# Understanding Core Tools: PFMEA and Control Plans

## Process Failure Modes and Effect Analysis (PFMEA)

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**Fifth Edition**

**June 2018**

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: Understanding Core Tools

- Understand how to ensure that the development and implementation of the manufacturing process meets all customer and program requirements
- Understand the activities involved in the realization of new products and processes
- Understand the role of PFMEAs
- Realize that process design and development should focus on robustness and error prevention rather than detection

# Course Agenda

- Chapter 1: APQP and Process Failure Mode and Effects Analysis (PFMEA) Introduction
- Chapter 2: APQP Inputs to the PFMEA, Process Flow
  - **Breakout Exercise 1: Process Flow Diagram**
- Chapter 3: Developing a Process FMEA
  - **Breakout Exercise 2: Starting the PFMEA Form**
  - **Breakout Exercise 3: Potential Causes**
  - **Breakout Exercise 4: Process Controls**
  - **Breakout Exercise 5: Effects, Severity and Actions Plans**
- Chapter 4: Developing a Control Plan
  - **Breakout Exercise 6: Creating a Control Plan**

# 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).
- 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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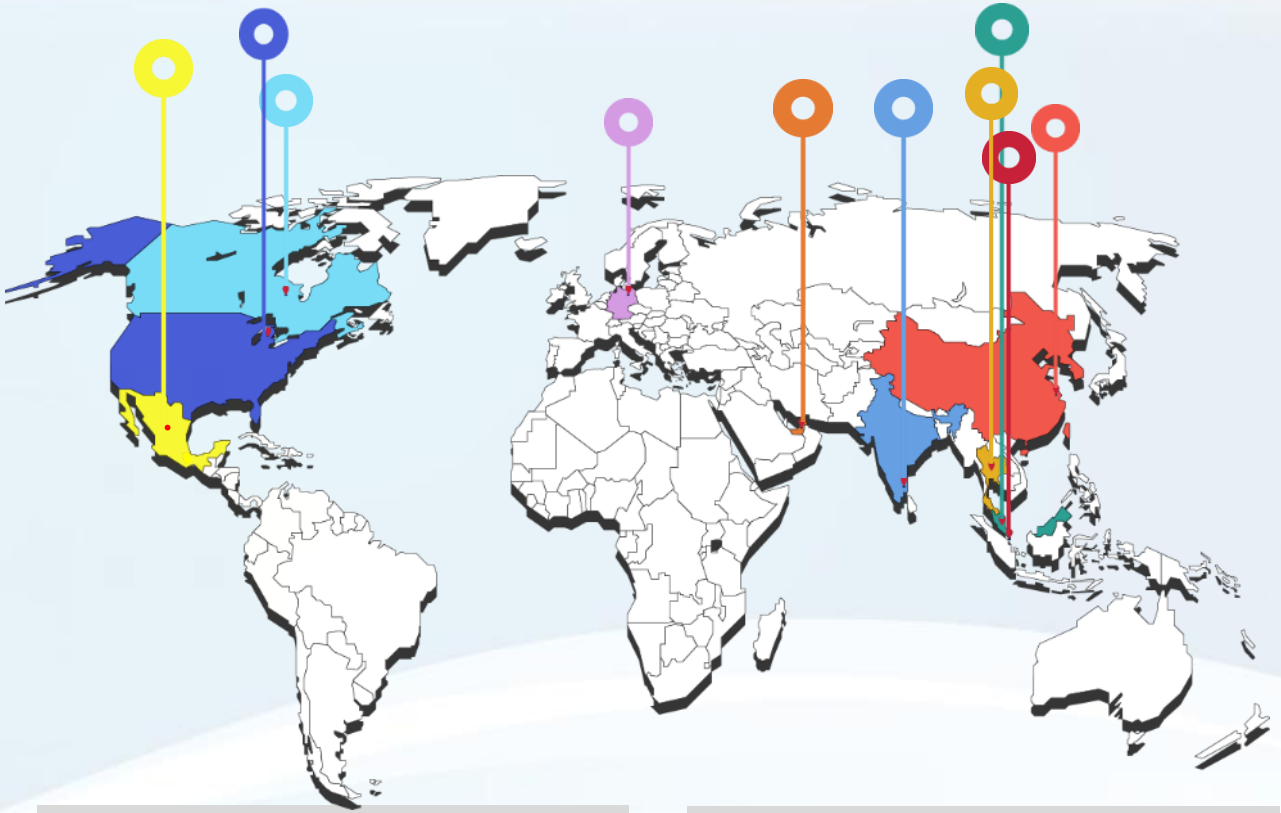


- Omnex Global Head Quarters (Michigan, USA)
  West Coast Operations (San Jose, CA)
- Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)
- China (Shanghai, Guangzhou, Wuhan, Chengdu)
- Canada (Mississauga)
- Europe (Berlin, Germany)
- Middle East (Dubai, Saudi Arabia, Bahrain)
- Thailand (Bangkok)
- Mexico (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 OMNEX
  - Position / Responsibilities
  - Your involvement in the APQP process?
  - Do you manage or use a PFMEA?
  - What do you expect to take away from this class?
  - Please share something unique and/or interesting about yourself.

