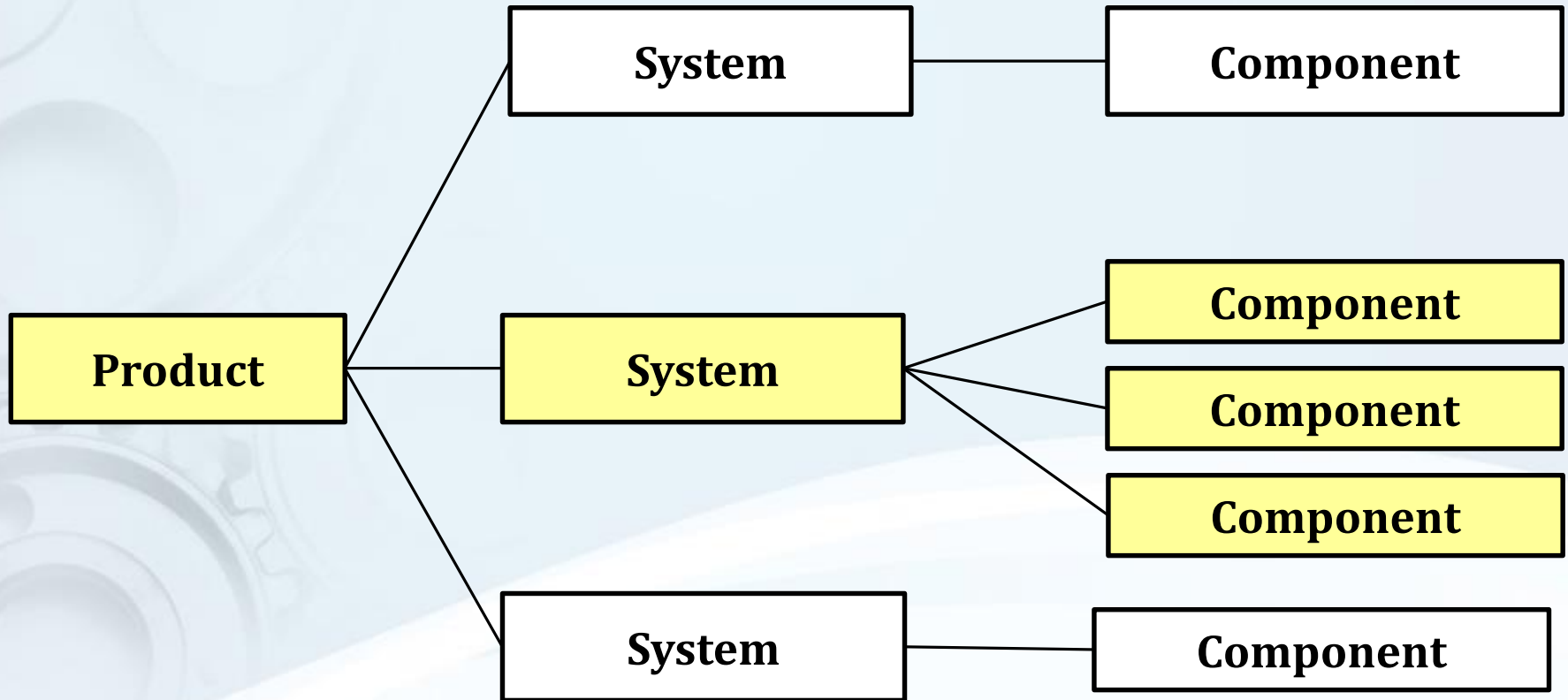


Structure Analysis: Structure Trees

The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections.

- A clearly structured illustration of the complete system is guaranteed to prevent redundancy by the fact that each system element exists only once.
- The interactions between System Elements may be described later as functions and represented by function nets (see Step 3 Function Analysis).
- There **IS** always a system element present, even if it **IS** only derived from the function and cannot yet be specified more clearly.

Structure Analysis: System Structure





Structure Analysis: System Structure in Excel

The system structure can be created in the Structure Analysis section of the Spreadsheet:

DESIGN FAILURE AND EFFECTS ANALYSIS (DFMEA)				
Company Name: _____		Subject: _____		
Engineering Location: _____		DFMEA Start Date: _____		
Customer Name: _____		DFMEA Revision Date: _____		
Model / Year / Part/Item: _____		RMEA Due Date: _____		
FMEA Team: _____				
STRUCTURE ANALYSIS			FUNCTION ANALYSIS	
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output

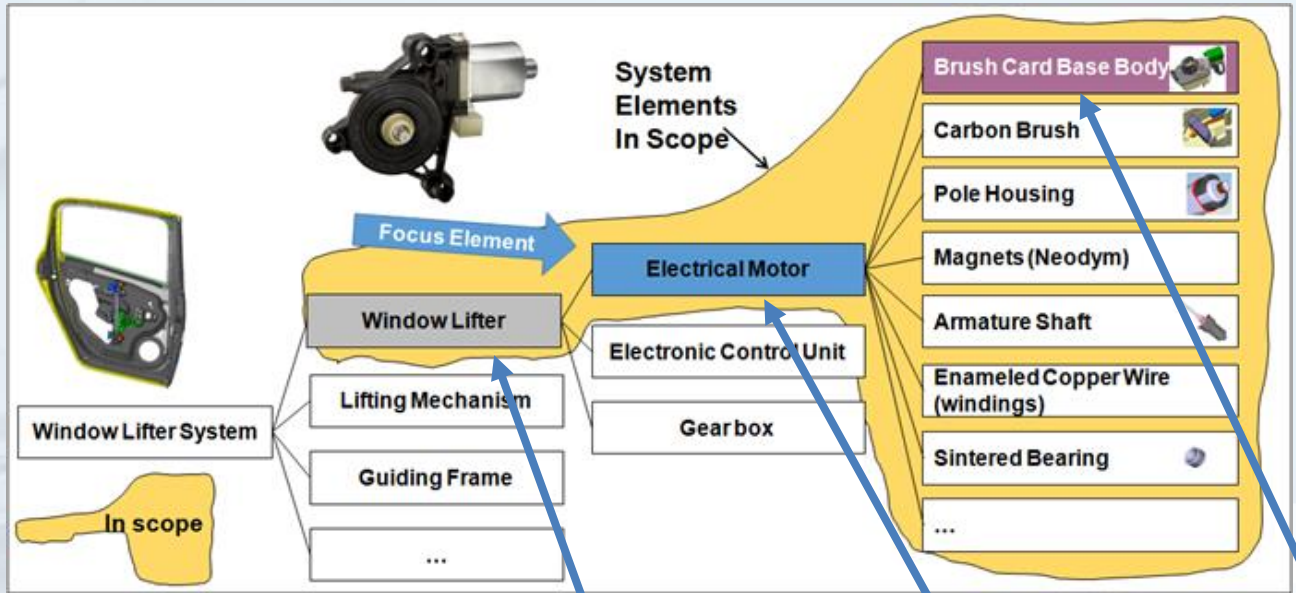
STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type [Geometry, Material, Surface Finish, Coating, etc.]

OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status [Unouched, Under Construction, In Progress, Completed, (Scrapped)]	Action Taken with Reference to Evidence	Completion Date	Severity (S1)	Occurrence # (O2)	Detection (D3)	AP

The term characteristic “type” is used because the design FMEA is a design “input” and the focus is on features; i.e. you do not have the characteristics yet!



Example of Structure



Software Version

Form or Matrix Version

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lifter	Electrical Motor	Brush Card Base Body
		Carbon Brush
		Pole Housing
		Etc.

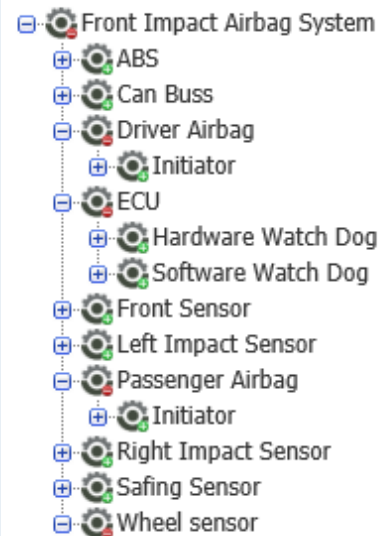


Structure Analysis – Guidance Rules



- System elements are arranged hierarchically in a system structure.
- The level of detail is obtained from its position in the supply chain.
- System elements that are “integrated” (without design responsibility), are treated as “Black-Box Systems” – for example Sealed Roller Bearings.
- Each system element is presented on only once in the analysis.

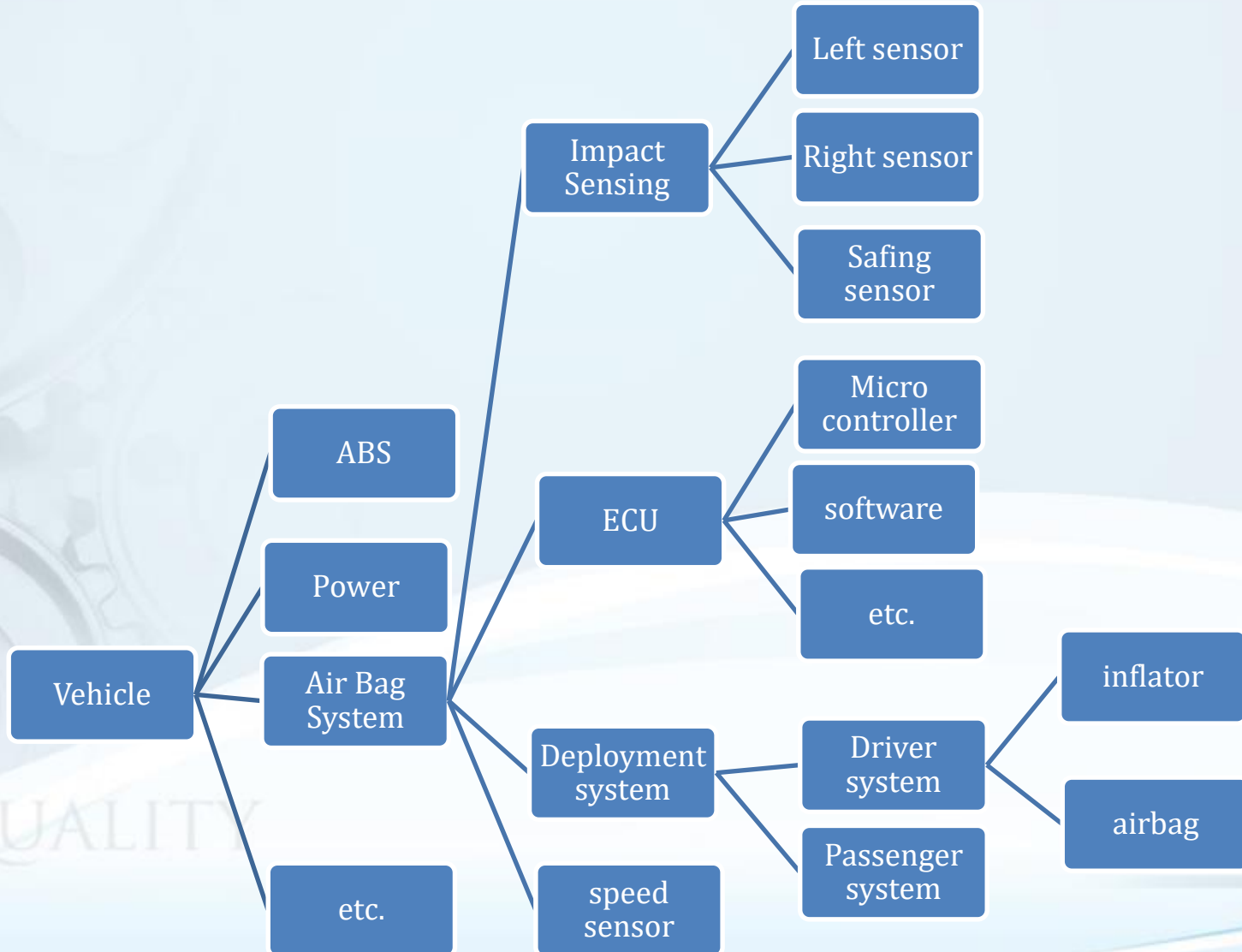
Bill Of Material



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System Structure



Breakout Exercise 2

Structure Analysis

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Breakout Exercise 2 – Structure Analysis



Instructions

- Using the previous example, develop a System Structure.
 - Develop a structure tree with at least three levels with the Focus Level being the Brake Assembly
 - Apply to Form
- Prepare to present and review as a class.

The system structure described by the Structure Elements provides the basis so that each Structure Element can be analyzed as differentiated as necessary with regard to its functions and failures in the system.

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Breakout Exercise 2 – Structure Analysis



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ROBUST DESIGNS

P-Diagram, Interface Diagrams

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Robust Designs

- How *could* the product/service be affected by...
 - Other systems (at the same level)?
 - The producing processes?
 - The customer use of the product?
- Tools
 - Subject Matter Expertise
 - Parameter Diagram → P-Diagram
 - Robustness Checklist (RCL)
 - Robustness Demonstration Matrix (RDM)
 - Interface Matrix
 - Quality Function Deployment (QFD) Matrix



Parameter (P) – Diagram

- A structured tool to help the team understand the physics related to the function(s) of the design.
 - The team analyzes the intended inputs (**Signals**) and outputs (**Functions**) for the design as well as those controlled and uncontrolled factors which can impact performance.
- Once the inputs and outputs are identified, error states, noise factors, and control factors are then established.

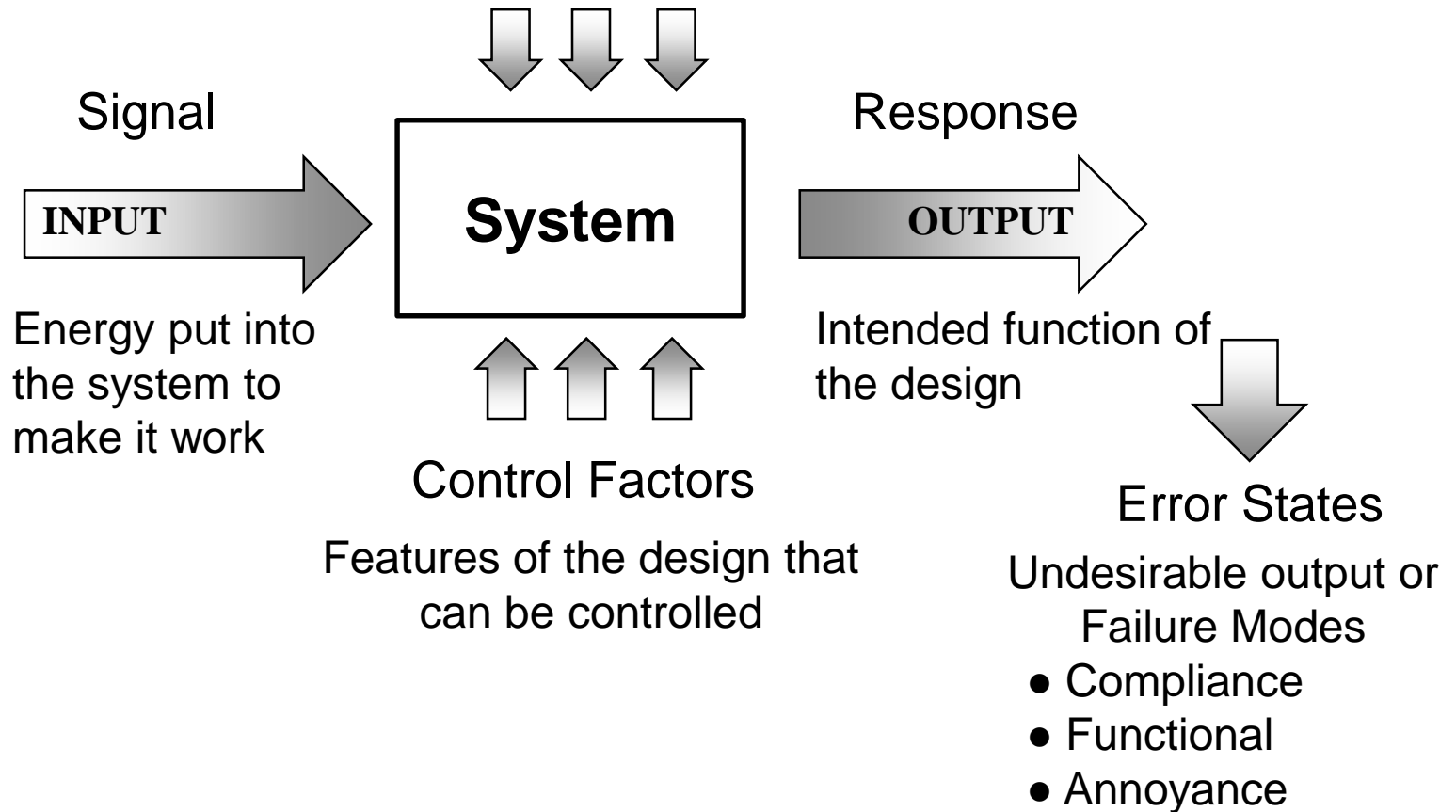
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Noise Factors

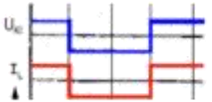
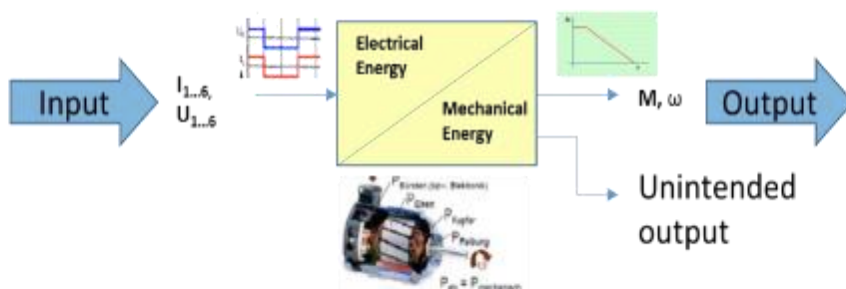
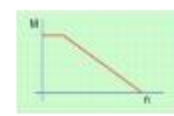
Sources that disrupt response that can not be controlled

- Piece to Piece
- Changes over Time/Usage
- Customer Usage
- External Environment
- Subsystem Interaction





P-Diagram Example

Noise Factors				
Noise 1	Noise 2	Noise 3	Noise 4	Noise 5
Piece to piece variation in a component and interference between components, e.g. variation in clearance between rotor and holding clamps	Change over time aging over life time, e.g. holding clamps become permanently magnetized, carbon brushes wear	Customer usage use out of desired spec., e.g. excessive use of window lift system by child playing	External environment conditions during customer usage, e.g. humidity, temperature, dust, external vibration, shock,...	System interaction interference between other systems, e.g. electromagnetic interference from ECU
Input Energy: e.g. Voltage, Current 	Electrical Motor 			Intended Output Energy: e.g. angle dependent electrical energy on solenoid 
Function Convert electrical energy into mechanical energy <i>Requirement/intended output:</i> generate motor characteristic curve (rotating speed, torque under specified rotating direction) according to spec 6790-1323	Target Move window glass up and down with a defined velocity	Control Factors Natural scientific factors which control the function, e.g. magnetic field strength, permeability,...	Non functional requirements Requirements which limit the design options, e.g. geometric interface to customer system, requirements regarding weight, material, size,...	Unintended Output energy losses, e.g. thermal energy,... NVH, EMC

Parameter (P) – Diagram

Project: Frontal Collision Air Bag

P-Diagram

Manufacturing Variation

Signal interference

Environment Contamination

Noise Factors

Closing Speed

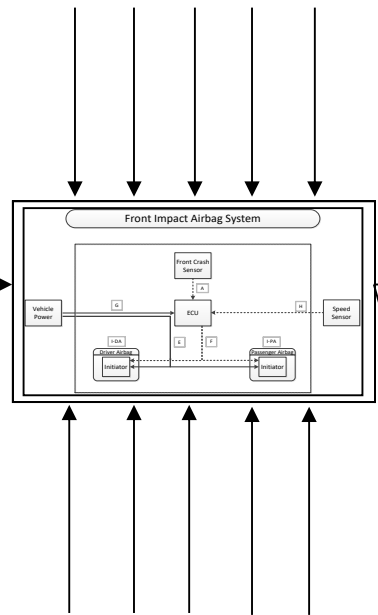
Customer usage

Signal Factor (M)

Power

Collision Signal

Speed Signal



Response (Y)
(Ideal Function)

Deploy on Demand

response time

Impact force

→ Error States

designed redundancies

design parameters

component selection

Control Factors

software algorithms

dimensional tolerances

no deployment on demand

delayed deployment

deployment without demand

too forceful deployment

late deflation





Interface Analysis

An interface analysis describes the interactions between elements of a system.

- There are five primary types of interaction:
 - Physical Connection (Brackets, Bolts, Clamps, Adhesive, etc.)
 - Material Exchange (Air, Hydraulic Fluid, Fuel, etc.)
 - Energy Transfer (Heat, Friction, High Voltage, or Motion)
 - Data Exchange (Inputs, Outputs, Carriers, information exchange, cyber security items)
 - Human-Machine (Controls, switches, mirrors, glass reflection, displays, seating)
 - Clearances
 - Interfaces between subsystem and components
- The interface analysis document is the boundary diagram and also the P-Diagram.



Interface Matrix

- Illustrates relationships between the subsystems, assemblies, subassemblies, and components within the object as well as the interfaces with the neighboring systems and environments.
- Documents the details, such as types of interfaces, strength/importance of interface, potential effect of interface, etc.

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Interface Matrix – Airbag

P	E
I	M

P: Physically touching E: Energy transfer
 I: Information exchange M: Material exchange

Numbers in each corner represent the above interface types, with values denoting the following:

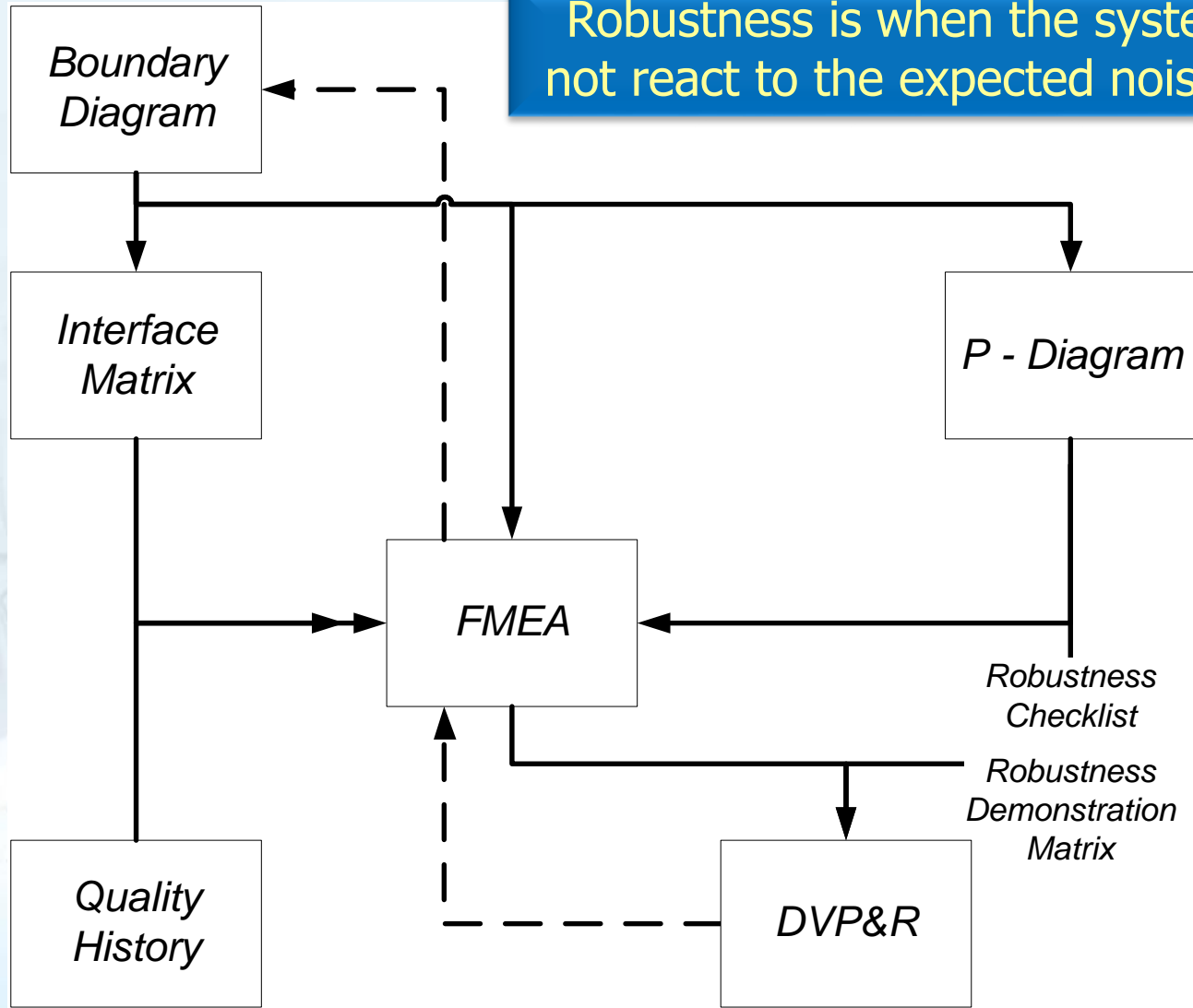
- +2 Interaction is necessary for function
- +1 Interaction is beneficial, but not absolutely necessary for functionality
- 0 Interaction does not affect functionality
- 1 Interaction causes negative effects but does not prevent functionality
- 2 Interaction must be prevented to achieve functionality

	Front Sensor	Control Unit	Initiator – Driver	Initiator – Passenger	Driver Airbag	Passenger Airbag	0	0
Front Sensor		0 2 0 0	0 -2 0 0	0 -2 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
Control Unit	2		0 2 0 0	0 2 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
Initiator – Driver	-2	2		0 -2 -2 0	0 0 2 0	0 0 -2 0	0 0 0 0	0 0 0 0
Initiator – Passenger	-2	2	-2		0 0 -2 0	0 0 2 0	0 0 0 0	0 0 0 0
Driver Airbag			2	-2		0 0 0 0	0 0 0 0	0 0 0 0
Passenger Airbag			-2	2			0 0 0 0	0 0 0 0



