Process Flow, PFMEA and Control Plans

AIAG-VDA FMEA Handbook for Practitioners and Facilitators

OMNEX

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Omnex provides training, consulting and software solutions to the international market with offices in the USA, Canada, Mexico, China (PRC), Germany, India, the Middle East, and SE Asia. Omnex offers over 400 standard and customized training courses in business, quality, environmental, food safety, laboratory and health & safety management systems worldwide.

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Course Objectives

- Demonstrate an ability to properly and effectively complete all steps in the PFMEA process.
  - Demonstrate an ability to properly construct a Process Flow Diagram.
  - Identify steps, requirements, failure modes, causes and controls and properly enter the information into a PFMEA.
- Explain the relationships among a Process Flow Diagram, PFMEA and Control Plan.
- Identify special characteristics in manufacturing process design.
- 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 – Process FMEA Prerequisites
  - **Breakout Exercise 1: Process Flow Diagram**
  - **Breakout Exercise 2: Structure Analysis**
  - **Breakout Exercise 3: Function Analysis**
- Chapter 4 – Developing the Process FMEA
  - **Breakout Exercise 4: Failure Modes**
  - **Breakout Exercise 5: Failure Net**
  - **Breakout Exercise 6: Process Controls**
  - **Breakout Exercise 7: Indices and Action Plans**
- Chapter 5 – Control Plan
  - **Breakout Exercise 8: Control Plan**
- 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

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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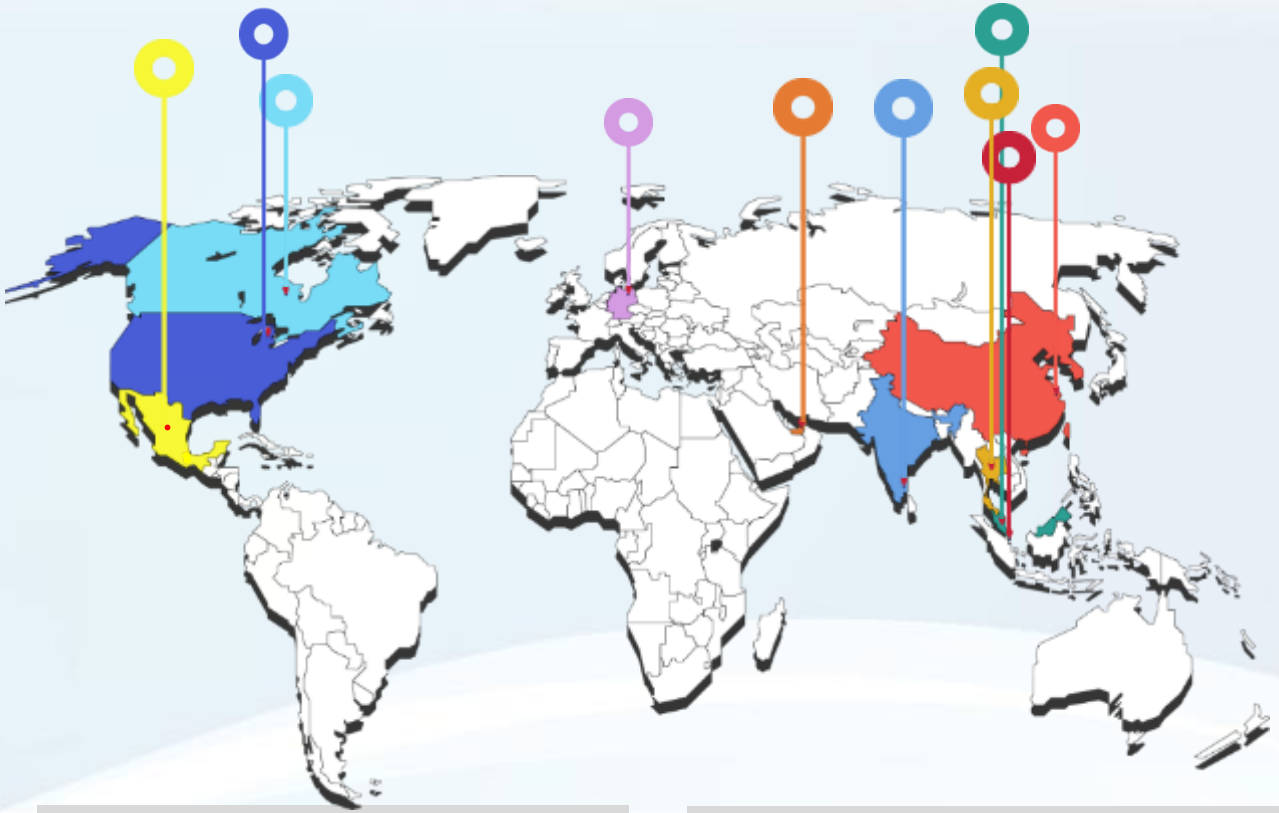


- Omnex Global Head Quarters (Michigan, USA) West Coast Operations (San Jose, CA)
- Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)
- China (Shanghai, Guangzhou, Wuhan, Chengdu)
- Canada (Mississauga)
- Europe (Berlin, Germany)
- Middle East (Dubai, Saudi Arabia, Bahrain)
- Thailand (Bangkok)
- Mexico (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 PFMEA?
  - 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

Chapter 1: Introduction to FMEA – What We Will Cover

Learning Objectives

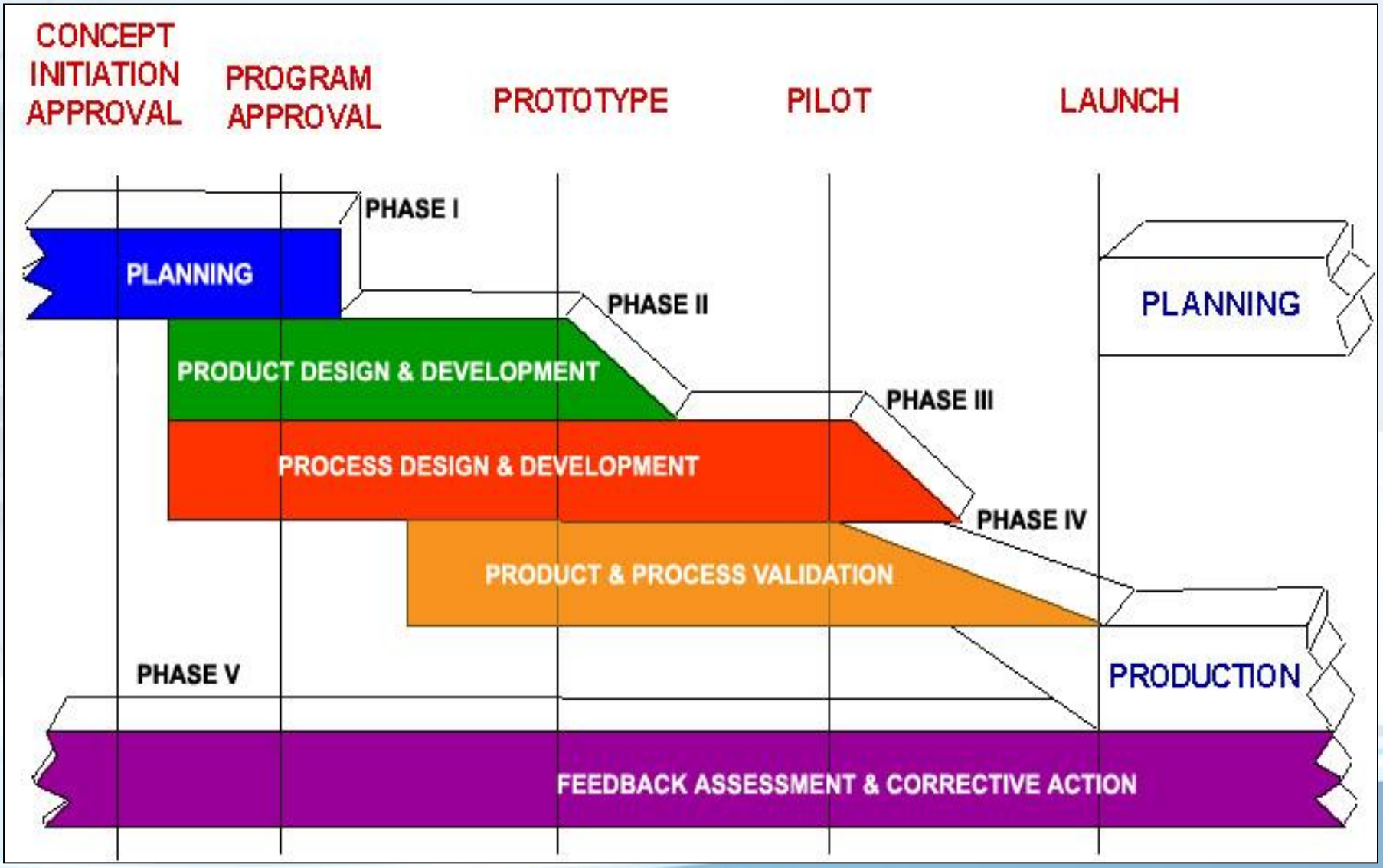
At the end of this chapter, you will be able to:

- Describe an FMEA
- Describe the benefits of an FMEA
- Describe the types of FMEAs

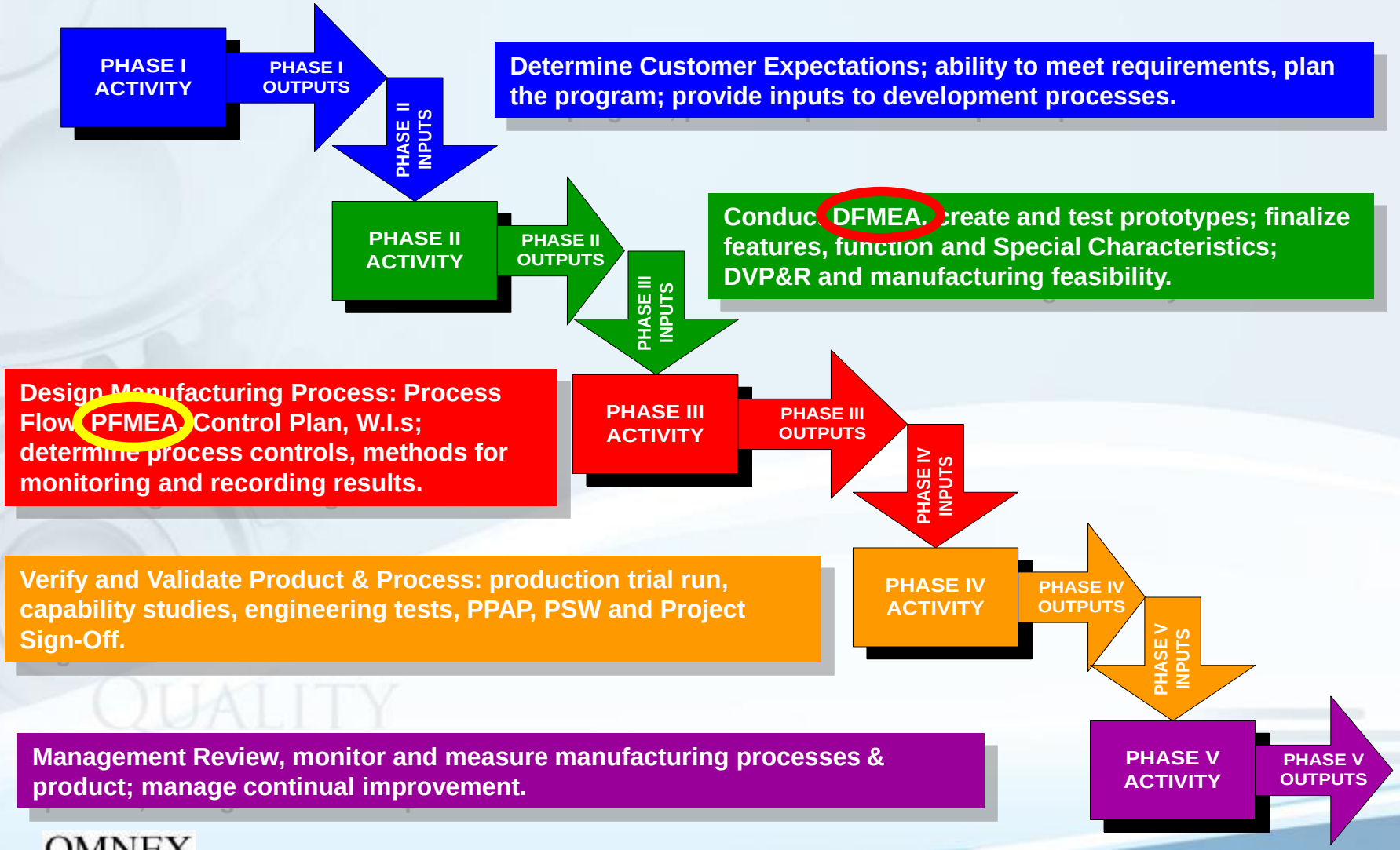
Chapter Agenda

- What is an FMEA?
- Maintaining FMEAs
- Types of FMEAs

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

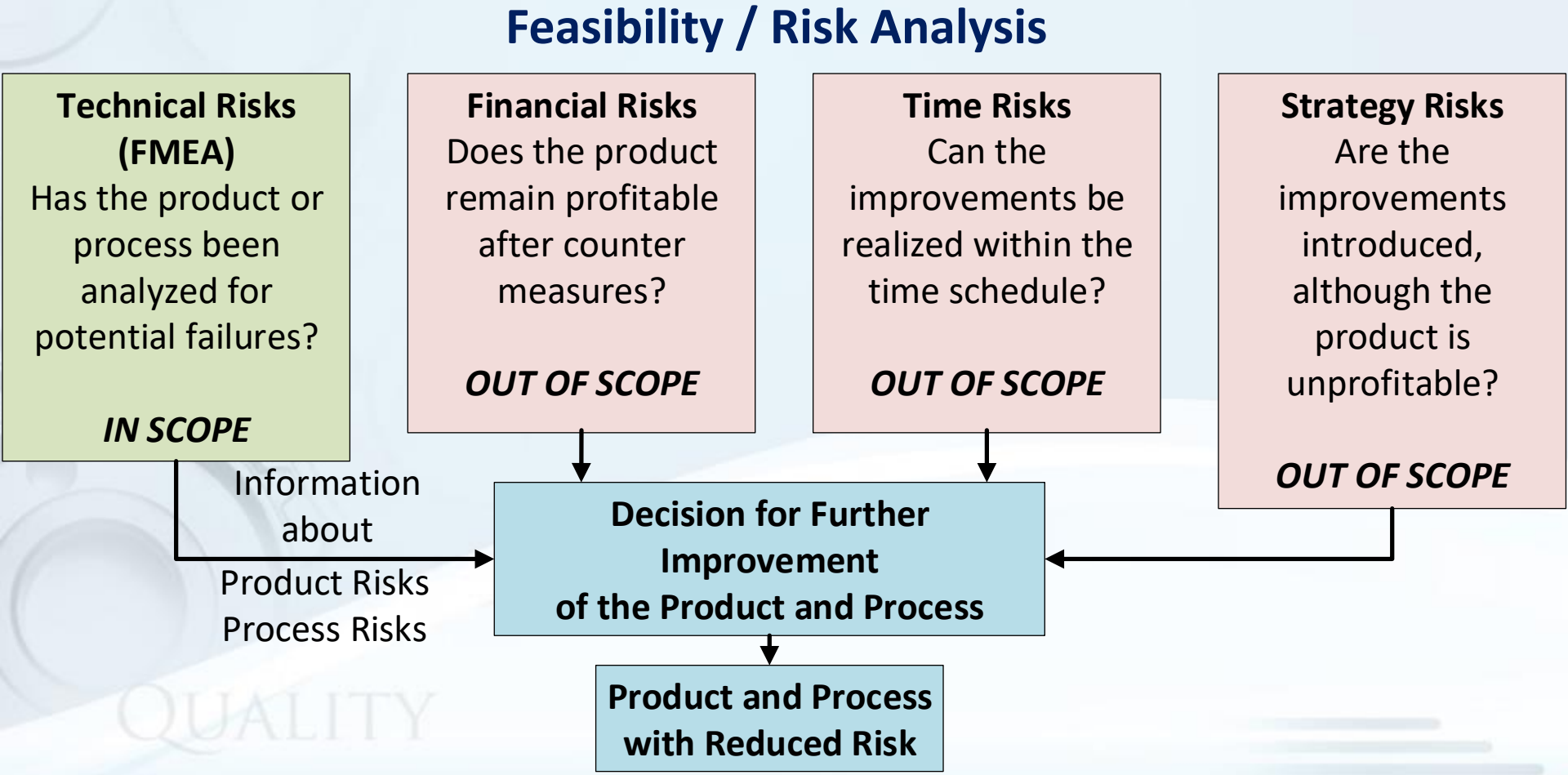
- The FMEA process is a structured approach to…
  - Improve the quality, reliability, and safety of products, processes, and services.
  - Increase customer satisfaction.
  - Reduce development timing and cost.
  - Document and track actions taken to reduce risk.
  - Enable knowledge management.

Concept

Identify ways the product or process can fail

Then plan to prevent those failures

Purposes and Benefits of FMEA

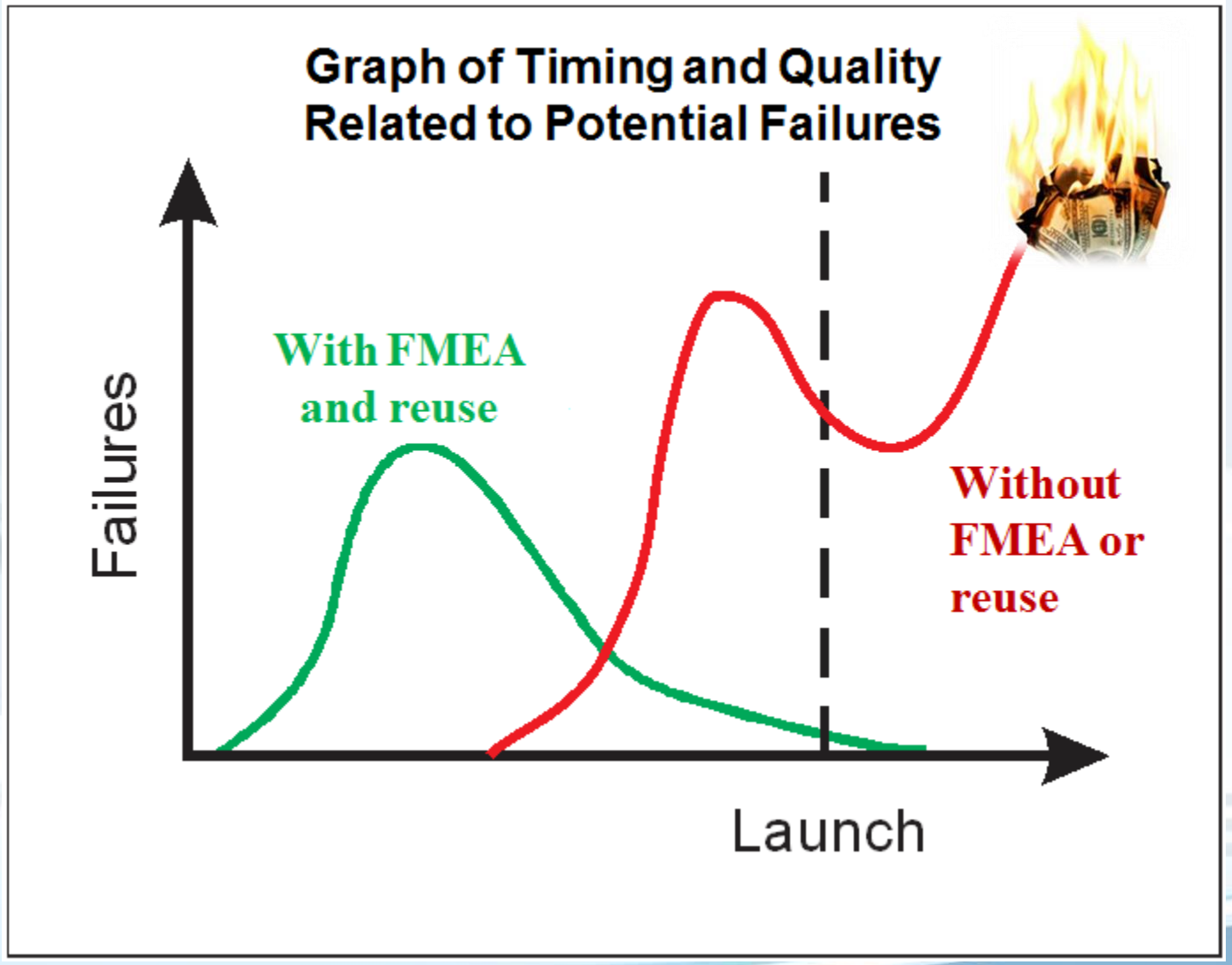


source: AIAG-VDA FMEA Handbook 1st Edition

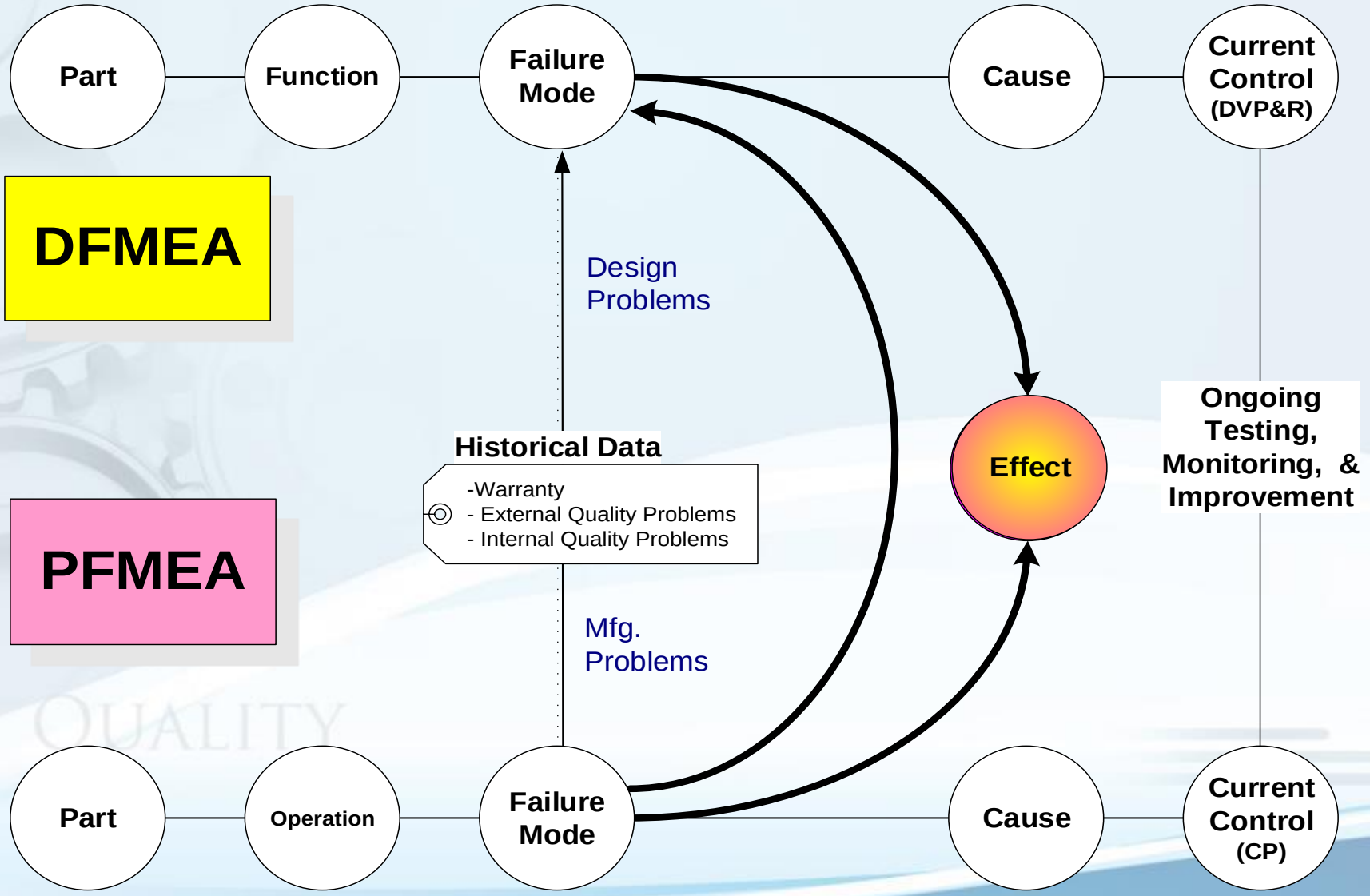
Risk Reduction and FMEA

- 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

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

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**.

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

Chapter Agenda

- What is an FMEA?
- Maintaining FMEAs
- Types of FMEAs

Chapter 2

Developing an FMEA

Process Applicable to Any Type of FMEA

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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

CONDUCTING AN FMEA

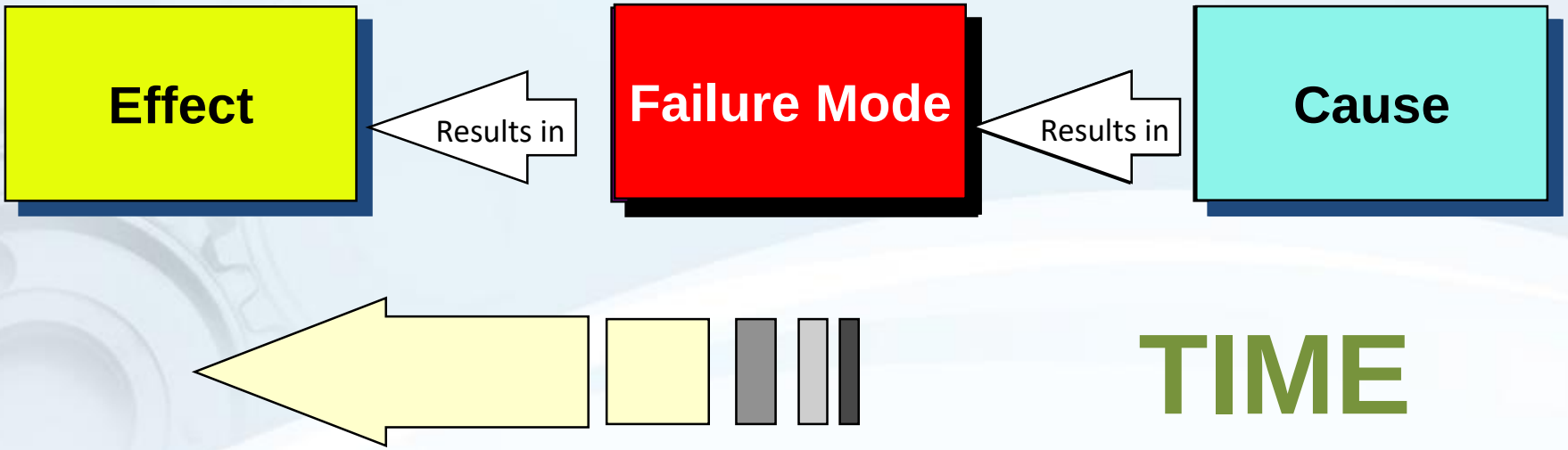
The intent is to provide a common foundation for FMEA across the sectors of the automotive industry represented by these organizations.