Robustness Linkages

Robustness is when the system does not react to the expected noise factors





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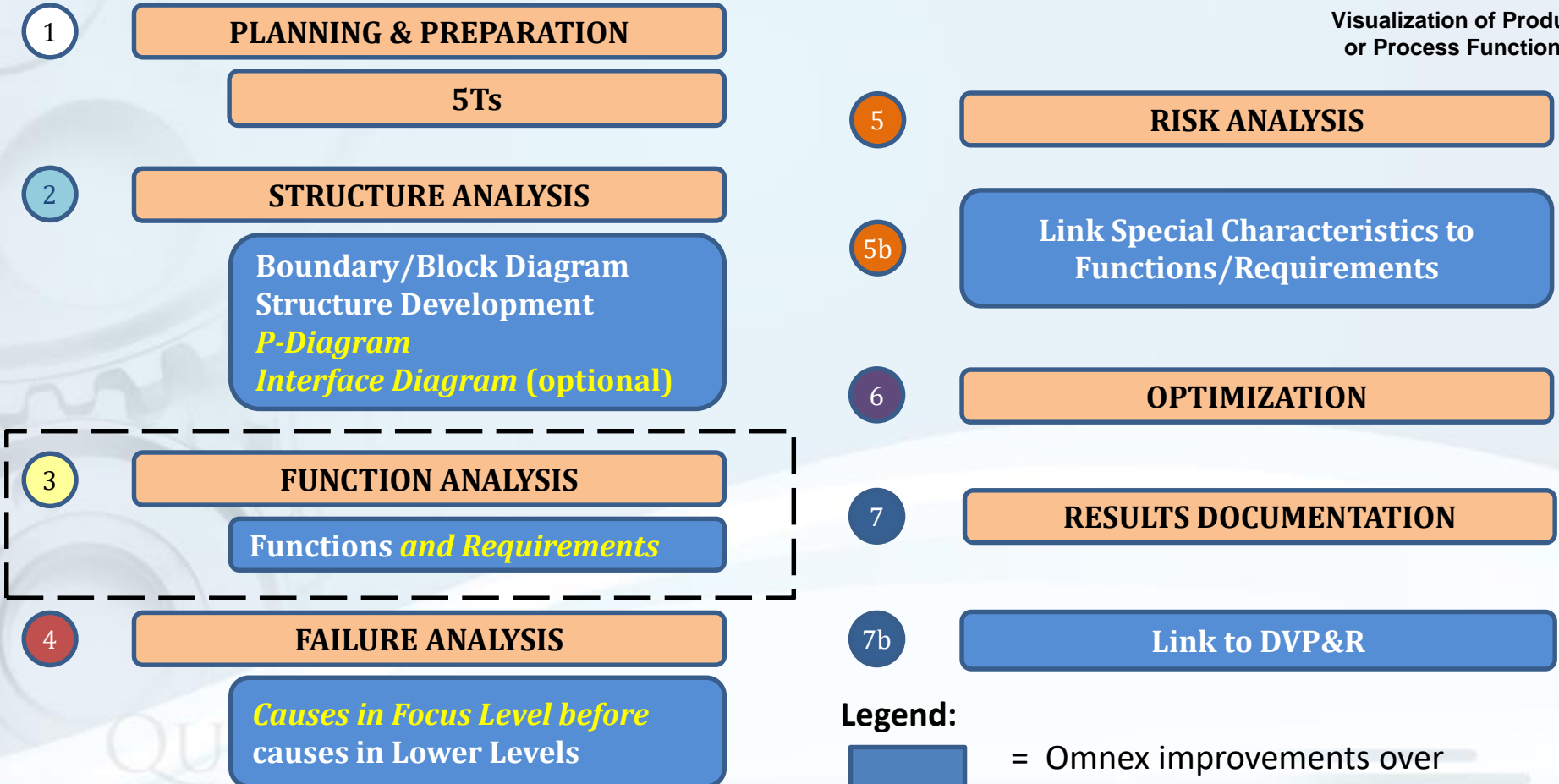
Interactive Example using EwQIMS Software

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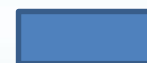


Visualization of Product
or Process Functions

FUNCTION ANALYSIS



Legend:



= Omnex improvements over
the AIAG-VDA DFMEA process

Italic font

= Omnex-specific changes to the
AIAG-VDA DFMEA process



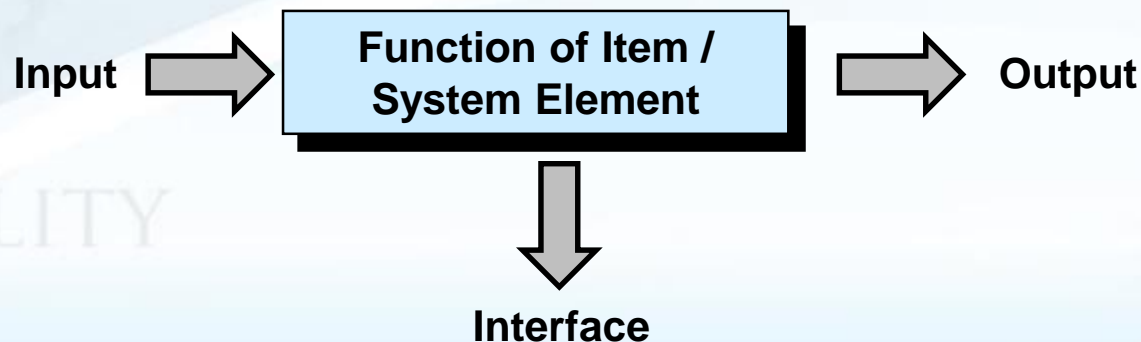
Goal of Function Analysis

- Overview of the product functionality and the flow of the functional requirements through the structure
- Verification against the customer requirements / specifications
- Function tree/net, or equivalent function matrix parameter diagram (P-diagram)
- Association of requirements or characteristics to functions
- Overview of cause and effect relationships
- Creating the basis for the failure analysis



Design Functions

- What **SHOULD** the product/service (structural elements) be doing?
 - What are the Functional Deliverables?
- The description of a function needs to be clear.
- Functions describe the relationship between the input and output of an item system element with the aim of fulfilling a task.





Design Functions

Caution:

- Clearly distinguish between the basic functions of a product, its detailed requirements and design constraints and assumptions.
- For example, a disk brake system has the basic function of stopping a vehicle on demand but it could also have...
 - A specific requirement that the vehicle stops within 200 feet of demand on dry pavement.
 - Design constraints: e.g. size, weight, environment, etc.
- A single function can have multiple requirements.

Note: some organizations combine the functions with their requirements. This can lead to confusion in subsequent analyses. It is recommended to record the requirements separate from the base functions.



Requirements

List all the requirements/deliverables for each function.

- List each requirement separately.
 - **Recommended:** Provide a name and number for each deliverable to be evaluated.
 - Show design level per engineering drawing.
- The recommended phrase format is to use an "action verb" followed by a "noun" to describe a measurable function.
- When the product/material must function under certain conditions, document those conditions.

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Example: Function Worksheet

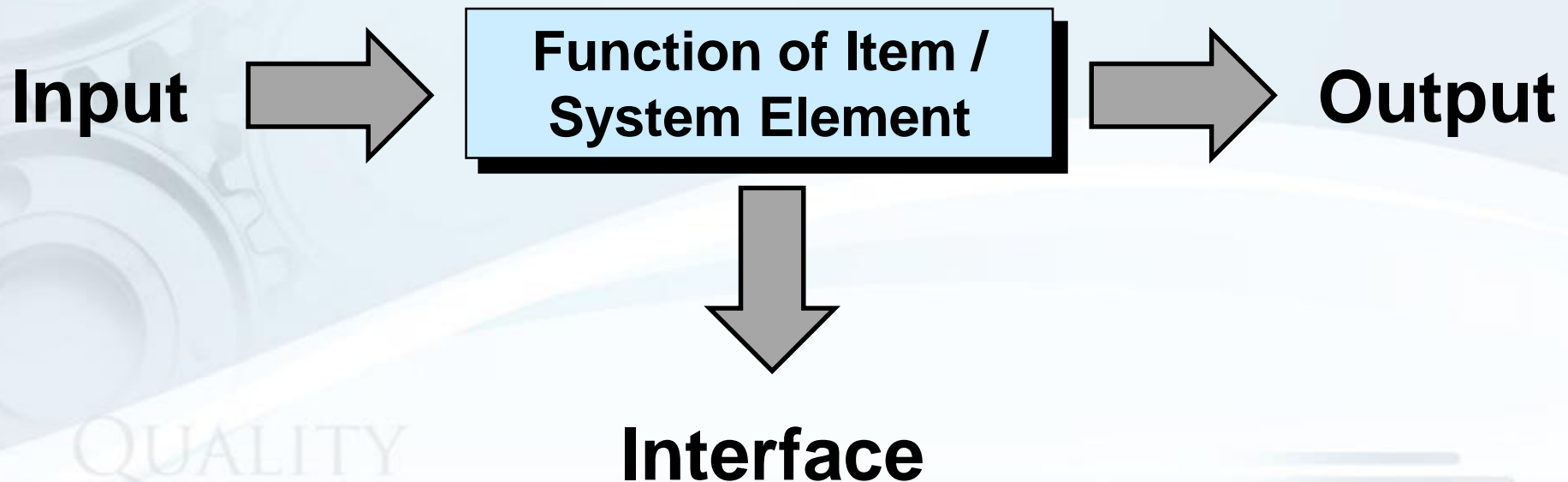
		Requirements	
Sl.	Function	When	How much
1	Leak-free Steering (without any leaks)	Operated at 90 Bar and During Idle condition.	Zero amount of oil over 300 sec
2	Smooth Steering (with out any noise)	Accelerated to full throttling.	Less than audible noise (~ 75 decibals)
3	Stop vehicle	on demand	within 70 meters from speed of 100 km/hr
4		on demand	within 40 msec with speed of 100 km/hr
5	Steering with Road feel / grip.	At 100 km/h speed	< x° amount of play.

Requirements:
When = under what conditions
How Much = acceptance criteria



Function Analysis

In addition to the primary functions of an item, other functions that may be evaluated include secondary functions such as interface functions, diagnostic functions, and serviceability functions.





Function Analysis

- Allocates the identified functional requirements to the system structural elements
- Flows down the functional requirements of the item to the lower level elements
- Answers the question *“What is the purpose of the specific level (system) element?”*

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Function Analysis

Product or Process functionality is ensured by allocating a description of activities, purposes or tasks intended for the product performance.

System : Car

- Safe transportation of passengers
- Any potential hazard will be minimized

Subsystem: Safety

- Protect passengers during collision
- Provide active or passive safety measures

Product : Airbag

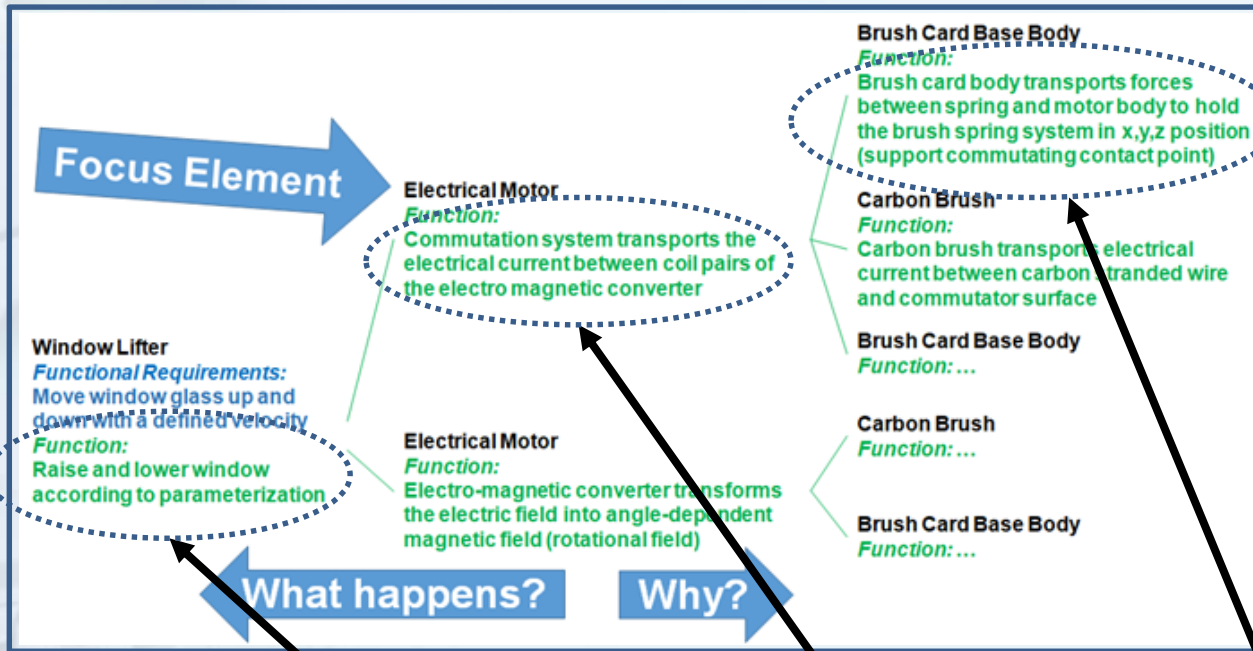
- Deploy on demand during collision
- Activate within 30 msec of collision

Component : Sensor

- Detect frontal collision
- Signal ECU when a collision at > 13 mph occurs



Example of Functional Analysis to Form



FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Raise and lower window according to parameterization.	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)

source: AIAG-VDA FMEA Handbook 1st Edition





Matrix Function Analysis

When using a spreadsheet approach, the following three templates should be used (see handout)

Higher Level

STRUCTURE ANALYSIS	FUNCTION ANALYSIS	FAILURE ANALYSIS	
1. System (Item)	1. Function of System and Requirement or Intended Output	Higher Level Failure Mode 1 Failure Effects (FE)	ID
		Focus Level	
STRUCTURE ANALYSIS	FUNCTION ANALYSIS	FAILURE ANALYSIS	
2. Focus Element	2. Function of the Focus Element	Focus Level Failure Mode 2. Failure Mode (FM)	ID
		Lower Level	
STRUCTURE ANALYSIS	FUNCTION ANALYSIS	FAILURE ANALYSIS	
3. Component Element (Item / Interface)	3. Function of Component Element and Requirement or Intended Output or Characteristic type	Next Lower Level Failure Mode; 3. Failure cause	ID

Breakout Exercise 3

Function Analysis

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Breakout Exercise 3: Function Analysis

Instructions

- For each entry (three levels) in the structure tree related to the focused element, identify the product functions and requirements.
 - i.e. what product functions would the different customers find important?
- Update the form.
- Prepare to present and review as a class.

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Interactive Example using EwQIMS Software

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Chapter 3: Design FMEA Prerequisites – What We Covered

Learning Objectives

You should now be able to :

- Describe who the customer is for FMEAs
- Explain design functions
- Complete a Function Analysis
- Describe Planning and Preparation
- Describe the scope of analysis
- Complete a Boundary Diagram
- Describe the purpose of a P-Diagram and Interface Matrix

Chapter Agenda

- Step 1: Planning and Preparation
 - Scope of Analysis
 - **Breakout Exercise 1**
- Step 2: Structure Analysis
 - Boundary Diagrams
 - **Breakout Exercise 2**
- Robust Designs
 - P-Diagram
 - Interface Matrix
- Step 3: Function Analysis – Product Design
 - **Breakout Exercise 3**




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Chapter 4

Developing the Design FMEA

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Failure Analysis and Risk Mitigation		
4 th Step Failure Analysis	5 th Step Risk Analysis	6 th Step Optimization
		
Establishment of the Failure Chain	Assignment of Existing and/or Planned Controls and Rating of Failures	Identification of the Actions Necessary to Reduce Risks

Chapter 4: Developing the Design FMEA – What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Explain design failure modes
- Identify failure modes from requirements
- Explain causes of failure modes
- Explain design controls
- Distinguish between prevention and detection controls
- Explain the key elements of the risk analysis
- Define requirements for Results Documentation and Communication

Chapter Agenda

- Design Failure Modes
- Step 4: Failure Analysis
 - **Breakout Exercise 4**
 - Potential Effects of Failure
 - Potential Causes of Failure
 - **Breakout Exercise 5**
- Step 5: Design Controls and Risk Analysis
 - **Breakout Exercise 6**
 - Evaluation: Indices and Action Plans
 - **Breakout Exercise 7**
- Step 6: Optimization
- Step 7: Results Documentation



Establishment of the
Failure Chain

FAILURE ANALYSIS

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Boundary/Block Diagram
Structure Development
P-Diagram
Interface Diagram (optional)

3 **FUNCTION ANALYSIS**

Functions *and Requirements*

4 **FAILURE ANALYSIS**

Causes in Focus Level before
causes in Lower Levels

5 **RISK ANALYSIS**

5b Link Special Characteristics to
Functions/Requirements

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b Link to DVP&R

Legend:



= Omnex improvements over
the AIAG-VDA DFMEA process

Italic font

= Omnex-specific changes to the
AIAG-VDA DFMEA process



Potential *Design* Failure Mode

1. Identify and List All the Requirements
2. *For Each Requirement*
 - – *Identify Potential Design Related Failure Modes*

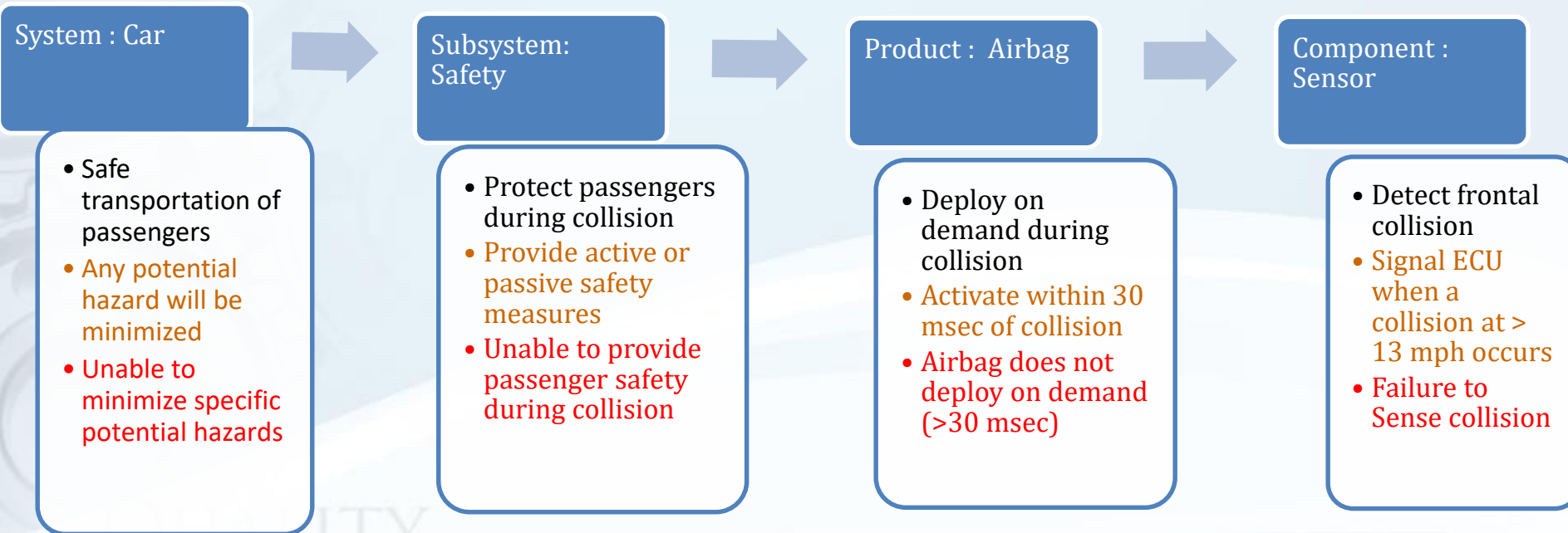
How the design could potentially fail to provide a defined function to a customer

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Failure Analysis

Failures of functions are deduced from the functions already identified in Step #3 and in this step (#4)





Potential Failure Mode

For each requirement – a description of what would be seen, heard, felt, etc. if the deliverable does not meet the identified requirement...

- Why would the item be unacceptable?
- How would the item not conform to the customer requirements?
- What would the customer consider unacceptable?
- How does the item fail to meet regulatory compliance?

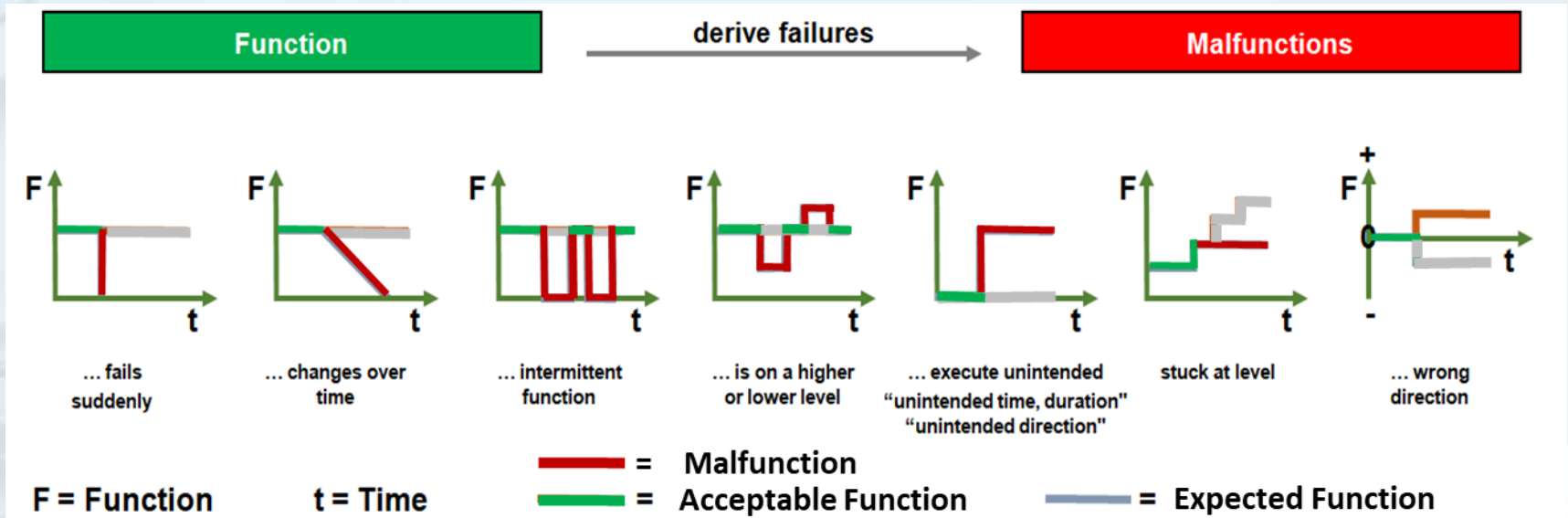
Failure Modes are the details of the malfunction as applied to the requirement

Related Malfunctions

1. No function
2. Partial function
3. Over function
4. Under / degraded function
5. Intermittent function
6. Unintended function



Types of Failures



source: AIAG-VDA FMEA Handbook 1st Edition

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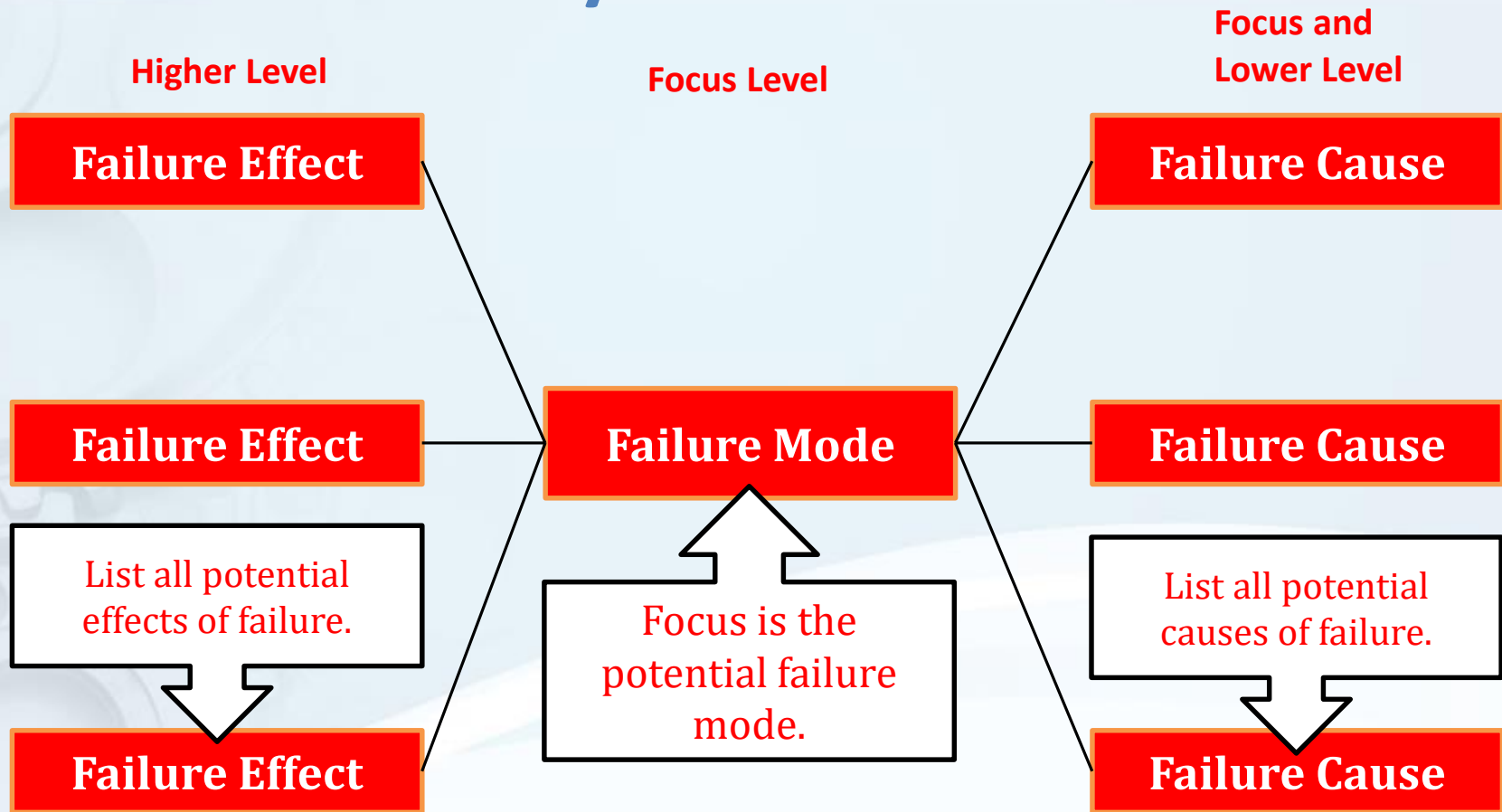
Example

Item	Function	Requirement	Failure Mode
Disk Brake system	Stop vehicle on demand	Stop vehicle traveling on dry pavement demand within 70 meters from 100 km/hr	Vehicle does not stop
			Vehicle stops in excess of 70 meters
			Activates with no demand; vehicle movement impeded
		Continues to activate with no demand – no movement	
		Stops vehicle with less than specified force on occupants	Stops vehicle with more than xx g's of force

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Failure Net Analysis



The relationships among the failure causes, modes and effects of the different levels are identified to show their relationships to enable risk assessment

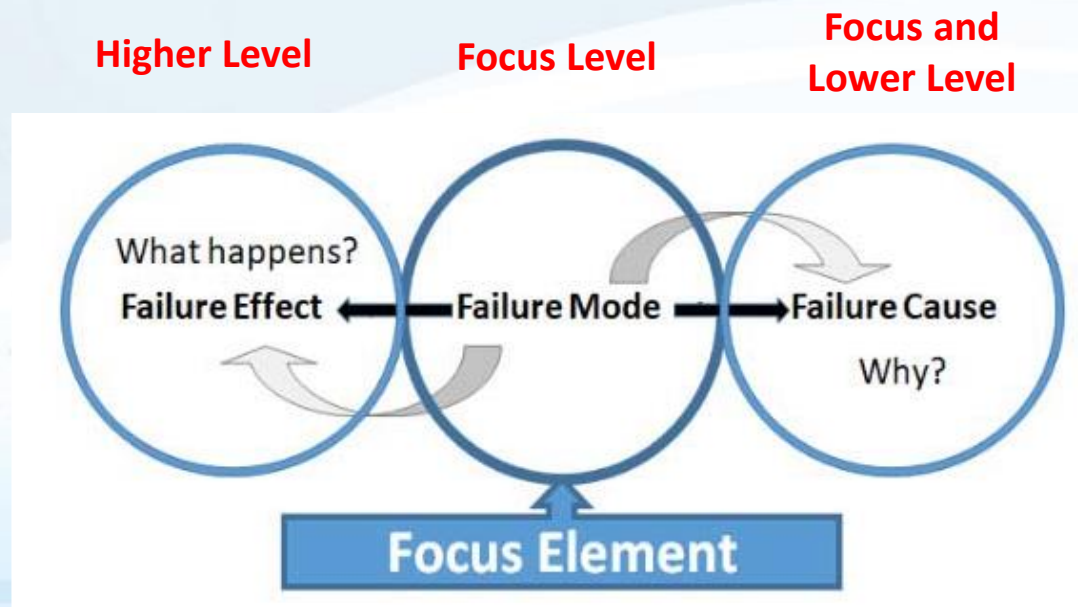


The Failure Chain

There are three different aspects of failures analyzed in an FMEA:

- **Failure Effect (FE)** the consequences of a failure mode
- **Failure Mode (FM)** manner in which an item could fail to meet or deliver the intended function
- **Failure Cause (FC)** indication of why the failure mode could occur

Note: these are all failure modes at different levels





Failure Chain Analysis

DFMEA Potential Failure Network and Chain Analysis						
Analysis Level	DFMEA at OEM	DFMEA at Level 1	DFMEA at Level 2	DFMEA at Level 3	Analysis Level Examples	Failure Examples
Vehicle	FE				Vehicle Door and Interface to Electrical and Signal Bus (environment for Window Lifter System)	Window is closing too slowly
System	FM	FE			Window Lifter System	Excessive friction between glass and guide rails
System Element	FC	FM	FE		Window Lifter (with gear drive)	Torque and rotating velocity of the window lifter motor too low
Sub-System Element		FC	FM	FE	Electrical Motor	Commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)
Component Element			FC	FM	Brush Card Base Body	Carbon brush transports too little current
(Design) Feature characteristic				FC	Brush Card Base Body Characteristics	Insufficient contact force specified between brush and commutator

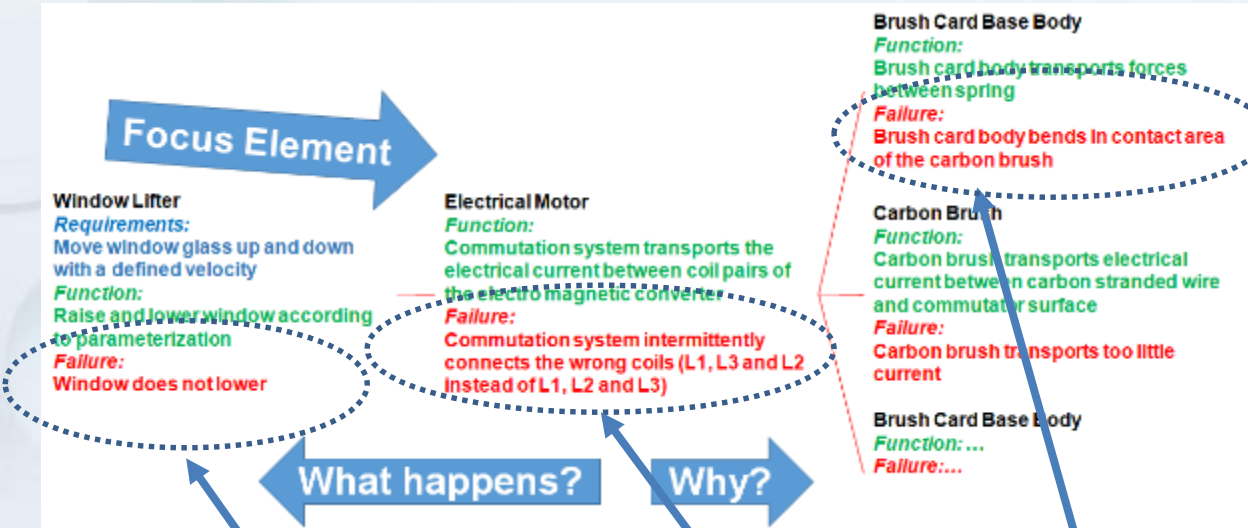
Focus Element

source: AIAG-VDA FMEA Handbook 1st Edition





Failure Analysis as Structure Tree and Form



FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
Window does not lower	Commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush

source: AIAG-VDA FMEA Handbook 1st Edition





Example Failure Modes – Unacceptable Description

- Poor Appearance
- Discoloration
- Vision Impaired
- Cannot Fasten
- Loss of Pressure
- Loss of Power
- Fading
- Intermittent operation
- Noise
- Erratic Operation
- Unstable
- Rough
- Regulatory Nonconformance
- Electromagnetic Capability (EMC)
- Radio Frequency Interference (RFI)

Note: Explain with sufficient detail on subject, conditions, and location so severity can be evaluated and appropriate actions taken. The better the description/detail, the more use the FMEA will have in problem solving activities.



Example Failure Modes – Better Descriptions

- Product will be rejected by customer
 - Fisheyes on class A surface
 - Uneven color / streaking
- Vision impaired due to oil spray; hazard
- Cannot be fastened to mating part
- Loss of steering control due to drop in hydraulic pressure
- Loss of power – hazard
- Fading brakes – potential hazard
- Will not lock
- Intermittent operation – potential hazard
- Noise (metal to metal) > 75 db
- Erratic operation cause loss of control (hazard)
- Unstable shelf life; loss of adhesion
- Misalignment due to rough mating surface
- Unpleasant odor
- Thermal event
- Regulatory nonconformance to ISI 686-7
- Electromagnetic Capability (EMC) sporadic due to Radio Frequency Interference (RFI)

The language used in FMEAs should be as specific as possible when describing an item (failure mode, cause, etc.) and not extend or extrapolate beyond the team's level of understanding as to what the failure effects may be

Breakout Exercise 4

Failure Modes

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FAILURE ANALYSIS (STEP 4)

1. Failure Effects (FE)
to the Next Higher
Level Element and/
or Vehicle End User

2. Failure Mode
(FM) of the Focus
Element

3. Failure Cause (FC)
at the Focus Level
and Next Lower
Element or
Characteristic





Breakout Exercise 4: Failure Modes

Working with the Function and Requirements worksheet related to the previous breakout:

- For each requirement at the three levels, identify known or potential failure modes.
- Be as specific as possible; quantify when possible (e.g. how much for how long?)
 - Consider possible malfunctions and add details related to the specific requirements.

Example Malfunctions

1. No function
2. Partial function
3. Over function
4. Under / degraded function
5. Intermittent function
6. Unintended function



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Interactive Example using EwQIMS Software

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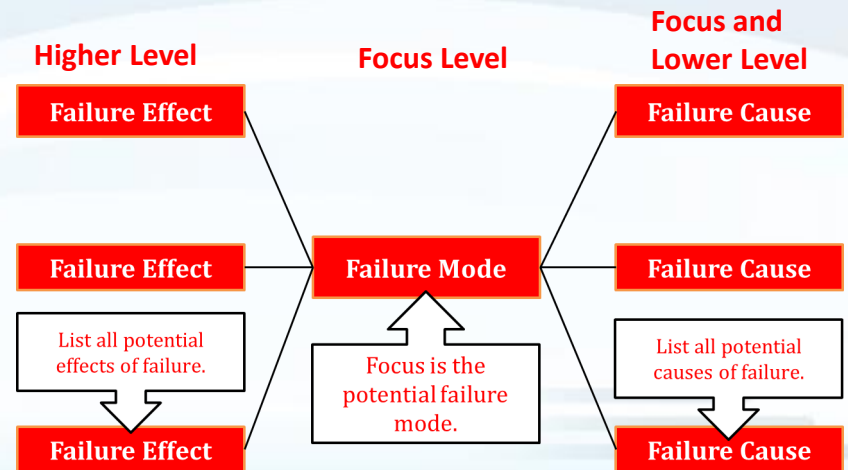
POTENTIAL EFFECTS OF FAILURE

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FMEA Process

1. Identify and List All the Requirements
2. For Each Requirement
 - Identify Potential Design Related Failure Modes
3. *For Each Failure Mode*
 - *Assess Potential Effects of Failures*
 - Identify the Cause(s)





Effect of a Failure Mode

“Potential effects of failure are defined as the effects of the failure mode on the function, as perceived by the customer.”

“Describe the effects of the failure in terms of what the customer might notice or experience, remembering that the customer may be an internal customer as well as the ultimate end user.”

Source: FMEA Fourth Edition, 2008

- Customer includes:
 - Manufacturing and Assembly processes of the Product
 - Next higher assembly
 - System
 - Vehicle
 - End-User
 - Government Regulation

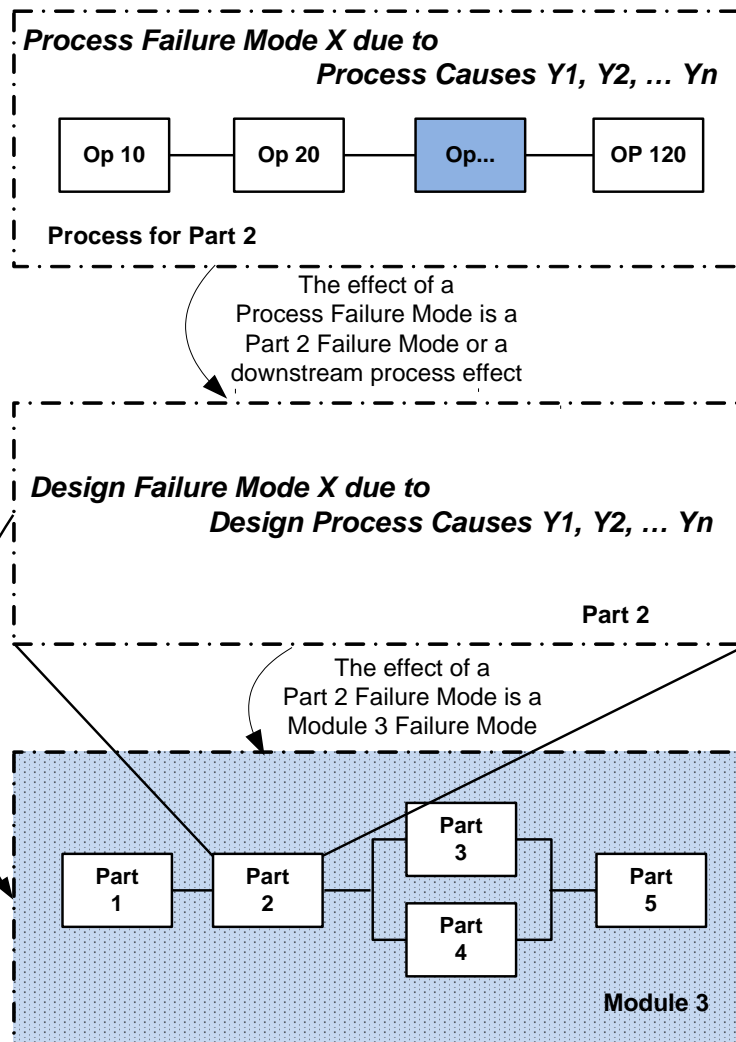
The “*so what*” factor – what will be the symptoms?



Effect Linkages

Effects propagate through the design levels till they reach the customer.

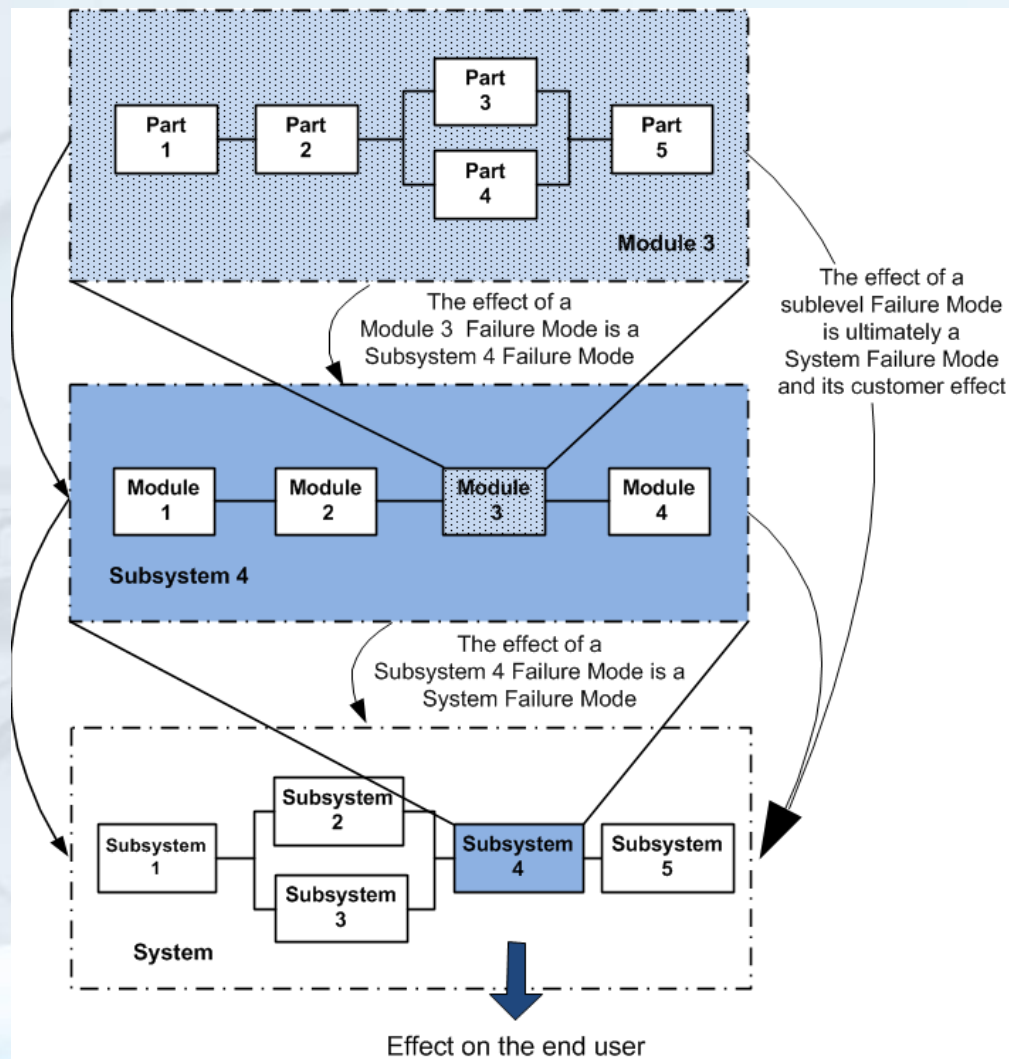
The effect of a Failure Mode at a lower level is a Failure Mode at a higher level and all its effects and severity.



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Effect Linkages

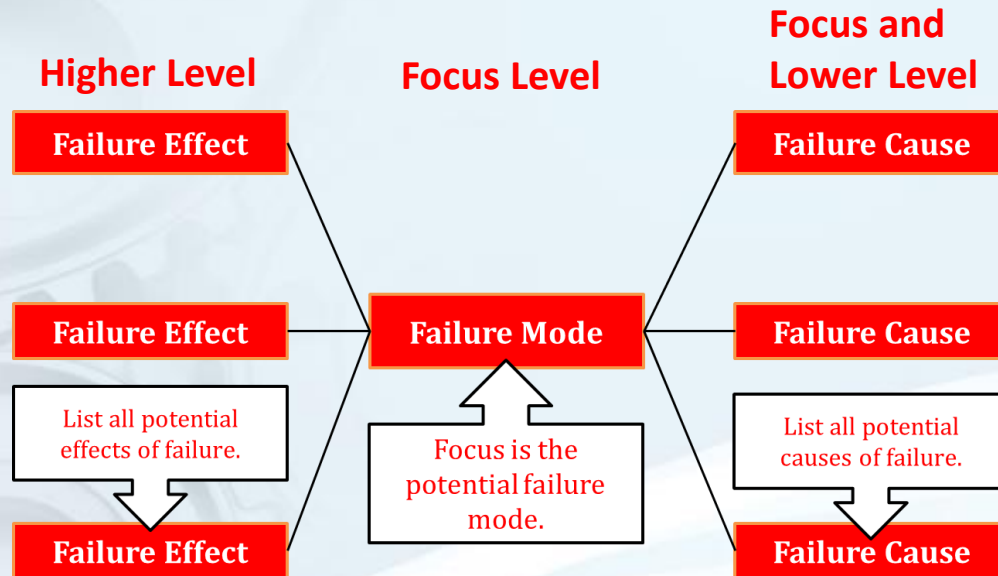


Effects propagate through the design levels till they reach the customer.



Effect in AIAG-VDA FMEA Handbook

In the AIAG-VDA FMEA approach, an effect is the failure mode of the higher level structural element.



FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) at the Focus Level and Next Lower Element or Characteristic



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Interactive Example using EwQIMS Software

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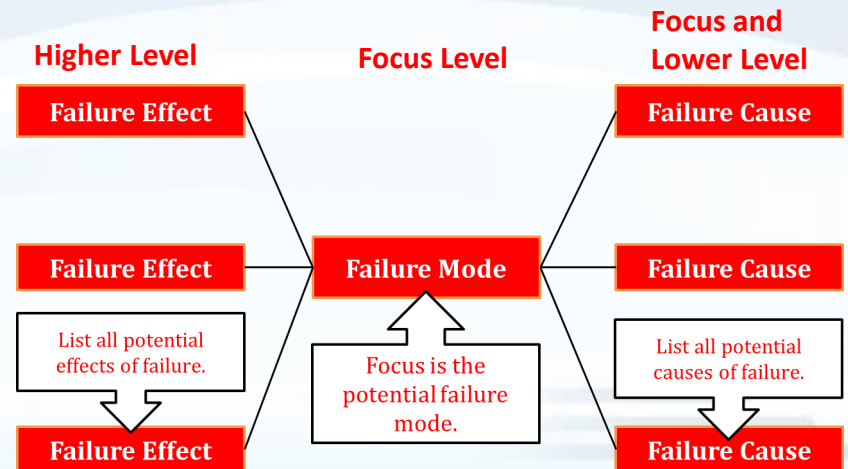
POTENTIAL CAUSES OF FAILURE

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Potential Cause(s) of Failure

1. Identify and List All the Requirements
2. For Each Requirement
 - Identify Potential Design Related Failure Modes
3. *For Each Failure Mode*
 - Assess Potential Effects of Failures
 - *Identify the Cause(s)*





Potential Cause(s) of Failure

Potential cause of failure is defined as an indication of *how the design process could allow* the failure to occur, described in terms of something that can be corrected or can be controlled.

Source: FMEA Fourth Edition, 2008

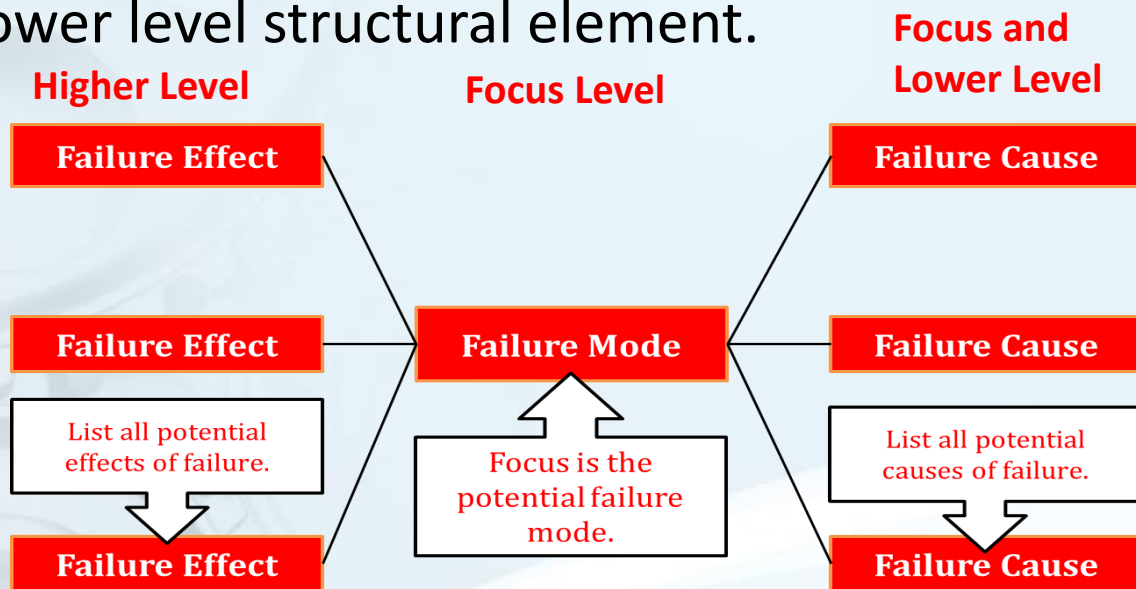
- Potential cause of failure may be an indication of a design weakness, the consequence of which is the failure mode.
- Causes are the circumstances that induce or activate a failure mechanism.

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Cause in AIAG-VDA FMEA Handbook

In the AIAG-VDA FMEA approach, a cause is the failure mode of the lower level structural element.



FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) at the Focus Level and Next Lower Element or Characteristic



Causes

Causes of Design Failure Modes can stem from

- A. Lack of understanding of the actual customer needs
 - B. Lack of understanding of all functional, safety and reliability requirements
 - C. Lack of understanding of the specific failure mechanisms
 - Especially related to interfaces
 - Including environmental impacts, expected abuses, etc.
 - D. Lack of understanding of variation and its propagation
- and**
- E. Lack of communication of A – D to lower design levels



Potential Cause(s) of Failure

Potential cause of failure is defined as how the failure mode could occur, described in terms of something that can be corrected or controlled.

- Each cause assignable to a failure mode should be listed and considered separately.
- In the development of the FMEA, the identification of all potential causes of the failure mode is key to subsequent analysis.
 - Although varied techniques (such as brainstorming) can be used to determine the potential cause(s) of the failure mode, it is recommended that the team should focus on an understanding of the failure mechanism for each failure mode.



Potential Cause(s) of Failure

- Investigation of causes needs to focus on the failure mode and **not** on the effect(s).
- In determining the cause(s), the team should assume the existence of the cause under discussion will result in the failure mode.
 - i.e. assume the failure mode does not require multiple causes to occur.
 - FMEAs assume Single Point Failures (SPF); i.e. the cause will produce the failure mode.
 - Fault Tree Analysis (FTA) allows for analysis of Multiple Point Failures (MPF) (i.e. redundancies).
- If there are several causes for a failure mode, this should result in multiple lines (cause branches) for the failure mode.

Assume the product / service is produced correctly



Example

Failure Mode	Mechanism	Cause
Vehicle does not stop	No transfer of force from pedal to pads	Mechanical linkage break due to design allowing environmental corrosion
		Master cylinder vacuum lock due to seal design
		Loss of hydraulic fluid due to incorrect connector torque specifications
		Loss of hydraulic fluid due to hydraulic lines crimped/compressed, inappropriate tube material specified
Vehicle stops in excess of yy feet	Reduced transfer of force from pedal to pads	Mechanical linkage joints stiff due to inappropriate lubrication specification
		Mechanical linkage joints corroded due to inadequate corrosion protection
		Partial loss of hydraulic fluid due to hydraulic lines crimped, inappropriate tube material specified



Failure Net Analysis

- At this point in the analysis, the functions and requirements and their relayed failure modes have been determined for all levels.
- To determine the causes and effects for each failure mode in each step, Failure Chains need to be developed.

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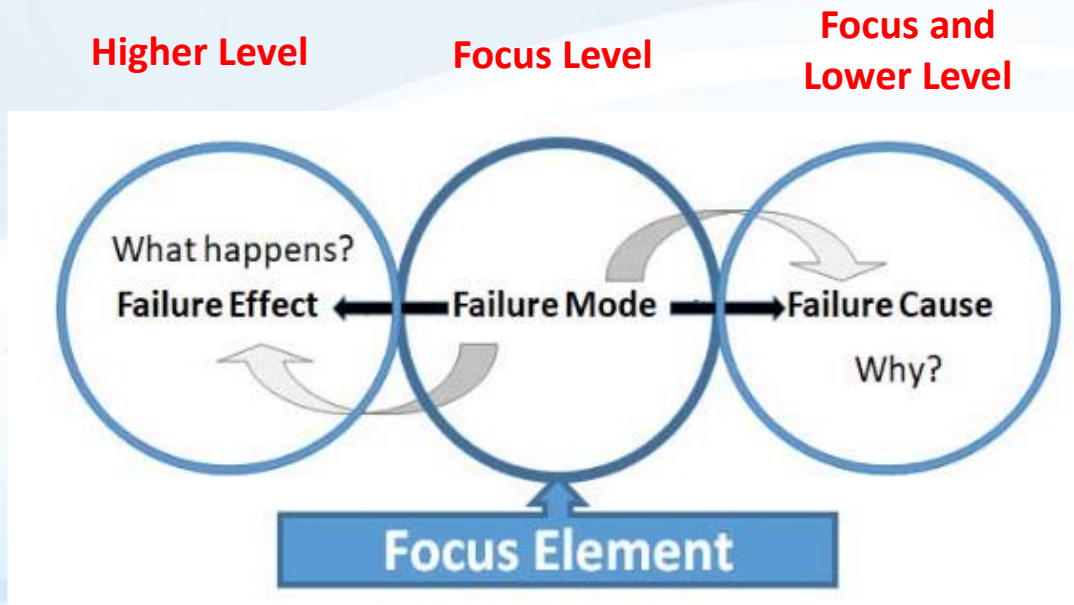


The Failure Chain

There are three different aspects of failures analyzed in an FMEA:

- **Failure Effect (FE)** the consequences of a failure mode
- **Failure Mode (FM)** manner in which an item could fail to meet or deliver the intended function
- **Failure Cause (FC)** indication of why the failure mode could occur

Note: these are all failure modes at different levels





Failure Analysis as a Matrix

By inspecting the items in the Function Analysis, begin building the Failure Chain.

- **Failure Effects (FE):**
The effect of failure associated with the “Function of System or System Element” in the Function Analysis.
- **Failure Mode (FM):**
The mode (or type) of failure associated with the “Function of System Element” in the Function Analysis.
- **Failure Cause (FC):**
The cause of failure associated with the “Function of Component Element and Output or Characteristic” in the Function Analysis.

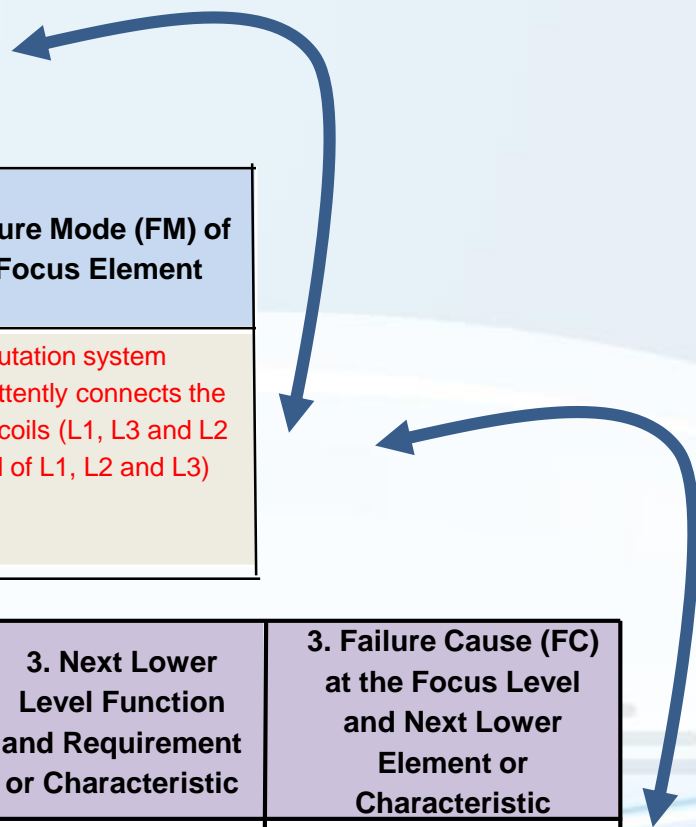


Example Using Spreadsheet Form

1. Next Higher Level	1. Next Higher Level Function and Requirement	1. Failure Effects (FE) at the Next Higher Level Element and/or Vehicle End User
Window Lifter Motor	Raise and lower window according to parameterization	Torque and rotating velocity of the window lifter motor too low

2. Focus Element	2. Focus Element Function and Requirement	2. Failure Mode (FM) of the Focus Element
Electrical Motor	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)

3. Next Lower Level or Characteristic Type	3. Next Lower Level Function and Requirement or Characteristic	3. Failure Cause (FC) at the Focus Level and Next Lower Element or Characteristic
Brush Card Base Body	Brush card body transports forces between spring	Brush card body bends in contact area of the carbon brush



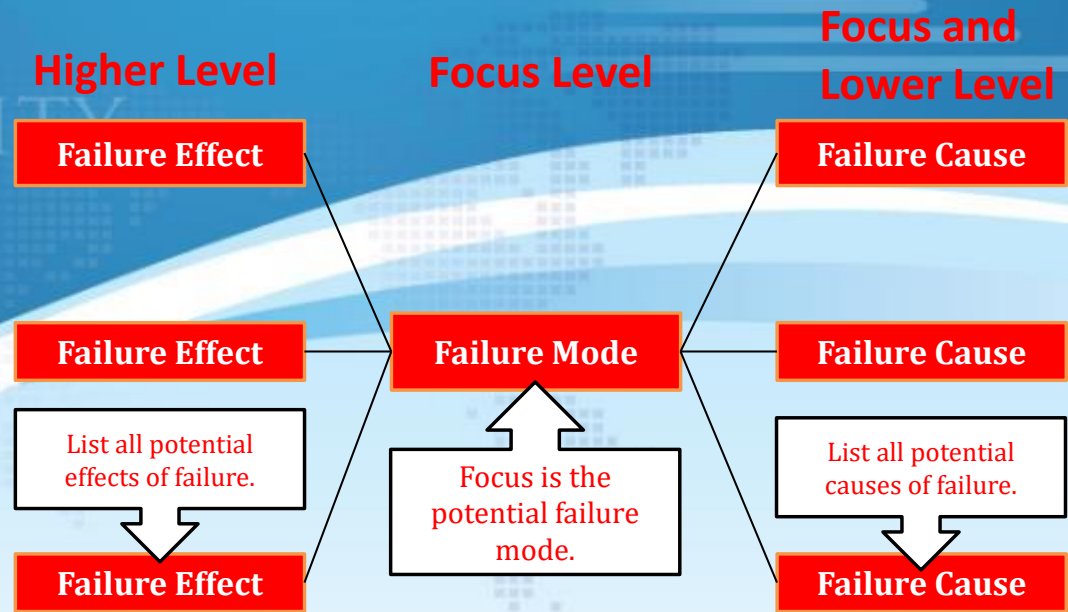
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Breakout Exercise 5

Failure Net

Link Effect ← Failure Mode ← Cause





Breakout Exercise 5: Failure Net

Working with the Function and Requirements / Failure Modes worksheet related to the previous breakout:

- For each focused Failure Mode, identify related Effects (higher level) and Cause (lower level).
- Update the form.
- Prepare to present and review as a class.

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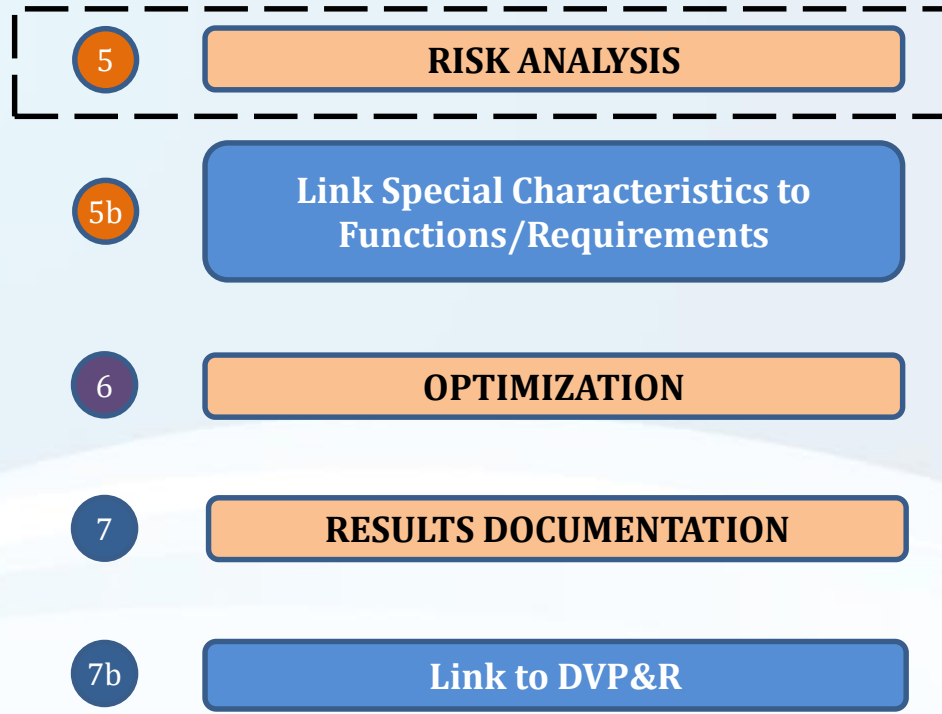
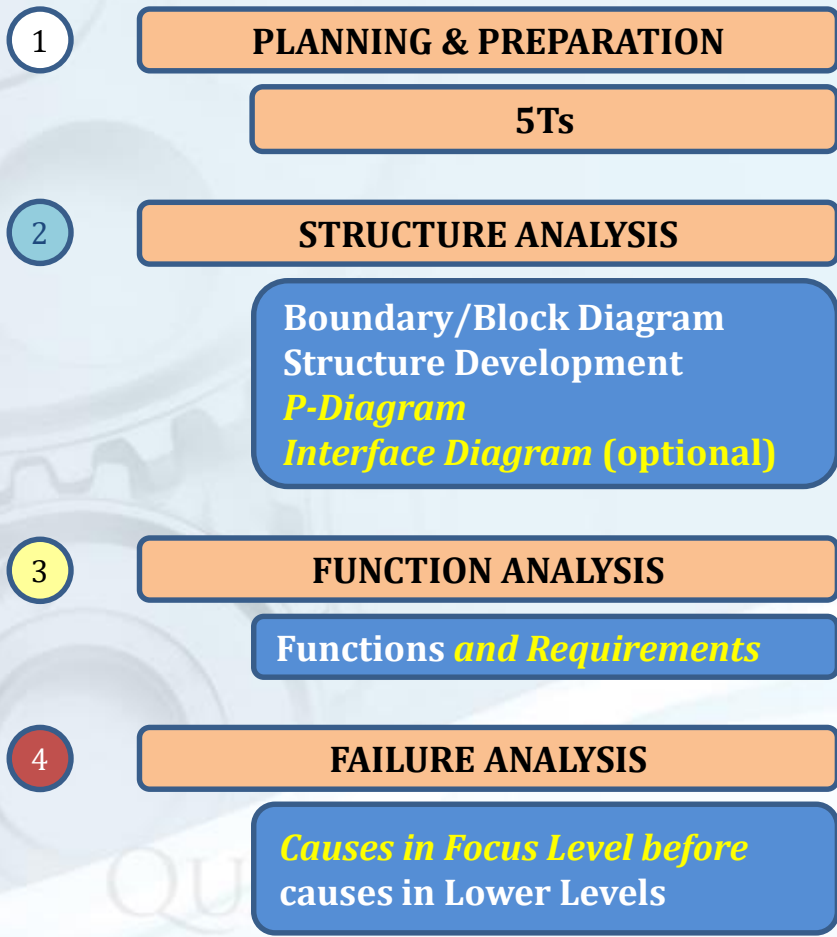
Interactive Example using EwQIMS Software

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Assignment of Existing and/or Planned Controls and Rating of Failures

RISK ANALYSIS



Legend:



= Omnex improvements over the AIAG-VDA DFMEA process

Italic font

= Omnex-specific changes to the AIAG-VDA DFMEA process





Design Controls

1. Identify and List All the Requirements
2. For Each Requirement
 - Identify Potential Design Related Failure Modes
3. For Each Failure Mode
 - Assess Potential Effects of Failures
 - Identify the Cause(s)
4. *For Each Cause*
 - *Identify what control(s) in the Design Process are/will be in place*



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Design Controls

“Current Design Controls are those activities conducted as part of *the design process* that have been completed or committed to and that will assure the design adequacy for the design functional and reliability requirements under consideration.”

Source: FMEA Fourth Edition, 2008

Types of Design Controls:

Prevention (P):

- Prevent the cause thus preventing the failure mode

Detection (D):

- Detect the cause
- Detect the failure mode



Design Controls

- The preferred approach is to first use prevention controls, if possible.
- The initial occurrence rankings will be affected by the prevention controls provided they are integrated as part of the design intent.

**First consider how to prevent,
then how to detect**



Prevention Controls in Design

These are analysis, testing, reviews, and other activities that will assure the design adequacy:

- Fail-safe designs
- Error-proofing by product design
- Analysis of concepts to establish design requirements
 - Studies on similar designs, phased testing from prototype through production, lessons learned and feedback loops
 - Designed Experiments to understand the variational model of the function
 - Simulation studies / virtual analysis consistent with real life
- Benchmarking studies
- Design and Material standards (internal and external)
- Documentation – records of best practices, lessons learned, etc.
- Prevention Controls impact the occurrence ranking



Detection Controls in Design

Design Analysis Techniques

(to detect causes)

- Analysis of the specifications to establish conformance to design requirements
 - Designed Experiments
 - Proven Modeling / Simulation / Virtual Analysis
- Tolerance Stack-up
- Material Compatibility
- Design Review
- Design Verification / Validation



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Detection Controls in Design

Development Tests Techniques

(to detect causes or failure modes)

- Design Reviews
- Vehicle Design Verification Tests
 - Prototype testing
 - Product/process validation testing
 - “Life of Product” validation testing
- Mock-up using
 - Similar parts
 - Supplier organization qualified components
 - Statistically significant quantity of engineering prototype samples
 - Small quantity of pre-production samples
- Simulation Studies – Validation of Design
- Design of Experiments

If an analytical technique is used to understand the variation model (determine a specification), it is preventive.

If it is used to verify or validate a design, it is detective.



Example

Failure Mode	Cause	Preventive	Detective
Vehicle does not stop	Mechanical linkage break due to environmental corrosion	Designed per material standard MS-845	Environmental stress test 03-9963
	Master cylinder vacuum lock due to seal design	Carry-over design with same duty cycle requirements	Pressure variability testing – system level
	Loss of hydraulic fluid due to incorrect connector torque specification	Designed per Torque requirements - 3993	Vibration step-stress test 18-1950
	Loss of hydraulic fluid due to hydraulic lines crimped / compressed; inappropriate tube material specified	Designed per material standard MS-1178	DOE – tube resiliency

The controls must relate to the cause or failure mode



Design Controls

- Design Control columns in the DFMEA describe the methods that will be used to control the design process.
- The Test Plan (DVP&R) provides the details of those controls.

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Confirmation of Current Prevention and Detection Controls

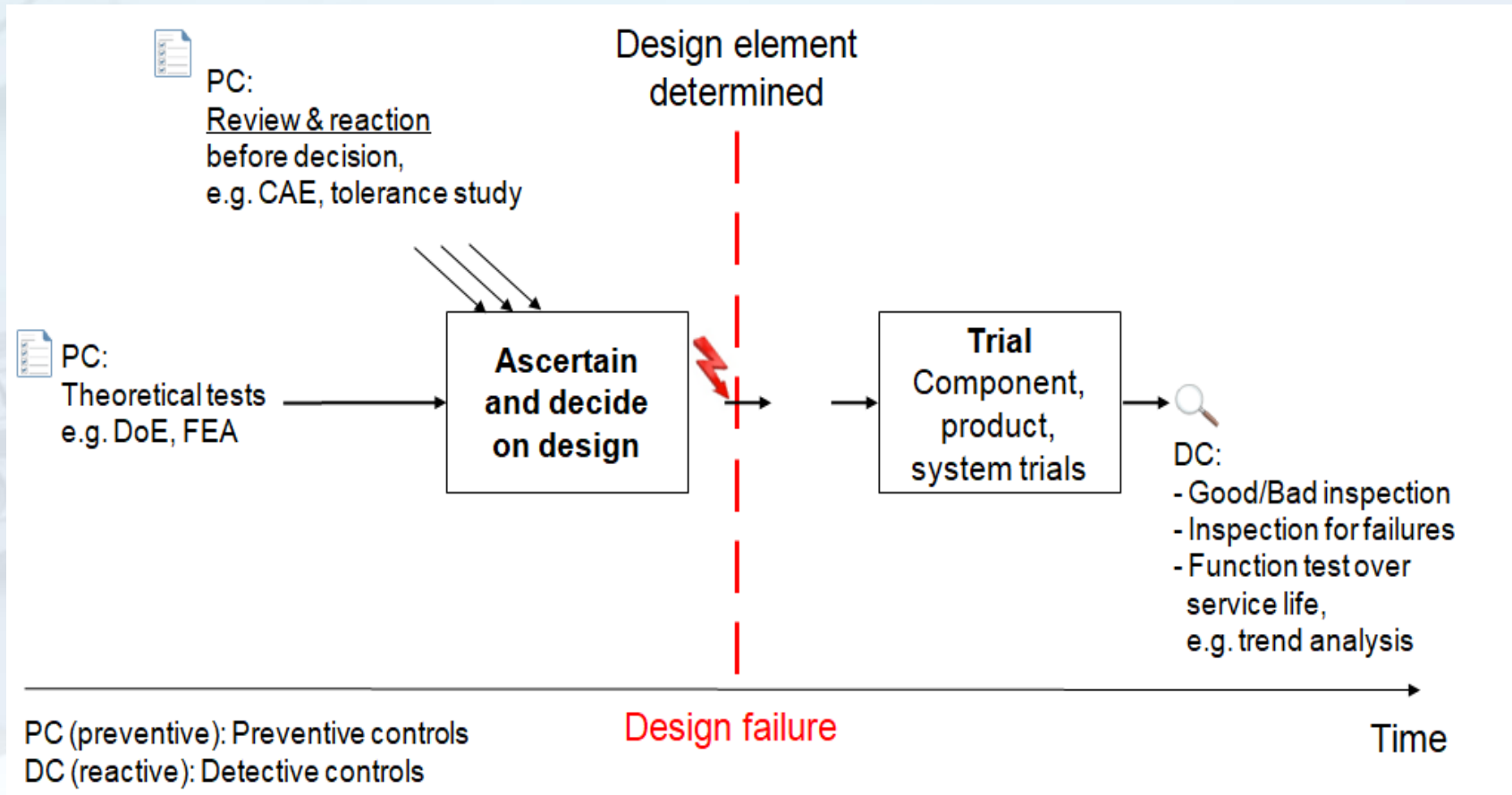


- The effectiveness of the current prevention and detection controls should be confirmed.
 - This can be done during validation teardown reviews.
 - Additional action may be needed if they are proven to not be effective.
- Such confirmation can be documented within the DFMEA, or within other project documents, as appropriate, according to the team's normal product development procedure and controls.

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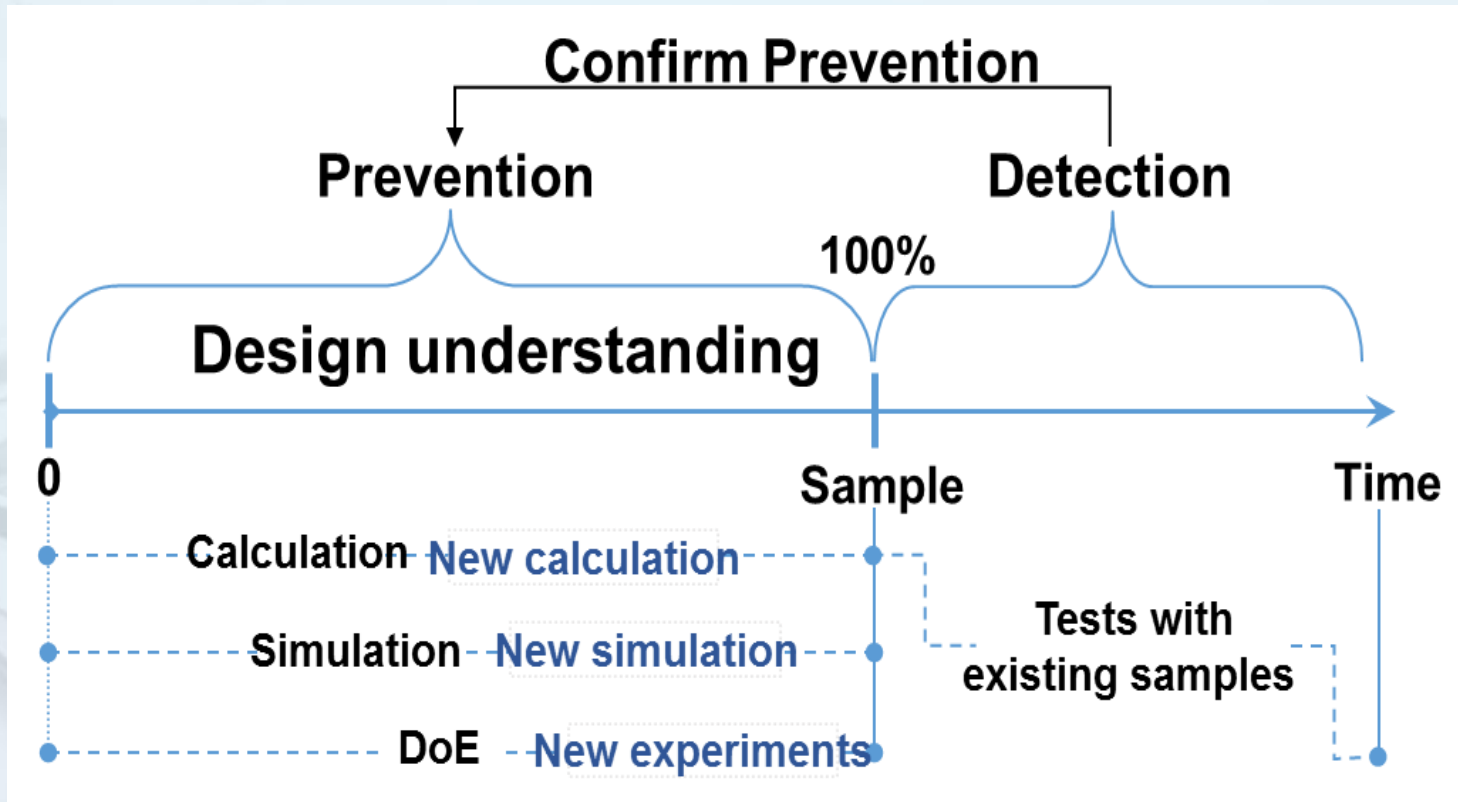
Prevention and Detection in DFMEA



source: AIAG-VDA FMEA Handbook 1st Edition



Roadmap of Design Understanding



source: AIAG-VDA FMEA Handbook 1st Edition

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Design Controls – Airbag

Class Case Study

Function	Requirements		Potential Failure Mode	Potential Effects of Failure: Sev	Sev	ASIL	Potential Cause(s)	Preventive Design Controls	Occ	Detective Design Controls: Det	Det
	ID	Description									
Deploy on Demand	IR001	frontal collision at speed > 14mph (23 km/h) (solid barrier); full deployment within n ms	full deployment > n ms	Occupant hits dashboard or steering wheel, Serious injuries:10	10		software timing priorities not consistent with needs	coporate architectural design and modeling guidelines	3	Fault injection testing:5	5
							excessive delay in ignitor circuits		4	degradation testing:3	3
			incomplete deployment	Occupant hits dashboard or steering wheel, Serious injuries:10	10		gas generant specification allow for contamination	Design Manual 31240	3	variation simulation:2	2
							gas generant packaging inhibits full ignition	Design manual 8452	2	variation simulation:2	2
			no deployment	Driver hit by airbag, Injury of driver:10	10		failure in ECU	SR05, SR13, SR16	2	degradation testing:3	3
							failure in sensors	SR14, SR23, SR24	3	degradation testing:3	3
							communications failure	SR06	2	Fault injection testing:5	5
							failure in ignitors	SR 13	3	Fault injection testing:5	5



AIAG VDA

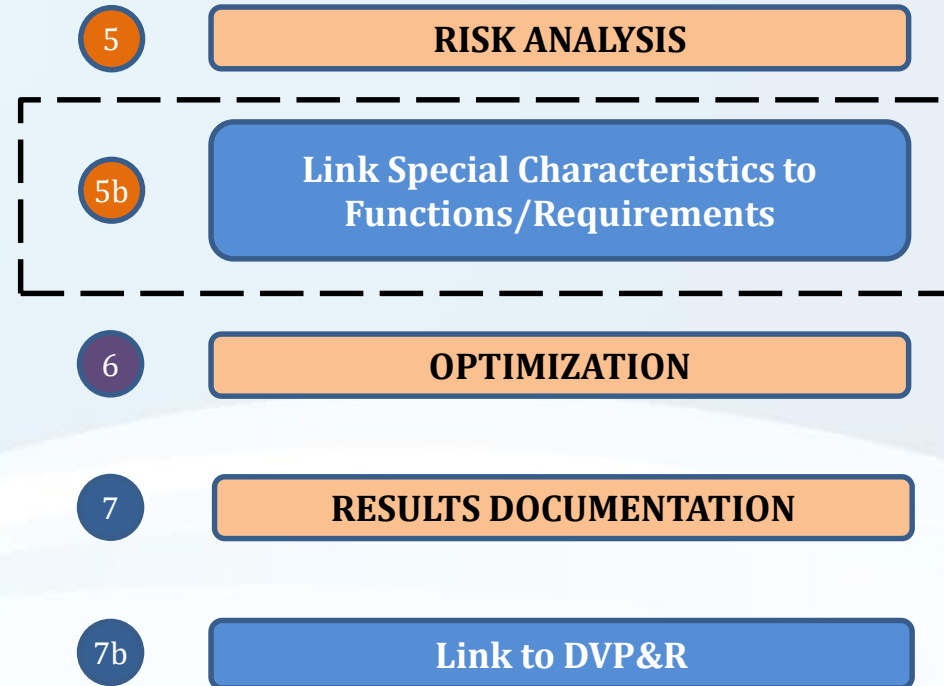
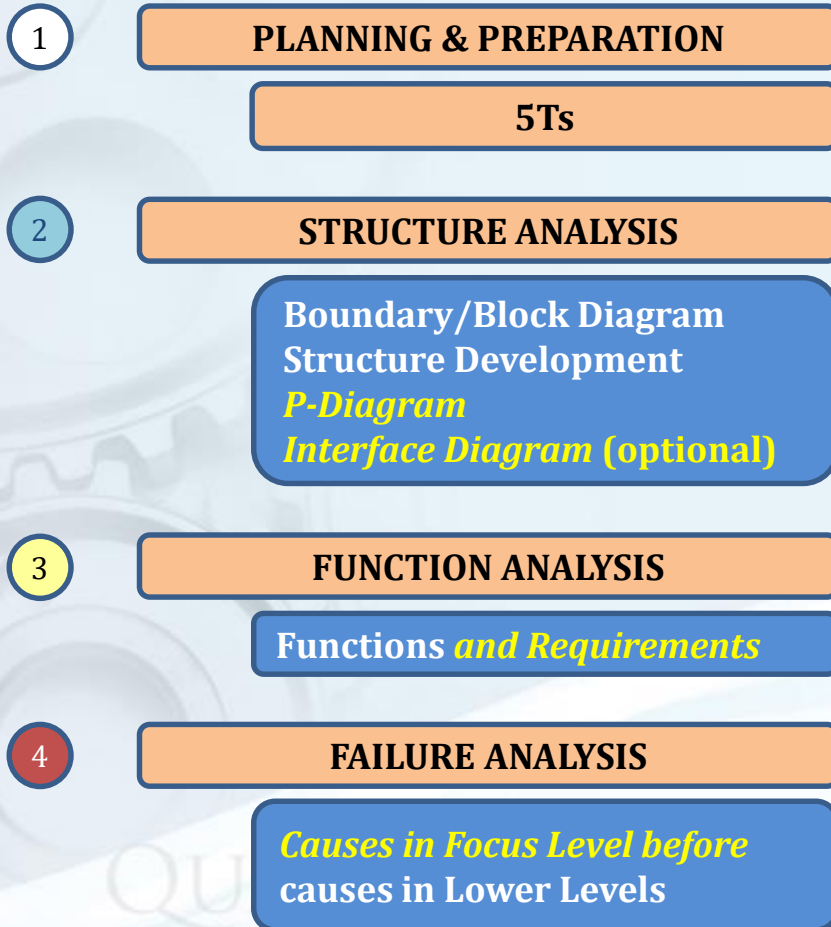
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Special Characteristics

Special Characteristics are, as defined by IATF 16949, a **product characteristic or manufacturing process parameter** that can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.

- Some companies require that all characteristics on the print be part of the process review. That is, all characteristics need to be included in the FMEA and Control Plan, and need to be studied for capability in PPAP. All types of measurement systems need to be studied for MSA as well.
- Control of characteristics designated as safety critical, function critical, and customer interface need to follow the customer-specific requirements or organization requirements, whichever is most stringent.

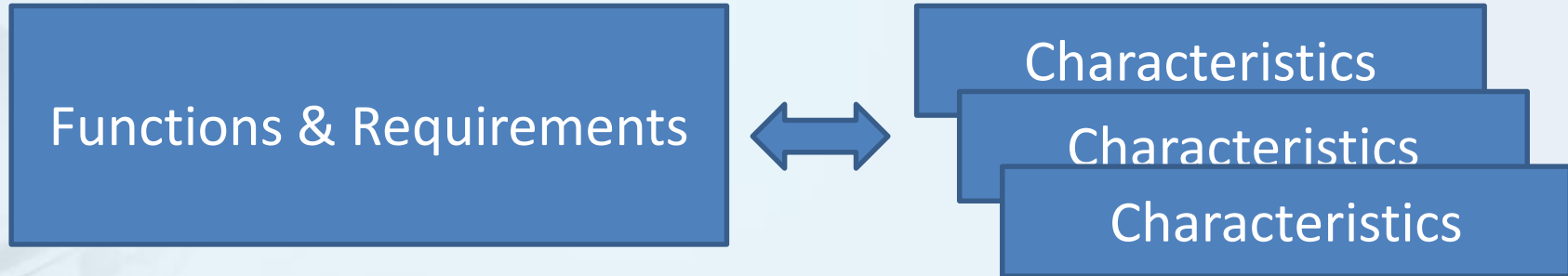


Linkage to Special Characteristics

- This step should be used to highlight high-priority failure modes and their associated causes.
- As a result of this analysis, the team may use this information to update the preliminary list of special characteristic by identifying those failure modes leading to special characteristics.
- A characteristic designated in the design record as special without an associated design failure mode identified in the DFMEA is an indication of a weakness in the design process.

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Characteristics and Requirements – Special Characteristics



Link the Design to Manufacturing to Shop Floor Controls

Sample rules for Special Functions	
Severity = 9 or 10	Safety Related
Severity = 5 to 8 with High Occurrence	Candidate



EVALUATIONS

Indices and Action Plans

NOTE : It is not appropriate to compare the ratings of one team's FMEA with the ratings of another team, even if the product / process appear to be identical, since each team's environment is unique and thus their respective individual ratings will be unique (i.e. the ratings are subjective).



Severity of Effect

Severity is the rank associated with the most serious effect of the failure mode on the customer:

- Assess the severity of each effect by team consensus using the ranking table, in the Effects column.
- Enter the ranking for the most serious effect in the “S” (Severity) column.