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 PFMEA Process

1. **PLANNING & PREPARATION**
   - **5Ts**
2. **STRUCTURE ANALYSIS**
   - ***Process Flow Diagram***
   - **Structure Tree**
   - *Note: Omnex software will generate Structure automatically*
3. **FUNCTION ANALYSIS**
   - ***Characteristics for Focus Level***
   - ***Do not populate Lower Level***
4. **FAILURE ANALYSIS**
   - ***Failure modes in Focus Level***
   - ***Causes in Lower Level,***
   - ***then populate 4M***
5. **RISK ANALYSIS**
5b. **PLANNING SHOP FLOOR CONTROL**
   - ***Work Instructions, PM, Setup, Other***
6. **OPTIMIZATION**
7. **RESULTS DOCUMENTATION**
7b. ***Link to Process Control Plan and Work Instruction/ Shop Floor Standardization***

Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA process

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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 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 organization, 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.

FMEA STRUCTURE

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

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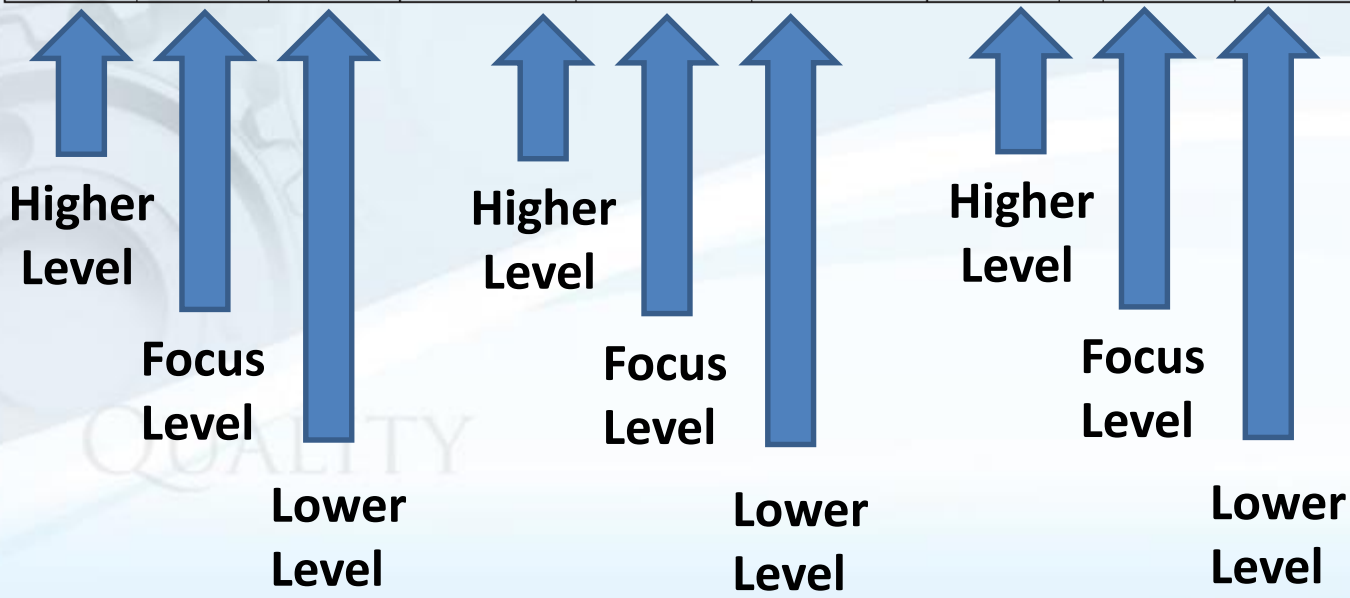

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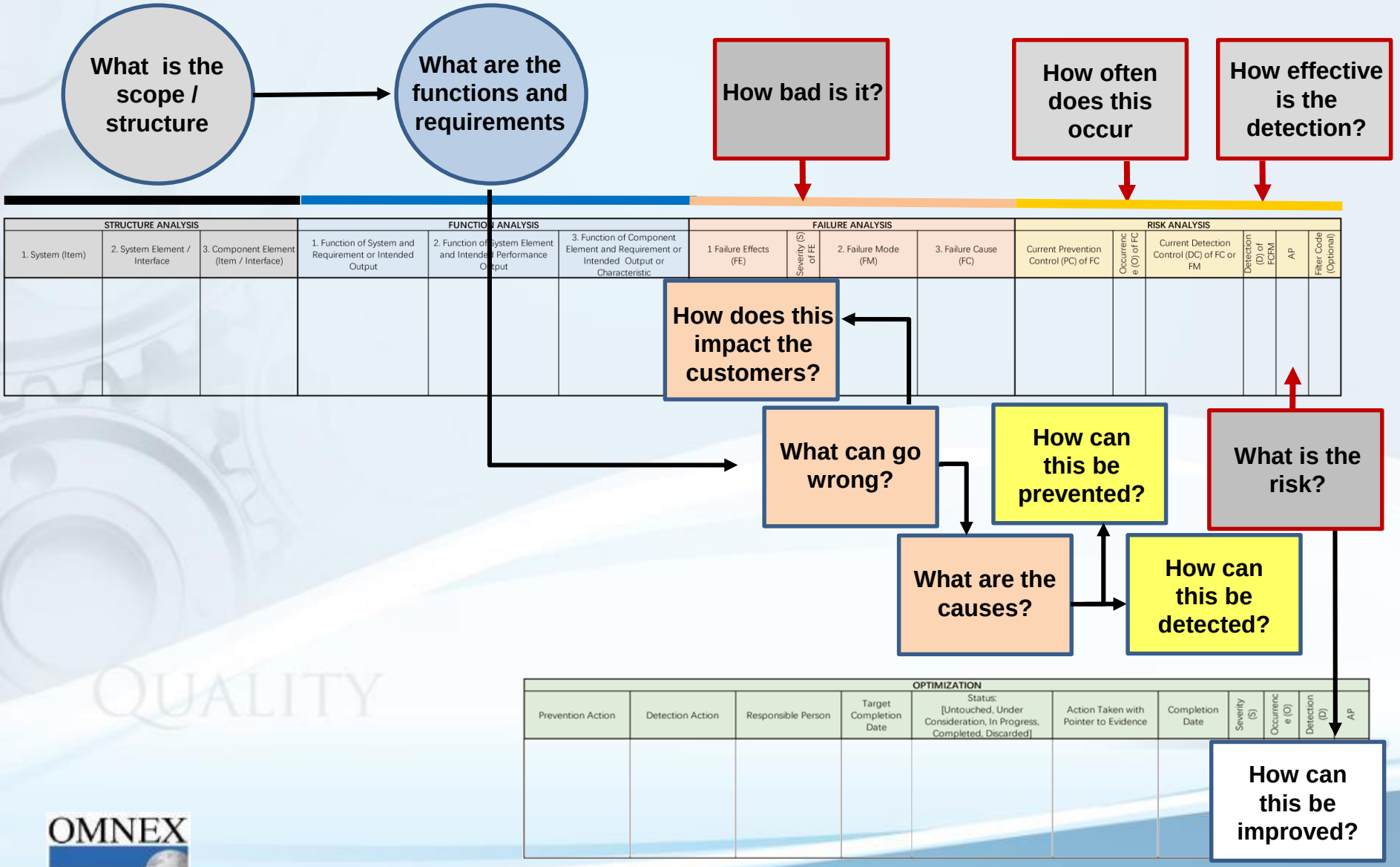
Sequence – AIAG-VDA FMEA Handbook

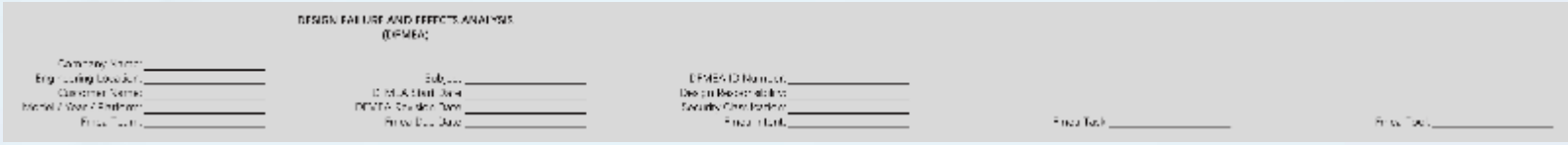


STRUCTURE ANALYSIS			FUNCTION ANALYSIS			FAILURE ANALYSIS				RISK ANALYSIS						
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of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

7-Steps and the Form

1st Step
Planning and Preparation



System Analysis and Risk Mitigation

2nd Step
Structure Analysis

3rd Step
Function 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

4th Step
Failure Analysis

5th Step
Risk Analysis

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 FC/FM	AP	Filter Code (Optional)

6th Step
Optimization

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

Chapter 3

Process FMEA Prerequisites

System Analysis (Prerequisites)		
1st Step Preparation	2nd Step Structure Analysis	3rd Step Function Analysis
		
Project Identification	Visualization of the Analysis Scope	Visualization of Product or Process Functions

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Chapter 3: Process FMEA Prerequisites – What We Will Cover

Learning Objectives

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

- Explain process characteristics
- Explain product characteristics
- Describe Planning and Preparation
- Describe the scope of analysis
- Complete a Process Flow Diagram and structure analysis

Chapter Agenda

- Step 1: Planning and Preparation
  - Scope of Analysis
- Step 2: Structure Analysis
  - Process Flow Diagram
  - **Breakout Exercise 1**
  - Structure Tree
  - **Breakout Exercise 2**
- Step 3: Function Analysis
  - **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 Process Design is Your Friend

Get to Know it Well

Steps 1-3 – AIAG-VDA FMEA Handbook

System Analysis (Prerequisites)		
1st Step Planning & Preparation	2nd Step Structure Analysis	3rd 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	Identification of process steps and sub-steps	Association of requirements or characteristics to functions
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

1st Step Planning and Preparation

Project Identification

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Process Flow Diagram
Structure Tree
Note: Omnex software will generate Structure automatically

3 **FUNCTION ANALYSIS**

Characteristics for Focus Level
Do not populate Lower Level

4 **FAILURE ANALYSIS**

Failure modes in Focus Level
Causes in Lower Level,
then populate 4M

5 **RISK ANALYSIS**

5b **PLANNING SHOP FLOOR CONTROL**

Work Instructions, PM, Setup, Other

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b ***Link to Process Control Plan and Work Instruction/***
Shop Floor Standardization

Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA process

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Step 1: Project Planning and Preparation

The purpose of the Process FMEA Preparation Step is to define what product/processes are to be included and excluded for review in the PFMEA project.

The main objectives of Process 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

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.

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.

THE FMEA TEAM

Purpose and Benefits

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
- Process Engineer
- Design Engineer
- Production Supervisor and Team Members
- 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.

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.

5Ts — 4. FMEA Tasks

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 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 organization, 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.

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

Identification of the Baseline or Foundation FMEA

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

- This includes the use of a baseline (foundation) PFMEA or product family PFMEA 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.

Identification of the Baseline or Foundation FMEA

A Family PFMEA is a specialized foundation process 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.

PFMEA HEADER INFORMATION

Header Information

During Scope Definition, the header of the PFMEA document should be completed. The header includes some of the basic PFMEA 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 PFMEA
- **Manufacturing Location:** Location of the plant – geographical designation for manufacturing and/or line unique identifier
- **Customer Name:** Name of customer(s) or Product Family
- **Model Year / Program(s):** Customer Application or Company Model / Style
- **Subject:** Name of PFMEA project
- **PFMEA Start Date:** The date the team initiates the PFMEA
- **PFMEA Revision Date:** The revision of the specific unique PFMEA document (latest date it was changed)
- **Cross-Functional Team:** PFMEA development team members
- **PFMEA ID Number:** A unique identification number for the PFMEA document
- **Process Responsibility:** Name of person who is responsible for PFMEA
- **Confidentiality Level:** The level of confidentiality determined by the PFMEA owner, e.g. Internal Business Use, Proprietary, Confidential

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Interactive Example using EwQIMS Software

STRUCTURE ANALYSIS

2nd Step
Structure Analysis

Visualization of the Analysis Scope

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Process Flow Diagram
Structure Tree
Note: Omnex software will generate Structure automatically

3 **FUNCTION ANALYSIS**

Characteristics for Focus Level
Do not populate Lower Level

4 **FAILURE ANALYSIS**

Failure modes in Focus Level
Causes in Lower Level,
then populate 4M

5 **RISK ANALYSIS**

5b **PLANNING SHOP FLOOR CONTROL**

Work Instructions, PM, Setup, Other

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b ***Link to Process Control Plan and Work Instruction/***
Shop Floor Standardization

Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA process

OMNEX

Step 2: Structure Analysis

Boundary or Extent of the PFMEA

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?
- Common Tools Used
  - Process Flow Diagram
  - Step 2 Activities
    - Structural (Tree) Analysis
    - Characteristic Matrix

PROCESS FLOW DIAGRAM

Process Flow Diagram

Objectives

- Diagram the entire process graphically from receiving to shipping
- Map requirements to operations / steps
- Identify potential sources of variation

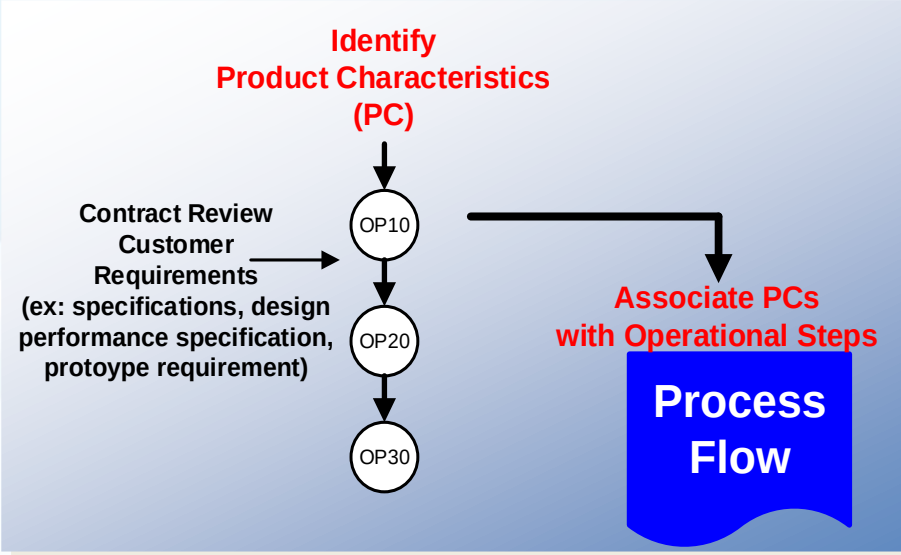
- A comprehensive Process Flow Diagram provides the foundation for the development of an effective Process FMEA, Control Plan and Work Instructions.

- **Note:** in the AIAG-VDA FMEA Handbook, the Process Flow contains information from Steps 1-3
  - It defines the scope of the activities
  - It contains the overall structure of the process
  - It identifies the requirements (functions) for each step

Process Flow

Common Elements in a Process Flow

- Process Step / Process Function (description)
  - Graphical flow of the process
- Sources of Variation
- Operation Type and/or Symbol
- Product Characteristic I.D.
  - Product characteristic description
- Process Characteristic I.D.
  - Process characteristic description
- Special Characteristics



Process Flow Header Information

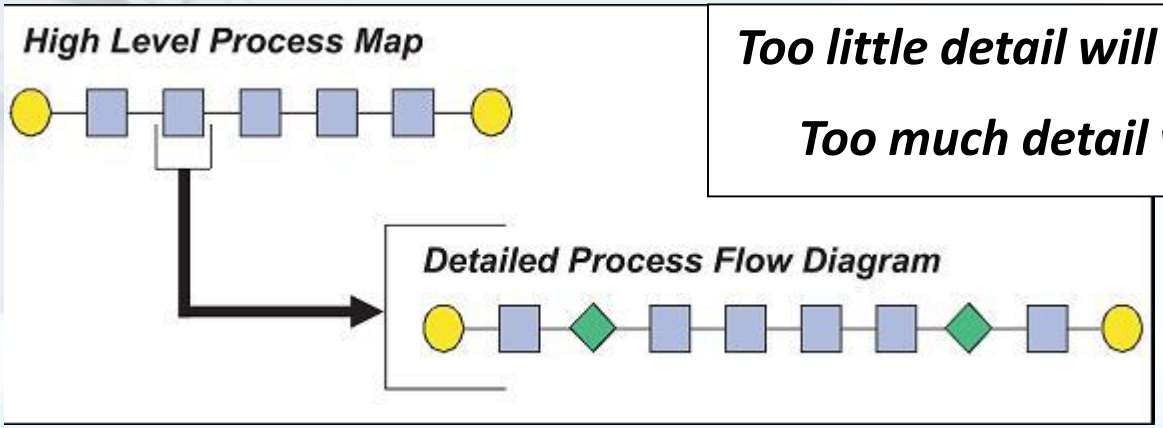
Common Header information: must be consistent with other PFMEA information

- FMEA Number
- Item
- Model Year/Vehicle(s)
- Process Identification
- Core Team
- Process Responsibility
- Key Date
- Prepared by
- Dates

Preparing a Process Flow

Process Step / Process Function (description) recommendations:

- Consecutive
- Consistent identification convention
- Consistent with other APQP documentation
- Appropriate level of detail



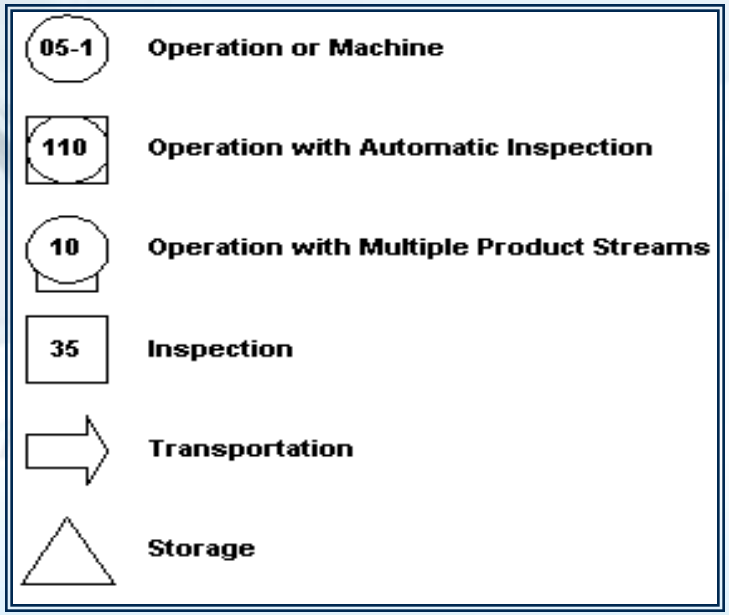
Too little detail will not expose the problem.

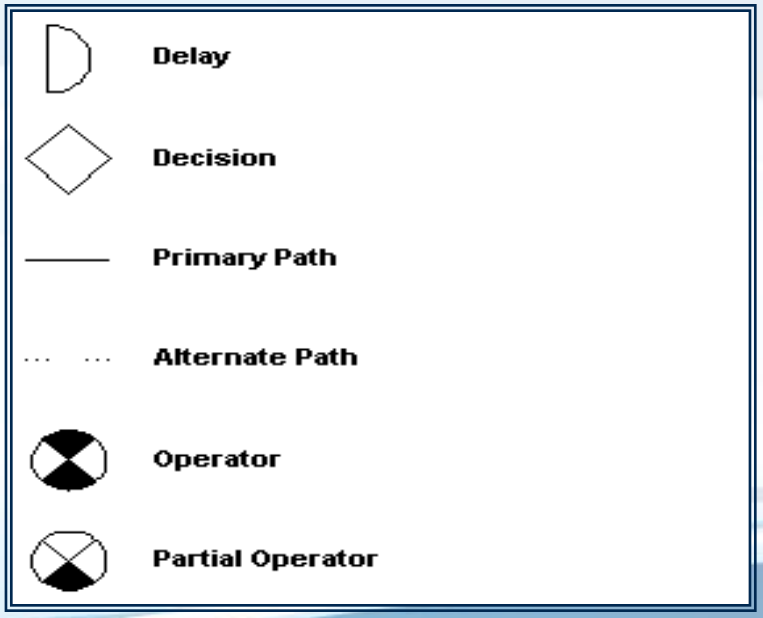
Too much detail will hide the problem.

Preparing a Process Flow

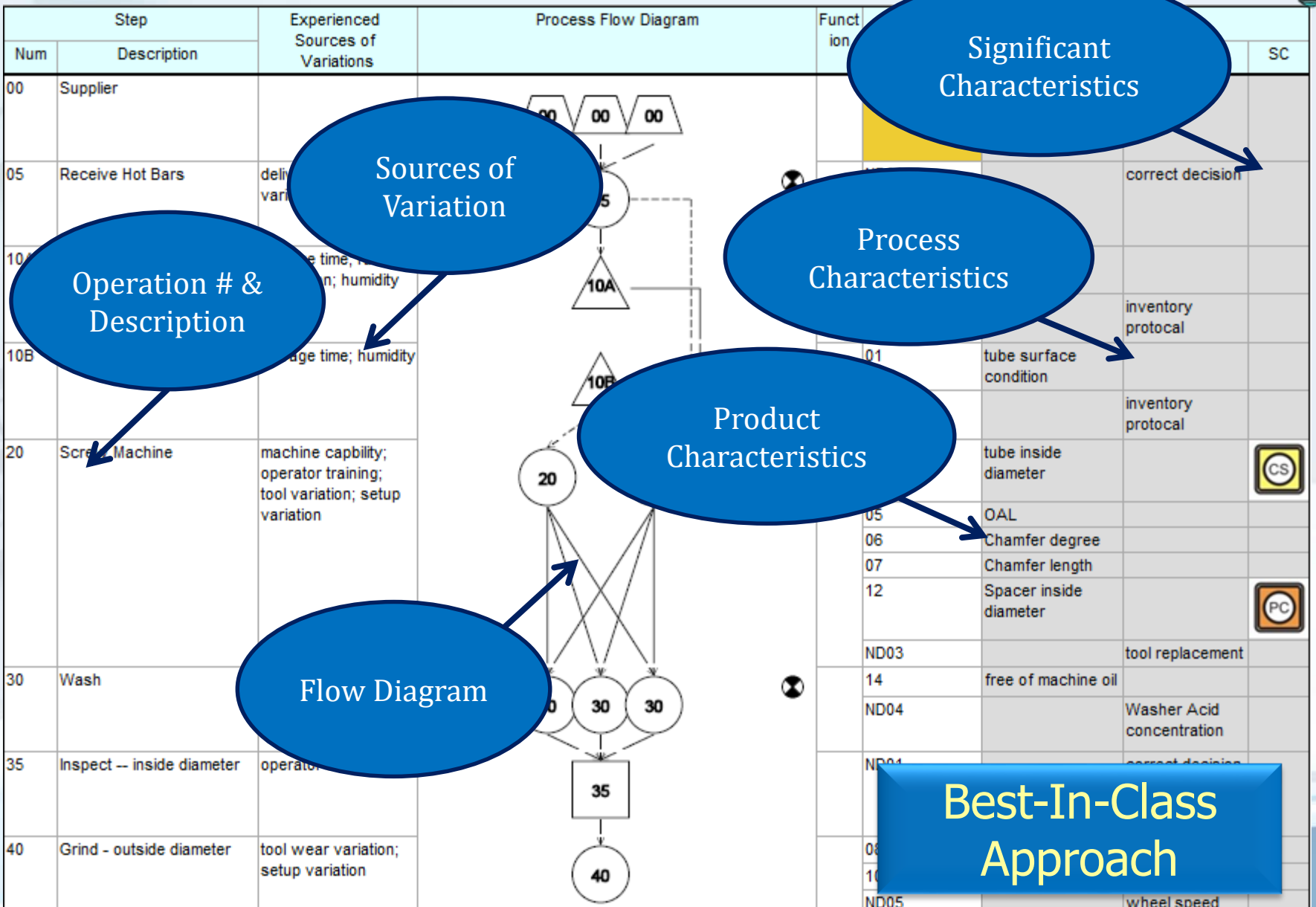
Process Flow Graphics

- Each process step should be represented by a symbol (icon).
- Some customers have specified a specific format or graphics but there is no single approach – be consistent.
- Example symbols:

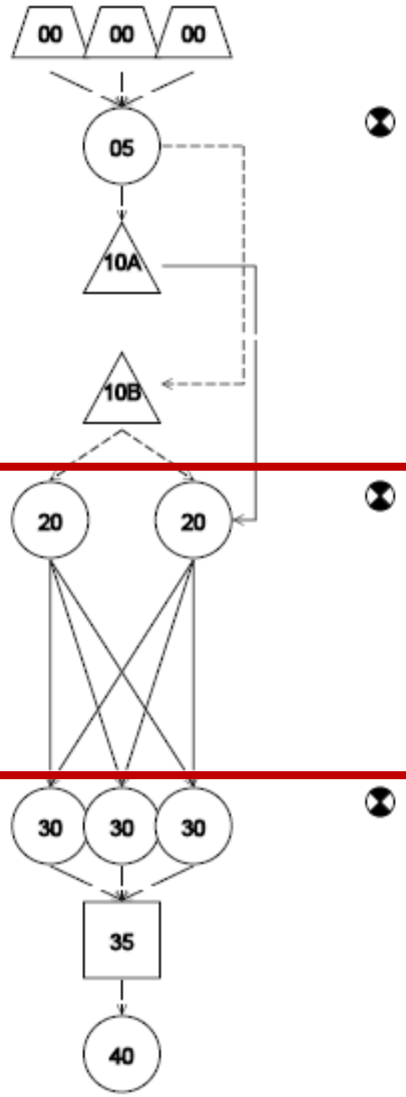




Manufacturing Process Flow Example



Manufacturing Process Flow

Step		Experienced Sources of Variations	Process Flow Diagram	Function	Requirement			
Num	Description				ID.	Product	Process	SC
00	Supplier							
05	Receive Hot Bars	delivery timing variation			ND01		correct decision	
10A	store bars inside	storage time; rack protection; humidity			01	tube surface condition		
					ND02		inventory protocal	
10B	store bars outside	storage time; humidity			01	tube surface condition		
					ND02		inventory protocal	
20	Screw Machine	machine capbility; operator training; tool variation; setup variation			04	tube inside diameter		CS
					05	OAL		
					06	Chamfer degree		
					07	Chamfer length		
					12	Spacer inside diameter		PC
					ND03		tool replacement	
30	Wash	Variation in solution; solution life			14	free of machine oil		
					ND04		Washer Acid concentration	
35	Inspect -- inside diameter	operator skill; gaging			ND01		correct decision	
40	Grind - outside diameter	tool wear variation; setup variation			08	Finished surface		
					10	Finished surface		
					ND05		wheel speed	
					ND06		wheel feed rate	