Recommendation: record the severity for each effect



DFMEA Severity – AIAG-VDA FMEA Handbook

SEV	Effect	Severity Criteria	Corporate or Product Line Examples
10	Very High	Affects safe operation of the vehicle and/or other vehicles, the health of operator or passenger(s) or road users or pedestrians	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p>The table may be augmented to include product specific examples.</p> </div>
9		Noncompliance with regulations	
8	High	Loss of primary vehicle function necessary for normal driving during expected service life	
7		Degradation of primary vehicle function necessary for normal driving during expected service life	
6	Moderate	Loss of secondary vehicle function	
5		Degradation of secondary vehicle function	
4		Very objectionable appearance, sound, vibration, harshness, or haptics	
3	Low	Moderately objectionable appearance, sound, vibration, harshness, or haptics	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics	
1	Very Low	No discernible effect	

Safety is 10 regardless of warning – Split rating of 10 and 9





Occurrence (Probability of)

The Occurrence rating (O) is a measure of the effectiveness of the prevention control, taking into account the rating criteria.

- Occurrence is an index linked to the likelihood that a specific cause will occur, resulting in the failure mode within the design life.
 - A consistent scale must be used to ensure continuity.
- Occurrence is directly related to the sensitivity of the design to the identified (special) causes.

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Occurrence

- **Best-in-Class:** identify whether the ranking is based on...
 - Consensus
 - Historical data on the same or similar designs
 - Statistical study (e.g. DOE) on the design
- The likelihood of occurrence ranking number has a relative meaning rather than an absolute value.

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Occurrence

- In determining this estimate, questions such as the following should be considered:
 - What is the service history/field experience with similar components, subsystems, or systems?
 - Is the item a carryover or similar to a previous level item?
 - How significant are changes from a previous level component, subsystem, or system?
 - Is the item radically different from a previous level item?
 - Is the item completely new?
 - Has the item's application and/or operational stresses changed?
 - Any environmental changes?
 - Has an engineering analysis (e.g. reliability) been used to estimate the expected comparable occurrence rate for the application?
 - Have preventive controls been put in place?



Occurrence

- A consistent occurrence ranking system should be used to ensure continuity.
- The occurrence ranking number is a relative rating within the scope of the FMEA and may not reflect the actual likelihood of occurrence.

Occurrence ranking will be affected by the
Prevention Design Controls



DFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Product Experience	Corporate or Product Line Examples
10	Extremely High	<p>First application of new technology anywhere without operating experience and/or under uncontrolled operating conditions. No product verification and/or validation experience.</p> <p>Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.</p>	
9	Very High	<p>First use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Prevention controls not targeted to identify performance to specific requirements.</p>	
8		<p>First use of design with technical innovations or materials on a new application. New application or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.</p>	

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DFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Product Experience	Corporate or Product Line Examples
7	High	New design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.	
6		Similar to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	

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DFMEA Occurrence – AIAG-VDA FMEA Handbook



OCC	Prediction of Failure Cause Occurring	Product Experience	Corporate or Product Line Examples
5	Moderate	<p>Detail changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.</p> <p>Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause, and provide some indication of performance.</p>	
4		<p>Almost identical design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.</p> <p>Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.</p>	

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DFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Product Experience	Corporate or Product Line Examples
3	Low	<p>Detail changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure.</p> <p>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design.</p>	
2	Very Low	<p>Almost identical mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.</p> <p>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.</p>	
1	Extremely Low	Failure eliminated through preventive control and failure cause is not possible by design	

DFMEA Occurrence – AIAG-VDA FMEA Handbook



Notes:

- **Product Experience:** History of product usage within the company (novelty of design, application or use case). Results of already completed detection controls provide experience with design.
- **Prevention Control:** Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins.
- A 10, 9, 8, 7 can drop based on product validation activities.



Detection

The Detection rating (D) is an estimated measure of the effectiveness of the detection control to reliably demonstrate the failure cause or failure mode before the item is released for production.

- Detection is the index associated with the best detection control shown in the Current Control (Detection) column.
 - When more than one control is identified, it is recommended that the detection ranking of each control be included as part of the description of the control.
 - Record the value with the lowest (most effective) ranking.
 - Only detection controls are ranked and recorded.



DFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
10	Very Low	Test procedure yet to be developed.	Test method not defined.	
9		Test method not designed specifically to detect failure mode or cause.	Pass-Fail, Test-to-Fail, Degradation Testing	
8	Low	New test method, not proven.	Pass-Fail, Test-to-Fail, Degradation Testing	
7		Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or retooling.	Pas-Fail Testing	
6	Moderate	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or retooling.	Test-to-Failure	
5			Degradation Testing	





DFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
4	High	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production.	Pass-Fail Testing	
3			Test-to-Failure	
2			Degradation Testing	
1	Very High	Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to always detect the failure mode or failure cause.		

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DFMEA Detection – AIAG-VDA FMEA Handbook

- Detection Controls shall be rated for each detection activity performed prior to delivery of the design for production.
- The timing of the detection control (before or after technical release) should also be considered as part of the detection rating.
 - Ratings 5 – 10: Post technical release and prior to production launch.
 - Ratings 1 – 4: Prior to technical release.

Considers capability to detect and timing

Breakout Exercise 6

Design Controls

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Breakout Exercise 6: Design Controls

Working with the DFMEA form from the previous breakout:

- For each cause of failure, identify current design controls, placing them, as appropriate, in the “Prevention” and “Detection” columns in the form.
 - Note that a current design control which operates by detecting the presence of the “Cause” is listed in the Detection column.

Remember...

- “Current Design Controls are those activities conducted as part *of the design process* that have been completed or committed to and that will assure the design adequacy for the design functional and reliability requirements under consideration.”

Source: FMEA Fourth Edition, 2008



Breakout Exercise 6: Design Controls

Referring to the previous index tables:

- Determine the likelihood of occurrence of the failure mode due to that cause, considering the effect of any preventive design action.
 - Since there is a greater or lesser likelihood of occurrence for each cause, provide a separate occurrence rating for each.
- Rate each “Detection” control in the detection action column. Select the rating for the most effective (lowest number) control.
 - Note that the same controls may operate for different causes, and are repeated.

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Action Priority

- At this point in the FMEA process, the team needs to decide if further efforts are needed to reduce any risks identified.
- Due to the inherent limitations on resources, time, technology, and other factors, the team needs to choose how to best prioritize these efforts.

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Action Priority

- The initial focus of the team should be oriented towards failure modes with the highest severity rankings.
 - When the severity is 9 or 10, it is imperative that the team needs to ensure that the risk is addressed through existing design controls or recommended actions (as documented in the FMEA).
- The priority of an action should be based on the discussions among the team considering the concerns and product/process knowledge as well as based on information captured by the FMEA process.

The actual logic to drive prioritization is left to each company and is not on the form

Action Priority (AP) – AIAG 4th Edition

- Risk Priority Number (RPN)

- RPN is calculated as:

$$\text{RPN} = \text{Severity} \times \text{Occurrence} \times \text{Detection}$$

- RPN is used to rank relative risk associated with specific failure modes.
 - Corrective action is taken thereafter to reduce the RPN, as appropriate.

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Cautions

“The use of an RPN threshold is NOT an acceptable practice for determining the need for recommended actions.”

Source: FMEA Fourth Edition, 2008

- There is no RPN value that requires mandatory action.
 - Applying thresholds assumes that RPNs are an accurate measure of relative risk (which they often are not) and that continuous improvement is not required (which it is).

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Action Priority (AP) – AIAG-VDA FMEA Handbook

The previous FMEA manuals include using RPN to determine action priorities. The AIAG-VDA FMEA Handbook uses an Action Priority (AP) Table.

- The AP Table provides the logic details for the FMEA team for all 1,000 possible combinations of S, O and D.
 - It includes a logic-based description for each of the action priority levels.
 - Actions may be prioritized based on individual evaluations of each of the S,O,D values and combinations of the values to identify the possible need to reduce risk.

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Action Priority (AP) – AIAG-VDA FMEA Handbook



- **IF** the organization chooses to modify the S,O,D tables for specific products, processes, or projects, the AP table should also be carefully reviewed and modified if necessary.
- It is recommended that potential Severity 9-10 failure effects and Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

Note — Interpretation:

- **This is not a prioritization of High, Medium, or Low risk, it is the prioritization of the need for actions to reduce risk.**

Action Priority (AP) – AIAG-VDA FMEA Handbook



- **Priority High (H): Highest priority for action**
 - The team *needs to* either identify an appropriate action to improve prevention and / or detection controls or justify and document why current controls are adequate.
- **Priority Medium (M): Medium priority for action**
 - The team *should* identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.
- **Priority Low (L): Low priority for action**
 - The team *could* identify actions to improve prevention or detection controls.

At a minimum the statement: "No Further Action is Needed" must be included.

Action Priority (AP) – AIAG-VDA FMEA Handbook



DFMEA

S 9-10

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	M	M	H	H	H	H
3	L	L	L	L	M	M	H	H	H	H
4	M	H	H	H	H	H	H	H	H	H
5	M	H	H	H	H	H	H	H	H	H
6	H	H	H	H	H	H	H	H	H	H
7	H	H	H	H	H	H	H	H	H	H
8	H	H	H	H	H	H	H	H	H	H
9	H	H	H	H	H	H	H	H	H	H
10	H	H	H	H	H	H	H	H	H	H

Action Priority (AP) – AIAG-VDA FMEA Handbook



DFMEA

S 7-8

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	M	M	H	H	H	H
3	L	L	L	L	M	M	H	H	H	H
4	M	M	M	M	M	M	H	H	H	H
5	M	M	M	M	M	M	H	H	H	H
6	M	H	H	H	H	H	H	H	H	H
7	M	H	H	H	H	H	H	H	H	H
8	H	H	H	H	H	H	H	H	H	H
9	H	H	H	H	H	H	H	H	H	H
10	H	H	H	H	H	H	H	H	H	H

Action Priority (AP) – AIAG-VDA FMEA Handbook



DFMEA

S 4-6

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	L	L	L	L	L	L
3	L	L	L	L	L	L	L	L	L	L
4	L	L	L	L	L	L	M	M	M	M
5	L	L	L	L	L	L	M	M	M	M
6	L	M	M	M	M	M	M	M	M	M
7	L	M	M	M	M	M	M	M	M	M
8	M	M	M	M	H	H	H	H	H	H
9	M	M	M	M	H	H	H	H	H	H
10	M	M	M	M	H	H	H	H	H	H

Action Priority (AP) – AIAG-VDA FMEA Handbook



DFMEA

S 2-3

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	L	L	L	L	L	L
3	L	L	L	L	L	L	L	L	L	L
4	L	L	L	L	L	L	L	L	L	L
5	L	L	L	L	L	L	L	L	L	L
6	L	L	L	L	L	L	L	L	L	L
7	L	L	L	L	L	L	L	L	L	L
8	L	L	L	L	M	M	M	M	M	M
9	L	L	L	L	M	M	M	M	M	M
10	L	L	L	L	M	M	M	M	M	M



Action Priority (AP) – AIAG-VDA FMEA Handbook



DFMEA

S 1

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	L	L	L	L	L	L
3	L	L	L	L	L	L	L	L	L	L
4	L	L	L	L	L	L	L	L	L	L
5	L	L	L	L	L	L	L	L	L	L
6	L	L	L	L	L	L	L	L	L	L
7	L	L	L	L	L	L	L	L	L	L
8	L	L	L	L	L	L	L	L	L	L
9	L	L	L	L	L	L	L	L	L	L
10	L	L	L	L	L	L	L	L	L	L

Breakout Exercise 7

Indices and Action Plans

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Breakout Exercise 7: Indices and Action Plans

Working with the DFMEA form from the previous breakout:

- For each failure mode identified:
 - Referring to the index table, determine an appropriate rating for each cause and control.
 - In the appropriate columns, enter the “highest” (most severe) index from among those identified.

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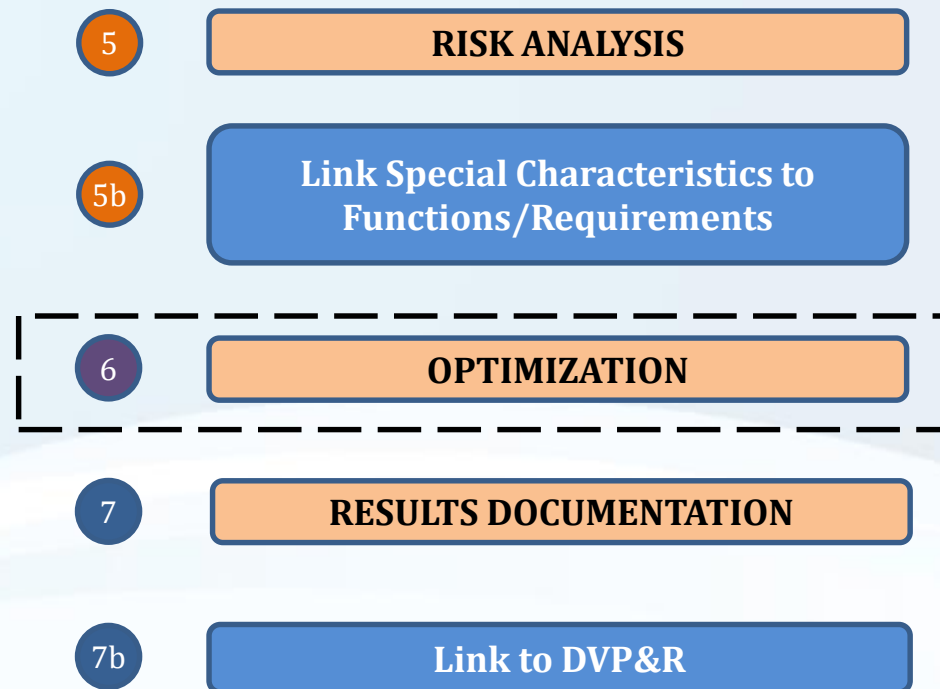
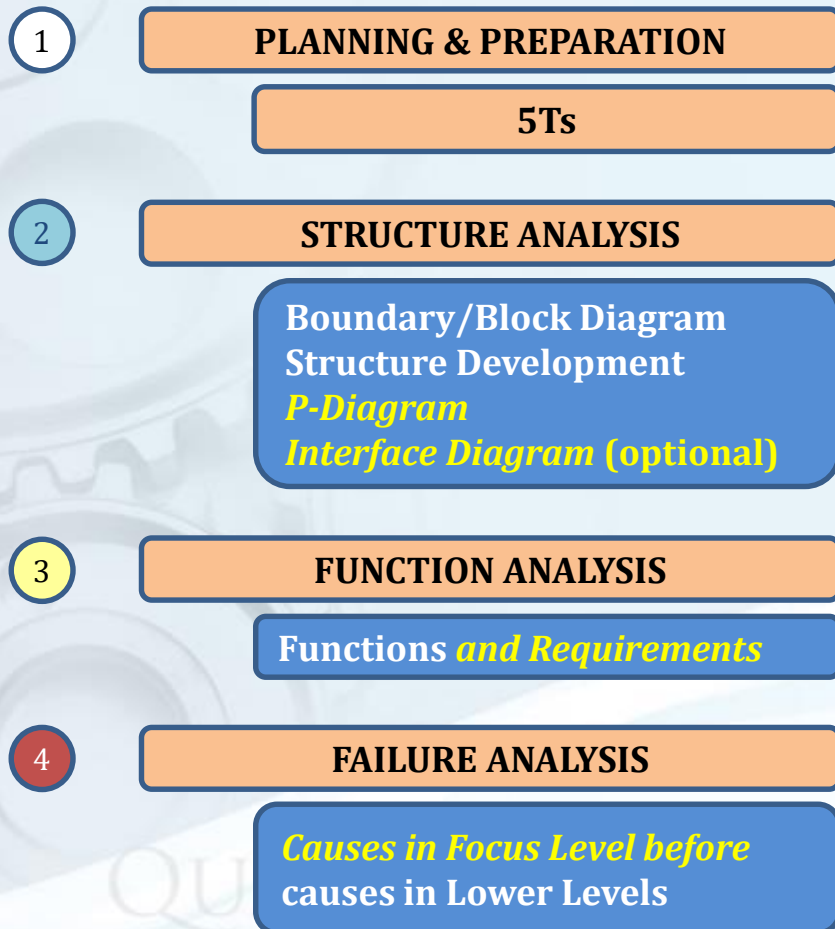
Interactive Example using EwQIMS Software

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Identification of the
Actions Necessary to
Reduce Risks

OPTIMIZATION



Legend:



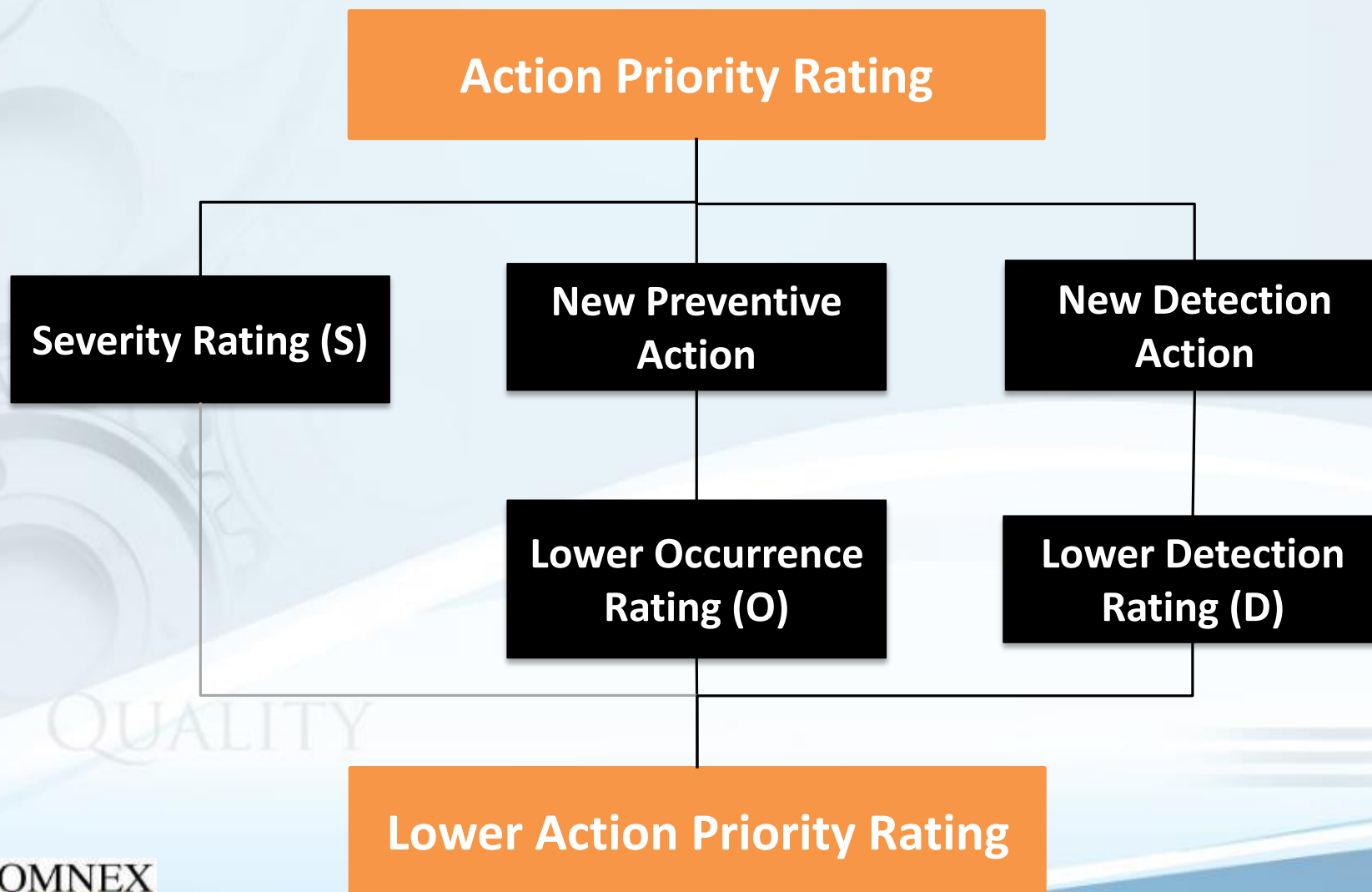
= Omnex improvements over
the AIAG-VDA DFMEA process

Italic font

= Omnex-specific changes to the
AIAG-VDA DFMEA process



Step 6: Optimization





Recommended Actions

Intent of any recommended action is to reduce any one or all of the occurrence, detection, and/or severity rankings.

To Reduce:	Consider This Action:	To Accomplish this:
Severity	<ul style="list-style-type: none">• Change the design	<ul style="list-style-type: none">• Eliminate or reduce the severity of the failure mode
Occurrence	<ul style="list-style-type: none">• Change the design or improve engineering specification• Error proofing	<ul style="list-style-type: none">• Prevent the cause or failure and its effect from occurring
Detection	<ul style="list-style-type: none">• Increase or change in the design validation / verification actions• Design change to enhance detection likelihood• Revised test plan	<ul style="list-style-type: none">• Detect that the cause has occurred and take corrective action• Detect that the failure mode has occurred and correct



Recommended Actions

AIAG-VDA FMEA Handbook: Recommended actions are split into prevention and detection actions.

OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	AP
				NEW!						

QUALITY



Recommended Actions

Suggested levels for Status of Actions:

- **Open**
The action has neither been defined nor discussed.
- **Decision Pending (optional)**
The action has been defined but has not yet been decided on. A decision paper is being created.
- **Implementation Pending (optional)**
The action has been decided on but has not yet been implemented.
- **Completed**
Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.
- **Discarded**
Discarded status is assigned when a decision is made to not implement an action. This may occur when risks related to cost, implementation timing, or business strategy are greater than technical risks.



Recommended Actions

Status of the Actions

- The FMEA is not considered “complete” until the team assesses each item’s Action Priority and either accepts the level of risk or documents closure of all actions.
- Closure of all actions should be documented before the FMEA is placed under revision control (or released) to Serial Production.

If no actions are recommended, at a minimum, the statement that “*No Further Action is Needed*” must be included

Recommended Actions – Assessment of Action Effectiveness



- When an action has been completed, Occurrence and Detection values are reassessed as a prediction of effectiveness, and a new Action Priority may be determined.
- However, the status of the action remains "implementation pending" until the effectiveness has been verified. Only then should it be changed to "completed."

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Action Priority (AP) – AIAG-VDA FMEA Handbook

- **IF** the organization chooses to modify the S,O,D tables for specific products, processes, or projects, the AP table should also be carefully reviewed and modified if necessary.
- It is recommended that potential Severity 9-10 failure effects and Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

Note — Interpretation:

- **This is not a prioritization of High, Medium, or Low risk, it is the prioritization of the need for actions to reduce risk.**



Continual Improvement

The DFMEA serves as a historical record for the process.

- Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers need to be visible or, at a minimum, available and accessible as part of version history.
- The completed analysis becomes a repository to capture the progression of process decisions and design refinements.
- However, original S, O, D ratings may be modified for foundation, family or generic DFMEAs because the information is used as a starting point for a process specific analysis.

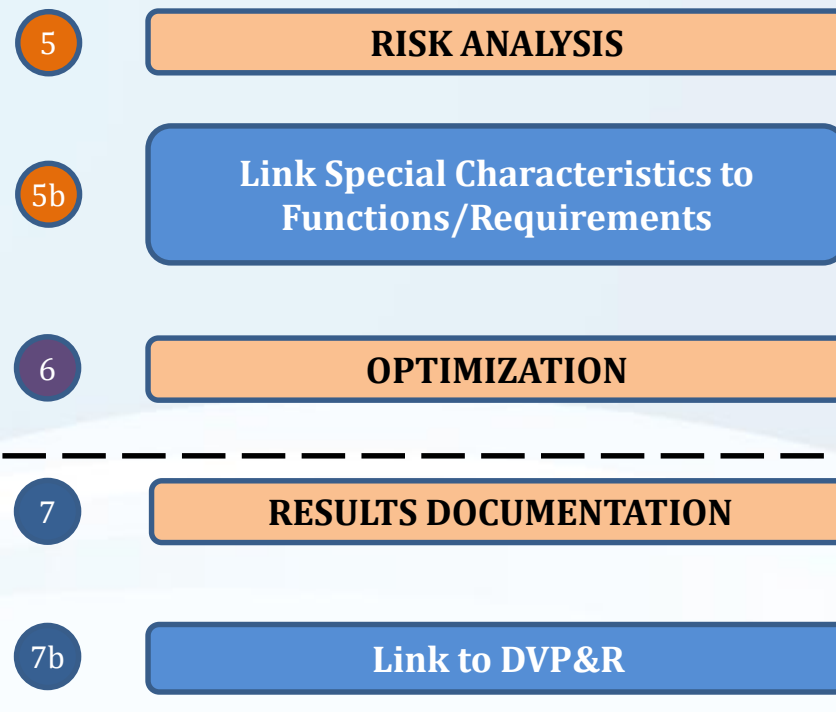
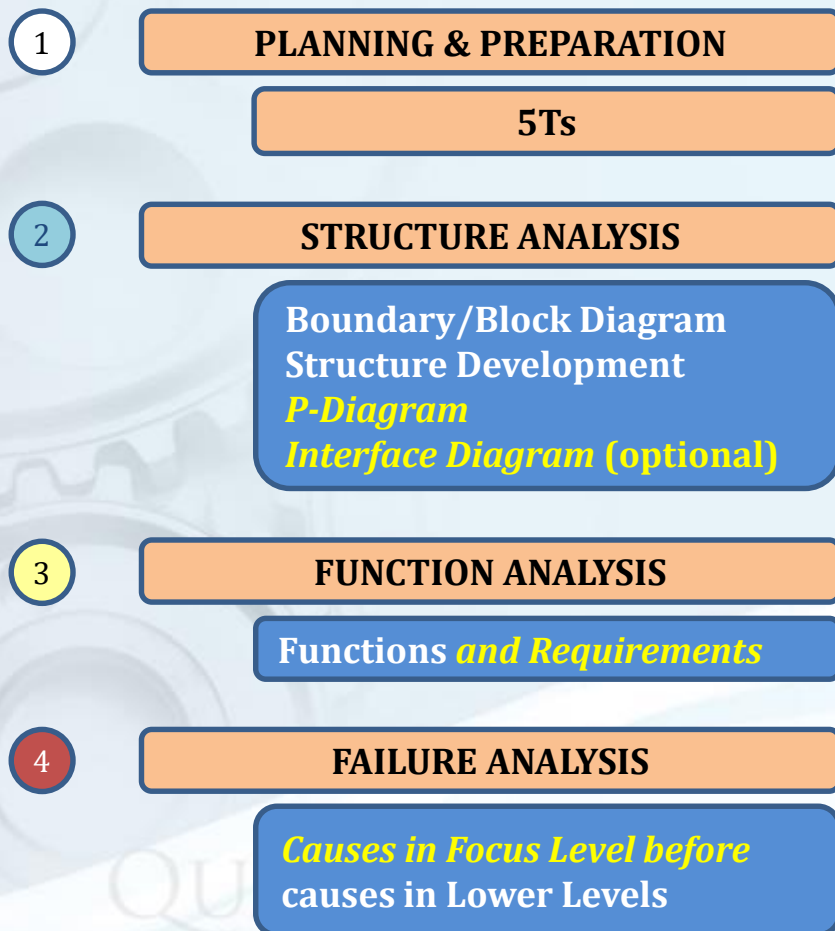
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Communication of Actions
Taken to Reduce Risks

RESULTS DOCUMENTATION



Legend:



= Omnex improvements over
the AIAG-VDA DFMEA process

Italic font

= Omnex-specific changes to the
AIAG-VDA DFMEA process



FMEA Results Documentation

- The scope and results of an FMEA should be summarized in a report.
- This report can be used for communication purposes within a company, or between companies. In this way, it is also ensured that all details of the analysis and the intellectual property remain at the developing company.

Note

- **The FMEA is not considered "complete" until the team assesses each item's Action Priority and either accepts the level of risk or documents closure of all actions.**
- **If "No Action Taken," then the Action Priority is not changed, and the risk of failure is carried forward into the product. Actions are open loops that need to be closed in writing.**



FMEA Results Documentation

The content of the documentation must fulfill the requirements of the intended reader and details may be agreed between the relevant parties.

The layout of the document may be company specific. The content may include the following:

- A. A statement of final status compared to original goals established in the Project Plan.
 - a. **FMEA InTent:** Purpose of this FMEA?
 - b. **FMEA Timing:** FMEA due date?
 - c. **FMEA Team:** List of participants?
 - d. **FMEA Task:** Scope of this FMEA?
 - e. **FMEA Tool:** How do we conduct the analysis method used?



FMEA Results Documentation

The layout of the document may be company specific. The content may include the following:

- B. A summary of the scope of the analysis and identify what is new.
- C. A summary of how the functions were developed.
- D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/O/D rating tables and method of action prioritization (i.e. Action Priority table).
- E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.



FMEA Results Documentation

The layout of the document may be company specific. The content may include the following:

- F. A plan and commitment of timing for ongoing FMEA improvement actions.
 - a. Commitment and timing to close open actions.
 - b. Commitment to review and revise the DFMEA during mass production to ensure the accuracy and completeness of the analysis as compared with the production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures.)
 - c. Commitment to capture "things gone wrong" in foundation DFMEAs for the benefit of future analysis reuse, when applicable.

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Linkage Between DFMEA and DVP&R

- The third step of the 7-Step Process, **Functional Analysis**, links the function-requirements.
- The fifth step, **Risk Analysis**, identifies “**preventive and detective controls**” linked to the function and the requirement.
- These controls are the same controls in the DVP&R or test plan.
 - Omnex recommends that DVP&R house both controls.
- The linkage between the requirements and the test plan in the “V” is provided by the DFMEA and DVPR linkages.

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AIAG VDA

Interactive Example using EwQIMS Software

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Chapter 4: Developing the Design FMEA – What We Covered

Learning Objectives

You should now be able to:

- Explain design failure modes
- Identify failure modes from requirements
- Explain causes of failure modes
- Explain design controls
- Distinguish between prevention and detection controls
- Explain the key elements of the risk analysis
- Define requirements for Results Documentation and Communication

Chapter Agenda

- Design Failure Modes
- Step 4: Failure Analysis
 - **Breakout Exercise 4**
 - Potential Effects of Failure
 - Potential Causes of Failure
 - **Breakout Exercise 5**
- Step 5: Design Controls and Risk Analysis
 - **Breakout Exercise 6**
 - Evaluation: Indices and Action Plans
 - **Breakout Exercise 7**
- Step 6: Optimization
- Step 7: Results Documentation

Chapter 5

Test Planning and Reporting

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Product Design Verification & Validation



Chapter 5: Test Planning and Reporting – What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe a Design Verification Plan
- Describe the elements of the DVP&R

Chapter Agenda

- Design Verification and Validation
- Elements of the DVP&R

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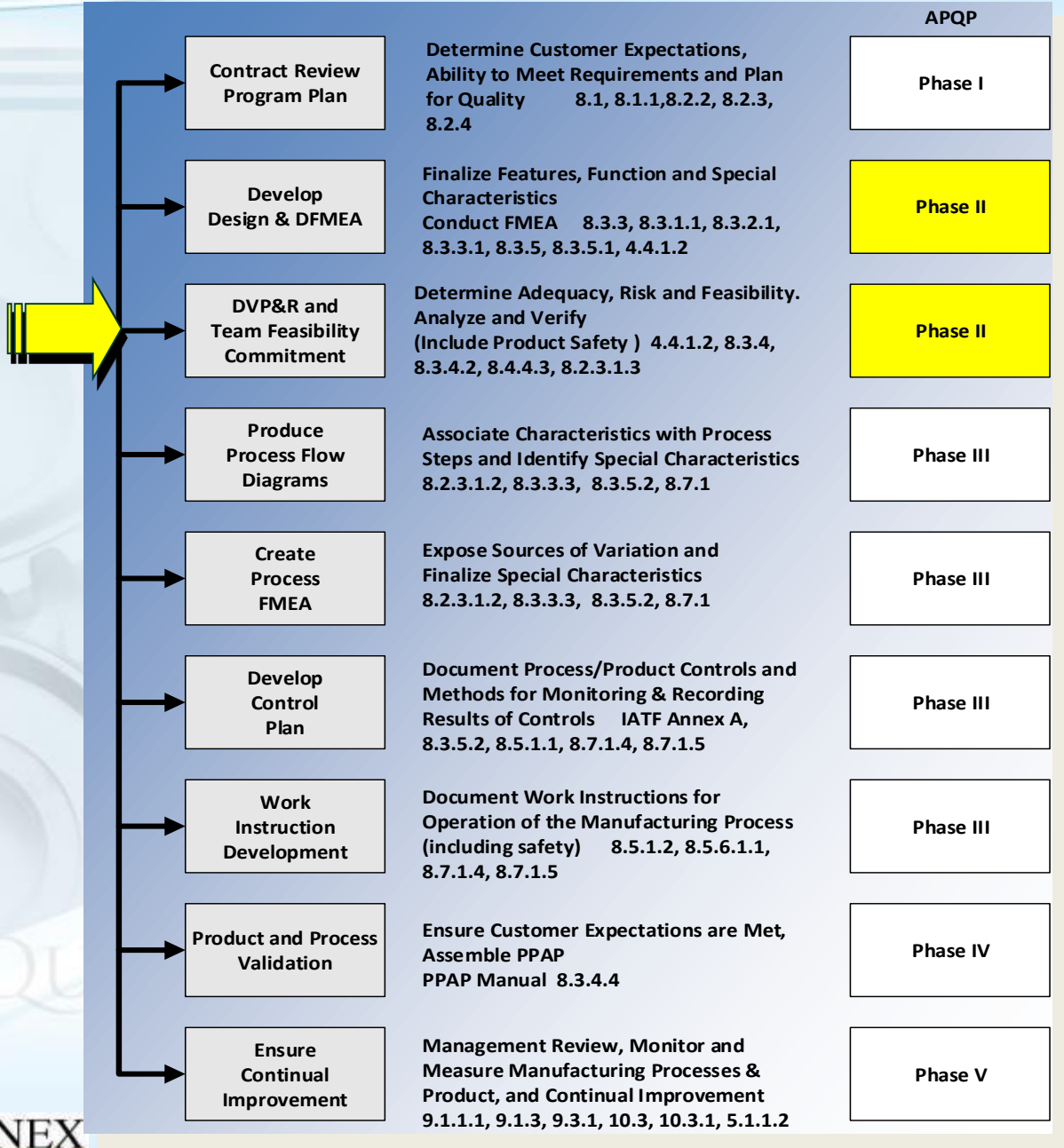


DESIGN VALIDATION

DVP&R: Design Verification Plan & Report

Note: ISO 9001 and IATF 16949 consider DVP&R to be a validation test plan, not design verification

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Product Development Process Model

Design Validation Plan

Objectives

- Itemizes all tests necessary to assure criteria and targets can and will be met
 - Specifies test responsibilities, quantities and timing requirements
- Provides test results and progress made toward design targets
- Allows the program/project to move forward

Uses

- Product development tool to layout plan to meet all requirements and present results
- Product assurance tool and working document to aid engineering personnel
- Test Schedule

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Design Validation Plan

Test Plan

- Test plan documents test activities during each phase of product development.

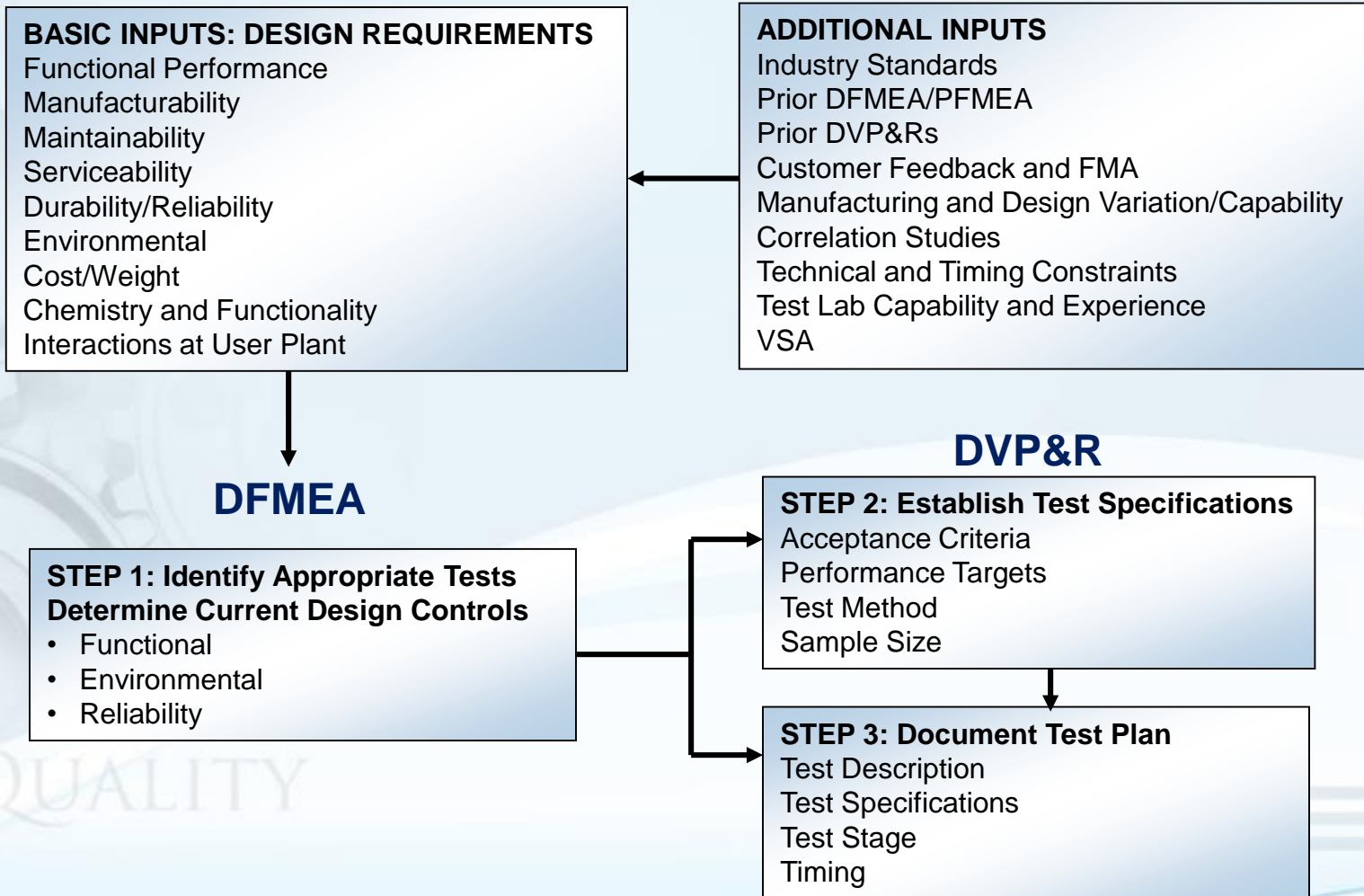
Test Plan Development

- Developed early in design phase of all new products.
- Revised based on significant changes in environment, design, government regulations, or customer requirements.

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Test Plan Flow Format



Sample Test Plan – DVP&R

TEST PLAN										
Item No.	Procedure or Standard	Test Description	Acceptance Criteria	Target Requirements	Test Responsibility	Test Stage	Sample		Timing	
							Qty	Type	Start	Comp.
1		Inherent Reliability Prediction	1000 Hours	R 95	ABC	DV			8/30/95	9/30/95
2	PF 99	Opening Effort	Max & Min Range Sec 4-8-2	No Failures Cp > 1.33 & No Failures Cpk > 1.33	ABC	DV	5	B	8/30/95	9/2/95
					ABC	PV	30	D	10/19/95	10/22/95
					ABC	CC		E	1/30/96	
				No Failures	ABC	DV	5	B	8/30/95	9/2/95
					ABC	PV	5	D	10/18/95	10/22/95
				No Failures	ABC	DV	6	B	8/28/95	9/5/95
					ABC	PV	6	D	10/19/95	10/22/95
5	PF 99	PG Test	30 K VE Sec 5-A-3	Four Consecutive Successes						

TEST STAGE CODES

ED	Engineering Development
DV	Design Verification
PV	Production Validation
CC	Continuing Conformance

SAMPLE TYPE CODES

A	Prototype (Handmade)
B	Prototype (Tooled)
C	Program Level
D	Initial Production
E	Full Volume Production

Sample Test Report

TEST REPORT				Notes
Samples Tested			Actual	
Qty	Type	Phase		
			R96	MIL - HDBK - 217 Prediction Test Report # 24375
5	B	I	No Fail	Test Report # 98476
30	D	I	No Fail Cp = 1.8	Test Report # 4876
5	B	I	No Failures	Test Report # 9487
5	D	I	No Failures	
6	B	I	R93	6 Tests to Failure (Weibull Analysis)
6	D	I	C90 R93 C90	
8	D	I	No Failures	Test Report # 02943

DVP&R Program Management Responsibility

To ensure that:

- Design engineer is responsible for plan execution
- Multi-disciplinary team is formed for completion of Design Verification Plan
- Specified tests, methods, equipment, acceptance criteria, sample size, design level and timing are clearly documented
- Test samples, equipment, facilities, services and resources are available and utilized for verification
- Tests are accomplished according to the DVP and project timing chart
- Results are reviewed, analyzed and addressed

DVP&R Summary

- DVP&R process is used to verify designs and production parts will fully meet design intent.
- In conjunction with the Control Plan, provides evidence of the ability to continue meeting product requirements.
- Continuing Conformance Testing may be incorporated into the Production Control Plan.

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Chapter 5: Test Planning and Reporting – What We Covered

Learning Objectives

You should now be able to:

- Describe a Design Verification Plan
- Describe the elements of the DVP&R

Chapter Agenda

- Design Verification and Validation
- Elements of the DVP&R

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Chapter 6

Effectively Using the AIAG-VDA FMEA Approach

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Chapter 6: Effectively Using the AIAG-VDA FMEA

– What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- List the top changes to the AIAG-VDA DFMEA
- Evaluate DFMEAs
- Identify the linkages from design to shop floor using AIAG-VDA FMEAs
- Describe Change Management, PPM and Design Reuse and application of AIAG-VDA FMEAs
- Make the organizational changes necessary and get started with AIAG-VDA FMEA

Chapter Agenda

- Key Changes to DFMEAs
- Evaluating DFMEAs
- Changes to the Organization and Supply Chain
 - Supply Chain Standards
 - Requirements Management and Decomposition
- Organization of DFMEA and PFMEA Libraries
 - Design and Process Reuse
 - PPM Defect History, Cost of Poor Quality and FMEA Linkages
 - APQP and Supply Chain Changes
 - Change Management

Key Changes to DFMEA (AIAG-VDA FMEA)

- 7-Step DFMEA Development Process
- More prescriptive Risk Analysis forms, which include a significant addition to the number of columns of data
- Introduction of three product levels: Higher, Focus, and Lower Levels
 - Failures at the Focus Level, effects at the Higher Level and causes at the Focus and Lower Levels
 - Amounts to a 3-Dimensional analytical structure difficult to represent in spreadsheet formats
- New definitions of Severity, Occurrence and Detection indices for Design and Process FMEA analyses
- Use of a new composite index called “Action Priority” to categorize relative risk
- Introduction of a new, supplemental Design FMEA for the risk analysis of “Monitoring and System Response” associated with a very specific type of electronic product (FMEA-MSR)

EVALUATING DFMEAS

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Evaluating DFMEAs —

Did the Supplier Use the Seven Steps?

Step 1 – Planning and Preparation

- Is there evidence of the use of the 5Ts?
Project Plan – inTent, Timing, Team, Tasks, Tools
- Has supplier defined the scope of the analysis (e.g. using a Boundary Diagram)?
- Does the scope of analysis include the interfaces and interactions necessary?
- Was this DFMEA event planned with a family DFMEA document for design reuse?
- Is failure history from Warranty, Customer, and internal plant data for surrogate parts available and considered for design improvement purposes?
- Are DFM and DFA being considered in functional requirements related to manufacturability.
- Is there a System DFMEA, Subsystem DFMEA, and Component DFMEA planned? What is the planning for linkages between the documents?

Evaluating DFMEAs —

Did the Supplier Use the Seven Steps?

Step 2 – Structure Analysis:

- Was the Structure Analysis conducted? The structure should include the Focus Element, and the Higher and Lower Elements at the very least.
- Is there an interface diagram or P-Diagram included? Does it include all the Key Functions and its requirements including the following:
 - Noise Factors
 - Control Factors
 - Unintended Output?
 - Input/Output
 - Non-functional Requirements

Step 3 – Function Analysis

- Does the Function Analysis include Functions and Requirements?
- Are the functions defined as “verb-noun” and do the requirements have the following characteristics – unambiguous; understandable; atomic (singular); achievable; verifiable?
- Are there interface functions for an assembly?

Evaluating DFMEAs — Did the Supplier Use the Seven Steps?

Step 4 – Failure Analysis

- Are the failure modes in terms of not achieving the requirement?
 - Are there failure modes for all requirements, as applicable?
- Is the effect a failure caused by the focus element failure?
- Is the cause focused on the “Focus Element” design and how the requirements or design at the Focus Element could cause the failure?

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Evaluating DFMEAs —

Did the Supplier Use the Seven Steps?

Step 5 – Risk Analysis

- Has the DFMEA applied the Severity, Occurrence and Detection correctly from the tables? Have a few been sampled for consistency?
 - The Severity should be based on the “highest” failure looking at the cause and effect linkage up to the customer.
 - The Occurrence is based on prevention controls. Is significant error-proofing applied?
 - Is the Detection control and rating based on the most effective detection control?
- Was the Action Priority (AP) logic correctly applied and sampled?
- Are the prevention and detection controls carefully transferred to the DVP&R or test plans and sampled?
- Are the Special Functions identified for Severity 9 & 10 Requirements / Functions and Severity 8 & 7 Requirements / Functions with **High Occurrence**?

Evaluating DFMEAs —

Did the Supplier Use the Seven Steps?

Step 6 – Optimization

- Does the recommended action follow the logic of the AP tables:
 - Severity 9 & 10 with **High** and **Medium** AP rating?
 - Severity 8 & 7 with **High** Occurrence or **High** Detection?
 - Is “**none**” recorded when there are no recommended prevention and detection controls actions?
- Is collaboration between the customer or supplier (including internal supplier) considered for severity reduction?
- Are there opportunities for error-proofing or ability to move a detection control up earlier in the design cycle?
- Is there a responsible party, promised date, status, and action taken with evidence of actions taken, completion date, and a reassessment of Severity, Occurrence, and Detection?
- Are there promised dates which have been missed? Are promised dates too far out into the future? Are action taken dates and promised dates showing consistent discrepancies?

Evaluating DFMEAs —

Did the Supplier Use the Seven Steps?

Step 7 – Results Documentation

- Is there evidence of risk communication? Did it go to the right parties?
- How is the organization communicating and linking to supplier DFMEAs? Customer DFMEAs?
- How much improvement was seen as a result of this AIAG-VDA DFMEA activity?
- How is this information captured for change management and lessons learned?

See Appendix for a Suitability Review checklist that can be used to evaluate DFMEAs

CHANGES TO THE ORGANIZATION AND SUPPLY CHAIN

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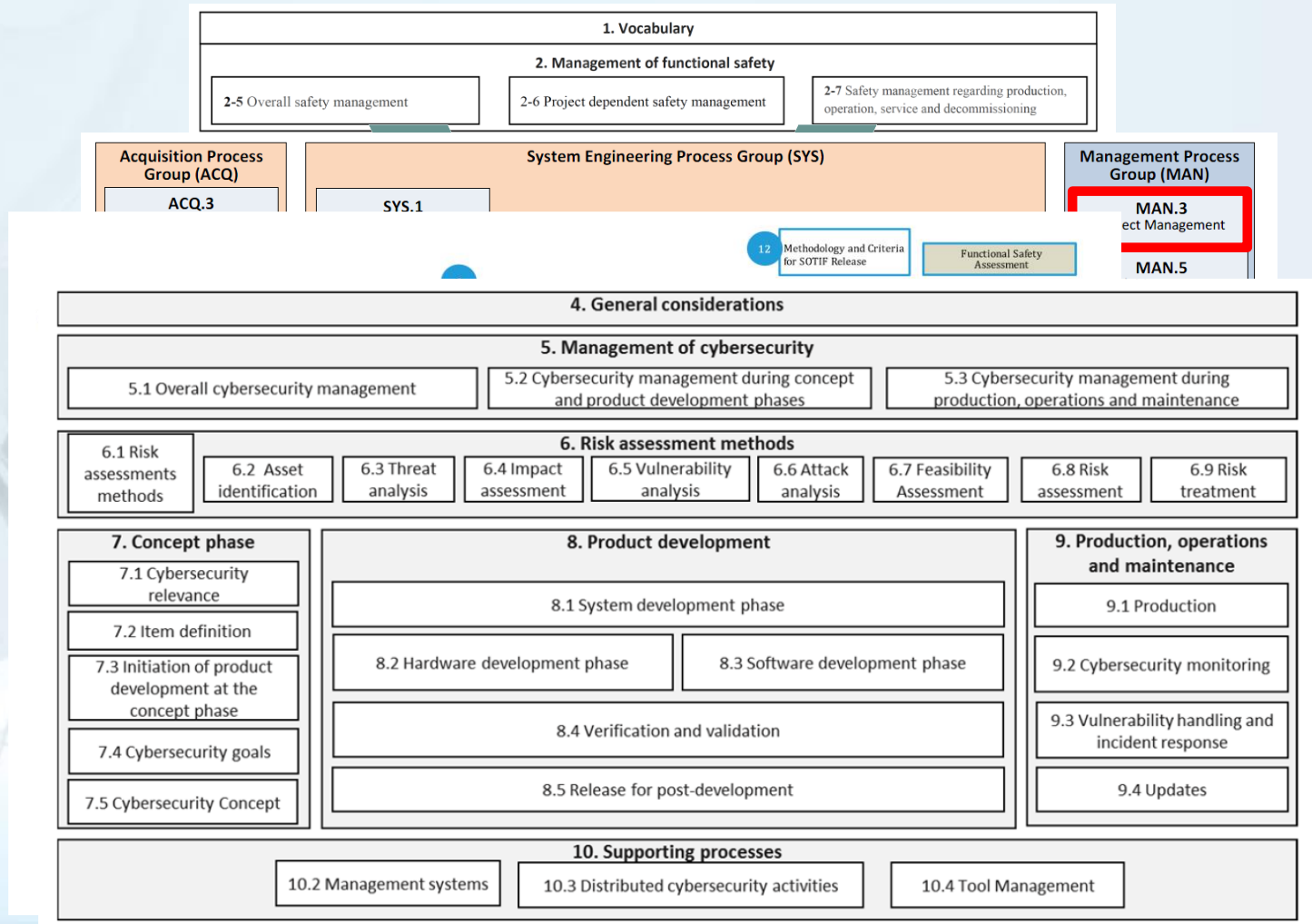
Context Changes To The Organization And Supply Chain

- Supply Chain Standards and why are they are important
- Requirements Management and Traceability
- Reuse of Information and Products/Process Families and Continual Improvement
- APQP Changes and Purchasing modifications (PO)

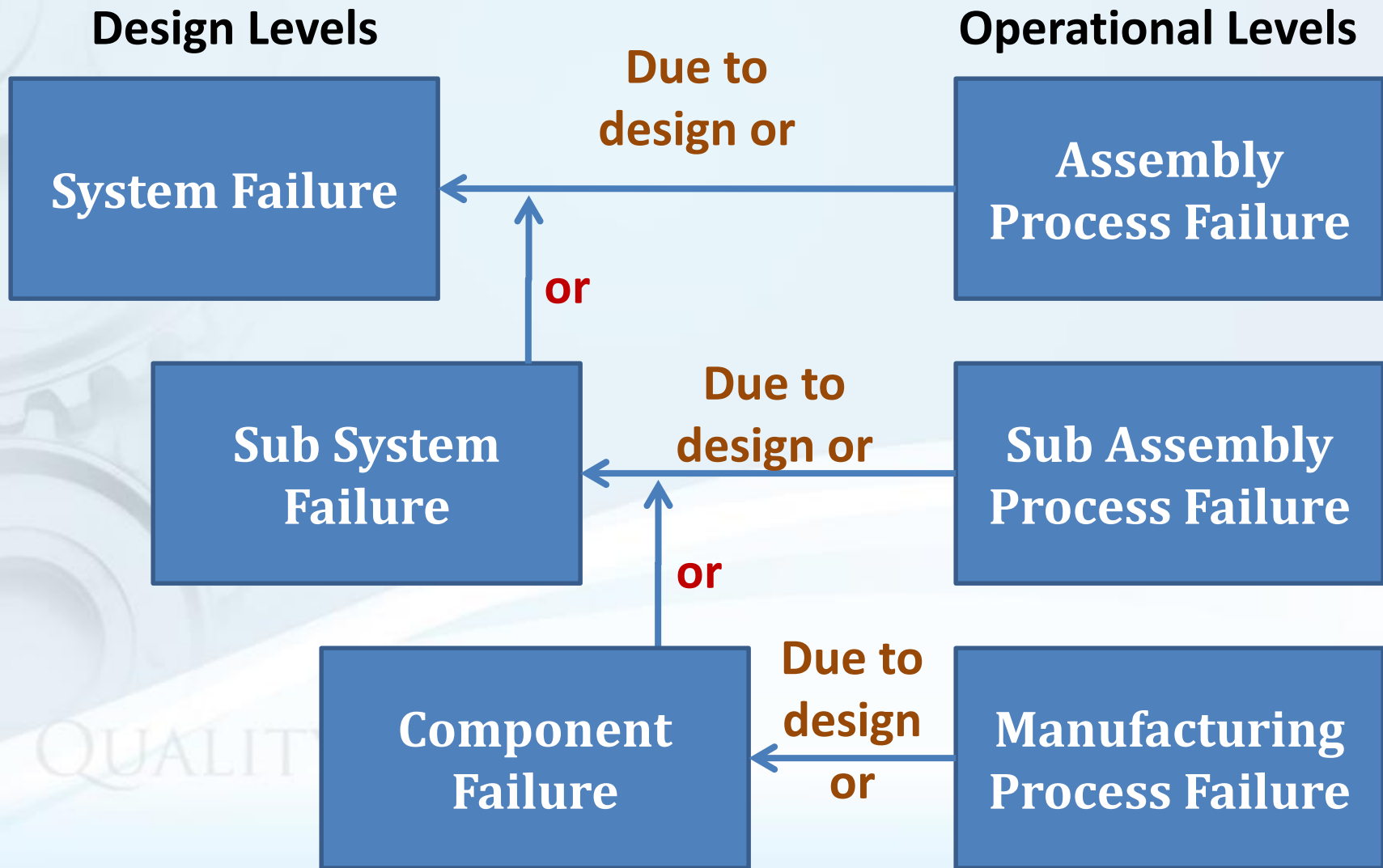
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Supply Chain Standards