Manufacturing Process Flow

adapted for AIAG-VDA FMEA Method

Process Flow

Item	Process Responsibility	Process Identification	
Product		Prepared By	
Core Team	Key Date	Date (Orig)	Date (Rev)

Lower Level

Step. / Brief Description	Experienced Sources of Variation	Process Flow Diagram	ID	Product Characteristics	Process Characteristics	SC	Work Element	Function

Focus Level

Process Functions / Requirements

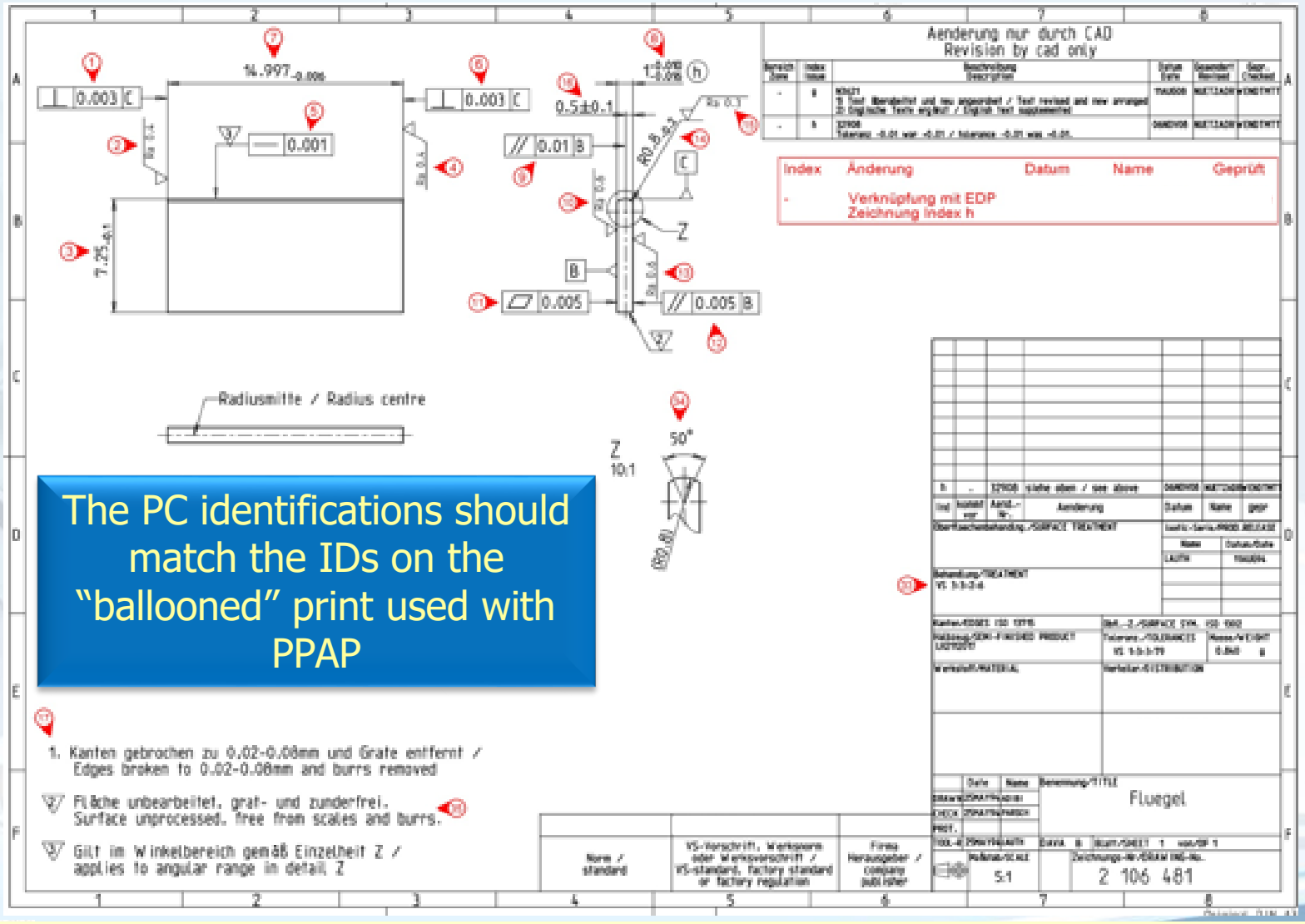
- What **SHOULD** the Operation/Process Step be doing?
- What are the expected outcomes for all uniquely identified print items and process characteristics ***at each step***?
- **What do we expect to see if the process step is operating correctly**, in terms of:
  - Product characteristics?
  - Process characteristics (parameters)?
  - Etc.

Preparing a Process Flow

Characteristics

- List all Product and Process Characteristics (requirements) for each process step.
  - *"what is this step in the process supposed to do or produce?"*
- It is recommended that each requirement be identified by a unique ID.
  - This should be consistent with the PPAP dimensional report IDs (Ballooned Drawing).

Print Preparation



Note: Number Product Characteristics with product identifications (PC IDs).

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.

Special Characteristics

The organization shall identify special characteristics and…

- Include all special characteristics in the Control Plan.
- Comply with customer-specified definitions and symbols.
- Identify special characteristics on process control documents:
  - Drawings
  - PFMEAs
  - Control Plan
  - Operator Instructions

Preparing a Process Flow

Sources of Variation (Experienced-based)

- This column is used to identify those sources of variation that can affect the process step.
- It is not intended to be a collection of all possible sources of variation, but only the dominant ones.

Recommendation:

- Enter only those sources of variation that have caused problems – for this step – in the past.

Other Process Flow Information

Organizations use the Process Flow Diagram to document other process related information:

- Capacity
  - Current process meets capacity requirements?
- Cost
  - Eliminate non-value added steps
  - Cost saving modifications
- Ergonomics and Safety
  - Minimize potential safety risks to employees, reduce operator fatigue and increase productivity
- Lead Time
  - Meet customer-established lead times
- Other Techniques
  - Value Engineering, Simulation, Testing, Line Balancing

Breakout Exercise 1

Process Flow Diagram

Breakout Exercise 1: Process Flow Diagram

Handouts

- Description of a manufacturing process.

Instructions

- Draw a Process Flow Diagram using the proposed manufacturing path.
  - For this exercise, do not include all the characteristic descriptions but only list the ID number.
  - Identify special characteristics.
  - Use the enlarged 11x17 Process Flow sheet or flip chart.
  - Be prepared to present your team's Process Flow Diagram to the class; rotate the team spokesperson.
  - Recommend improvements to the proposed flow.

AIAG VDA

Interactive Example using EwQIMS Software

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
  - Visual indication of the interaction between process steps and its work elements, i.e. the Influencing Factors; 4Ms
  - Allows for the reuse of process elements
  - Allows for the Function Analysis and Failure Analysis steps that follow

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

Higher Level > Focus Level > Lower Level

Structure Analysis: Structure Trees

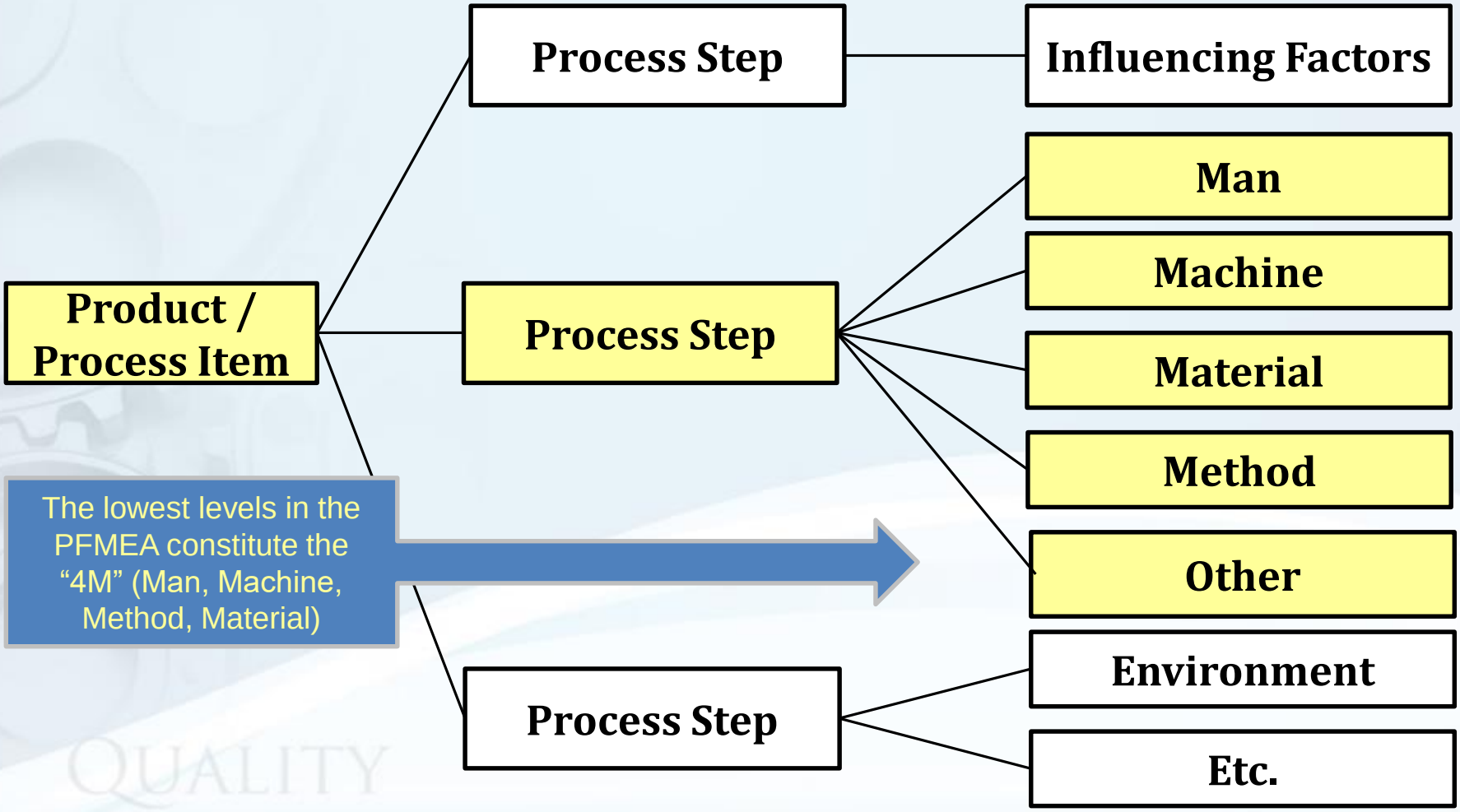
The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections.

- This pictorial structure allows for an understanding of the relationships between the Process Item, Process Steps and Process Work Elements.
- Each of these is a building block that will have functions and failures added in subsequent steps.

Collaboration between Customer and Supplier Engineering Teams (interface responsibilities)

The output of the Structure Analysis (visualization of the Process Flow) provides a tool for collaboration between customers and suppliers (including machine suppliers) during technical reviews of the process design and/or PFMEA project.

Structure Analysis: Tree Structure



Note: the AIAG-VDA FMEA requires at least 3 levels in the structure:
Higher Level > Focus Level > Lower Level

Levels of Examination: 4M+

- Man
  - Fitter
  - Machine operator
- Machine
  - Robot
  - Mixing unit
- Material
  - Bearing surface
  - Granules
- Method
  - Heat
  - Dust
  - Conditions / Contamination
- Other

Structure Analysis: System Structure in Excel

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

STRUCTURE ANALYSIS			FUNCTION A	
1. Process Item	2. Process Step	3. Process Work Element	1. Function of the Process Item	2. Function of Step and P Characte

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

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	2 Process Step Station No. and Name of Focus Element	3. Process Work Element [Man, Machine, Indirect Material, Environment, etc.]

To assist in function and failure analyses, it is recommended that this relate to a DFMEA

Breakout Exercise 2

Structure Analysis

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 Handle Stem Manufacturing
  - Develop the Structure tree graphically
  - 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 and differentiated as necessary with regard to its functions and failures in the system.

Breakout Exercise 2 – Structure Analysis

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Interactive Example using EwQIMS Software

FUNCTION ANALYSIS

3rd Step
Function Analysis

Visualization of Product or Process Functions

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Process Flow Diagram
Structure Tree
Note: Omnex software will generate Structure automatically

3 **FUNCTION ANALYSIS**

Characteristics for Focus Level
Do not populate Lower Level

4 **FAILURE ANALYSIS**

Failure modes in Focus Level
Causes in Lower Level,
then populate 4M

5 **RISK ANALYSIS**

5b **PLANNING SHOP FLOOR CONTROL**

Work Instructions, PM, Setup, Other

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b ***Link to Process Control Plan and Work Instruction/***
Shop Floor Standardization

Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA process

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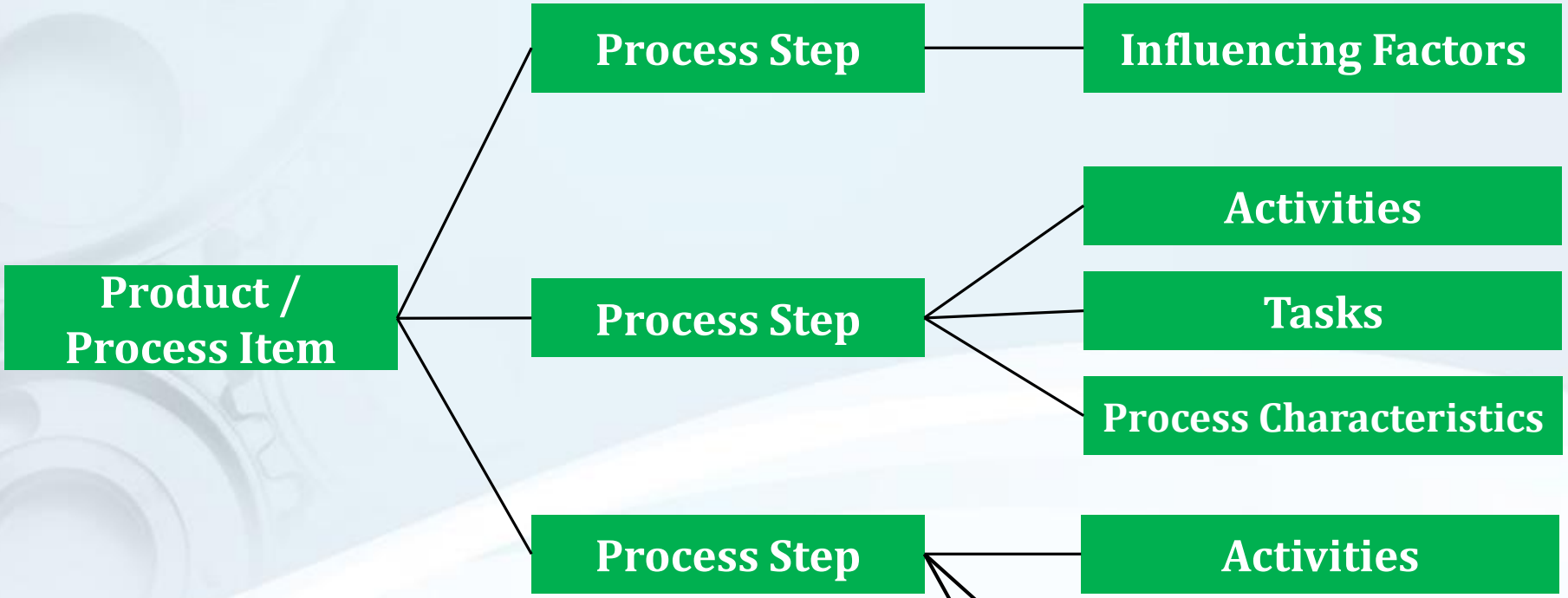
Goal of Function Analysis

- Overview of the product functionality and the flow of the functional requirements through the structure
- Flows down the functional requirements of the item to the lower level elements
- Answers the question *"What is the Function/Requirements of the specific level element?"*
- Verification against the customer requirements / specifications
- Overview of cause and effect relationships
- Creating the basis for the failure analysis

Function Analysis

Expands the Structure Tree by including function and requirements at each level



Expands the system structure to include functional requirements – at all levels

Process Functions / Requirements

The results of this activity should be…

At the Product/Process Item Level: a list of all the functional requirements of the product being assembled or manufactured as well as any process or logistical requirements in the process.

At the Focused (Process Step) Level: a list of all requirements/deliverables for each step of the process (from the Process Flow Diagram)

- List each requirement separately
  - Provide a name and number for each deliverable to be evaluated
  - Show process design level per engineering drawing
- Requirements should be described by an action verb followed by a noun
  - Describe the requirement in terms that can be measured

Function Analysis

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

FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item [In-plant, Ship-to-plant, Process Item, Vehicle End User, when known]	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic

Function Analysis

Functional Statements for the Specific Level Elements

1st Level	2nd Level	3rd Level
• Whole Process • Root Element	• Process Steps • Sub-processes	• Influencing Factors
Functions are: • Technical product specifications • Process results • Health and safety • Logistical results	**Functions are:** • Results after process step • Product state to be achieved • Product characteristics to be achieved	**Functions are:** • Activities to be executed • Tasks to be completed • Process characteristics to be achieved

We will defer identifying the influencing factors until we have a better understanding of the Focus Level failure mode

Special Characteristic Classification

- The Special Characteristic (SC) column should be used to highlight characteristics designated as safety, significant, and special.
- If product characteristics/attributes can have normal variation resulting in movement outside their design-intended robust range which results in significant impact experienced by the customer, they are designated special, and must be controlled by special controls.

Special product or process characteristic symbols and their usage are directed by specific company policy and is not standardized

Function Analysis

Collaboration between Engineering Teams (Systems, Safety, and Components)

- Engineering teams within the company need to collaborate to make sure information is consistent for a project or customer program, especially when multiple PFMEA teams are simultaneously conducting the technical risk analysis.
  - For example: design information from systems, safety, and/or component groups helps the PFMEA team understand the functions of the product they manufacture. This collaboration may be verbal (program meetings) or written as a summary.

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. Product / Process Item	1. Function of the Product / Process Item	Higher Level Failure Mode 1 Failure Effects (FE)

ID

Focus Level

STRUCTURE ANALYSIS	FUNCTION ANALYSIS	FAILURE ANALYSIS
2. Process Step	2. Function of the Process Step and Product Characteristic	Focus Level Failure Mode 2. Failure Mode (FM)

ID

Lower Level

STRUCTURE ANALYSIS	FUNCTION ANALYSIS	FAILURE ANALYSIS
3. Process Work Element (Influencing Factors)	3. Function of the Process Work Element and Process Characteristic	Lower Level Failure Mode 3. Failure Cause (FC)

ID

Breakout Exercise 3

Function Analysis

Breakout Exercise 3: Function Analysis

Instructions

- For each entry (for the Higher and Focus Levels) in the structure tree related to the focused element, identify the product functions and feature functions.
  - i.e. what product functions would the different customers find important?
- Include the process steps 20 and 50 and focus on the characteristics (ID) numbers 01, 02, 05 and 14.
- Allocate the functions to the proper levels of the system structure.
- Prepare to present and review as a class.

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Interactive Example using EwQIMS Software

Characteristic Matrix

What is It?

A matrix which…

- Displays relationships among requirements
- Identifies how one requirement can impact others
- Indicates where common tooling is used
- Aids in identifying the vital few

How to construct one:

- List all design or print (final or output) requirement (BPs) in order on top row of matrix
- List all operations in order by step # on left column of matrix
- Place relationship symbols in the interior cells of the matrix

Characteristic Matrix

Legend

- ✶ - Requirement changed
- ● - Interrelated Requirements
- S - Special Cause
- L - Locator
- C - Clamp

T – Common Tooling
A –Associated

Operations	Dimensions								
	1	2	3	4	5	6	7	8	9
OP 05	*								
OP 10	C	*	*	*					
OP 20		CL		L	* TA	* TA	* TA	* TA	
OP 30		CL							*

Chapter 3: Process FMEA Prerequisites – What We Covered

Learning Objectives

You should now be able to:

- Explain process characteristics
- Explain product characteristics
- Describe Planning and Preparation
- Describe the scope of analysis
- Complete a Process Flow Diagram and structure analysis

Chapter Agenda

- Step 1: Planning and Preparation
  - Scope of Analysis
- Step 2: Structure Analysis
  - Process Flow Diagram
  - **Breakout Exercise 1**
  - Structure Tree
  - **Breakout Exercise 2**
- Step 3: Function Analysis
  - **Breakout Exercise 3**

Chapter 4

Developing the Process FMEA

Failure Analysis and Risk Mitigation		
4th Step Failure Analysis	5th Step Risk Analysis	6th 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

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

Learning Objectives

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

- Explain process failure modes
- Identify failure modes from requirements
- Explain causes of failure modes
- Identify three key items for causes
- Explain process controls
- Distinguish between prevention and detection controls
- Explain the key elements of the risk analysis
- Complete a Process FMEA

Chapter Agenda

- Potential Process 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
  - Indices and Action Plans
  - **Breakout Exercise 6**
  - **Breakout Exercise 7**
- Step 6: Optimization
- Step 7: Results Documentation

FAILURE ANALYSIS

4th Step
Failure Analysis

Establishment of the Failure Chain

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Process Flow Diagram
Structure Tree
Note: Omnex software will generate Structure automatically

3 **FUNCTION ANALYSIS**

Characteristics for Focus Level
Do not populate Lower Level

4 **FAILURE ANALYSIS**

Failure modes in Focus Level
Causes in Lower Level,
then populate 4M

5 **RISK ANALYSIS**

5b **PLANNING SHOP FLOOR CONTROL**

Work Instructions, PM, Setup, Other

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b ***Link to Process Control Plan and Work Instruction/***
Shop Floor Standardization

Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA process

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Potential *Process* Failure Mode

1. Identify and List All the Requirements
   - Use information from the Process Flow Diagram
2. *For Each Requirement*
   - *Identify Potential Process Related Failure Modes*

How a process step could potentially fail to operate as defined

Potential *Process* Failure Mode

Defines how the output of the process could fail to:

- Meet the functional requirements
- Meet the design intent (fit, form)
- Meet the processing intent

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) [In-plant, Ship-to plant, Process Item, Vehicle End User, when known]	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element

Potential Failure Mode(s)

Traditional Approach: Brainstorm Failure Modes

Bent	Distorted	Porous
Binding	Eccentric	Rough
Blistered	Hole Missing	Short Circuited
Burred	Leaking	Scratched
Brittle	Seeds	Tight
Broken	Loose	Under Size
Corroded	Melted	Warped
Cracked	Misaligned	Sticky
Deformed	Omitted	Viscosity
Dirty	Open Circuited	Excessive TIR
Discolored	Oversize	Out of position

Not Recommended

Potential Failure Mode(s)

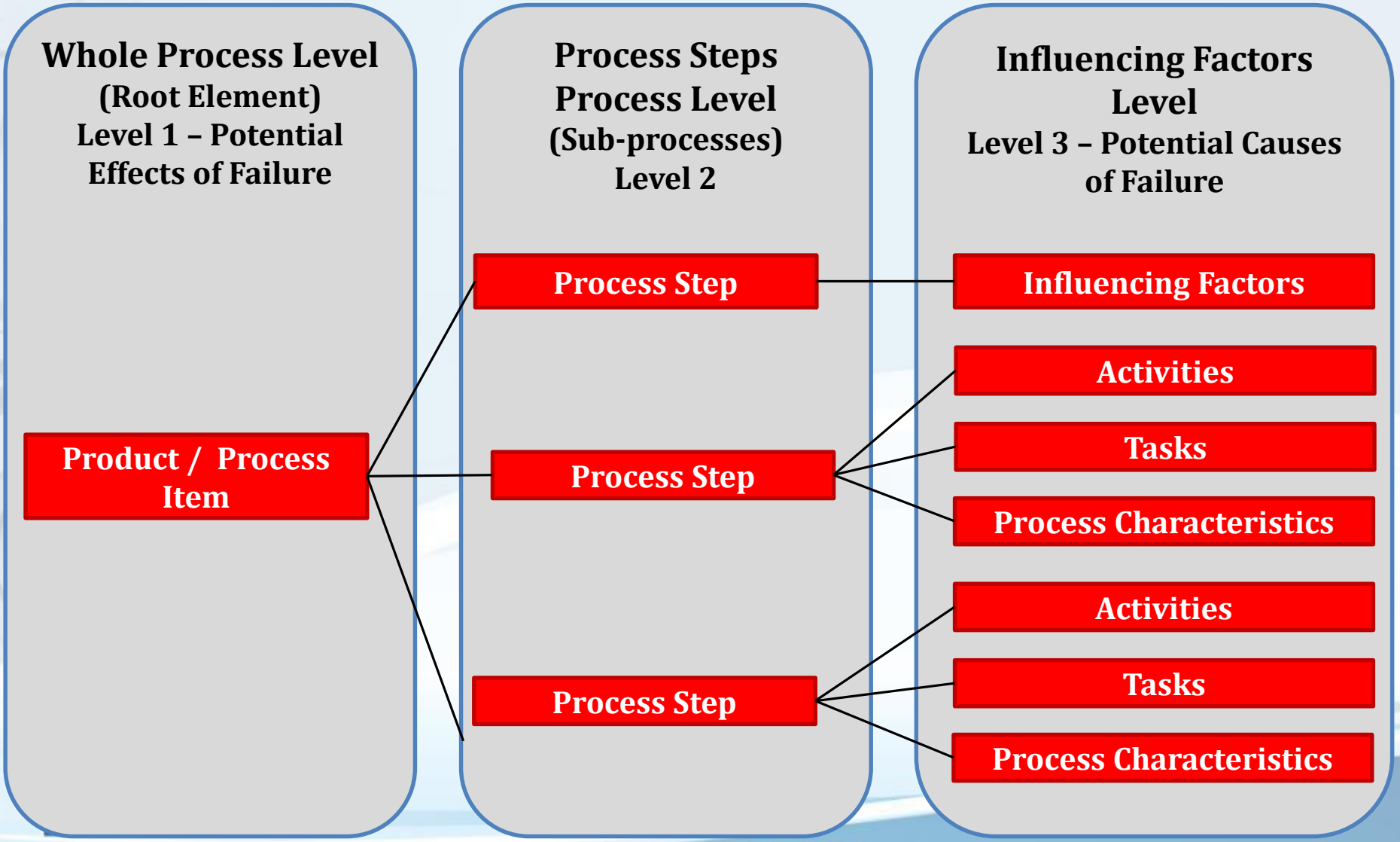
- **Recommended – BIC:** Analyze the requirements and use subject matter expertise to determine the failure modes.
- If more than 4 – 5 failure modes are identified, then the requirement definition is too "*vague*"; i.e. not operationally defined.

Note: this requires that the "pre-work" is complete and comprehensive

Example

Process Function	Requirement	Failure Mode
Operation 20: Attach seat cushion to track using a torque gun	Four screws	Less than four screws
	Specified screws	Wrong screw used (larger dia)
		Wrong screw used (smaller dia)
	Assembly sequence: First screw in right front hole	Starting screw placed in any other hole
	Screws fully seated	Screw not fully seated
	Screws torqued to dynamic torque specification	Screw torqued too high
		Screw torqued too low

Failure Analysis ➔ Potential Failure Modes



Failure Analysis

Failures of functions are deduced from the functions already identified in Step #3 and in this step (#4); i.e. for all levels

Product: Airbag

- Deploy on demand
- During a collision > 13 mph
- Airbag does not deploy on demand

Process Step: Secure Sensor

- Identify collision event to activate airbag
- Solder joint to provide electrical path
- Open path

Work Element

- Solder connector
- Electrically complete solder joint
- Open solder joint

Breakout Exercise 4

Failure Modes

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) [In-plant, Ship-to plant, Process Item, Vehicle End User, when known]	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element

OMNEX

Breakout Exercise 4: Failure Modes

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

- **For each Function/Requirement at the three levels**, identify known or potential failure modes, creating a separate branch for each in the form.
- Be as specific as possible; quantify when possible.
  - Include the process steps 20 and 50 and focus on the characteristics (ID) numbers 01, 02, 05 and 14.
  - Provide a unique identification (ID) for each failure mode at all levels
  - Include any process characteristics identified in the Process Flow Diagram.
  - Use the recommended format or the workbook provided by the instructor.
  - Be prepared to present your team's PFMEA to the class; rotate the team spokesperson.

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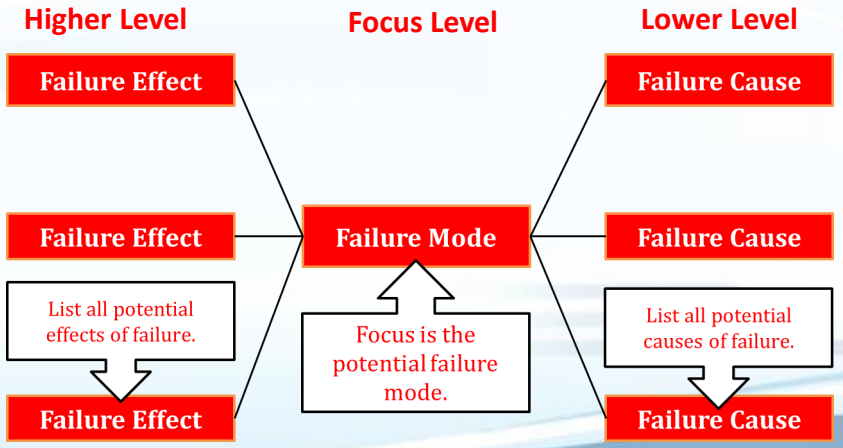
Interactive Example using EwQIMS Software

POTENTIAL EFFECTS OF FAILURE

FMEA Process

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

Failure Net Analysis



Effect of a Failure Mode

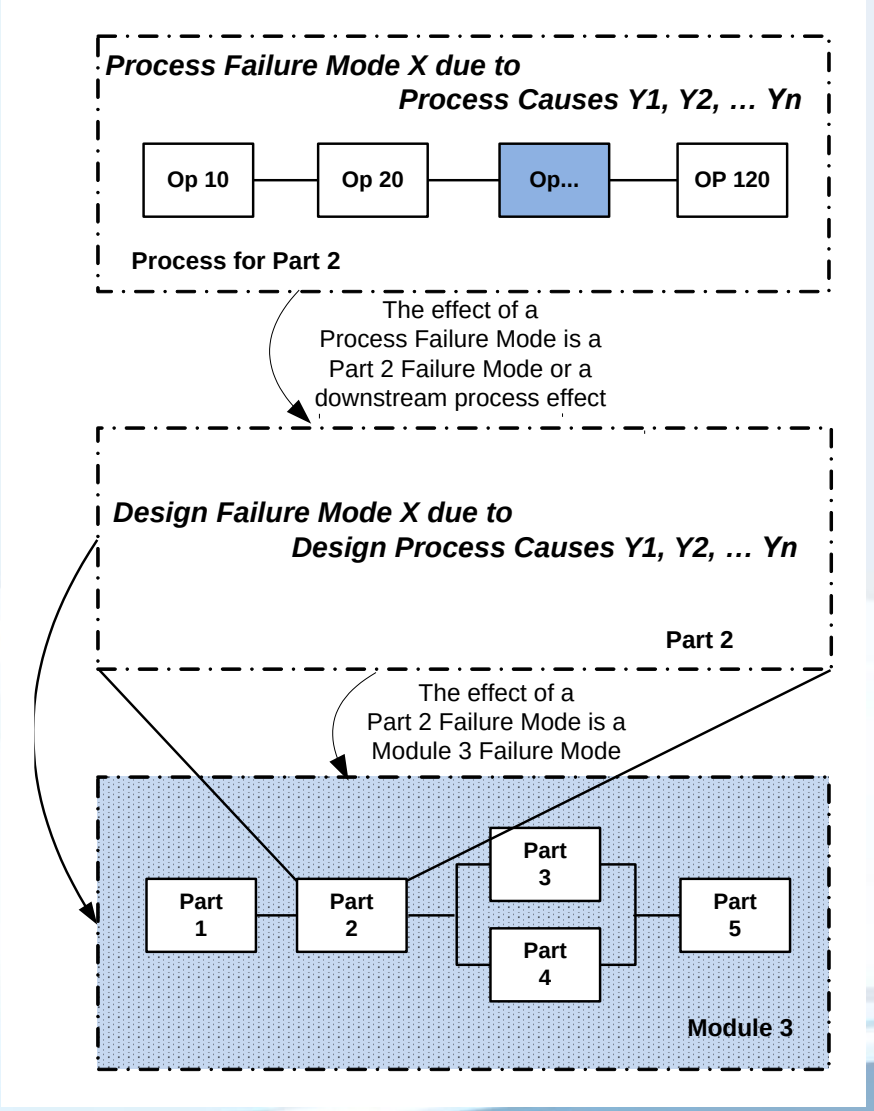
- Answers the "*So What*" question.
- Describes the effect of the failure mode on the customer including:
  - Vehicle operation
  - End user
  - Government regulation
  - Operator safety
  - Next user
  - Downstream users
  - Machines/equipment

Typically available from the related DFMEA

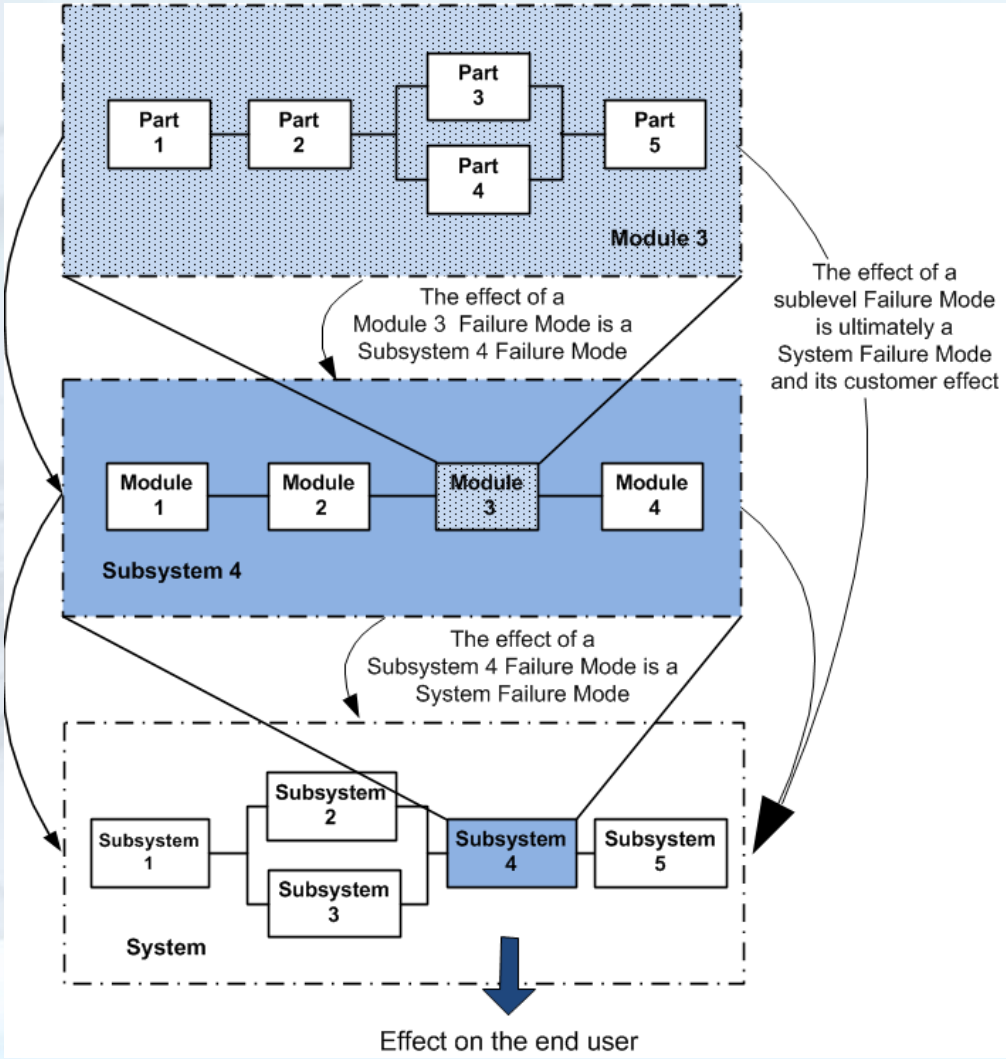
Effect Linkages

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.



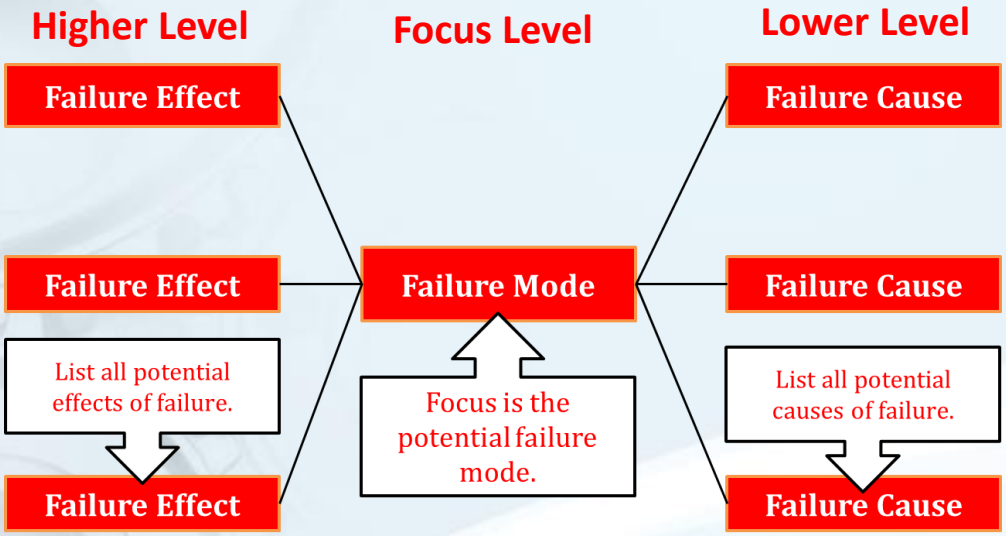
Effect Linkages



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) of the Next Lower Element or Characteristic**

Effect in AIAG-VDA FMEA Handbook

Failure Effects should be described in terms of what a customer might notice or experience even if they are not directly in the higher level. Failures that could impact safety or cause noncompliance to regulations should be clearly identified in the PFMEA.

What is the potential impact on the End User?

- Independent of any controls planned or implemented including error or mistake-proofing, consider what happens to the process item that leads to what the End User would notice or experience.
- This information should be available within the DFMEA. If an effect is carried from the DFMEA, the description of the product effects in the PFMEA should be consistent with those in the corresponding DFMEA.

Effect in AIAG-VDA FMEA Handbook

Does the failure mode physically impact downstream processing or cause potential harm to equipment or operators? Examples could include:

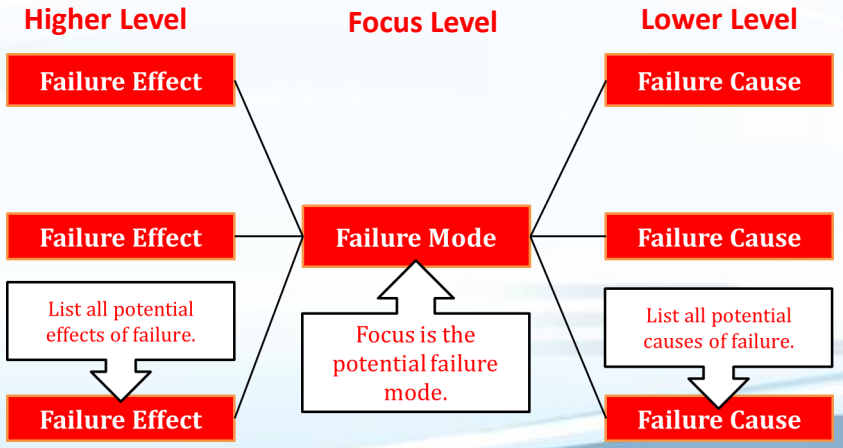
- Unable to assemble at operation x
- Unable to attach at customer facility
- Unable to connect at customer facility
- Cannot bore at operation x
- Causes excessive variation at operation x
- Causes excessive tool wear at operation x
- Damages equipment at operation x
- Endangers operator at customer facility

POTENTIAL CAUSES OF FAILURE

Potential Cause(s) of Failure

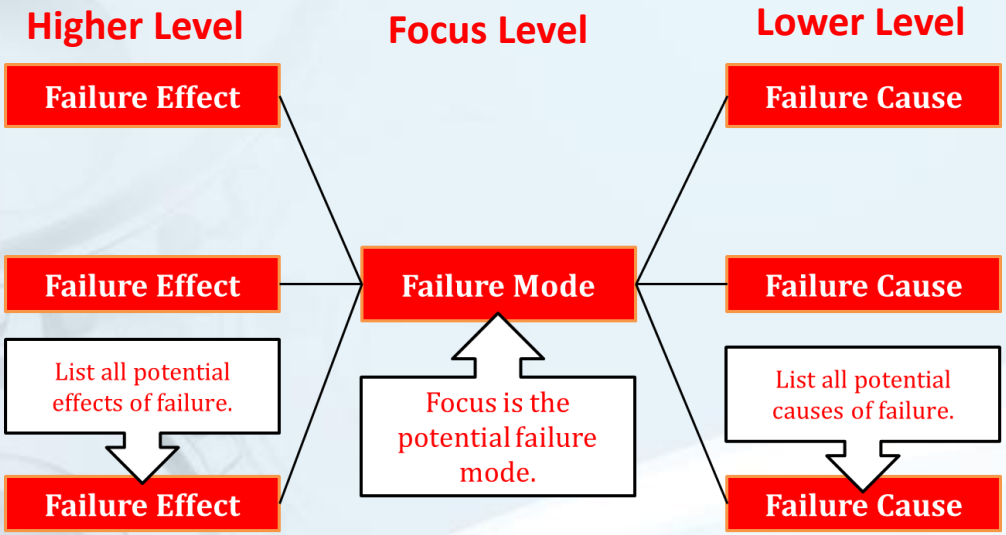
1. Identify and List All the Requirements
   - Use information from the Process Flow Diagram
2. For Each Requirement
   - Identify Potential Process Related Failure Modes
3. *For Each Failure Mode*
   - Assess Potential Effects of Failures
   - *Identify the Cause(s)*

Failure Net Analysis



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) of the Next Lower Element or Characteristic**

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.

Cause vs. Mechanism of a Failure Mode

- A failure mechanism is the physical, chemical, electrical, thermal, or other process that results in the failure mode.
  - For a system, the failure mechanism is the process of error propagation following a component failure which leads to a system failure.
  - A product or process can have several failure modes which are correlated to each other because of a common failure mechanism behind them.
- Causes are the circumstances that induce or activate a failure mechanism.
- Failure mechanisms are used to determine and understand the causes of a failure mode.
- Control methods and improvement actions are focused on the causes, not failure mechanism.

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.

Causes of Failure

Consider the Functional Statements for the System Elements at the third level for the causes of failures

1st Level	2nd Level	3rd Level
• Whole Process • Root Element	• Process Steps • Sub-processes	• Influencing Factors
Functions are: • Technical product specifications • Process results • Health and safety • Logistical results	**Functions are:** • Results after process step • Product state to be achieved • Product characteristics to be achieved	**Functions are:** • Activities to be executed • Tasks to be completed • Process characteristics to be achieved

These are candidates for causes

Example

[OP 30] Sintered Bearing Press-In Process

Process Characteristic:
Press in sintered bearing to achieve axial position in pole housing to max gap per print

Machine Function
Machine aligns sintered bearing to the bearing seat in pole housing

Machine Function
Machine centers the sintered bearing to the bearing seat in pole housing

Machine Function
Machine press in the sintered bearing into the bearing seat in pole housing until the defined axial position

(Extracted)

Potential Cause(s) of Failure

A failure cause is an indication of why a failure mode could occur.

- The consequence of a cause is the failure mode. Identify, to the extent possible, every potential manufacturing or assembly cause for each failure mode.

- The cause should be listed as concisely and completely as possible so that efforts (controls and actions) can be aimed at appropriate causes.

Potential Cause(s) of Failure

Typical failure causes categories may include the classic Ishikawa's 4Ms, but are not limited to:

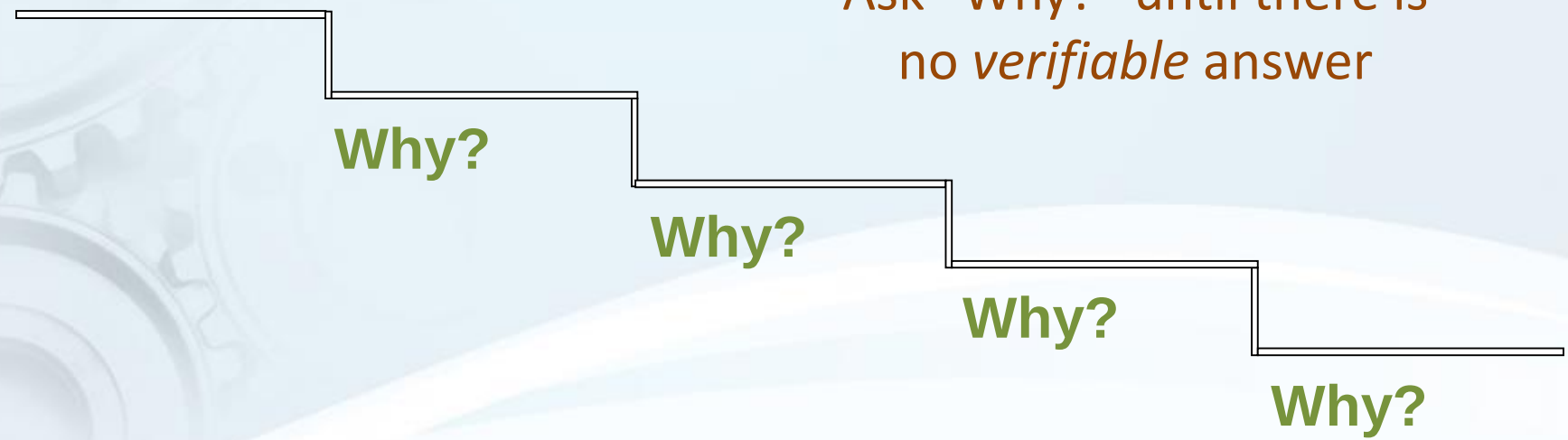
- **Man:** set-up worker, machine operator / associate, material associate, maintenance technician etc.
- **Machine/Equipment:** robot, hopper reservoir tank, injection molding machine, spiral conveyor, inspection devices, fixtures, etc.
- **Indirect Material:** machining oil, installation grease, washer concentration, (aid for operation), etc.
- **Milieu/Environment:** ambient conditions such as heat, dust, contamination, lighting, noise, etc.

Note: In preparing the FMEA, assume that the incoming part(s) / material(s) are correct. Exceptions can be made by the FMEA team where historical data indicate deficiencies in incoming part quality.

Cause Analysis Tools

Why Ladder/5-Why

Ask "Why?" until there is no *verifiable* answer



Do not confuse a causal chain with multiple causes

Example

Requirement	Failure Mode	Cause
Screws torqued until fully seated	Screw not fully seated	Nut runner not held perpendicular to work surface by operator
Screws torqued to dynamic torque specification	Screw torqued too high	Torque setting set too high by non-set-up personnel
		Torque setting set too high by set-up personnel
	Screw torqued too low	Torque setting set too low by non-set-up personnel
		Torque setting set too low by set-up personnel

Using the Spreadsheet Form

Higher Level

STRUCTURE ANALYSIS	FUNCTION ANALYSIS	FAILURE ANALYSIS
1. Product / Process Item	1. Function of the Product / Process Item	Higher Level Failure Mode 1 Failure Effects (FE)

ID

Focus Level

STRUCTURE ANALYSIS	FUNCTION ANALYSIS	FAILURE ANALYSIS
2. Process Step	2. Function of the Process Step and Product Characteristic	Focus Level Failure Mode 2. Failure Mode (FM)

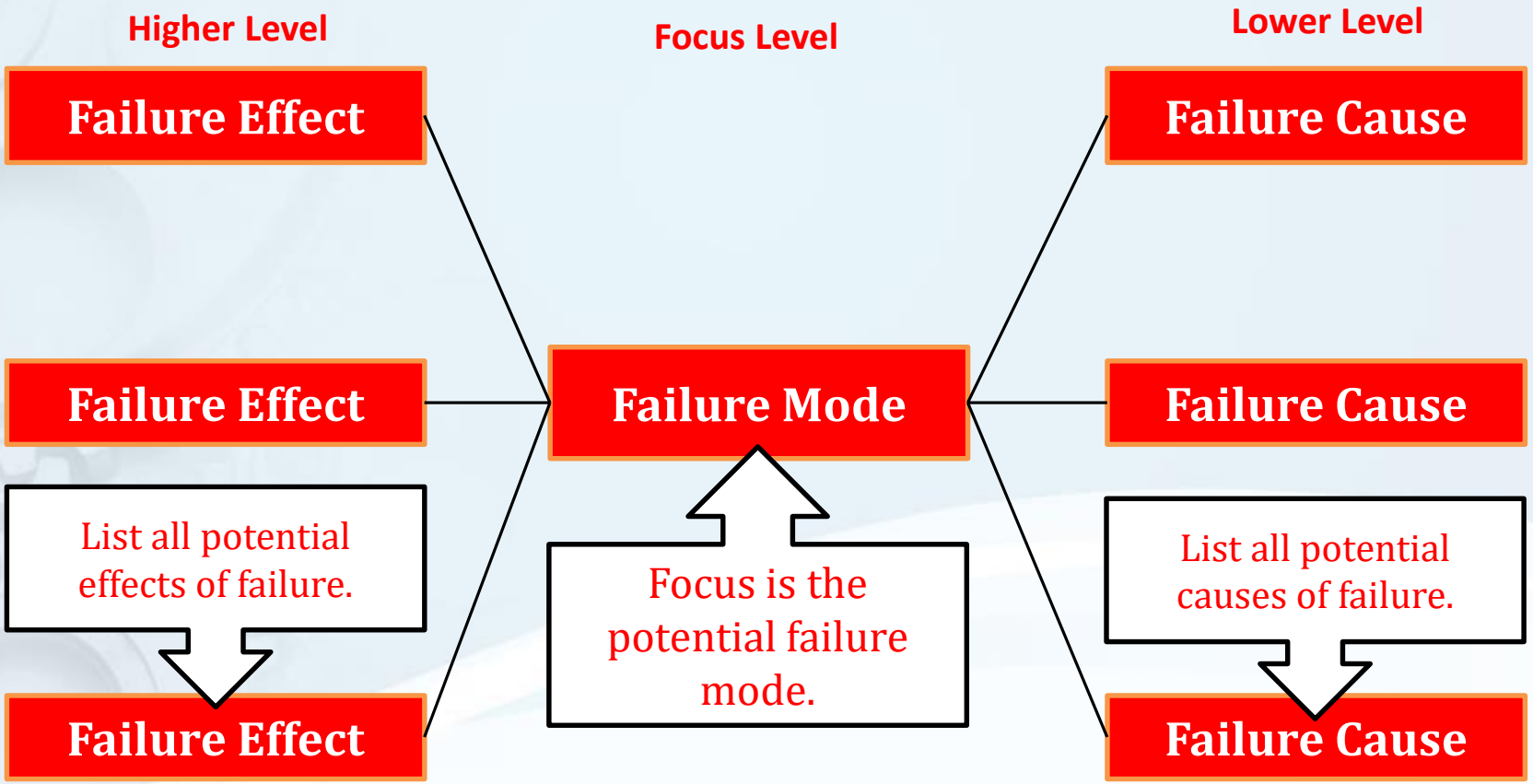
ID

Lower Level

STRUCTURE ANALYSIS	FUNCTION ANALYSIS	FAILURE ANALYSIS
3. Process Work Element (Influencing Factors)	3. Function of the Process Work Element and Process Characteristic	Lower Level Failure Mode 3. Failure Cause (FC)

ID

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

Failure Net Analysis

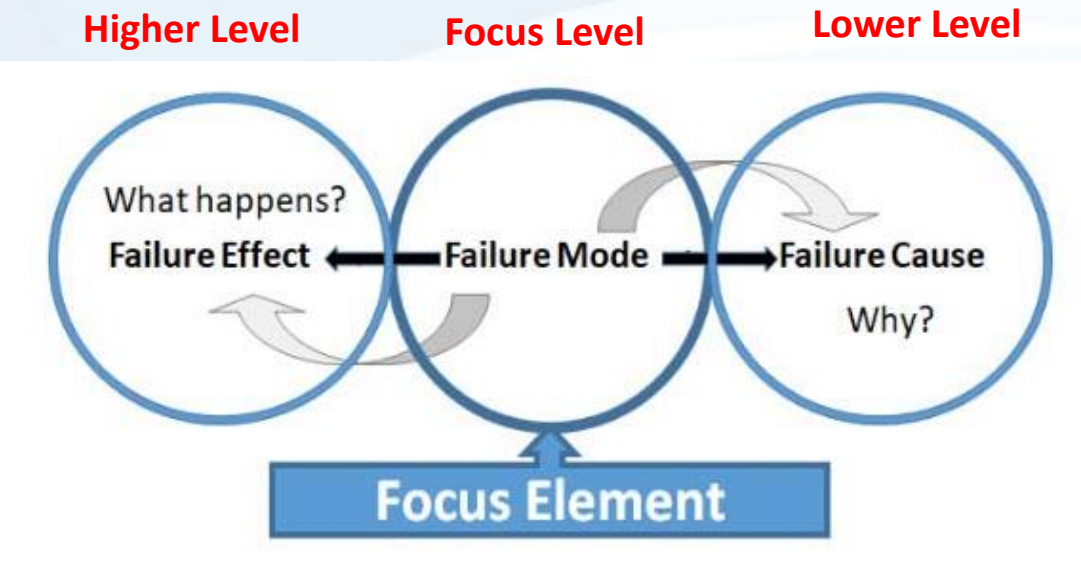
- At this point in the analysis, the functions and requirements and their relayed failure modes have been determined for all levels.
- To determine the causes and effects for each failure mode in each step, Failure Chains need to be developed.