Product Shift from Gas to Diesel to Electric and Autonomous Cars

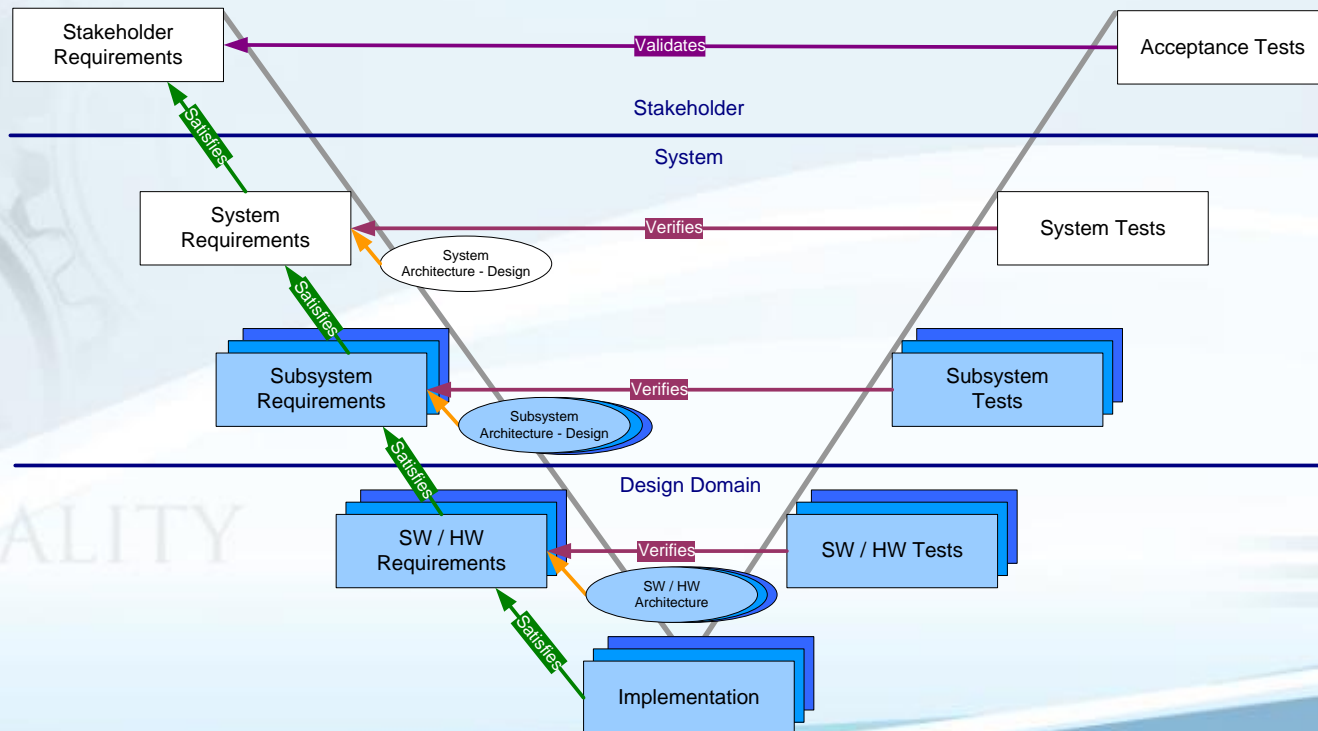


Historical Failures at System Level



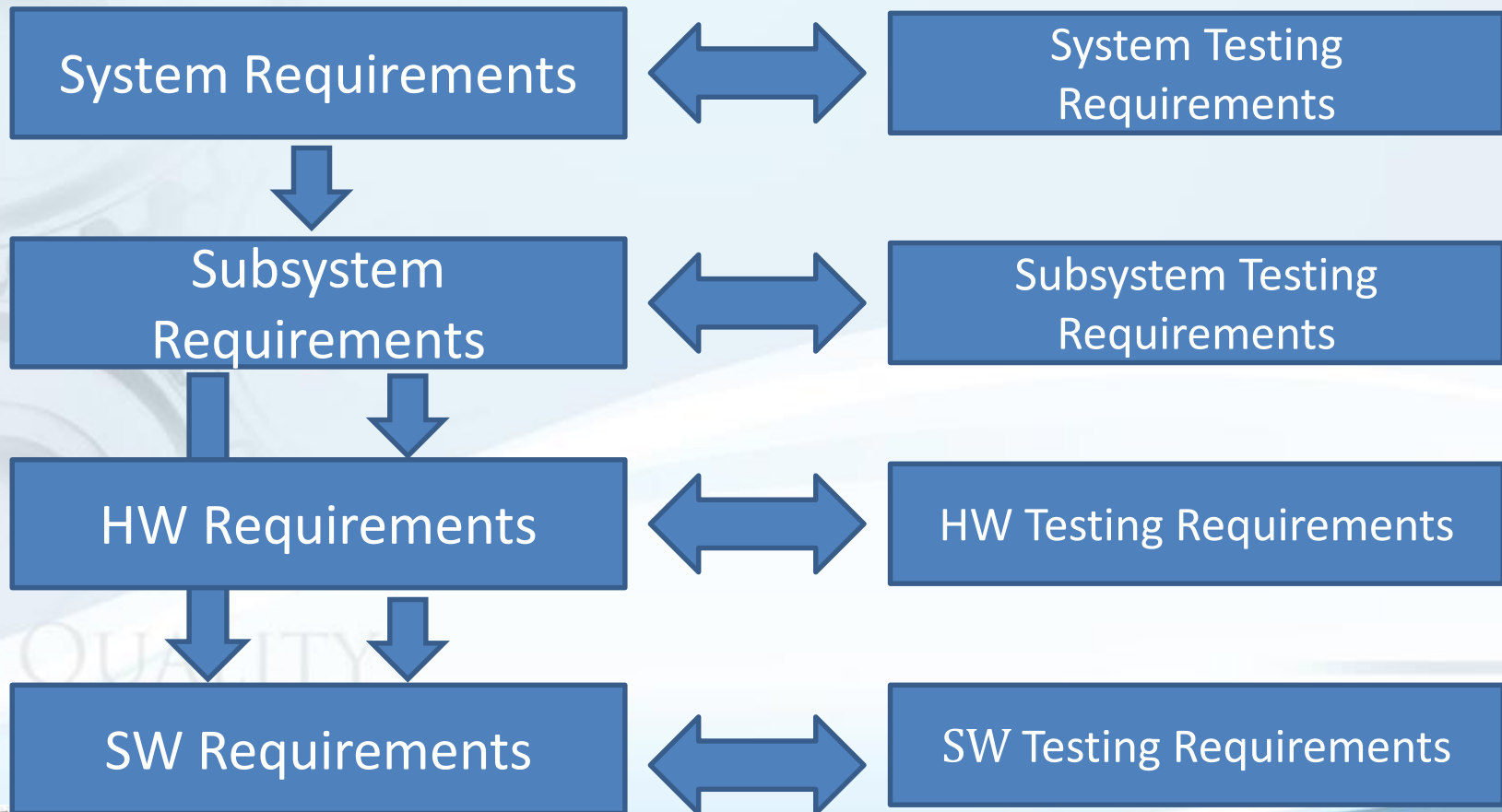
Requirements Management

- The industry is moving a “V” model approach for relating requirements and testing, including traceability
- Functional Safety, SOTIF, ASPICE, and Cybersecurity Standards require this!



Requirements Decomposition

**AIAG-VDA DFMEA Linkages in Function Analysis
which then needs to be integrated with DVP&R**



ORGANIZATION OF THE DFMEA AND PFMEA LIBRARIES

Design and Process Reuse

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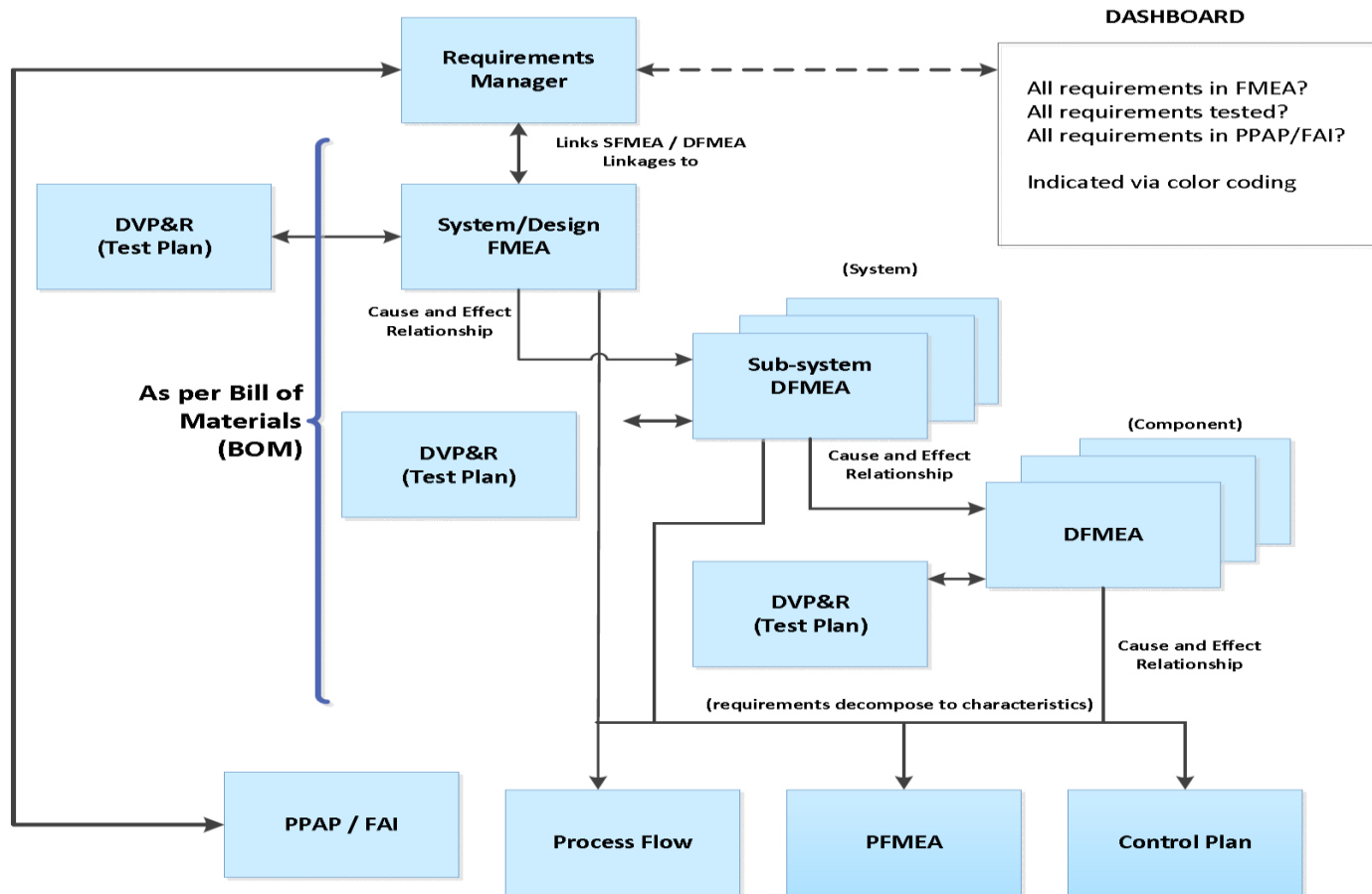
Linkage Between DFMEA and DVP&R

- The third step of the 7-Step Process, **Functional Analysis**, links the function-requirements.
- The fifth step, **Risk Analysis**, identifies “**preventive and detective controls**” linked to the function and the requirement.
- These controls are the same controls in the DVP&R or test plan.
 - Omnex recommends that DVP&R house both controls.
- The linkage between the requirements and the test plan in the “V” is provided by the DFMEA and DVPR linkages.*

***Not addressed in AIAG-VDA FMEA Handbook**

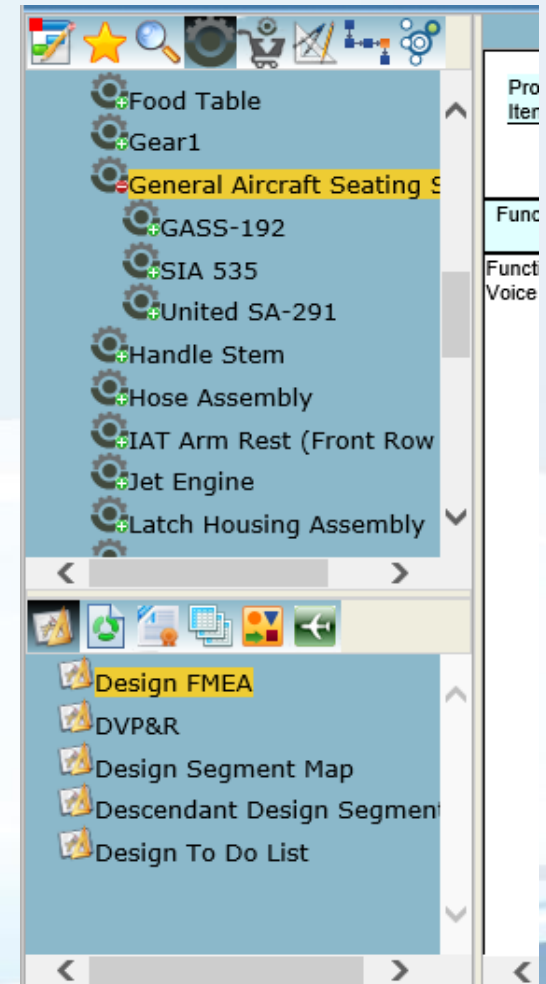
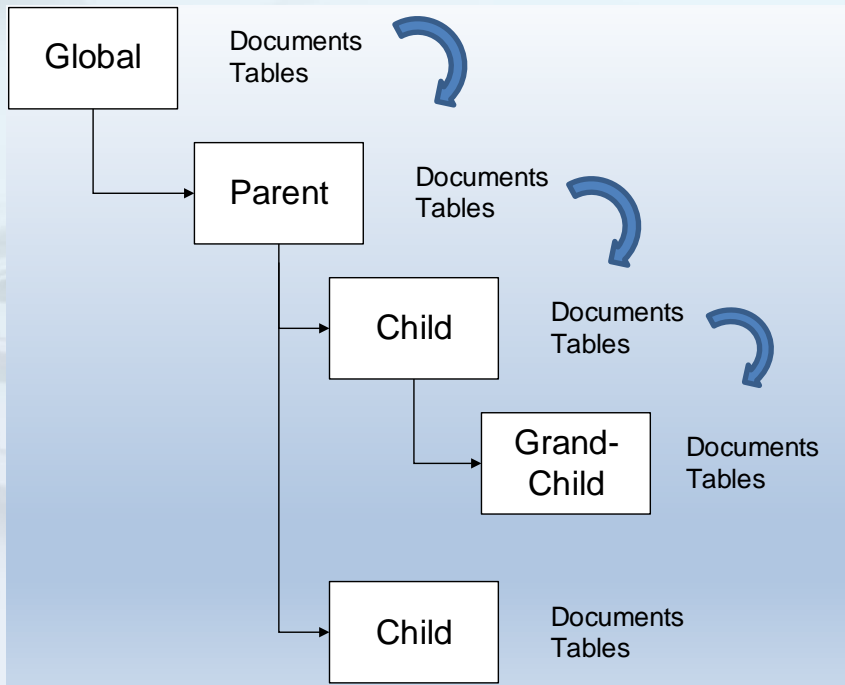
Linkages Between DFMEA, PFMEA and the Shop Floor

Requirements Manager / Flow Down and Risk Analysis

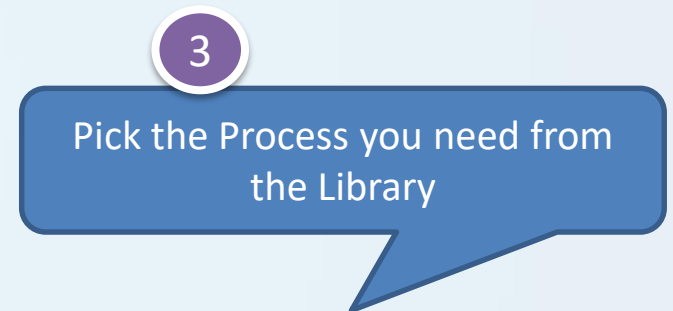
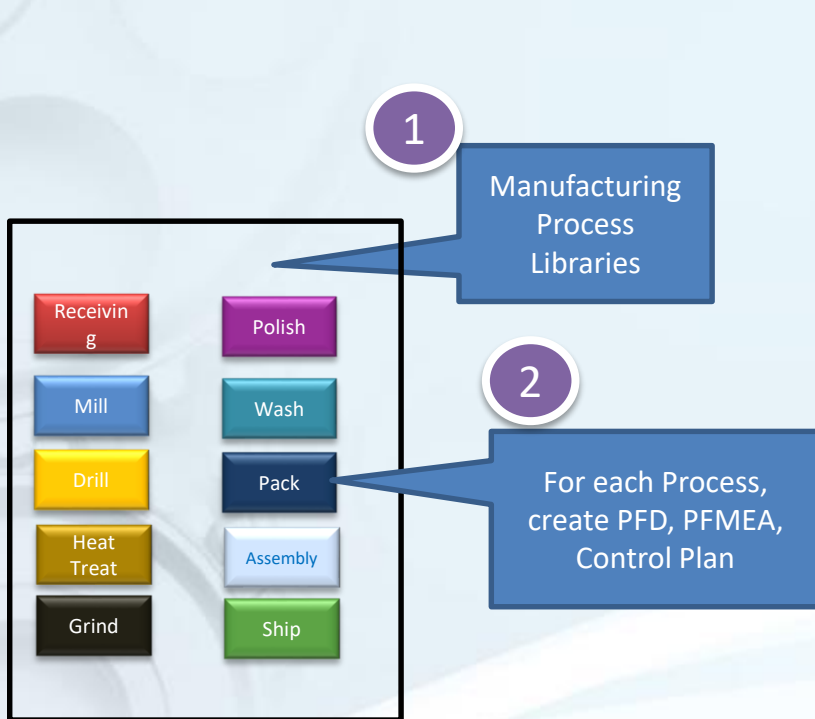


Family of Parts

Creating Design and Process Documents using Inheritance



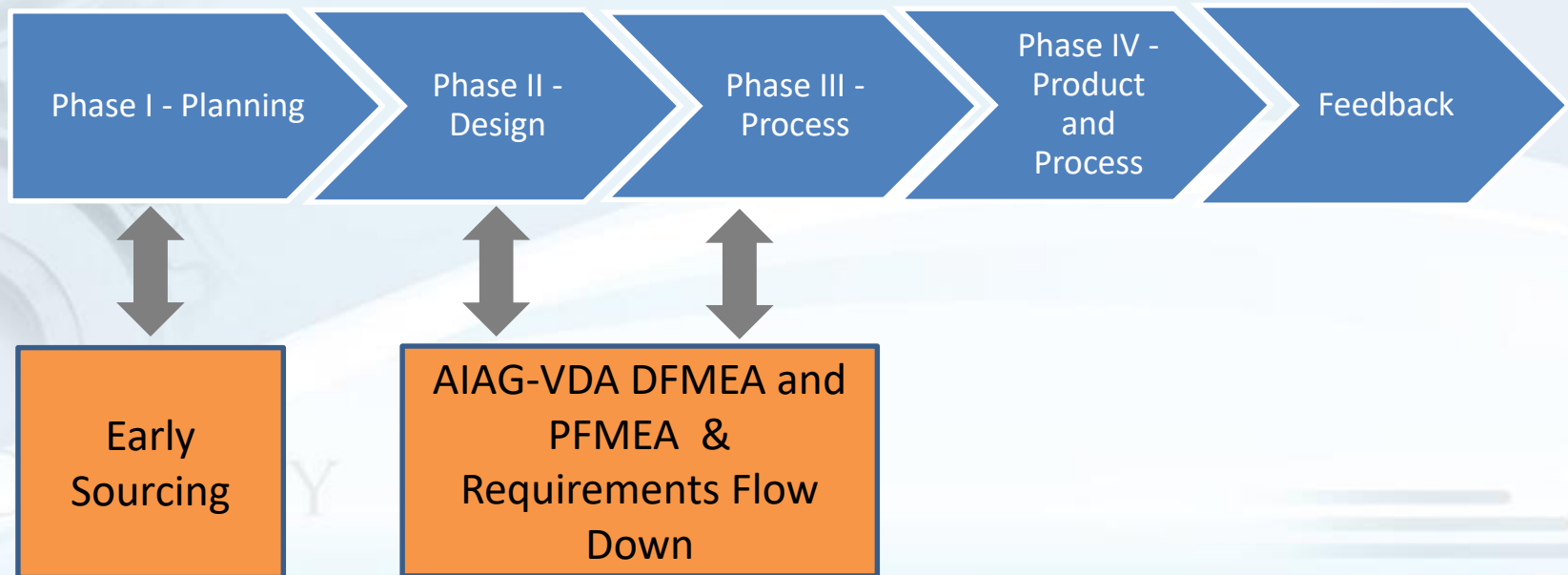
Design and Process Reuse Libraries



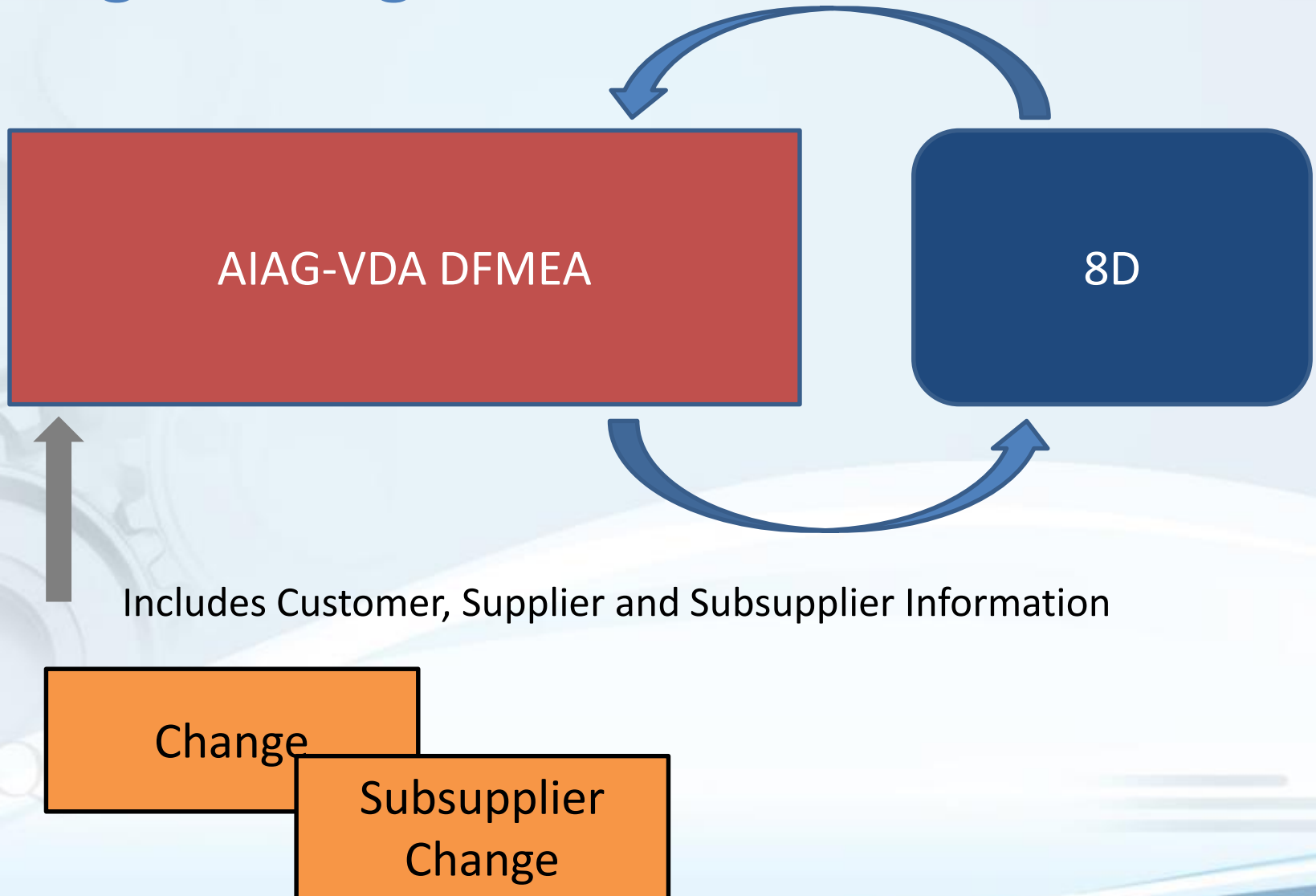
PROCESS EXAMPLE

APQP and Supply Chain Changes

Sales and Purchasing may need to have language on collaboration between customer, supplier and subsupplier



Change Management and AIAG-VDA FMEA



Getting Started Checklist and Action Plan

- Conduct Executive Overview
- Train Facilitators and Team
- Procure AIAG-VDA Software that incorporates the 7 steps and provides linkages to DVP&R and Control Plans
- Incorporate AIAG-VDA FMEA into APQP Process
- Establish Customer and Supply Chain Linkages
- Update Purchasing
- Establish Requirements Management Process
- Procure Software and Establish Libraries and Reuse Strategy
- Develop strategy for pilot and launch program



Chapter 6: Effectively Using the AIAG-VDA FMEA

– What We Covered

Learning Objectives

You should now be able to:

- List the top changes to the AIAG-VDA DFMEA
- Evaluate DFMEAs
- Identify the linkages from design to shop floor using AIAG-VDA FMEAs
- Describe Change Management, PPM and Design Reuse and application of AIAG-VDA FMEAs
- Make the organizational changes necessary and get started with AIAG-VDA FMEA

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 - APQP and Supply Chain Changes
 - Change Management

FMEA Summary

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FMEA Summary

- FMEA is a systematic analysis tool that, if used by an experienced team of qualified SMEs and performed with reliable evaluation of concepts, allows for fewer potential failures in systems, products or processes
- FMEA ensures that potential failure modes and their causes are recognized and prevented
- FMEA puts process and product knowledge together
- FMEA provides the strategic underpinnings to make development and operational processes as bug-free as possible

Knowledge Management!



FMEA Objectives

Risk reduction through:

- Support of the development and improvement processes
- Identification of potential types of errors and their causes, and the effects in products, and process-related activities
- Assistance in the analysis of new or modified products, machinery, manufacturing and assembly processes
- Evaluation of potential failure consequences for the customer, the operator of the process or the environment
- Identification and development of process characteristics and key variables on which inspection checks are to be concentrated
- Development of a ranking for errors, mainly for instituting corrective and preventive actions

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Analytical Approach

- How could the product fail and not meet expectations?
 - In the application?
 - In the assembly process?
 - In the field / service, or in testing?
- What would be the consequence of error?
 - For customers?
 - For the sites?
 - During the life of the program?
 - How might the failure effects be noticed or perceived?

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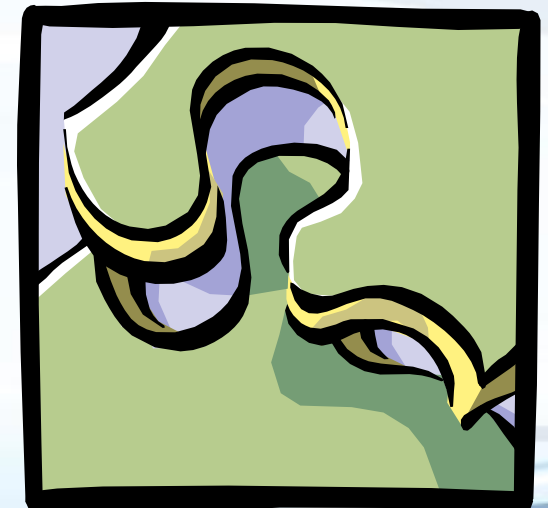
Analytical Approach

- How could the failure mode occur?
 - What potentially caused the failure mode?
 - Brainstorm with SMEs
 - How often has the error occurred in the past?
- What is in place to catch our mistakes (Detection)?
 - Current detection actions?
 - Avoidance, verification, validation?
 - How effective are our actions?