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



FMEA Failure Analysis: Relationships

FMEA
System **S**

Potential Effect	Failure	Potential Cause
• Brake system malfunction	• Brake Control does not open	• Piston is stuck

DFMEA
Product **D**

Potential Effect	Potential Failure	Potential Cause
• Brake Control does not open	• Piston is stuck	• Cylinder is too small

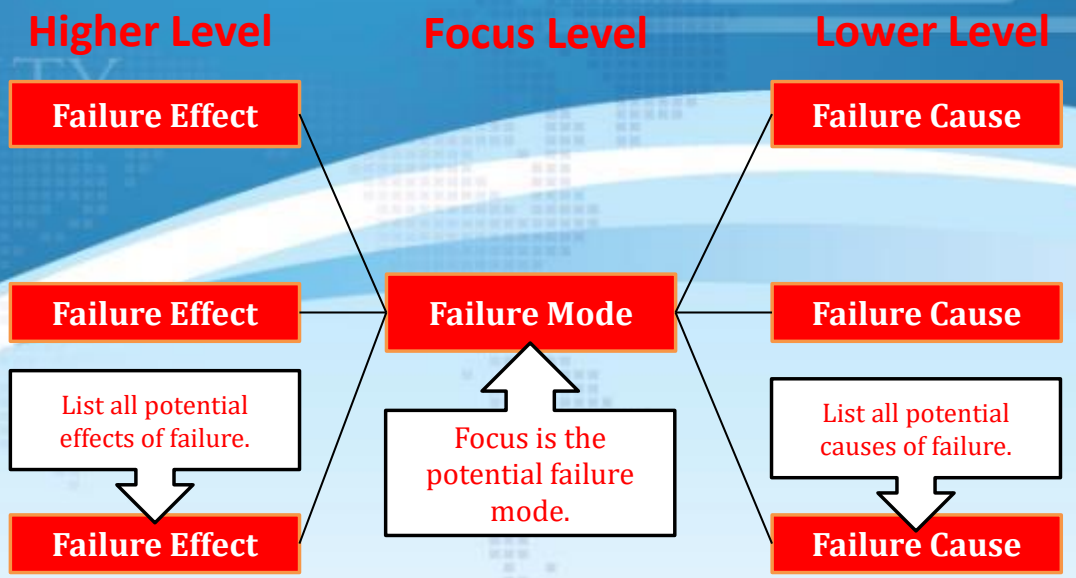
PFMEA
Process **P**

Potential Effect	Potential Failure	Potential Cause
• Piston is stuck	• Cylinder is too small	• Wrong/Worn Cutting Tool • Wrong Parameter

Breakout Exercise 5

Failure Net

Link Effect ← Failure Mode ← Cause



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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).
  - The IDs can be used instead of writing the entire failure modes.
- Update the form.
- Prepare to present and review as a class.

AIAG VDA

Interactive Example using EwQIMS Software

RISK ANALYSIS

5th Step
Risk Analysis

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

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Process Flow Diagram
Structure Tree
Note: Omnex software will generate Structure automatically

3 **FUNCTION ANALYSIS**

Characteristics for Focus Level
Do not populate Lower Level

4 **FAILURE ANALYSIS**

Failure modes in Focus Level
Causes in Lower Level,
then populate 4M

5 **RISK ANALYSIS**

5b **PLANNING SHOP FLOOR CONTROL**

Work Instructions, PM, Setup, Other

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b ***Link to Process Control Plan and Work Instruction/***
Shop Floor Standardization

Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA process

OMNEX

Process Controls

1. Identify and List All the Requirements
   - Use information from the Process Flow Diagram
2. For Each Requirement
   - Identify Potential Process 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) are/will be in place to prevent the cause or detect the cause or failure mode*
   - Identify and implement continual improvement actions

Process Controls

Process Controls are descriptions of actions or activities that are (or will be) in place to:

- Prevent the cause of failure mode; thereby preventing the failure mode.
- Detect the cause of the failure mode.
- Detect the failure mode.

Types of Process Controls:

Prevention (P):

- **Prevent the cause thus preventing the failure mode**

Detection (D):

- **Detect the cause**
- **Detect the failure mode**

Process 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

Variation and Control Methods

- Strategy for Selecting Control Methods
  - Meet all customer requirements.
  - Control *Process* rather than *Product*.
  - *Prevention* rather than *Detection*.
  - Targeting *Nominal* rather than *Limits*.
  - *Error-proofing* rather than *Inspection*.
  - At the *process step* rather than at the *end of the line*.
  - *Managing* the control method.

- Determine Control Method based on Sources of Variation

Process Controls

Controls should be based on the dominant source(s) of variation:

- Setup
- Machine/Equipment
- Maintenance
- Component
- Operator
- Fixture/pallet
- Tooling
- Measurement System
- Environment, etc.

Examples of Preventive Controls

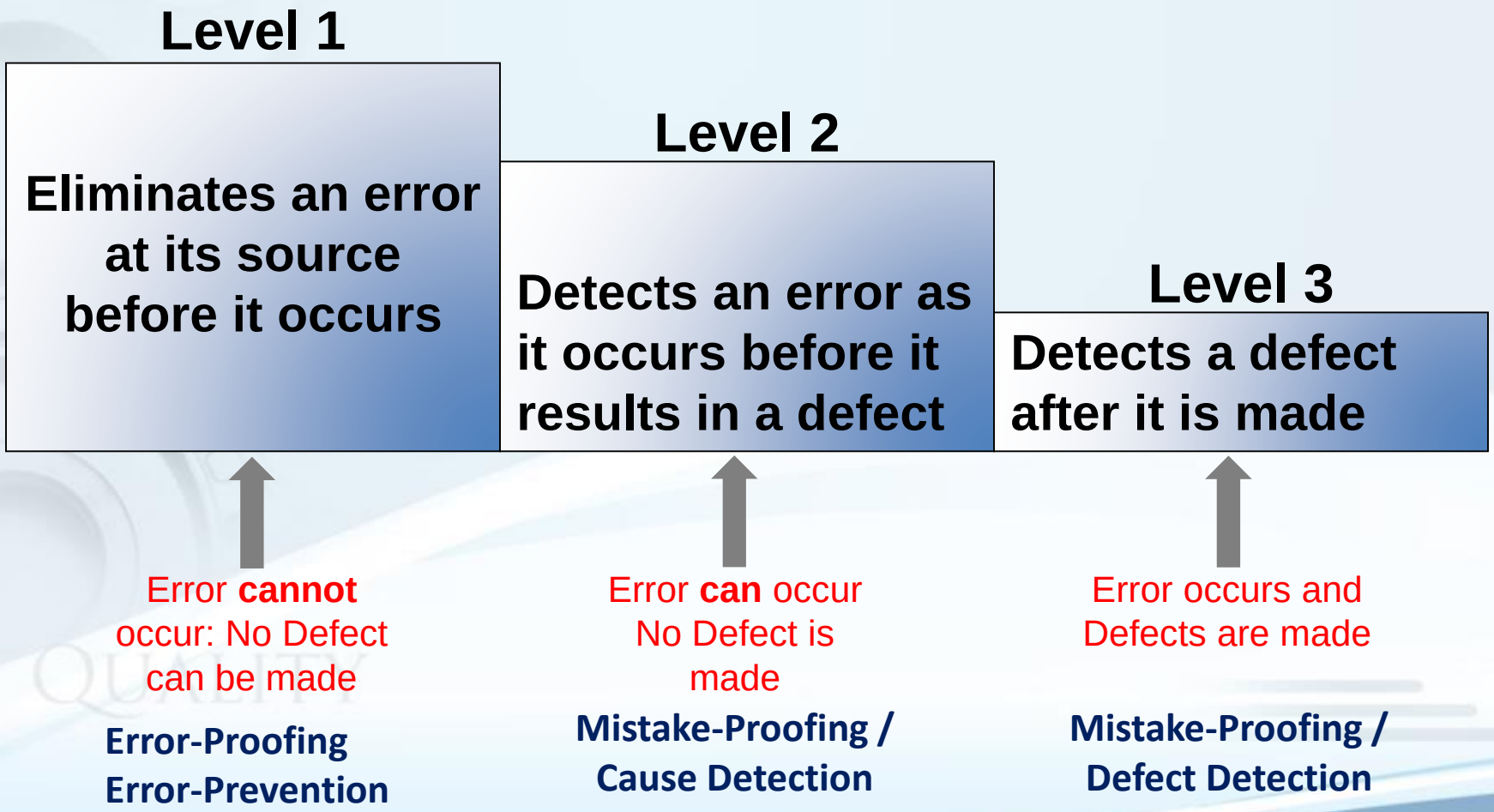
Type	Control Methods
Preventive Maintenance	Cycle Based Time Based
Error Proofing	Product Design Process Design Fixture Design Tooling Sensing Equipment Sensing
Other	Off-line Set-up Set-up Verification with SPC Process Control (SPC)

Examples of Detection Controls

Type	Control Methods
Audits	Dock Audits Process Parameter
Checking	Operator Checks 100% Automatic Gauging Visual Inspection
Inspection	In-process Final (dimension, functional)
Other	Mistake Proofing Set-up Validation Lab Test Alarms

Types of Controls

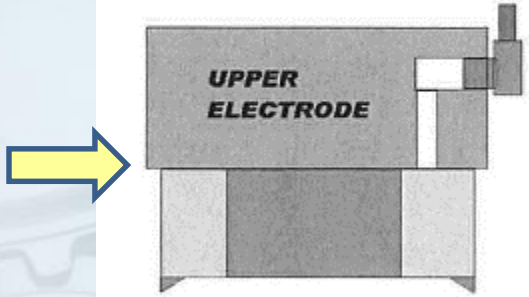
There are three main types of controls. These are as follows:



Error Proofing Example

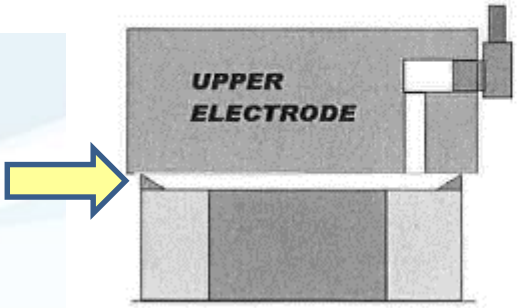
Upside-down Nut Prevention – Process Design

Right side up



Hole in the upper electrode is positioned to seal when the fastener is in position.

Upside-down nut



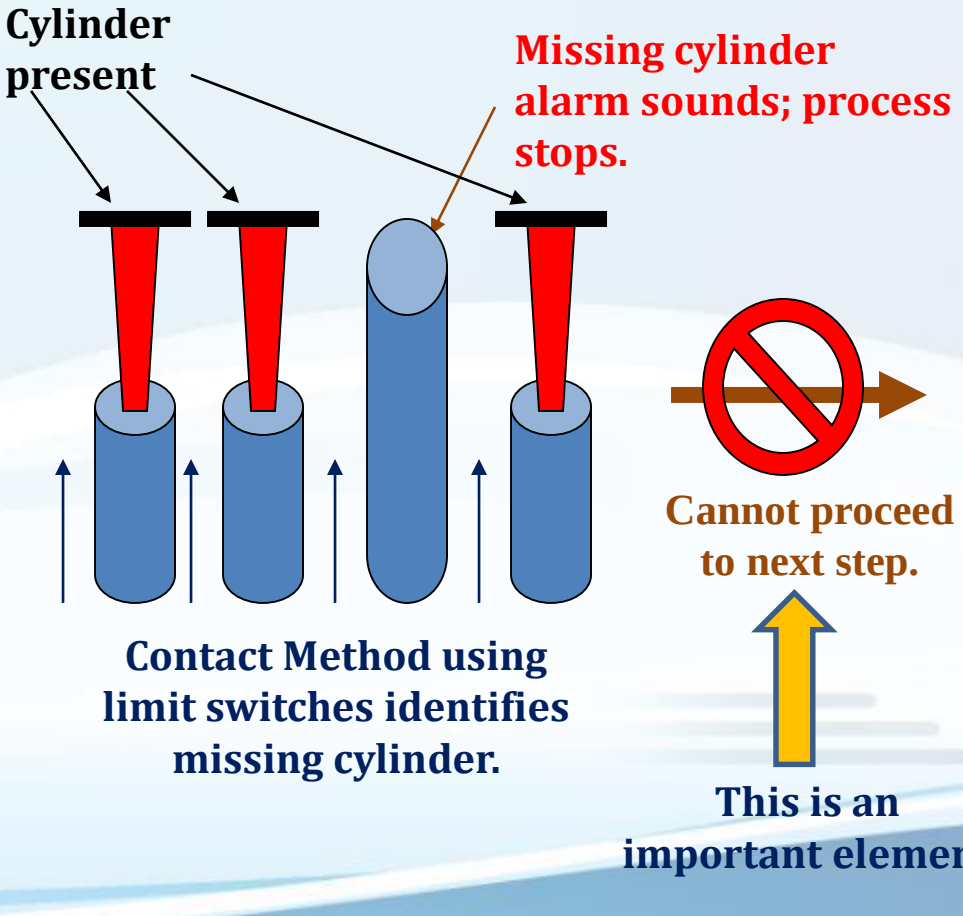
- Projections break the seal and the sensor picks up the flow of air.
- The weld control doesn't initiate a weld

It is often possible to eliminate the error condition through a re-design of the process or part (e.g. to be symmetrical or asymmetrical).

Mistake Proofing Example

- A contact method functions by detecting whether a sensing device makes contact with a part or object within the process.

Limit switches are pressed when cylinders are driven into a piston. The switches are connected to pistons that hold the part in place. In this example, a cylinder is missing and the part is not released to the next process.



Types of Mistake Proofing Devices

- The types of devices useful in ***mistake proofing*** include:
  1. Sensors
  2. Limit switches
  3. Stop gates
  4. Defect delivery chute
  5. Odd-part-out isolation
  6. Counters
  7. Templates
  8. Guides/reference point/interference pins
  9. Sequence restriction
  10. Critical condition indicator
  11. Standardize and solve
  12. Mistake-proof the mistake-proof device
- Mistake proofing devices should be planned in the product and or process design stage, rather than implementing these after a problem occurs. The PFMEA can identify areas where Mistake Proofing (and Error Proofing) should be applied.

Process Controls

- Process Control columns in the PFMEA describes the methods that will be used to control the process.
- The Control Plan provides the details of those controls.

Confirmation of Current Prevention and Detection Controls

- The effectiveness of the current prevention and detection controls should be confirmed.
  - Additional action may be needed if they are proven to not be effective.

- Such confirmation can be documented within the PFMEA, or within other project documents, as appropriate, according to the team's normal process development procedure and controls.

Example

Requirement	Failure Mode	Cause	Prevention Control	Detection Control
Screws torqued until fully seated	Screw not fully seated	Nut runner not held perpendicular to work surface by operator	Operator training; Visual Aids at station; Mistake proofing (angle sensor)	Angle sensor included in unit to detect cross-threading not allowing part to be removed from fixture until value is satisfied
Screws torqued to dynamic torque specification	Screw torqued too high	Torque setting set too high by non-set-up personnel	Password protected control panel (only set-up personnel have access)	Torque validation box included in set-up procedure to validate setting prior to running
		Torque setting set too high by set-up personnel	Training of set-up personnel	Torque validation box included in set-up procedure to validate setting prior to running
			Set-up instructions define torque settings	
	Screw torqued too low	Torque setting set too low by non-set-up personnel	Password protected control panel (only set-up personnel have access)	Torque validation box included in set-up procedure to validate setting prior to running
		Torque setting set too low by set-up personnel	Training of set-up personnel	Torque validation box included in set-up procedure to validate setting prior to running
			Set-up instructions define torque settings	

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 which can include the rest of the process (manufacturing and assembly):

- 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

PFMEA Severity – AIAG-VDA FMEA Handbook

SEV	Effect	Impact to Your Plant	Impact to Ship-to Plant (when known)	Impact to End User (when known)	Corporate or Product Line Examples
10	**High**	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Affects safe operation of the vehicle and/or other vehicles, the health of the driver or passenger(s) or road users or pedestrians.	
9		Failure may result in in-plant regulatory noncompliance.	Failure may result in in-plant regulatory noncompliance.	Noncompliance with regulations.	
8	**Moderately High**	100% of production run affected may have to be scrapped. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker.	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		Product may have to be sorted and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed or added manpower.	Line shutdown from 1 hour to full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance.	**Degradation** of primary vehicle function necessary for normal driving during expected service life.	

PFMEA Severity – AIAG-VDA FMEA Handbook

SEV	Effect	Impact to Your Plant	Impact to Ship-to Plant (when known)	Impact to End User (when known)	Corporate or Product Line Examples
6	**Moderately Low**	100% of product run may have to be reworked off-line and accepted.	Line shutdown up to one hour.	**Loss** of secondary vehicles function.	
5		A portion of the production run may have to be reworked off-line and accepted.	Less than 100% of product affected; strong possibility for additional defective product; sort required; no line shutdown.	**Degradation** of secondary vehicle function.	
4		100% of production run may have to be reworked in-station before it is processed.	Defective product triggers significant reaction plan; additional defective products not likely; sort not required.	Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	A portion of the production run may have to be reworked in-station before it is processed.	Defective product triggers minor reaction plan; additional defective products not likely; sort not required.	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slight inconvenience to process, operation, or operator.	Defective product triggers minor reaction plan; additional defective products not likely; sort not required; requires feedback to supplier.	Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very Low**	No discernible effect.	No discernible effect or no effect.	No discernible effect.	

Occurrence

- Occurrence is an index linked to the likelihood that a specific cause will occur.
  - This has a relative meaning rather than an absolute value.
  - A consistent scale must be used to ensure continuity.
- Occurrence is directly related to identified special causes acting on the process.
  - Process capability and performance is considered only if the process is unacceptable.
- **Best-in-Class:** identify whether the index is based on…
  - Consensus
  - Historical data on the same or similar processes
  - Statistical study (e.g. DOE) on the process

Prevention Control Effectiveness

Consider if prevention controls are

- **Technical** (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error proofing, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.),

— or —

- **Behavioral** (rely on certified or non-certified operators, skilled trades, team leaders, etc.)

when determining how effective the prevention controls will be.

PFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Type of Control	Prevention Controls	Corporate or Product Line Examples
10	**Extremely High**	None	No prevention controls.	
9	**Very High**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8				
7	**High**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6				
5	**Moderate**		Prevention controls are effective in preventing failure cause.	
4				
3	**Low**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Very Low**			
1	**Extremely Low**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention controls – **Failure Mode cannot be physically produced** due to the Failure Cause.	

Detection

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.
- **Remember: Prevention controls only affect occurrence.**

PFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
10	**Very Low**	No testing or inspection method has been established or is known.	The failure mode will not or cannot be detected.	
9		It is unlikely that the testing or inspection method will detect the failure mode.	The failure mode is not easily detected through random or sporadic audits.	
8	**Low**	Test or inspection method **has not been** proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results, marginal on comparable process or this application, etc.)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause.	
7			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.) or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause.	

PFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
6	**Moderate**	Test or inspection method **has been** proven to be effective and reliable (e.g. plant has experience with method, gauge R&R results are acceptable on comparable process or this application, etc.)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks).	
5			Machine-based detection (semi-automated with notification by light, buzzer, etc.) or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks).	

PFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
4	**High**	System has been proven to be effective and reliable (e.g. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect failure mode **downstream,** prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
3			Machine-based automated detection method that will detect failure mode **in-station,** prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	

PFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
2	**High**	Detection method has been proven to be effective and reliable (e.g. plant has experience with method, error-proofing verifications, etc.)	Machine-based detection method that will detect the cause and prevent the failure mode (discrepant part) from being produced.	
1	**Very High**	Failure mode cannot be physically produced as-designed or processed, or detection methods proven to **always** detect the failure mode or failure cause.		

Breakout Exercise 6

Process Controls

OMNEX

Breakout Exercise 6: Process Controls

Working with the PFMEA form from the previous breakout:

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

Breakout Exercise 6: Process 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 process control.
  - 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 control column. Select the rating for the most effective (lowest number) control.
  - Note that the same controls may operate for different causes or failure modes, and are repeated.

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Interactive Example using EwQIMS Software

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.

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:

RPN = Severity x Occurrence x Detection

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

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).

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.

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

PFMEA

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

PFMEA

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

PFMEA

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

PFMEA

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

PFMEA

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

Evaluation – 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

Interactive Example using EwQIMS Software

Breakout Exercise 7

Indices and Action Plans

Breakout Exercise 7: Indices and Action Plans

Working with the PFMEA form from the previous breakout:

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

AIAG VDA

Interactive Example using EwQIMS Software

RISK ANALYSIS

5th Step
Risk Analysis

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

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Process Flow Diagram
Structure Tree
Note: Omnex software will generate Structure automatically

3 **FUNCTION ANALYSIS**

Characteristics for Focus Level
Do not populate Lower Level

4 **FAILURE ANALYSIS**

Failure modes in Focus Level
Causes in Lower Level,
then populate 4M

5 **RISK ANALYSIS**

5b **PLANNING SHOP FLOOR CONTROL**

Work Instructions, PM, Setup, Other

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b ***Link to Process Control Plan and Work Instruction/***
Shop Floor Standardization

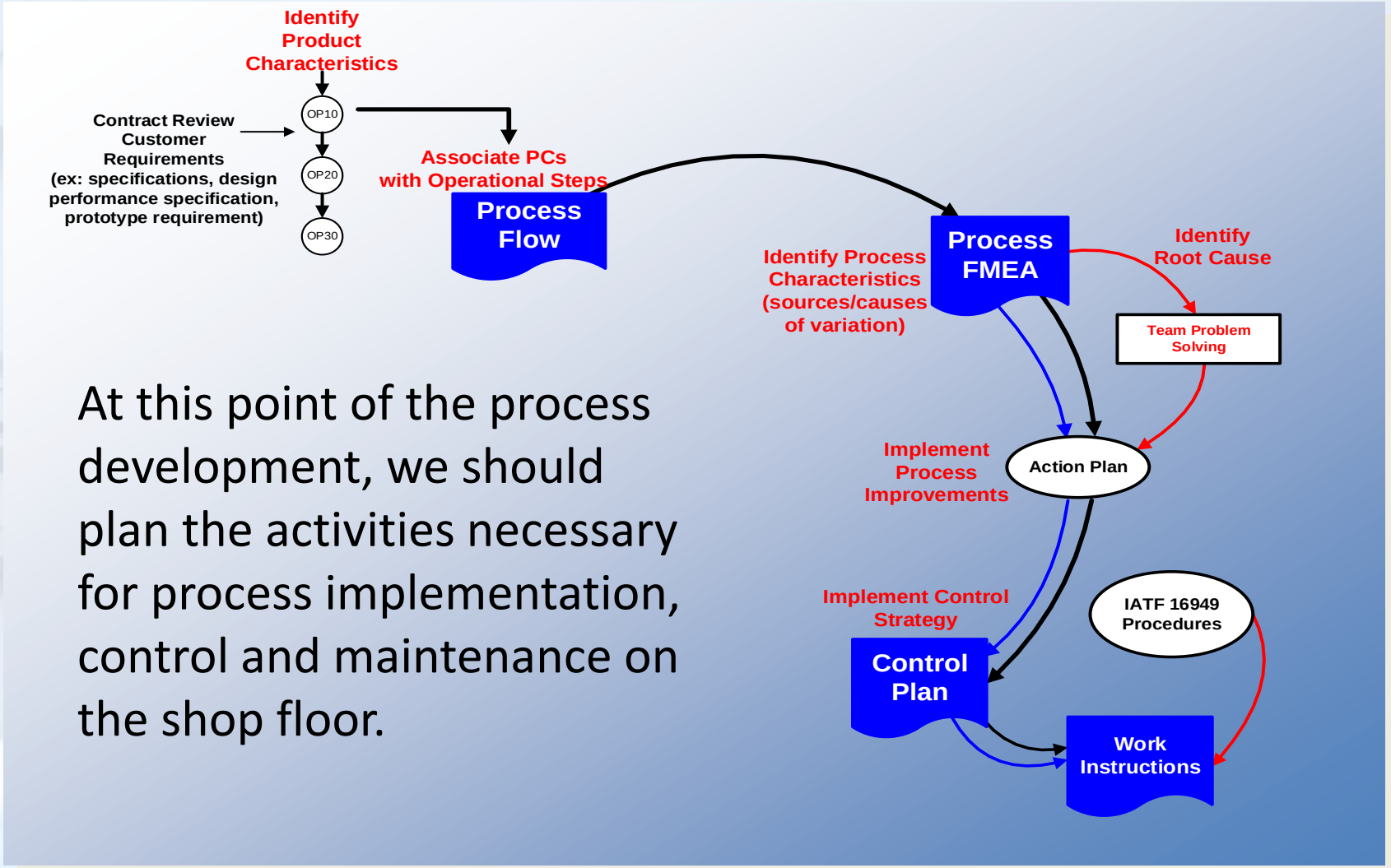
Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA process

OMNEX

Planning Shop Floor Control



At this point of the process development, we should plan the activities necessary for process implementation, control and maintenance on the shop floor.