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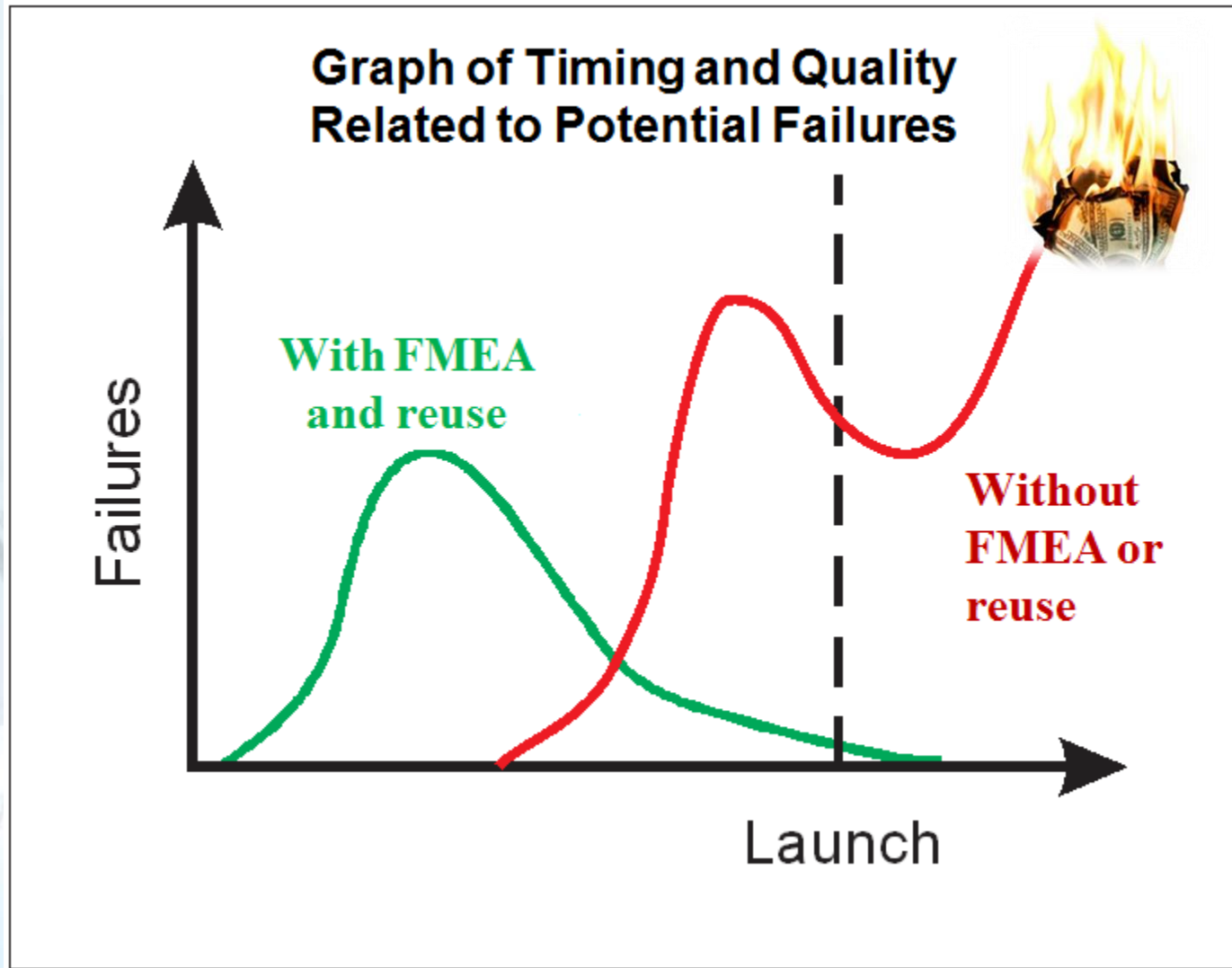
Analytical Approach

- What is the acceptable level of risk?
 - Health, safety, compliance?
 - Compared to others products / processes?
- What should we do about those potential risks?
 - Who is responsible for corrective actions?
 - What actions are appropriate?
 - What risks will we accept?
 - How can we reduce the RPN?



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FMEA Advantage



Maintaining FMEAs

The FMEA documents living information and should be reviewed whenever there is a product design change, and should be updated as required.

- To have value, FMEA updates must occur at these change points:
 - New design or process is planned
 - Modification to a component, system or process is planned
 - **Important** – Update FMEA to capture problem solving analyses and results
 - Component or system is used in a new environment, location or application

Knowledge Management

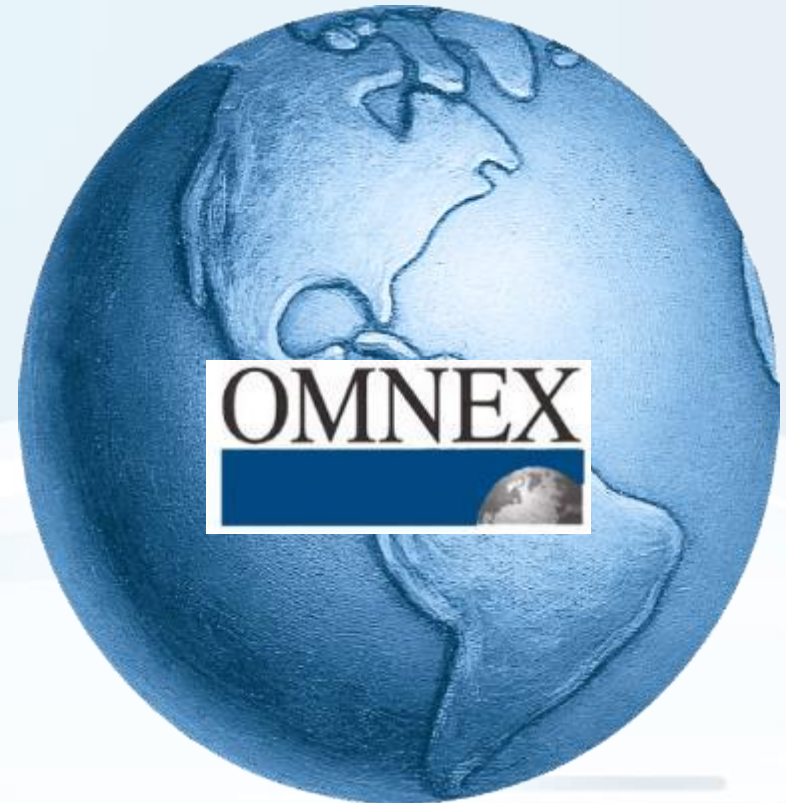
FMEA Keys

- Manage Quantified Risk
 - Focus on Known Potential Risks First
- Act
 - Improvement Proposals
 - Responsibility, Timing, Tracking
 - Verification

The Design FMEA must **not** rely on the process controls to overcome potential design weaknesses, and must take into account the limitations of the manufacturing process (concurrent engineering).

Thank You!

Questions?



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Appendix

DFMEA Form Comparison
Team Information
IT Support
Tables

Home > The Association > Departments > Quality management centre (QMC)



Verband der
Automobilindustrie

Quality Management Steering Committee

- 7 OEMs

- 7 Suppliers

- 2 VDA-QMC

Work Groups

- > 1 OEM

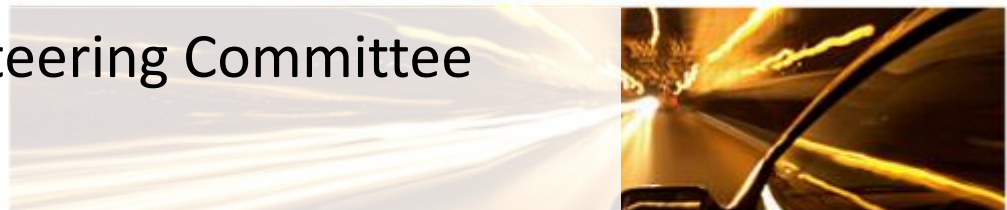
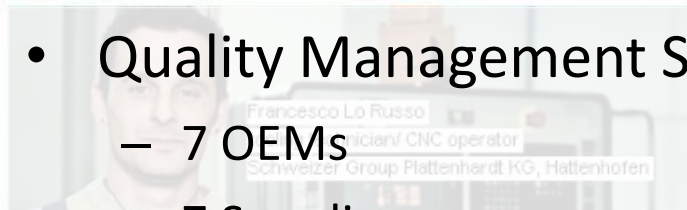
- Suppliers

- Draft to VDA

- Comments

- Revision

- Published as a new “red book”



Quality management centre (QMC): The Team

Quality management centre (QMC) – Variety with

The Quality Management Center (QMC) has existed for the benefit of the German automotive industry and its partners since August 1, 1997. The roles and responsibilities undertaken by the QMC are as varied as the questions surrounding quality management in the automotive industry which occupy us on a daily basis. The spectrum ranges from developing systems and methods to shaping the future of quality management systems in the automotive industry. These developments as well as the direction of QMC are steered by the top-level committee regarding quality matters in the German automotive industry, the QM Commission, chaired by Mr. Tuch from Volkswagen. This Commission is composed of the QM Directors of the VDA members and a VDA Executive Director.

Link to QMC-Website www.vda-qmc.de

The Team

Click here for a listing of the Department Team members.

Your contact person



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Quality Management Center
im Verband der Automobilindustrie

VDA Publications

- A total of 30 Volumes available in the English language.
- VDA volumes which impact the APQP Training Initiative:
 - Vol 2: Quality Assurance for Suppliers: Production Process and Product Approval
 - Vol 4: Quality Assurance in the Process Landscape
 - Chapter 5: Product and Process FMEA
 - Vol 5: Capability of Measurement Processes (and Systems)
 - Vol 6: Quality Standard of the German Automotive Industry
 - Part 3: Process Audit

Comparison of AIAG FMEA 4th Edition and AIAG-VDA FMEA Handbook

STRUCTURE ANALYSIS		
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)

FUNCTION ANALYSIS		
1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic

FAILURE ANALYSIS			
1 Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)

Item	Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detection	RPN
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Recommended Action	Responsibility	Target Completion Date	Action Results				
			Actions Taken	Effective Date	Severity	Occurrence	Detection

RISK ANALYSIS					
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Control (DC) of FC or FM	Detection (D) of FCFM	AP	Filter Code (Optional)

OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	AP



System Level

Item:
Jet engine

Function:
provide propulsion
on demand

Requirements:
Fuel combustion on
demand xxxx

Failure Mode
Combustion without
demand

Cause:
Design allows
internal leak
(pooling of fuel
outside
chamber)

Effect:
Uncontained
Failure

Sub-System Level

Item:
Fuel Transfer
Ass'y

Function:
transfer fuel to
combustion
chamber on
demand

Requirements:
XXXXXXXXXX

Failure Mode
Fuel transfer
external to
chamber

Cause:
Ass'y design
allows integrity
failure due to
function or
manufacturing

Effect:
Internal leak

Component

Item:
Fuel Tubing

Function:
Contain fuel from
storage to chamber

Requirements:
XXXXXXXXXX

Failure Mode
Leakage external
to chamber

Cause:
tube design
allows integrity
failure due to
function or
manufacturing

Effect:
integrity failure
of tube ass'y

Component Mfg

Step xx

Function:
Form Tubing

Requirements:
XXXXXXXXXX

Failure Mode
Out of Spec:
Geometry or wall
thickness

Cause:
* Fixture setup;
* incoming material
* Excess forming
pressure applied

Effect:
integrity failure
of tube

7-Steps and the Form

1st Step

Planning and Preparation



DESIGN FAILURE AND EFFECTS ANALYSIS (DFMEA)

Company Name: _____	Subject: _____	DFMEA Number: _____
Engineering Division: _____	Product Unit: _____	Date of Birth: _____
Customer Name: _____	DFMEA Study Team: _____	Security Classification: _____
Internal Code / Revision: _____	Project Code: _____	Final Date: _____
Project Title: _____		Final Title: _____

System Analysis

2nd Step

Structure Analysis



3rd Step

Function Analysis



and Risk Mitigation

4th Step

Failure Analysis



5th Step

Risk Analysis



STRUCTURE ANALYSIS			FUNCTION ANALYSIS		
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic

6th Step Optimization



FAILURE ANALYSIS			RISK ANALYSIS			
1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Control (DC) of FC or FM
						Detection (D) of FCFM
						AP
						Filter Code (Optional)

OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	AP

7th Step Results

Documentation



Layout of document may be company-specific



Evaluating DFMEAs — DFMEA SR Checklist



APQP – DFMEA Suitability Review Checklist

Recommendation:

Product/Component:

Date of Review:

Prepared For:

Supplier [X]

Peer []

Supplier/Peer Name:

Prepared By:

FMEA Number:

Indicate Yes/No by Checking the appropriate box

Note: Items checked N indicate improvement is needed

<u>Y</u>	<u>N</u>	<u>General</u>
<input type="checkbox"/>	<input type="checkbox"/>	1) Are the Failure Modes, Effects, Causes and Design Controls properly distinguished?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2) Is there evidence that a cross-functional team was used to develop the FMEA?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3) Are applicable entries in the Header completed?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4) Does the DFMEA appear to drive Design Improvements as the <i>primary</i> objective?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5) Is the DFMEA document completely filled out, including header information, action plans and recalculated RPN?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6) Does the DFMEA address internal, customer and warranty issues and other Quality indicators
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7) Is there a Block Diagram and does it include interfaces and interactions, as appropriate?



Evaluating DFMEAs —

DFMEA SR Checklist

<u>Y</u>	<u>N</u>	<u>Item / Function/Requirements</u>
<input type="checkbox"/>	<input type="checkbox"/>	8) Is the design intent, or purpose clear? Are Performance Requirements specified?
<input type="checkbox"/>	<input type="checkbox"/>	9) Are functional requirements described clearly (verb-noun format)?
<u>Y</u>	<u>N</u>	<u>Failure Modes</u>
<input type="checkbox"/>	<input type="checkbox"/>	10) Are the failure modes developed from the functional requirements and interface functions?
<input type="checkbox"/>	<input type="checkbox"/>	11) Does the DFMEA address all failure modes identified as high risk with executable action plans?
<u>Y</u>	<u>N</u>	<u>Effects of Failure</u>
<input type="checkbox"/>	<input type="checkbox"/>	12) Are effects on safe operation and government regulation considered?
<input type="checkbox"/>	<input type="checkbox"/>	13) Are multiple effects higher element, system, customer (end user) considered?
<u>Y</u>	<u>N</u>	<u>Cause(s)</u>
<input type="checkbox"/>	<input type="checkbox"/>	14) Are the Root Causes identified appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	15) Are design deficiencies considered that may result in manufacturing / assembly variation or misbuilds?
<input type="checkbox"/>	<input type="checkbox"/>	16) Are manufacturing / assembly causes excluded? (addressed in PFMEA)
<input type="checkbox"/>	<input type="checkbox"/>	17) Are all causes listed on a separate line?
<input type="checkbox"/>	<input type="checkbox"/>	18) Are causes described in terms of the design and process development process and lower level?
<u>Y</u>	<u>N</u>	<u>Current Prevention Design Controls</u>
<input type="checkbox"/>	<input type="checkbox"/>	19) Can the Design Controls listed eliminate or ameliorate the Cause(s) of Failure Modes prior to engineering release?
<input type="checkbox"/>	<input type="checkbox"/>	20) Are error proofing controls used for high risk failure modes?
<input type="checkbox"/>	<input type="checkbox"/>	21) Do Design Controls stress Prevention and Analytical over Physical testing?

Evaluating DFMEAs —

DFMEA SR Checklist

<input checked="" type="checkbox"/>	<input type="checkbox"/>	Current Detection Design Controls
<input checked="" type="checkbox"/>	<input type="checkbox"/>	22) Can the Design Controls listed detect the Cause(s) of Failure Modes, or detect the Failure Modes prior to engineering release?
<input type="checkbox"/>	<input type="checkbox"/>	23) Are manufacturing / assembly Detection methods excluded?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	24) Is there a distinction between Prevention and Detection type design controls?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	25) Are the Detection Type Design Controls individually ranked?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Severity Rating
<input checked="" type="checkbox"/>	<input type="checkbox"/>	26) Are Severity ratings based on the most serious consequence of the Failure Mode?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Occurrence Rating
<input checked="" type="checkbox"/>	<input type="checkbox"/>	27) Is the Occurrence rating based on the AP Tables and based on the prevention control
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Detection Rating
<input checked="" type="checkbox"/>	<input type="checkbox"/>	28) Are ratings based on the AP Tables?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Classification
<input checked="" type="checkbox"/>	<input type="checkbox"/>	29) Are Function Class for Safety and Special Functional <u>candidates</u> identified as appropriate
<input checked="" type="checkbox"/>	<input type="checkbox"/>	AP
<input checked="" type="checkbox"/>	<input type="checkbox"/>	30) Do the recommended actions focus on High and Medium Risks
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Recommended Actions
<input checked="" type="checkbox"/>	<input type="checkbox"/>	31) Are Recommended Actions listed that reduce the Severity Occurrence and Detection for the hi
<input checked="" type="checkbox"/>	<input type="checkbox"/>	32) Are responsibility and timing for Recommended Actions listed?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	33) Are preventive, instead of detection, actions listed? Do the Recommended Action exclude manufacturing / assembly controls?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	34) Are Severity, Occurrence, Detection, and the resulting Severity, Occurrence, and Detection numbers recalculated for the identified
<input checked="" type="checkbox"/>	<input type="checkbox"/>	35) Are the Recommended Actions actionable and executable?

TEAM INFORMATION

QUALITY





5Ts — 3. FMEA Team

The Core Team may consist of the following people:

- Facilitator
- Design Engineer
- System Engineer
- Component Engineers
- Test Engineer
- Quality/Reliability Engineer
- Others responsible for the development of the product

QUALITY



5Ts — 3. FMEA Team

The Extended Team may consist of the following people:

- Technical Experts
- Process/Manufacturing Engineer
- Service Engineer
- Project Manager
- Functional Safety Engineer
- Purchasing
- Supplier
- Customer Representative
- Others that may have specialized knowledge which will help the core team analyze specific aspects of the product



5Ts — 3. FMEA Team

Management, e.g. project manager:

- Authority to make decisions about the acceptability of identified risks and the execution of actions
- Define the persons responsible for pre-work activities, FMEA facilitation, and the design/process engineer responsible for implementation of actions resulting from the analysis
- Management has the ultimate responsibility of selecting and applying resources and ensuring an effective risk management process is implemented within scheduled project timing
- Responsibility and ownership for development and maintenance of the FMEAs
- Management responsibility also includes providing direct support to the team(s) through on-going reviews and eliminating roadblocks
- Responsible for budget



5Ts — 3. FMEA Team

Lead Design/Process Engineer (Technical Lead):

- Technical responsibility for the FMEA contents
- Preparation of the Business Case for technical and/or financial decisions
- Definition of elements, functions, requirements, and interfaces
- Focusing on the topics
- Procurement of the necessary documents and information
- Incorporating lessons learned

QUALITY



5Ts — 3. FMEA Team

FMEA Facilitator:

- Coordination and organization of the workflows in the FMEA
- Mitigation of conflicts
- Participation in the team formation
- Participation in the preparation of the rough schedule
- Participation in the invitation to the first team meeting for the analysis phase
- Participation in the preparation of the decision guidelines/criteria
- Development of corporate or product line examples for rating tables (optional) with support from Design/Process Engineer



5Ts — 3. FMEA Team

FMEA Facilitator (*cont'd*):

- Method competence (FMEA) and familiarization of participants in the FMEA method
- FMEA Software documentation competence (as necessary)
- Social skills, able to work in a team
- Competent moderator, ability to convince, organization and presentation skills
- Managing execution of the 7 steps of FMEA method
- If necessary, preparation or wrap-up of FMEA meetings
- Moderation of the FMEA workgroup

NOTE: Any team member with the relevant competence and training in the VDA FMEA Handbook, and software or spreadsheet method, may fulfill the role of facilitator. It's recommended the team member must have been actively involved in FMEAs using the AIAG-VDA FMEA Handbook methods to be able to facilitate or be certified.



5Ts — 3. FMEA Team

Core Team Members:

- Contribute knowledge from relevant product and process experience
- Contribute necessary information about the product or process that is the focus of the FMEA
- Contribution of existing experiences from previous FMEAs already known
- Participation in the execution of the 7 steps of FMEA
- Involvement in the preparation of the Business Case
- Incorporating lessons learned



5Ts — 3. FMEA Team

Extended Team Members / Experts:

- Contribution of additional information about special topics
- Contribution of necessary information about the product or process that is the focus of the FMEA
- Involvement in the preparation of the Business Case

QUALITY



TABLES

QUALITY

DFMEA Severity – AIAG-VDA FMEA Handbook

SEV	Effect	Severity Criteria	Corporate or Product Line Examples
10	Very High	Affects safe operation of the vehicle and/or other vehicles, the health of operator or passenger(s) or road users or pedestrians	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> The table may be augmented to include product specific examples. </div>
9		Noncompliance with regulations	
8	High	Loss of primary vehicle function necessary for normal driving during expected service life	
7		Degradation of primary vehicle function necessary for normal driving during expected service life	
6	Moderate	Loss of secondary vehicle function	
5		Degradation of secondary vehicle function	
4		Very objectionable appearance, sound, vibration, harshness, or haptics	
3	Low	Moderately objectionable appearance, sound, vibration, harshness, or haptics	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics	
1	Very Low	No discernible effect	

Safety is 10 regardless of warning – Split rating of 10 and 9

DFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Product Experience	Corporate or Product Line Examples
10	Extremely High	<p>First application of new technology anywhere without operating experience and/or under uncontrolled operating conditions. No product verification and/or validation experience.</p> <p>Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.</p>	
9	Very High	<p>First use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Prevention controls not targeted to identify performance to specific requirements.</p>	
8		<p>First use of design with technical innovations or materials on a new application. New application or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.</p>	

QUALITY

DFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Product Experience	Corporate or Product Line Examples
7	High	<p>New design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.</p>	
6		<p>Similar to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience.</p> <p>Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.</p>	

QUALITY

DFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Product Experience	Corporate or Product Line Examples
5	Moderate	<p>Detail changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.</p> <p>Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause, and provide some indication of performance.</p>	
4		<p>Almost identical design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.</p> <p>Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.</p>	

QUALITY

DFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Product Experience	Corporate or Product Line Examples
3	Low	<p>Detail changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure.</p> <p>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design.</p>	
2	Very Low	<p>Almost identical mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.</p> <p>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.</p>	
1	Extremely Low	<p>Failure eliminated through preventive control and failure cause is not possible by design</p>	

DFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
10	Very Low	Test procedure yet to be developed.	Test method not defined.	
9		Test method not designed specifically to detect failure mode or cause.	Pass-Fail, Test-to-Fail, Degradation Testing	
8	Low	New test method, not proven.	Pass-Fail, Test-to-Fail, Degradation Testing	
7		Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or retooling.	Pas-Fail Testing	
6	Moderate	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or retooling.	Test-to-Failure	
5			Degradation Testing	

DFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
4	High	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production.	Pass-Fail Testing	
3			Test-to-Failure	
2			Degradation Testing	
1	Very High	Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to always detect the failure mode or failure cause.		

QUALITY

C1.3.1 DFMEA OCCURRENCE (O): Incidents per Thousand Values

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate			Blank until filled by user
O	Incidents per 1000 items/vehicles	Occurrence criteria - DFMEA	Corporate or Product Line Examples
10	≥ 100 per thousand >= 1 in 10	<p>First application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience.</p> <p>Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.</p>	
9	50 per thousand, 1 in 20	<p>First use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Prevention controls not targeted to identify performance to specific requirements.</p>	
8	20 per thousand, 1 in 50	<p>First use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.</p>	
7	10 per thousand 1 in 100	<p>New design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.</p>	
6	2 per thousand 1 in 500	<p>Similar to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience.</p> <p>Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.</p>	

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate			Blank until filled by user
O	Incidents per 1000 items/vehicles	Occurrence criteria - DFMEA	Corporate or Product Line Examples
5	.5 per thousand 1 in 2000	<p>Detail changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.</p> <p>Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.</p>	
4	.1 per thousand 1 in 10,000	<p>Almost identical design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.</p> <p>Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.</p>	
3	.01 per thousand 1 in 100,000	<p>Detail changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure.</p> <p>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design.</p>	
2	≤ .001 per thousand 1 in 1,000,000	<p>Almost identical mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.</p> <p>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.</p>	
1	Prevention controls eliminate failure	Failure eliminated through prevention control and failure cause is not possible by design	

Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

Note: OCC 10, 9, 8, 7 can drop based on product validation activities.

Table C1.3.1 - Alternate DFMEA Occurrence (O)

C1.3.2 DFMEA Occurrence (O) with Time Based Failure Prediction Values

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	Time Based Failure Cause Prediction	Occurrence criteria - DFMEA	Corporate or Product Line Examples
10	Every time	<p>First application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience.</p> <p>Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.</p>	
9	Almost every time	<p>First use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Prevention controls not targeted to identify performance to specific requirements.</p>	
8	More than once per shift	<p>First use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.</p>	
7	More than once per day	<p>New design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.</p> <p>Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.</p>	
6	More than once per week	<p>Similar to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience.</p> <p>Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.</p>	
5	More than once per month	<p>Detail changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.</p> <p>Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.</p>	

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	Time Based Failure Cause Prediction	Occurrence criteria - DFMEA	Corporate or Product Line Examples
4	More than once per year	<p>Almost identical design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.</p> <p>Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.</p>	
3	Once per year	<p>Detail changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure.</p> <p>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design.</p>	
2	Less than once per year	<p>Almost identical mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.</p> <p>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.</p>	
1	Never	Failure eliminated through prevention control and failure cause is not possible by design	

Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

Note: OCC 10, 9, 8, 7 can drop based on product validation activities.

Table C1.3.2 – Alternate DFMEA Occurrence (O)

Action Priority (AP) – AIAG-VDA FMEA Handbook

DFMEA

S 9-10

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	M	M	H	H	H	H
3	L	L	L	L	M	M	H	H	H	H
4	M	H	H	H	H	H	H	H	H	H
5	M	H	H	H	H	H	H	H	H	H
6	H	H	H	H	H	H	H	H	H	H
7	H	H	H	H	H	H	H	H	H	H
8	H	H	H	H	H	H	H	H	H	H
9	H	H	H	H	H	H	H	H	H	H
10	H	H	H	H	H	H	H	H	H	H

Action Priority (AP) – AIAG-VDA FMEA Handbook

DFMEA

S 7-8

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	M	M	H	H	H	H
3	L	L	L	L	M	M	H	H	H	H
4	M	M	M	M	M	M	H	H	H	H
5	M	M	M	M	M	M	H	H	H	H
6	M	H	H	H	H	H	H	H	H	H
7	M	H	H	H	H	H	H	H	H	H
8	H	H	H	H	H	H	H	H	H	H
9	H	H	H	H	H	H	H	H	H	H
10	H	H	H	H	H	H	H	H	H	H

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DFMEA

S 4-6

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	L	L	L	L	L	L
3	L	L	L	L	L	L	L	L	L	L
4	L	L	L	L	L	L	M	M	M	M
5	L	L	L	L	L	L	M	M	M	M
6	L	M	M	M	M	M	M	M	M	M
7	L	M	M	M	M	M	M	M	M	M
8	M	M	M	M	H	H	H	H	H	H
9	M	M	M	M	H	H	H	H	H	H
10	M	M	M	M	H	H	H	H	H	H

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DFMEA

S 2-3

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	L	L	L	L	L	L
3	L	L	L	L	L	L	L	L	L	L
4	L	L	L	L	L	L	L	L	L	L
5	L	L	L	L	L	L	L	L	L	L
6	L	L	L	L	L	L	L	L	L	L
7	L	L	L	L	L	L	L	L	L	L
8	L	L	L	L	M	M	M	M	M	M
9	L	L	L	L	M	M	M	M	M	M
10	L	L	L	L	M	M	M	M	M	M

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DFMEA

S 1

O/D	1	2	3	4	5	6	7	8	9	10
1	L	L	L	L	L	L	L	L	L	L
2	L	L	L	L	L	L	L	L	L	L
3	L	L	L	L	L	L	L	L	L	L
4	L	L	L	L	L	L	L	L	L	L
5	L	L	L	L	L	L	L	L	L	L
6	L	L	L	L	L	L	L	L	L	L
7	L	L	L	L	L	L	L	L	L	L
8	L	L	L	L	L	L	L	L	L	L
9	L	L	L	L	L	L	L	L	L	L
10	L	L	L	L	L	L	L	L	L	L