OPTIMIZATION

6th Step
Optimization

Identification of the Actions Necessary to Reduce Risks

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Process Flow Diagram
Structure Tree
Note: Omnex software will generate Structure automatically

3 **FUNCTION ANALYSIS**

Characteristics for Focus Level
Do not populate Lower Level

4 **FAILURE ANALYSIS**

Failure modes in Focus Level
Causes in Lower Level,
then populate 4M

5 **RISK ANALYSIS**

5b **PLANNING SHOP FLOOR CONTROL**

Work Instructions, PM, Setup, Other

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b ***Link to Process Control Plan and Work Instruction/***
Shop Floor Standardization

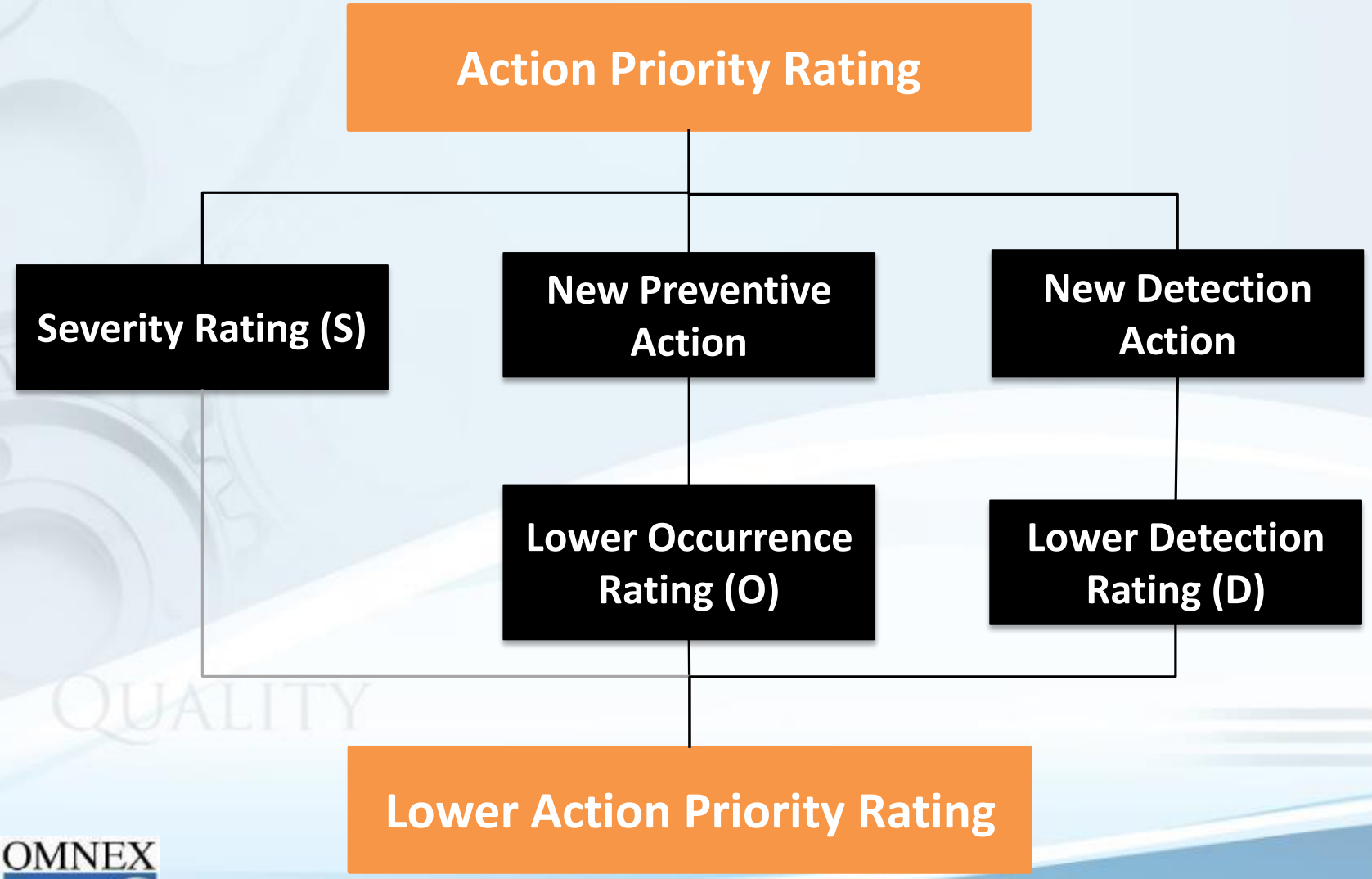
Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA process

OMNEX

Step 6: Optimization



Key Characteristics

Identification of Key Characteristics

Criteria	
Severity = 9 or 10	Safety Related
Severity = 5 to 8 and Occurrence = 4 to 10	Candidate

Note: Use customer specific symbols/designations as required

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	• Change the design	• Eliminate or reduce the severity of the failure mode
Occurrence	• Change the design or improve engineering specification • Error proofing	• Prevent the cause or failure and its effect from occurring
Detection	• Increase or change in the design validation / verification actions • Design change to enhance detection likelihood • Revised test plan	• 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!						

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

- As the living document is updated to reflect activity in the "**Recommended Actions**" columns, consider changes that will:
  - Eliminate the cause of the failure mode
  - Eliminate the failure mode
  - Mitigate the effect
  - Change the design related to the product characteristic (geometry, material, etc.)
  - Change the effect of failure mode on the product performance

"Recommended Actions" should focus on "Prevention"

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."

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 PFMEA 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 PFMEAs because the information is used as a starting point for a process specific analysis.

RESULTS DOCUMENTATION

7th Step
Results Documentation

Communication of Actions Taken to Reduce Risks

1 **PLANNING & PREPARATION**

5Ts

2 **STRUCTURE ANALYSIS**

Process Flow Diagram
Structure Tree
Note: Omnex software will generate Structure automatically

3 **FUNCTION ANALYSIS**

Characteristics for Focus Level
Do not populate Lower Level

4 **FAILURE ANALYSIS**

Failure modes in Focus Level
Causes in Lower Level,
then populate 4M

5 **RISK ANALYSIS**

5b **PLANNING SHOP FLOOR CONTROL**

Work Instructions, PM, Setup, Other

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b ***Link to Process Control Plan and Work Instruction/***
Shop Floor Standardization

Legend:

= Omnex improvements over the AIAG-VDA PFMEA process

Italic font = Omnex-specific changes to the AIAG-VDA PFMEA 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 PFMEA 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 PFMEAs for the benefit of future analysis reuse, when applicable.

FMEA Results Documentation

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

G. Implementation of the planned linkages to the process control plan, work instructions and shop floor standardization.
   a. Verify development and implementation of Work Instructions, PM, Setup, Others.
   b. Verify consistency of the Work Instructions, PM, Setup, and Others process documents with the Process FMEA.

AIAG VDA

Interactive Example using EwQIMS Software

Chapter 4: Developing the Process FMEA – What We Covered

Learning Objectives

You should now be able to:

- Explain process failure modes
- Identify failure modes from requirements
- Explain causes of failure modes
- Identify three key items for causes
- Explain process controls
- Distinguish between prevention and detection controls
- Explain the key elements of the risk analysis
- Complete a Process FMEA

Chapter Agenda

- Potential Process 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
  - Indices and Action Plans
  - **Breakout Exercise 6**
  - **Breakout Exercise 7**
- Step 6: Optimization
- Step 7: Results Documentation

Chapter 5

Process Control Plan

Chapter 5: Process Control Plan — What We Will Cover

Learning Objectives

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

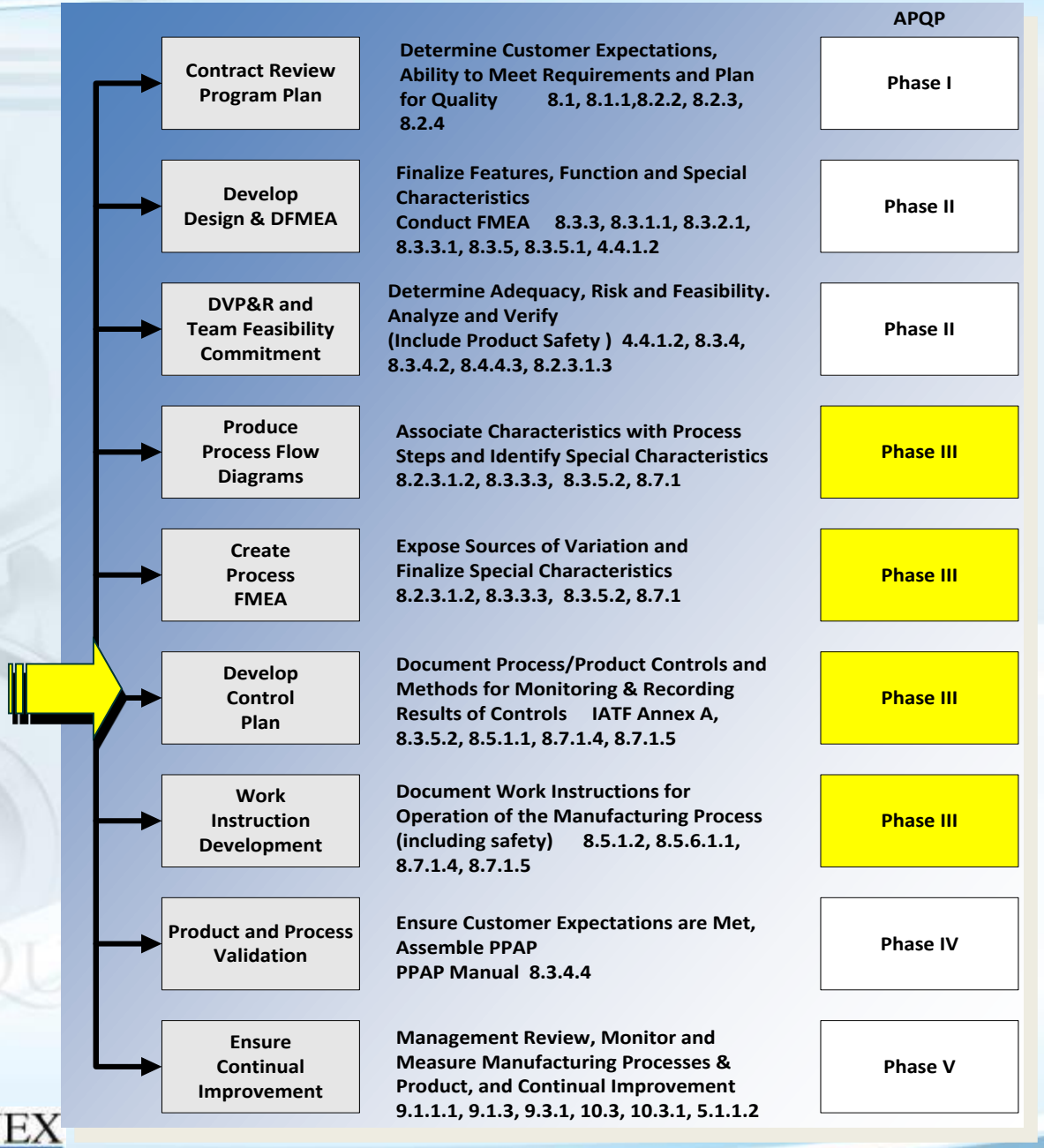
- Explain the purpose of a Control Plan
- Identify where Control Plan requirements can be found in IATF 16949
- Complete a Control Plan

Chapter Agenda

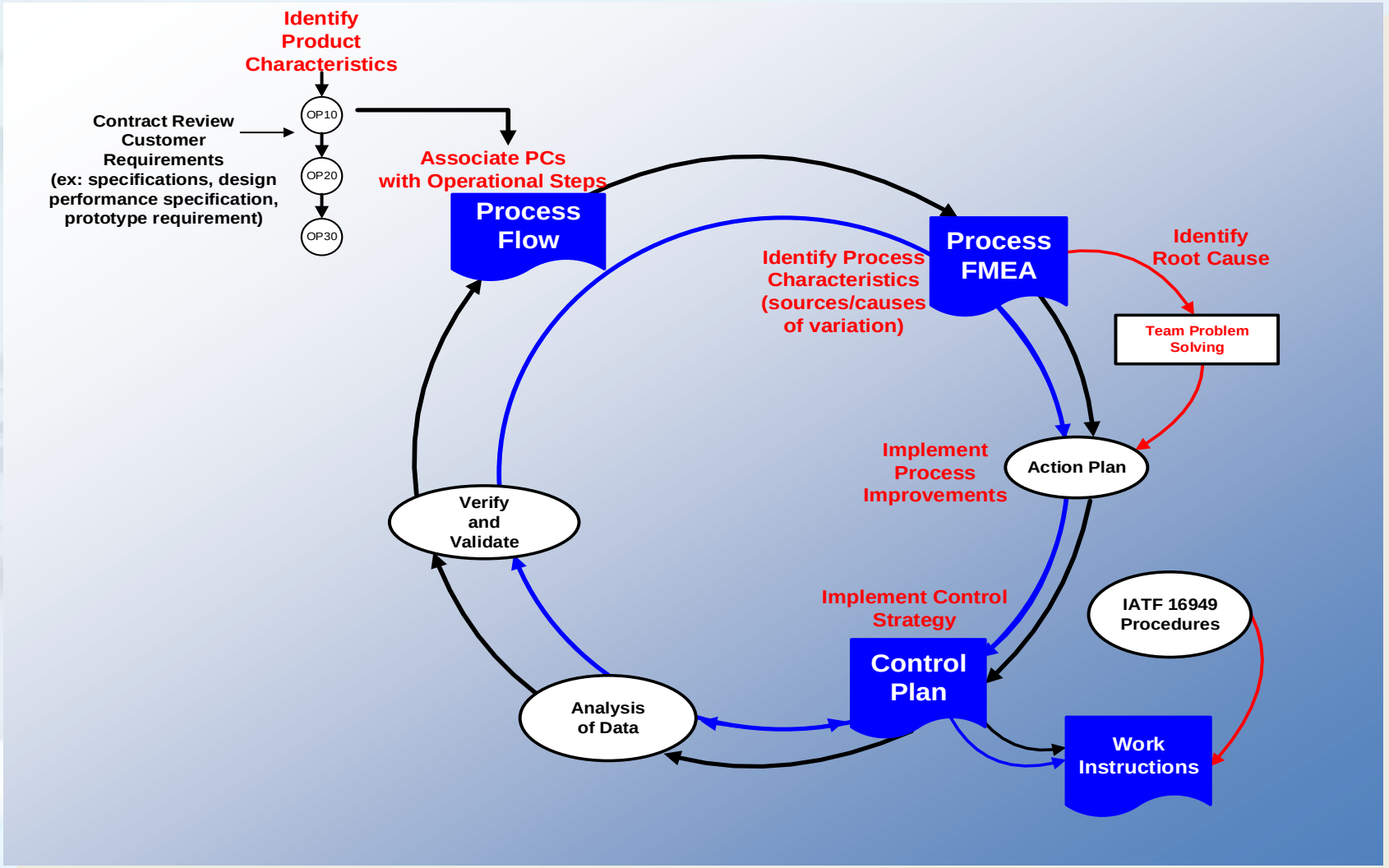
- What is a Control Plan?
- IATF 16949 Requirements
- Control Plan Header Information
- Control Plan Fields
- **Breakout Exercise 8**

WHAT IS A CONTROL PLAN?

Product Development Process Model



System Diagram



What is a Control Plan?

- Written description of systems for controlling product and process variation in manufacturing and assembly processes
- Contract between the supplier and the customer
- Summarizes entire control strategy for a system, subsystem or component
- Basis for development of process work instructions—not a substitute for it!
- Identifies statutory, regulatory, customer, supplier, special and critical characteristics

Control Plan

- The PFMEA (current process controls) describes the methods which will be used to control the process from Receiving to Shipping.
- The Control Plan provides the details of those controls.
- Control Plan is maintained and used throughout the product life cycle.
- A Control Plan may apply to a group or family of products produced by the same process.

Sources of Information

Primary Source: the Related Process FMEA and Process Flow Diagram

Other information

- System / Design / Special Characteristics
- Lessons Learned from similar parts and/or processes
- Team knowledge of the Process (and Product)
- Development Reviews (Design and Process)
- Robust Design Analysis (DFSS, QFD, DOE)

Sample Form

Control Plan

	Prototype		Pre-launch		Production	Key Contact/Phone		Date (Original)	Date (Revised)
Control Plan Number									
Part Number/Latest change Level						Core Team		Customer Engineering Approval/Date (If Required)	
Part Name/Description						Supplier/Plant Approval/Date		Customer Quality Approval/Date (If Required)	
Supplier/Plant		Supplier Code				Other Approval/Date (If Required)		Other Approval/Date (If Required)	

Part/Process Number	Process Name/ Operation Description	Tool and/ or Technique	Characteristics			Special Characteristic Class	Methods					Reaction Plan
			No.	Product	Process		Product/Process Specification Tolerance	Evaluation Measurement Technique	Sample		Control Method	
									Size	Frequency		

"An alternate format may be used as long as it contains the same information, as a minimum"—APQP 2nd Edition

IATF 16949 REQUIREMENTS

IATF 16949 Requirements: Control Plan

General Data

- Control Plan Number
- Issue Date, and Revision Date, if any
- Customer Information (see customer requirements)
- Organization Name/Site Designation
- Part Number(s)
- Part Name/Description
- Engineering Change Level
- Phase Covered (Prototype, Pre-launch, Production)
- Key Contact
- Part/Process Step Number
- Process Name/Operation Description
- Functional group/area responsible

Ref: Annex A, IATF 16949

IATF 16949 Requirements: Control Plan

Product Control

- Product-related Special Characteristics
- Other Characteristics for Control (Number, Product or Process)
- Specification/Tolerance

Process Control

- Process Parameters (including process settings & tolerances)
- Process-related Special Characteristics
- Machines, Jigs, Fixtures, Tools for Manufacturing (including identifiers, as appropriate)

Ref: Annex A, IATF 16949

IATF 16949 Requirements: Control Plan

Methods

- Evaluation Measurement Technique
- Error-proofing
- Sample Size and Frequency
- Control Method

Reaction Plan and Corrective Actions

- Reaction Plan (include or reference)

Ref: Annex A, IATF 16949

CONTROL PLAN HEADER INFORMATION

Header Information

- Document Control
- Revision Control

- Must be consistent with
  - DFMEA
  - DVP&R
  - Process Flow
  - PFMEA

- For Efficiency
  - Group by commonality
    - parts
    - assemblies
    - features
    - design
    - processes

Header Information

1. Indication of CP type:
   Prototype, Pre-launch , Production
2. Control Plan Number
3. Part Number Latest Change Level
4. Part Name / Description
5. Organization / Plant
6. Organization Code (Supplier Code)
7. Key Contact / Phone And Other Contact Information
8. Core Team
9. Organization / Plant Approval / Date
10. Date (Orig.)
11. Date (Rev.)
12. Customer / Engineering Approval Date
13. Customer / Quality Approval Date
14. Other Approval/Date

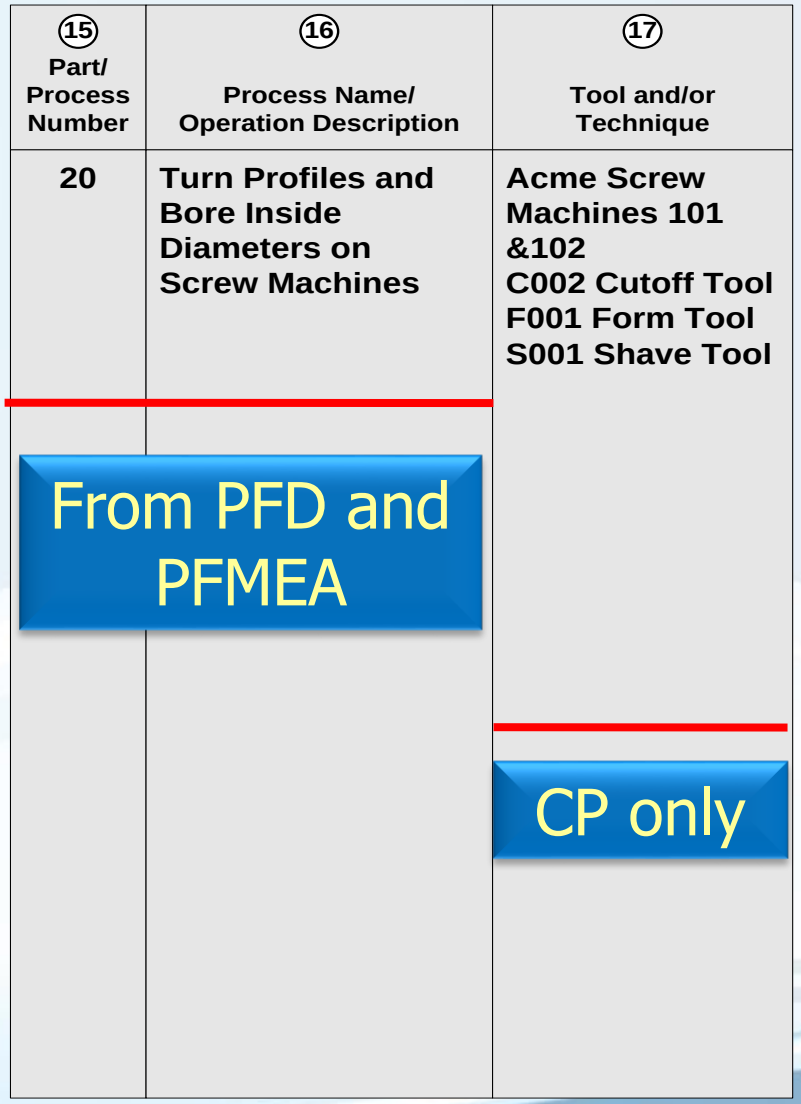
CONTROL PLAN FIELDS

Control Plan

Part/Process Number

Process Name / Operation Description

Machine, Device, Jig, Tools For Manufacturing



Control Plan

Characteristics

- Number
- Product
- Process
- Special / Classification
  - Customer Specific, when required

Characteristics			21
18 No.	19 Product	20 Process	Special Characteristic Class
04	Spacer ID		D
05	OAL		D
06	Chamfer Degree		
07	Chamfer Length		
		Tool Replacement	
		Speed Control	

From PFD and PFMEA

Specifications

What the characteristic will be controlled to; information can be found in:

- Drawings / Prints
- Specifications / Tolerances
- Standards
- CAD Data
- Manufacturing / Assembly Standards

Control Plan

Control Method
- From the PFMEA

Sample Size
- How many

Frequency
- How often

Evaluation / Measurement Technique
- By what means

Evaluation Measurement Technique (23)	Sample (24)		Control Method (25)
	Size	Frequency	
Inside mic IM--001	6 pcs	At Setup minimum	First Piece inspection & Documented on First Artide Checksheet
Inside mic IM--001	6 pcs	Every 300 Pieces & at Tool Change	Xbar - R
Hgt Stand GV--002	6 pcs	At Setup minimum	First Piece inspection & Documented on First Artide Checksheet
Hgt Stand GV--002	6 pcs	Every 300 Pieces & at Tool Change	Sample Inspection and Documented on Inprocess Checksheet
Comparator C--001	6 pcs	At Setup minimum	First Piece inspection & Documented on First Artide Checksheet
Comparator C--001	6 pcs	Every 300 Pieces & at Tool Change	Sample Inspection and Documented on Inprocess Checksheet
Comparator C--001	6 pcs	At Setup minimum	Fir... Ar...
Comparator C--001	6 pcs	Every 300 Pieces & at Tool Change	Sa... Inprocess Checksheet
Tool Schedule	100%	As Indicated by CRT Display Lights	Tool Change Verification Log
Meter		1 Test	Record Result on Setup Checksheet
Diagnostic Test 002	At Setup	1 Test	Record Result on Setup Checksheet

From PFMEA

CP only

Control Methods

- The current controls in the Control Plan must be consistent with the control methods in the PFMEA.

- Evidence must be available for each control method.

Control Method

- Determining the sample size and frequency:
  - The "**how many**" and "**how often**"

- Depends on:
  - The importance / impact level (severity) of the failure mode
  - The control factors – the dominant source(s) of variation
  - The capability and performance of the process

Control Intensity and Process Capability

Robustness of Control Strategy is Based on Risk and Capability

Capability	Control Intensity
Less than 1.33	Fix
1.33 ≤ Cpk ≤ 1.67	High
Greater than 1.67	Low

Control Method Details

Determine the Evaluation / Measurement System that should be used.

- For equipment-based evaluation, identify the measurement system.
  - For equipment uniquely designed for the product, include identification name and/or number.
- For non-equipment based evaluation, identify the methodology, instructions, aids, etc. as appropriate.

Reaction Plans

Reaction plan specifies what to do when:

- Failure occurs
- Process goes out of control
- Process improves
- The extent of operator authority

- Typical reactions:
  - Contain
  - Investigate
  - Record (good and bad incidents)
  - Problem Solving and verification of Corrective and Preventive Actions
  - Re-verify product

Breakout Exercise 8

Creating a Control Plan

Breakout Exercise 8: Creating a Control Plan

Handouts:

- Blank Control Plan Form

Instructions

- Create a Production Control Plan for the XJ-770 part, operation OP 20, characteristic ID 14 and OP 50, ID 02.
- Use the data provided from the previous breakouts as inputs.
- Focus on:
  - Prevention rather than detection.
  - Process rather than product.
  - Enough but not too much.
- Be prepared to report to the class:
  - The recommended actions your team has developed.
  - The reasons leading to the actions.

Chapter 5: Process Control Plan — What We Covered

Learning Objectives

You should now be able to:

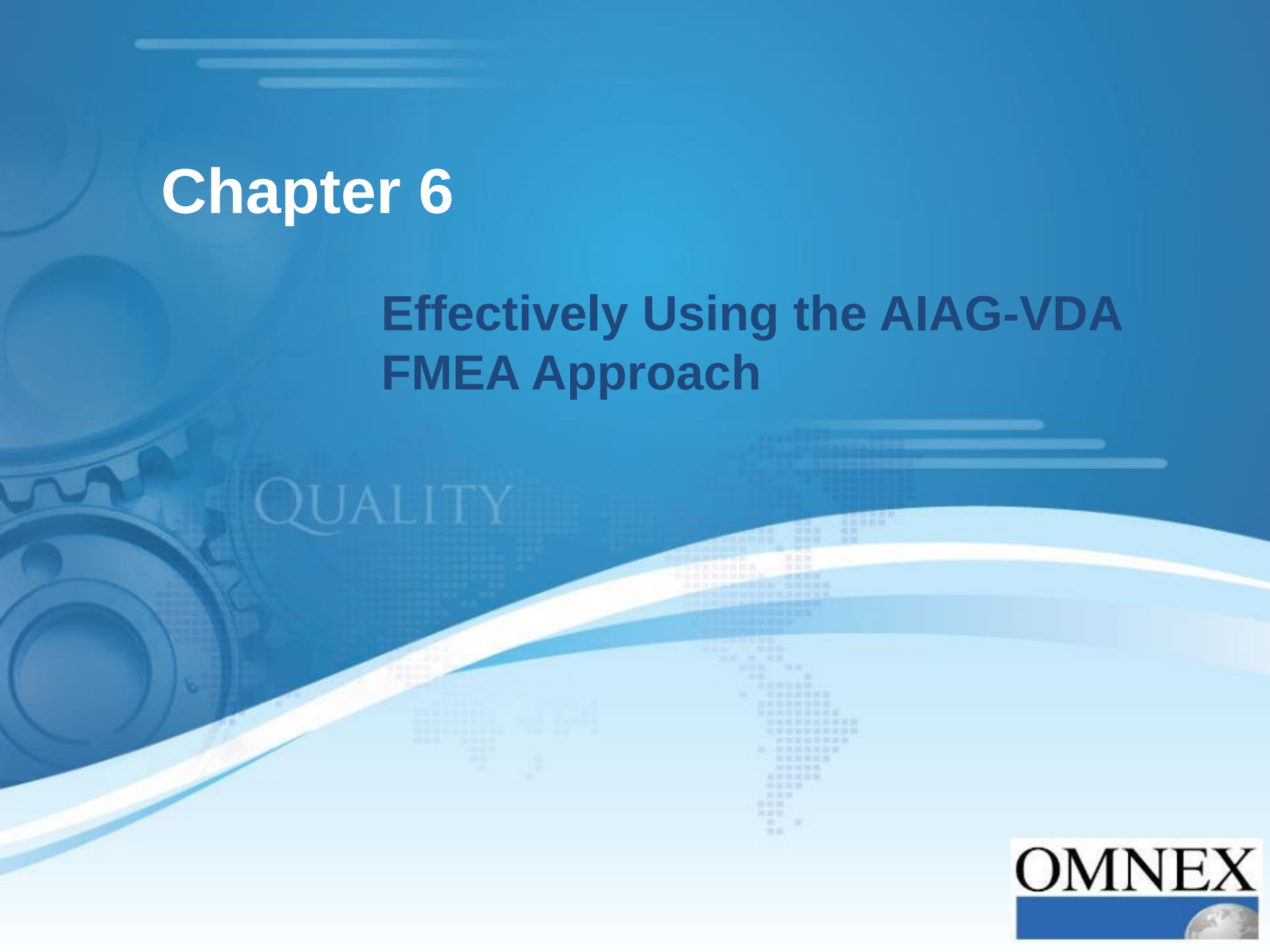
- Explain the purpose of a Control Plan
- Identify where Control Plan requirements can be found in IATF 16949
- Complete a Control Plan

Chapter Agenda

- What is a Control Plan?
- IATF 16949 Requirements
- Control Plan Header Information
- Control Plan Fields
- **Breakout Exercise 8**

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 PFMEA
- Evaluate PFMEAs
- 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 PFMEAs
- Evaluating PFMEAs
- 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 PFMEA (AIAG-VDA FMEA)

- 7-Step FMEA Development Process
- Use of Structure Tree as an option instead of the Process Flow
- Use of 4M and 1E, or Cause and Effect Diagram for identifying causes to a failure
- Three levels of analysis including Production Line, Operation, and 4M/1E as Higher, Focus, and Lower Levels
- Addition of Characteristics to the Function Analysis
- More prescriptive Risk Analysis forms, which include a significant addition to the number of columns of data
- Use of Structure, Function and Failure Analysis Nets
- New definitions of Severity, Occurrence and Detection indices for Design and Process FMEA analyses
- Separation of Preventive and Detective Improvement Actions
- Results documentation and reporting
- Use of a new composite index called “Action Priority” to categorize relative risk
- Management oversight and approval of Acceptable Risk

EVALUATING PFMEAS

Evaluating PFMEAs — 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 Process Flow Diagram)?
- Was this PFMEA event planned with a family PFMEA document for process reuse?
- Is failure history from Warranty, Customer, and internal plant data for surrogate parts available and considered for process improvement purposes?
- Is DFM and DFA being considered for product/process redesign for manufacturability?
- Is there a System PFMEA, Subsystem PFMEA, and Component DFMEA planned? What is the planning for linkages between the documents?

Evaluating PFMEAs — Did the Supplier Use the Seven Steps?

Step 2 – Structure Analysis:

- Was the Structure Analysis conducted? The structure should include the product, operations, and influencing factors (4M).
- Is there a Process Flow Diagram conducted to show the relationship between operations and characteristics? When possible, do they include both product and process characteristics?

Step 3 – Function Analysis

- Does the Function Analysis include Functions and Characteristics? Are all characteristics from the ballooned diagram included?
  - If software is being used, does it check it?
- Are the functions of the production line linked to functional requirements in the DFMEA?
- Are the focused level functions linked to 4M functions?

Evaluating PFMEAs — Did the Supplier Use the Seven Steps?

Step 4 – Failure Analysis

- Are the failure modes in the "Focus Element" a negation of the characteristic? Are there failure modes for different failures of a characteristic?
  - Example: for a diameter – there is undersize diameter, oversize diameter, out of round diameter, marks on the diameter, etc. based on the product.
- Is the effect a DFMEA-related failure mode?
- Are the causes linked to 4M failure modes? When possible, are these linked to the actual documents for easy access and study.

Evaluating PFMEAs — Did the Supplier Use the Seven Steps?

Step 5 – Risk Analysis

- Has the PFMEA 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 next 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 detection and prevention controls carefully transferred to the Control Plans and sampled?
- Are the Special Characteristics identified for Severity 9 & 10 Requirements / Functions and Severity 8 & 7 Requirements / Functions with **High** Occurrence?

Evaluating PFMEAs — 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 mistake-proofing?
- 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 PFMEAs — Did the Supplier Use the Seven Steps?

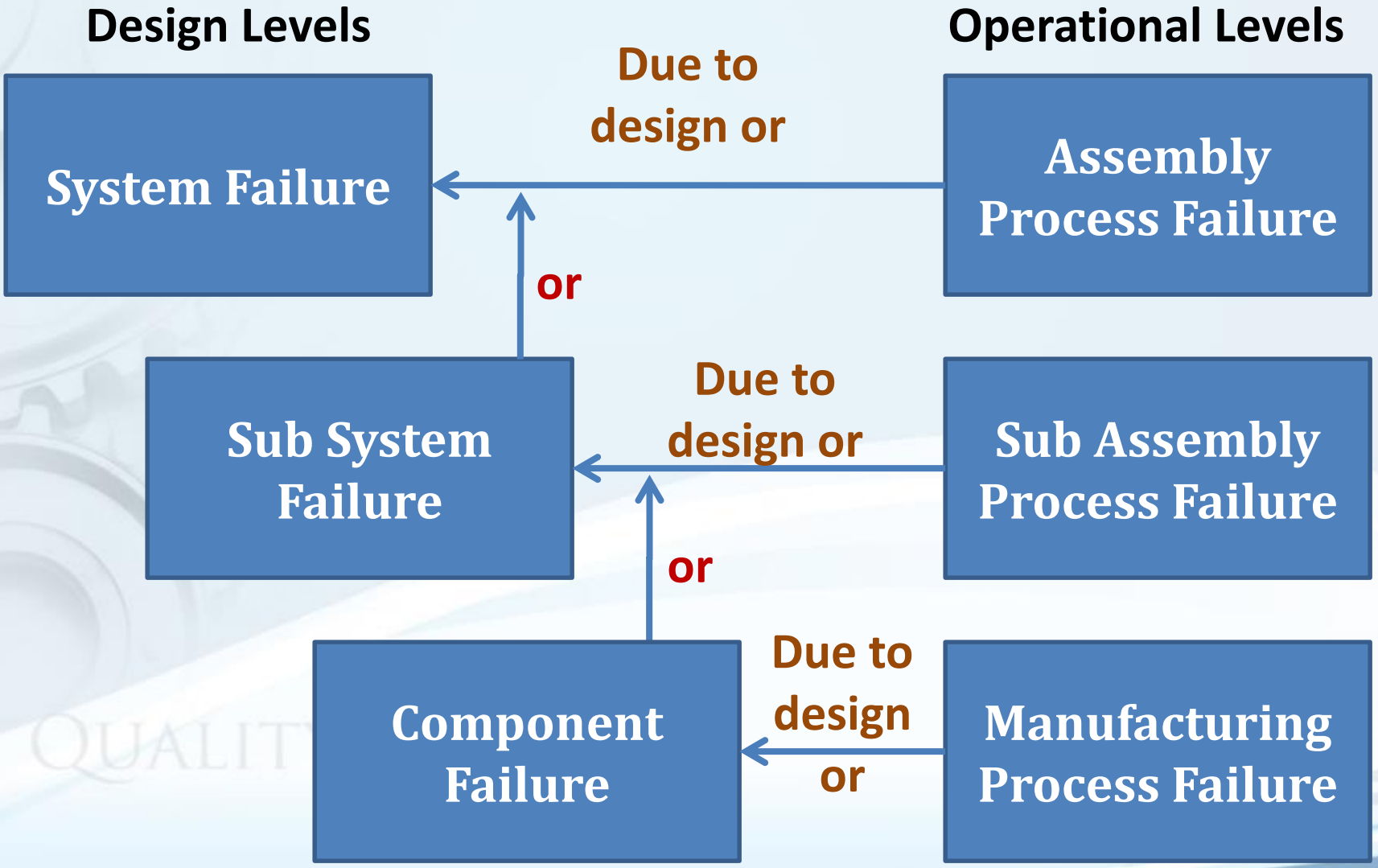
Step 7 – Results Documentation

- Is there evidence of risk communication? Did it go to the right parties?
- How is the organization communicating and linking to supplier DFMEAs and PFMEAs? Customer DFMEAs?
- How much improvement was seen in this AIAG-VDA PFMEA 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 PFMEAs

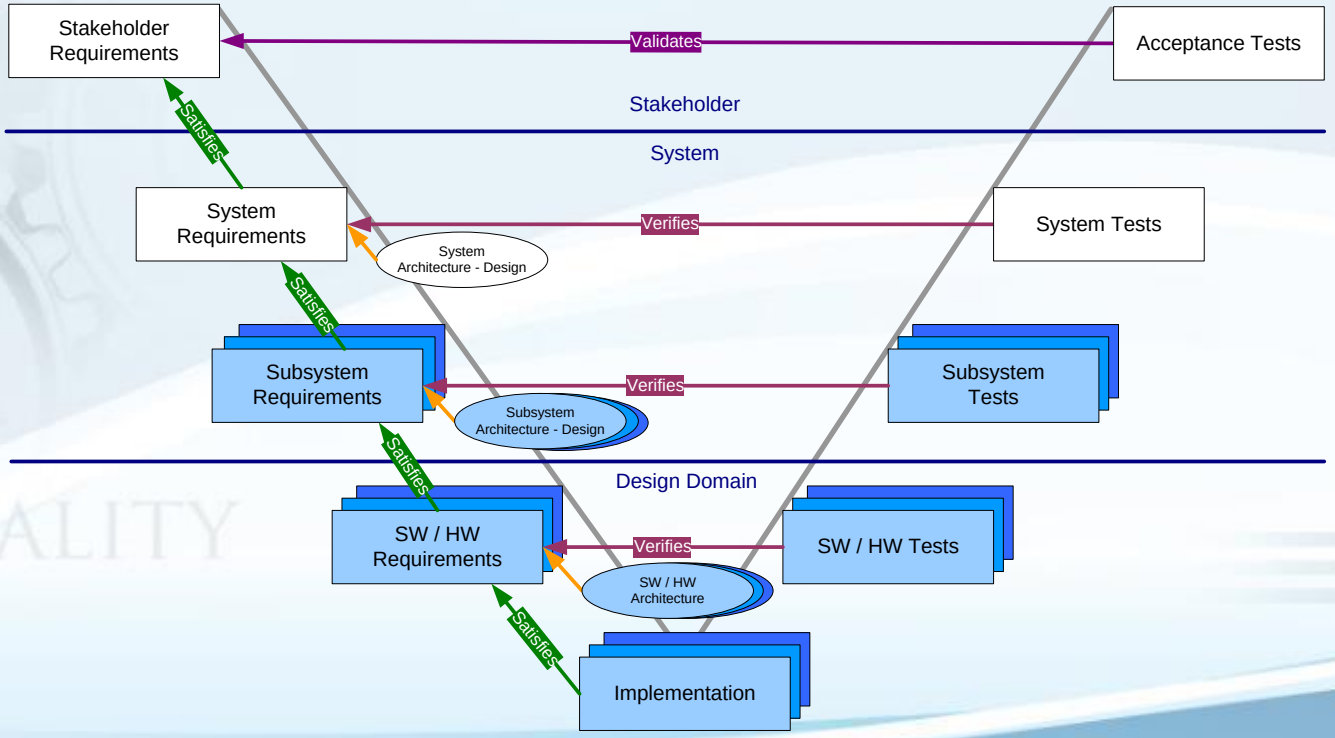
CHANGES TO THE ORGANIZATION AND SUPPLY CHAIN

Historical Failures at System Level

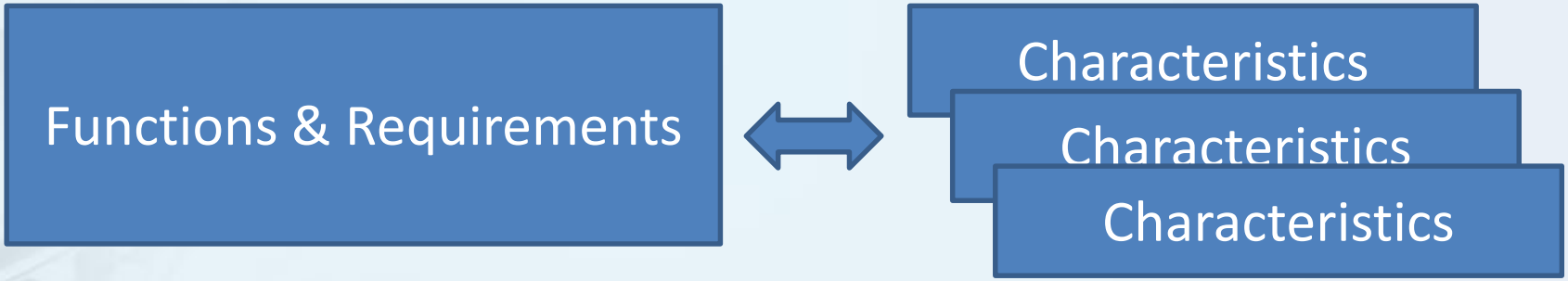


Requirements Management

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



Characteristics and Requirements – Special Characteristics



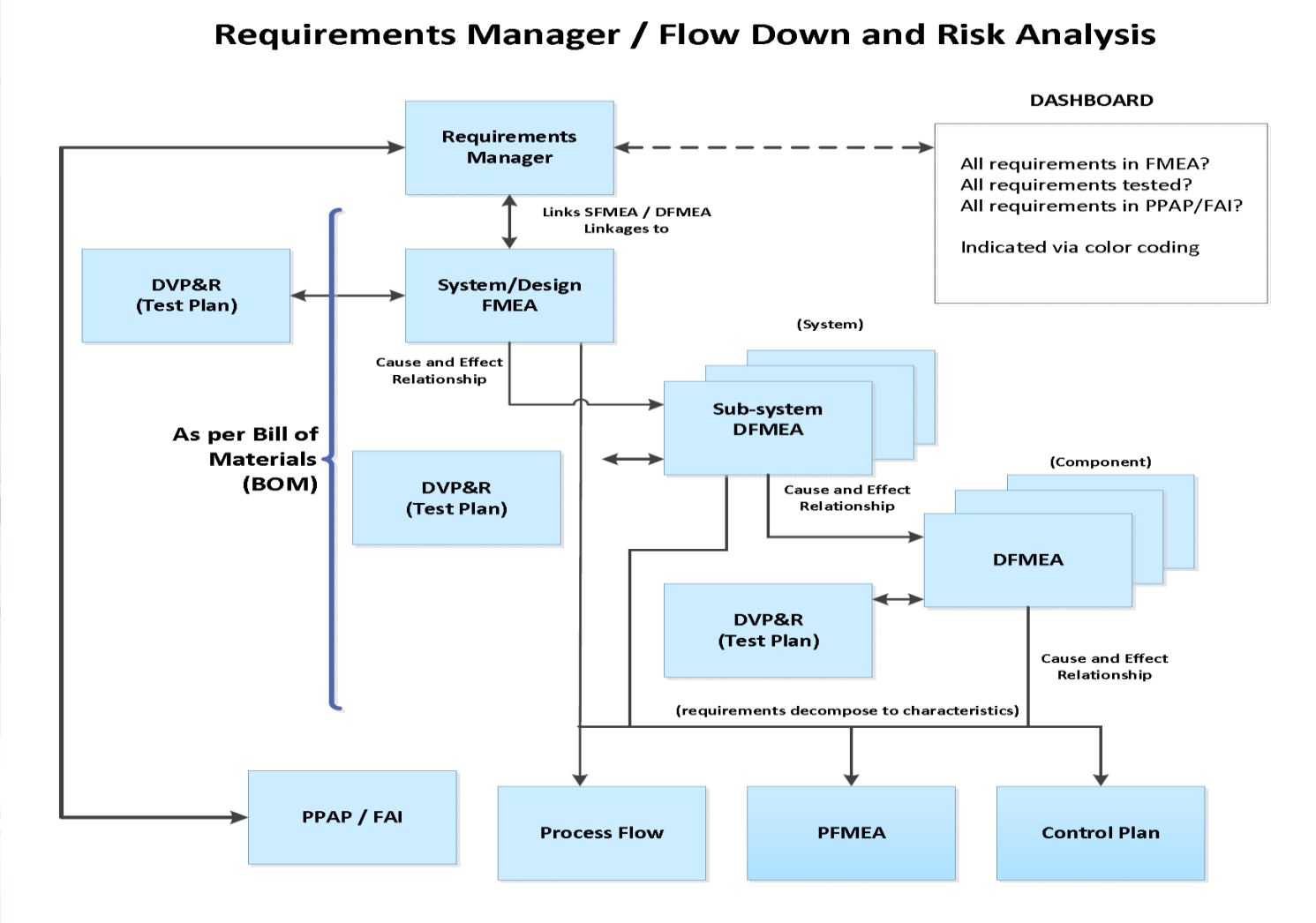
Link the Design to Manufacturing to Shop Floor Controls

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

ORGANIZATION OF THE DFMEA AND PFMEA LIBRARIES

Design and Process Reuse

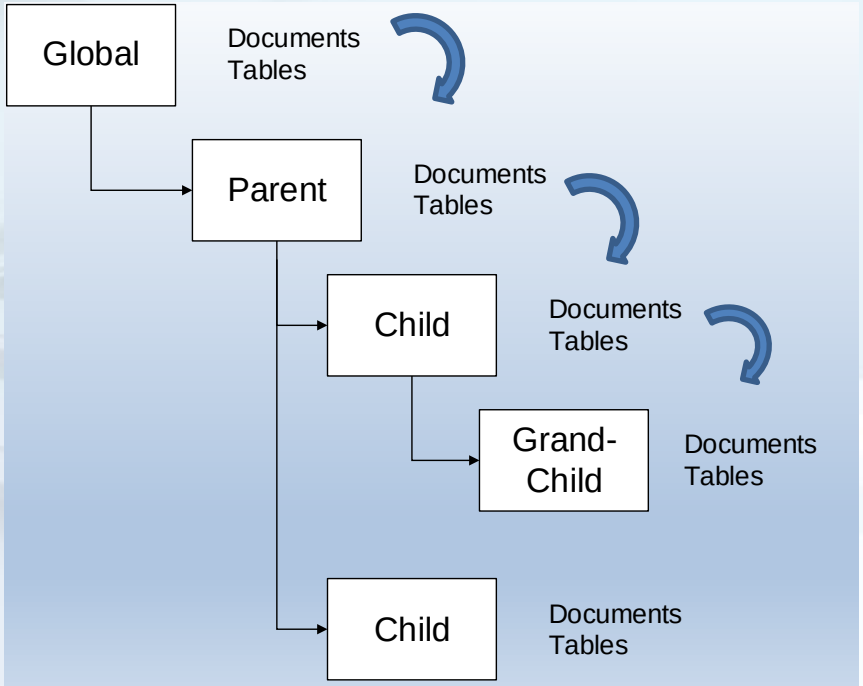
Linkages Between DFMEA, PFMEA and the Shop Floor



Family of Parts

AQuA pro product realization software

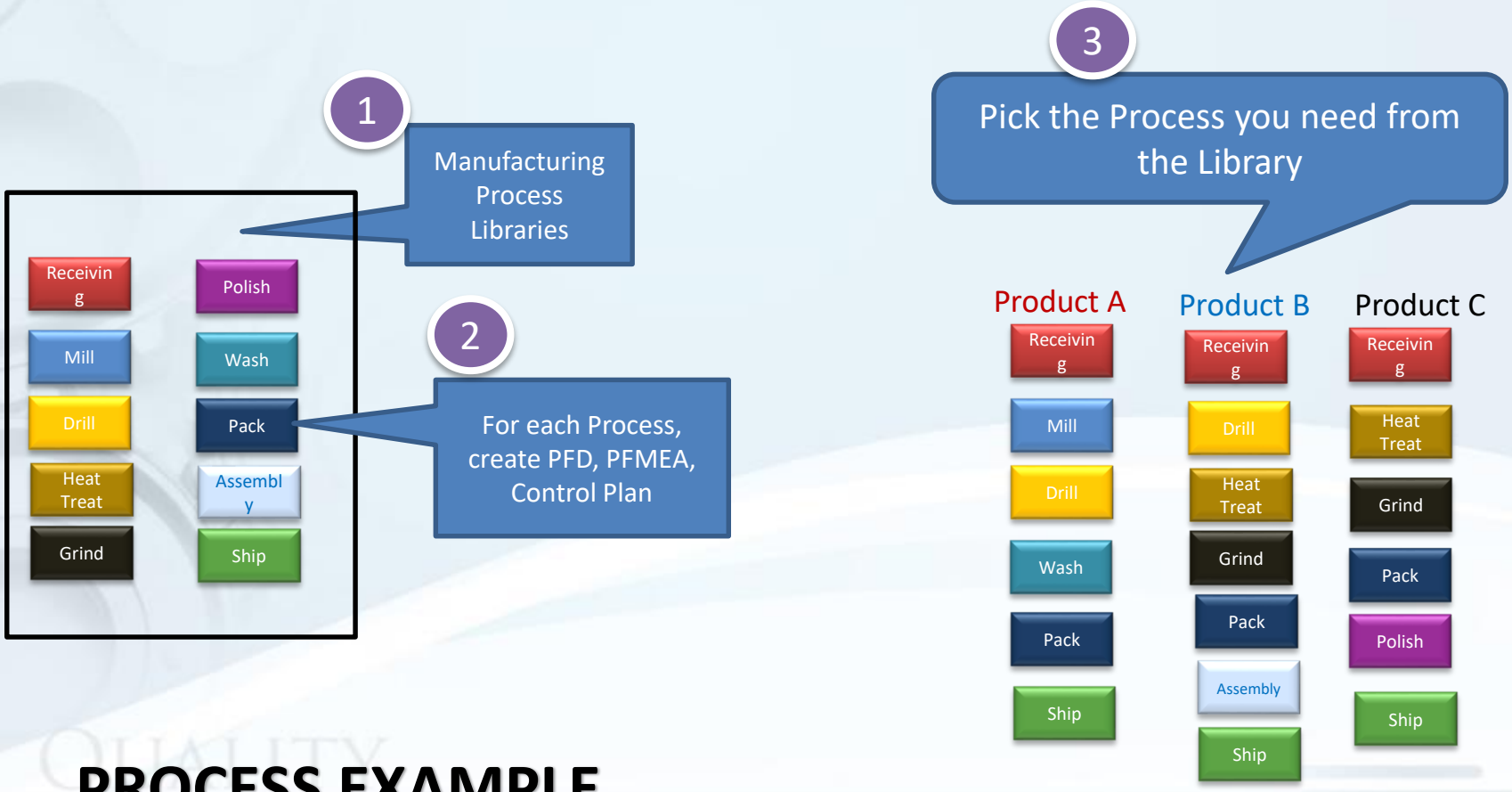
Creating Design and Process Documents using Inheritance



OMNEX SYSTEMS

OMNEX

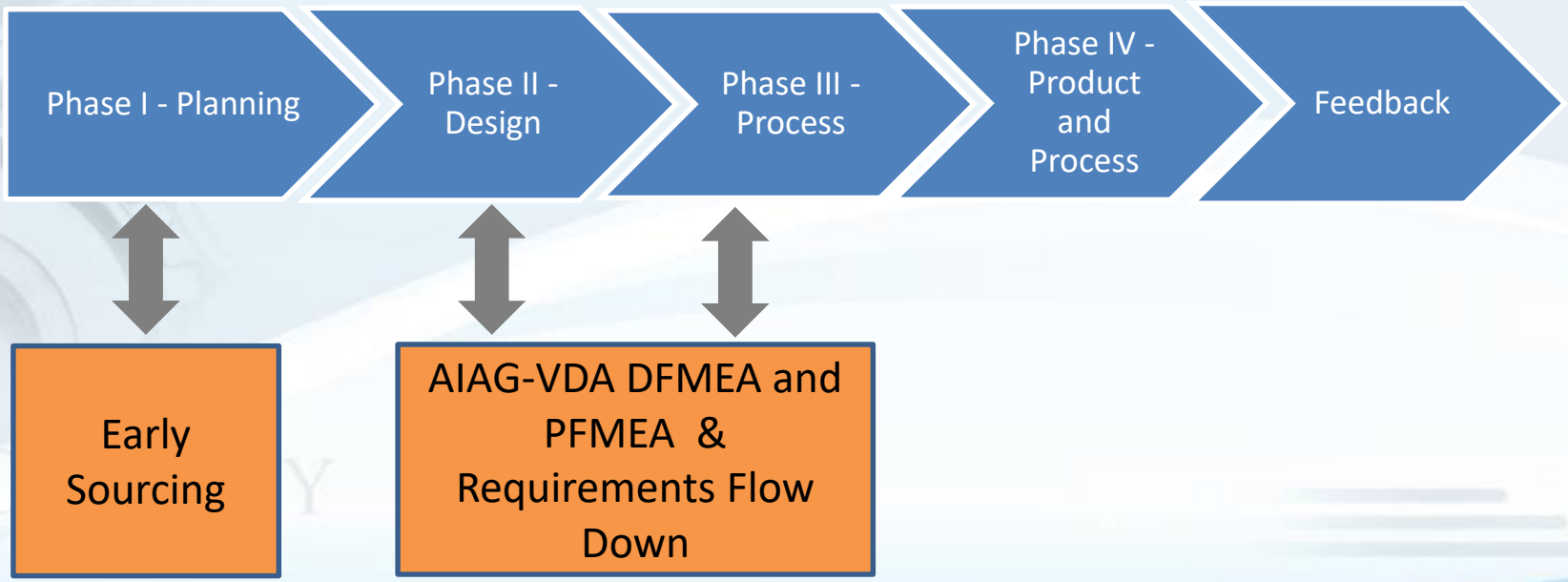
Design and Process Reuse Libraries



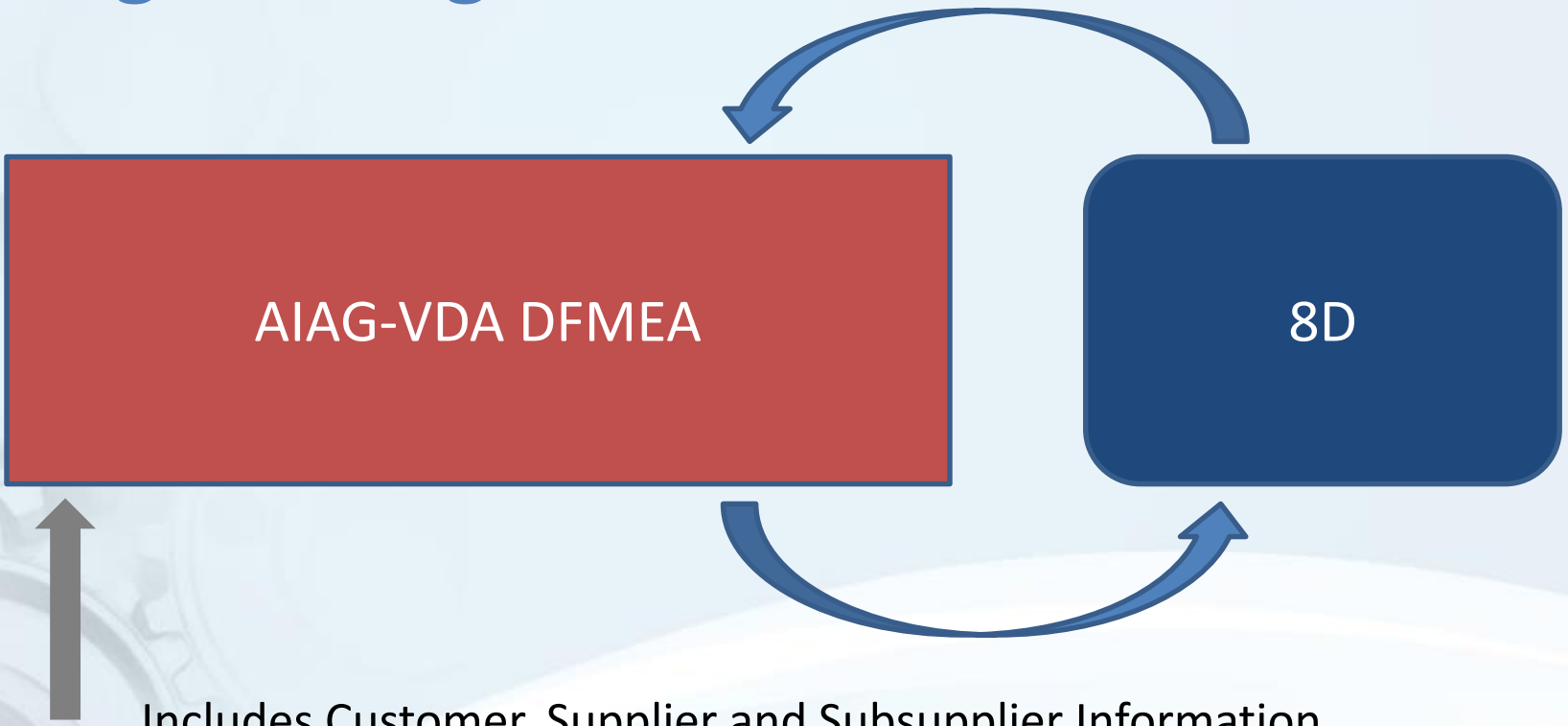
PROCESS EXAMPLE

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 PFMEA
- Evaluate PFMEAs
- 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 PFMEAs
- Evaluating PFMEAs
- 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

FMEA Summary

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

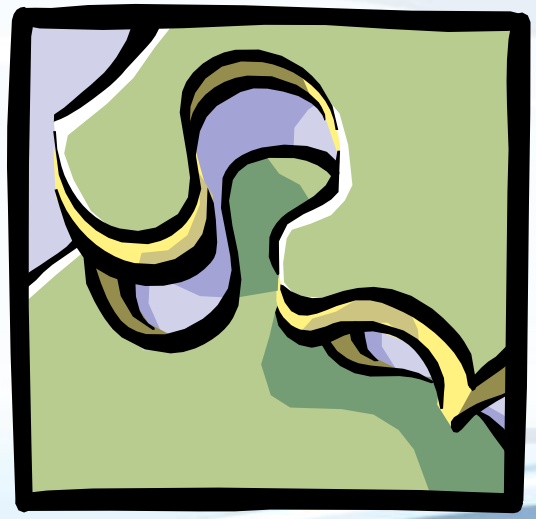
Analytical Approach

- 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?

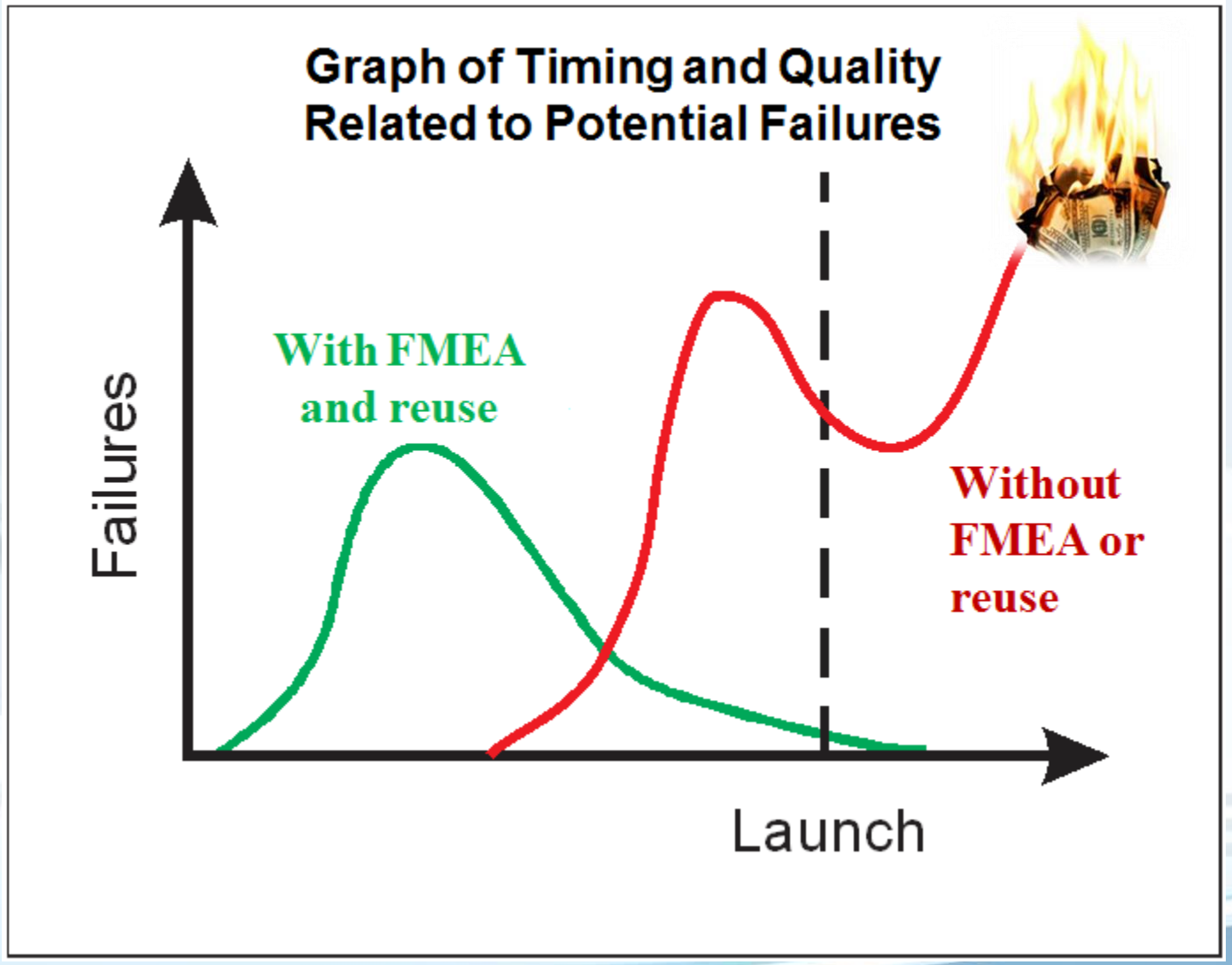
Analytical Approach

- 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?



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 (like 8D Problem Solving)
  - Component or system is used in a new environment, location or application

Knowledge Management

Thank You!

Questions?

info@omnex.com
734.761.4940

Appendix

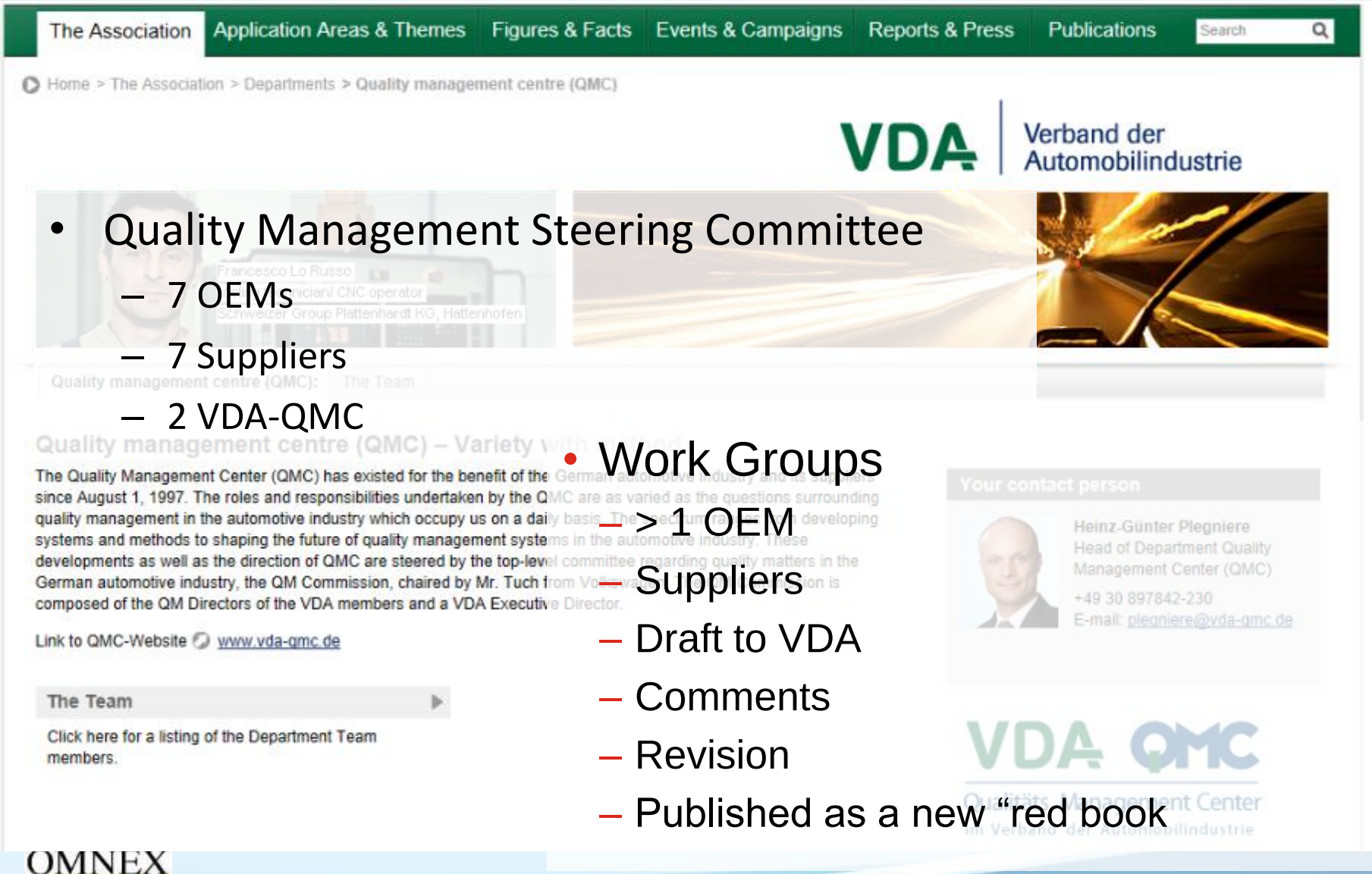
PFMEA Form Comparison

Team Information

IT Support

Tables

VDA



- 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

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

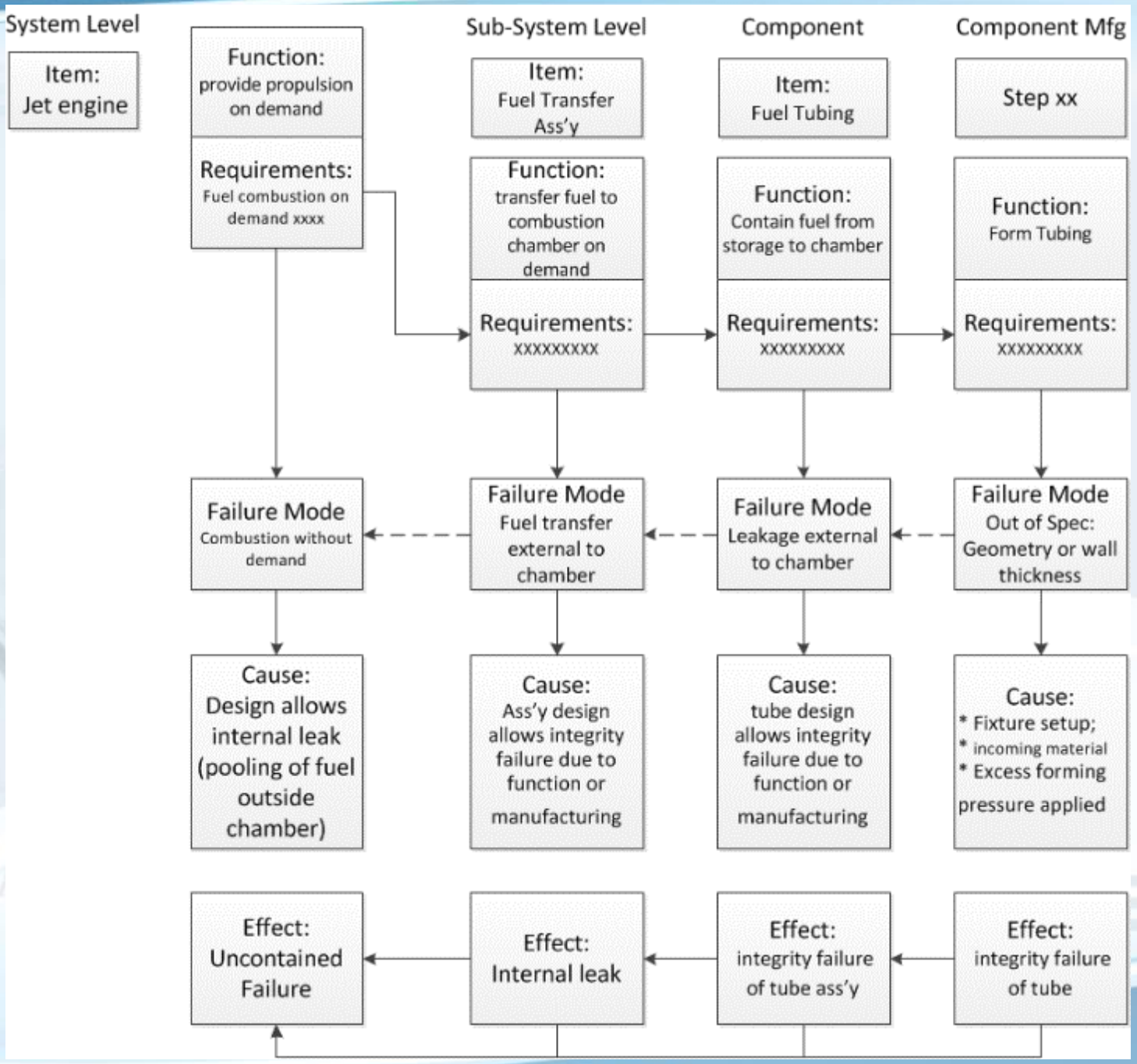
FAILURE ANALYSIS			
1 Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)

Item	Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Sevenity	Classification	Potential Cause(s) of Failure	Current Design Controls Prevention	Occurrence	Cirrent Design Controls Detection	Detection	RPN

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)

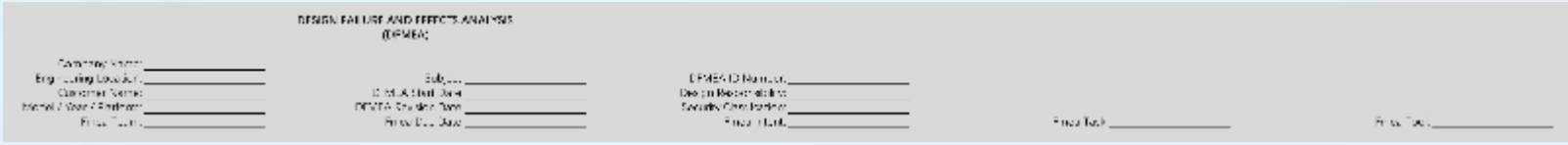
Recommended Action	Responsibility	Target Completion Date	Action Results				
			Actions Taken	Effective Date	Severity	Occurance	Detection	RPN

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



7-Steps and the Form

1st Step
Planning and Preparation



System Analysis and Risk Mitigation

2nd Step
Structure Analysis

3rd Step
Function 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

4th Step
Failure Analysis

5th Step
Risk Analysis

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 FC/FM	AP	Filter Code (Optional)

6th Step
Optimization

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 PFMEAs — PFMEA SR Checklist

AQP – PFMEA 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 **No** indicate improvement is needed*

Y	N	General
☐	☐	**1)** Are the Failure Modes, Effects, Causes and Process Controls properly distinguished?
☐	☐	**2)** Is there evidence that a cross-functional team was used to develop the FMEA?
☐	☐	**3)** Are applicable entries in the Header completed?
☐	☐	**4)** Does the PFMEA appear to drive Process Improvements as the primary objective?
☐	☐	**5)** Is the PFMEA document completely filled out, including header information, action plans and recalculated RPN?
☐	☐	**6)** Does the PFMEA address RNCs, Fracas, Hardy Perennials, and other Quality indicators?
☐	☐	**7)** Is there a Process Flow Chart and does it include all process steps / IDs and requirements. Are these also found in the PFMEA with the same process step identification and descriptions

Evaluating PFMEAs — PFMEA SR Checklist

Y	N		
		Step / Function/Requirements	
☐	☐	**8)**	Is the process intent, or purpose clear? Are Performance Requirements specified?
☐	☐	**9)**	Are characteristics fro each operation clearly identified?
		Failure Modes	
☐	☐	**10)**	Are failure modes related to process requirements and interrelationships?
☐	☐	**11)**	Does the PFMEA address all failure modes identified with High Severity and Occurrence
		Effects of Failure	
☐	☐	**12)**	Are effects on safe operation/manufacturing and government regulation considered?
☐	☐	**13)**	Are multiple effects on the process step, next higher assembly, system, customer (end user) (
		Cause(s)	
☐	☐	**14)**	Are the Root Causes identified appropriate?
☐	☐	**15)**	Are process deficiencies considered that may result in subsequent manufacturing / assembly variation or misbuilds?
☐	☐	**16)**	Are design / supplier and assembly causes excluded? (addressed in DFMEA and Supplier PFMEA)
☐	☐	**17)**	Are all causes listed on a separate line?
☐	☐	**18)**	Are causes described in terms of the process implementation activities?
		Current Prevention Controls	
☐	☐	**19)**	Can the Controls listed eliminate or ameliorate the Cause(s) of Failure Modes prior to end of line?
☐	☐	**20)**	Is error proofing used for high risk items?
☐	☐	**21)**	Do Controls stress Prevention and Analytical Evaluation over inspection?

Evaluating PFMEAs — PFMEA SR Checklist

Y	N		
			Current Detection Controls
☐	☐	**22)**	Can the Controls listed detect the Cause(s) of Failure Modes, or detect the Failure Modes prior to end of line?
☐	☐	**23)**	Are customer Control methods excluded?
☐	☐	**24)**	Is there a distinction between Prevention and Detection type design controls?
☐	☐	**25)**	Are the Detection Type Controls individually ranked?
			Severity Rating
☐	☐	**26)**	Are Severity ratings based on the most serious consequence of the Failure Mode?
			Occurrence Rating
☐	☐	**27)**	Are Occurrence ratings based on the projected cause probability and reflect the effect of Prevention Controls?
			Detection Rating
☐	☐	**28)**	Are ratings based on the likelihood of detecting the Failure Mode ***prior*** to End of line release?
			Classification
☐	☐	**29)**	Are Special Characteristics identified as appropriate ?
			AP
☐	☐	**30)**	Does the optmization focus on the AP High and Medium Risks?
			Recommended Actions
☐	☐	**31)**	Are Recommended Actions listed that reduce the Severity Occurrence and Detection for the hi
☐	☐	**32)**	Are responsibility and timing for Recommended Actions listed?
☐	☐	**33)**	Are preventive, instead of detection, actions listed?
☐	☐	**34)**	Are Severity, Occurrence, Detection, and the resulting risk recalculated for the identified Recommended Actions?
☐	☐	**35)**	Are the Recommended Actions actionable and executable?

TEAM INFORMATION

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

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

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

TABLES

PFMEA Severity – AIAG-VDA FMEA Handbook

SEV	Effect	Impact to Your Plant	Impact to Ship-to Plant (when known)	Impact to End User (when known)	Corporate or Product Line Examples
10	**High**	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Affects safe operation of the vehicle and/or other vehicles, the health of the driver or passenger(s) or road users or pedestrians.	
9		Failure may result in in-plant regulatory noncompliance.	Failure may result in in-plant regulatory noncompliance.	Noncompliance with regulations.	
8	**Moderately High**	100% of production run affected may have to be scrapped. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker.	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		Product may have to be sorted and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed or added manpower.	Line shutdown from 1 hour to full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance.	**Degradation** of primary vehicle function necessary for normal driving during expected service life.	

PFMEA Severity – AIAG-VDA FMEA Handbook

SEV	Effect	Impact to Your Plant	Impact to Ship-to Plant (when known)	Impact to End User (when known)	Corporate or Product Line Examples
6	**Moderately Low**	100% of product run may have to be reworked off-line and accepted.	Line shutdown up to one hour.	**Loss** of secondary vehicles function.	
5		A portion of the production run may have to be reworked off-line and accepted.	Less than 100% of product affected; strong possibility for additional defective product; sort required; no line shutdown.	**Degradation** of secondary vehicle function.	
4		100% of production run may have to be reworked in-station before it is processed.	Defective product triggers significant reaction plan; additional defective products not likely; sort not required.	Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	A portion of the production run may have to be reworked in-station before it is processed.	Defective product triggers minor reaction plan; additional defective products not likely; sort not required.	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slight inconvenience to process, operation, or operator.	Defective product triggers minor reaction plan; additional defective products not likely; sort not required; requires feedback to supplier.	Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very Low**	No discernible effect.	No discernible effect or no effect.	No discernible effect.	

PFMEA Occurrence – AIAG-VDA FMEA Handbook

OCC	Prediction of Failure Cause Occurring	Type of Control	Prevention Controls	Corporate or Product Line Examples
10	**Extremely High**	None	No prevention controls.	
9	**Very High**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8				
7	**High**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6				
5	**Moderate**		Prevention controls are effective in preventing failure cause.	
4				
3	**Low**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Very Low**			
1	**Extremely Low**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention controls – Failure Mode cannot be physically produced due to the Failure Cause.	

PFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
10	**Very Low**	No testing or inspection method has been established or is known.	The failure mode will not or cannot be detected.	
9		It is unlikely that the testing or inspection method will detect the failure mode.	The failure mode is not easily detected through random or sporadic audits.	
8	**Low**	Test or inspection method **has not been** proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results, marginal on comparable process or this application, etc.)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause.	
7			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.) or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause.	

PFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
6	Moderate	Test or inspection method **has been** proven to be effective and reliable (e.g. plant has experience with method, gauge R&R results are acceptable on comparable process or this application, etc.)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks).	
5			Machine-based detection (semi-automated with notification by light, buzzer, etc.) or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks).	

PFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
4	**High**	System has been proven to be effective and reliable (e.g. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect failure mode **downstream,** prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
3			Machine-based automated detection method that will detect failure mode **in-station,** prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	

PFMEA Detection – AIAG-VDA FMEA Handbook

DET	Ability to Detect	Detection Maturity Method	Opportunity for Detection	Corporate or Product Line Examples
2	**High**	Detection method has been proven to be effective and reliable (e.g. plant has experience with method, error-proofing verifications, etc.)	Machine-based detection method that will detect the cause and prevent the failure mode (discrepant part) from being produced.	
1	**Very High**	Failure mode cannot be physically produced as-designed or processed, or detection methods proven to **always** detect the failure mode or failure cause.		

C2.3.1 PFMEA Occurrence (O) with Incidents per Thousand Values

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Incidents per 1000 items/vehicles**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**≥ 100 per thousand >/= 1 in 10**	None	No prevention controls.	
9	**50 per thousand 1 in 20**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8	**20 per thousand 1 in 50**			
7	**10 per thousand 1 in 100**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6	**2 per thousand 1 in 500**			
5	**.5 per thousand 1 in 2000**		Prevention controls are effective in preventing failure cause.	
4	**.1 per thousand 1 in 10,000**			
3	**.01 per thousand 1 in 100,000**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**< .001 per thousand 1 in 1,000,000**			
1	**Failure is eliminated through prevention control**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table C2.3.1 – Alternate PFMEA OCCURRENCE (O)

C2.3.2 PFMEA OCCURRENCE (O) with Time Based Failure Prediction Values

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**Every time**	None	No prevention controls.	
9	**Almost every time**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8	**More than once per shift**			
7	**More than once per day**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6	**More than once per week**			
5	**More than once per month**		Prevention controls are effective in preventing failure cause.	
4	**More than once per year**			
3	**Once per year**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Less than once per year**			
1	**Never**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table C2.3.2 – Alternate PFMEA OCCURRENCE (O)

Action Priority (AP) – AIAG-VDA FMEA Handbook

PFMEA

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

PFMEA

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

PFMEA

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

PFMEA

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

PFMEA

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