# Chapter 1

## APQP and Process Failure Mode and Effects Analysis (PFMEA) Introduction

# Chapter 1: APQP and PFMEA Introduction – What We Will Cover

## Learning Objectives

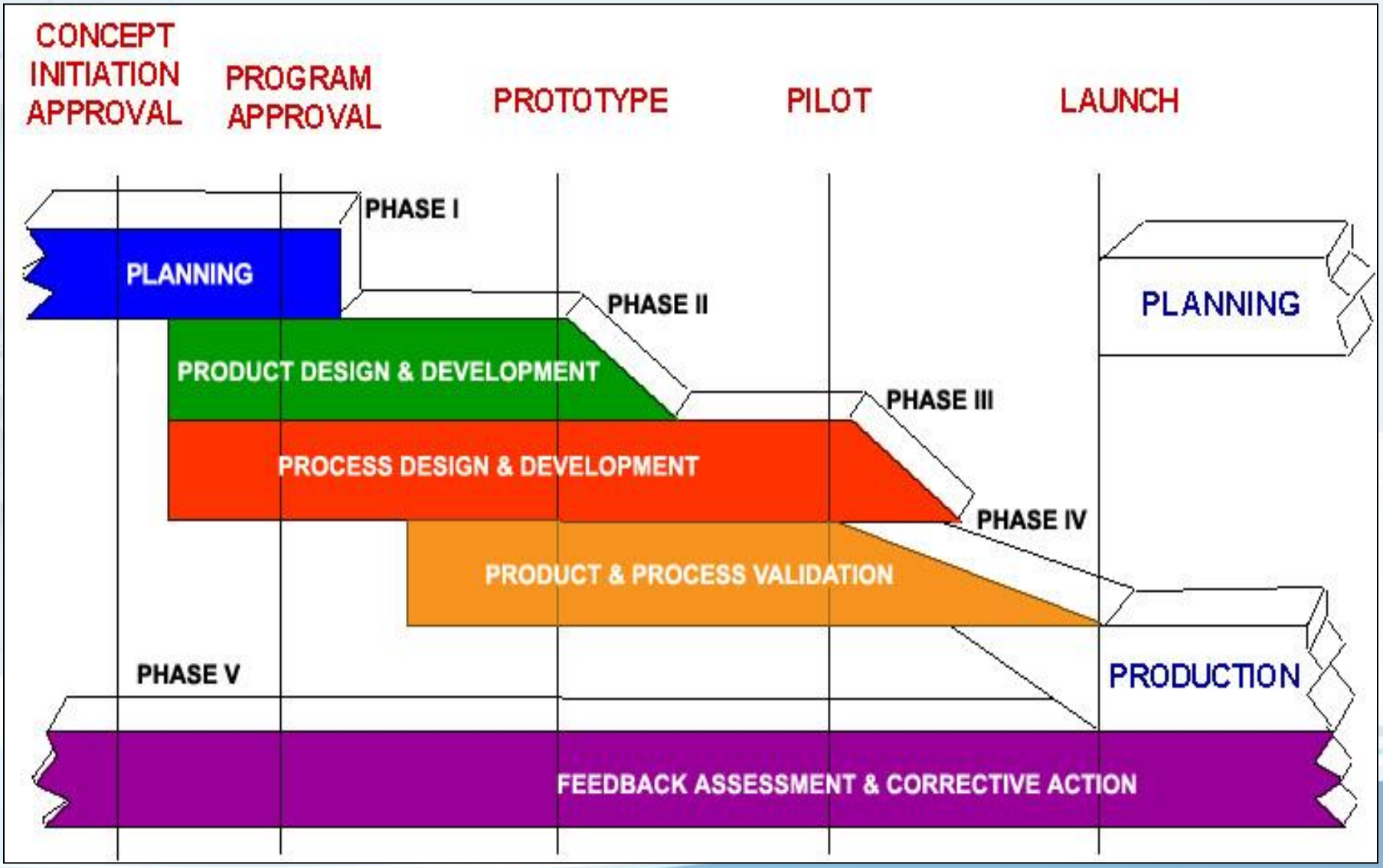
At the end of this chapter, you will be able to:

- Note the phases in the Advance Product Quality Planning (APQP) process where the FMEA is initiated
- Describe the purpose of the PFMEA

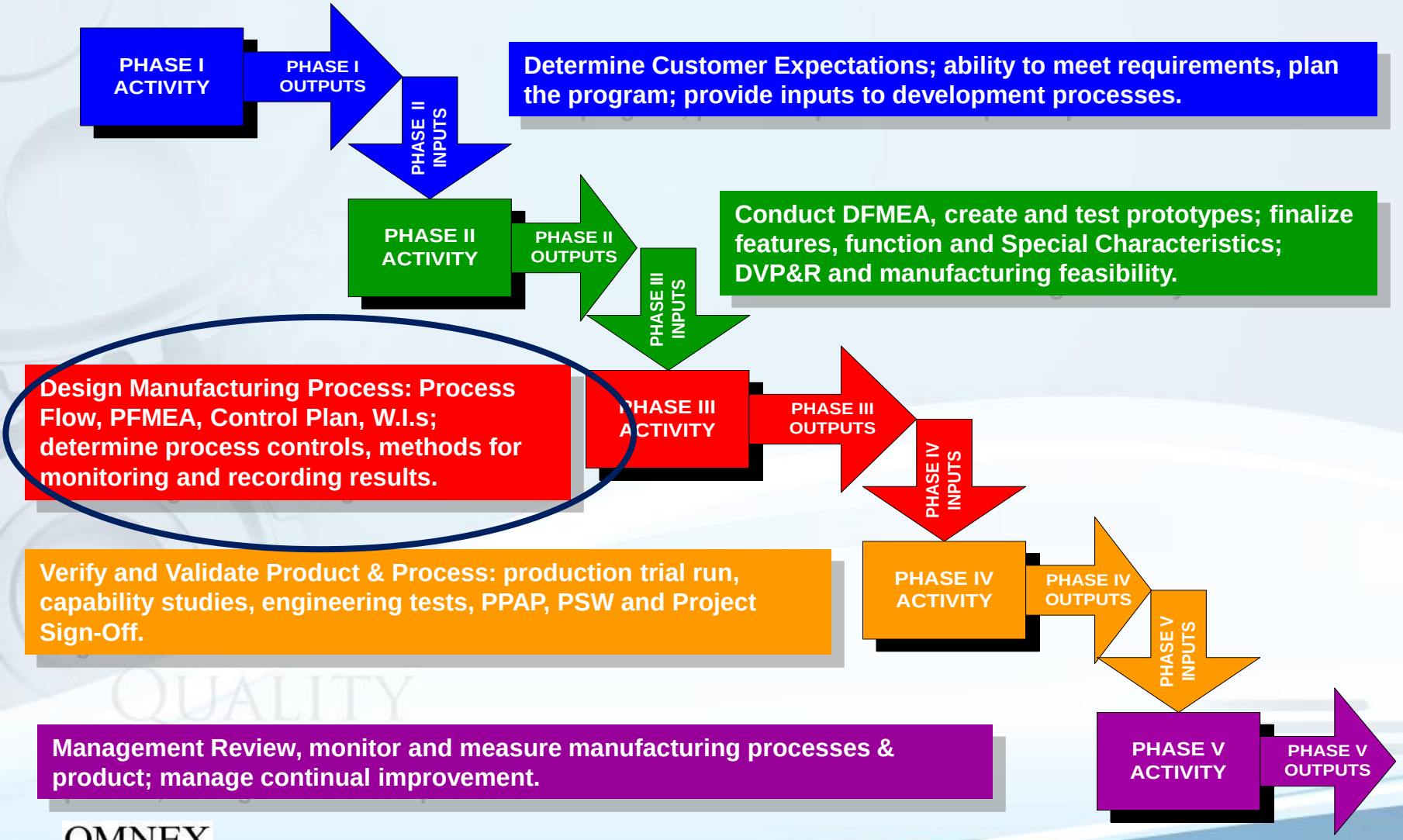
## Chapter Agenda

- APQP Phases
- Concurrent Engineering
- PFMEA Defined
- PFMEA as a Living Document

# Alignment of APQP Processes



# Outputs of Each Phase are Inputs to Subsequent Phases



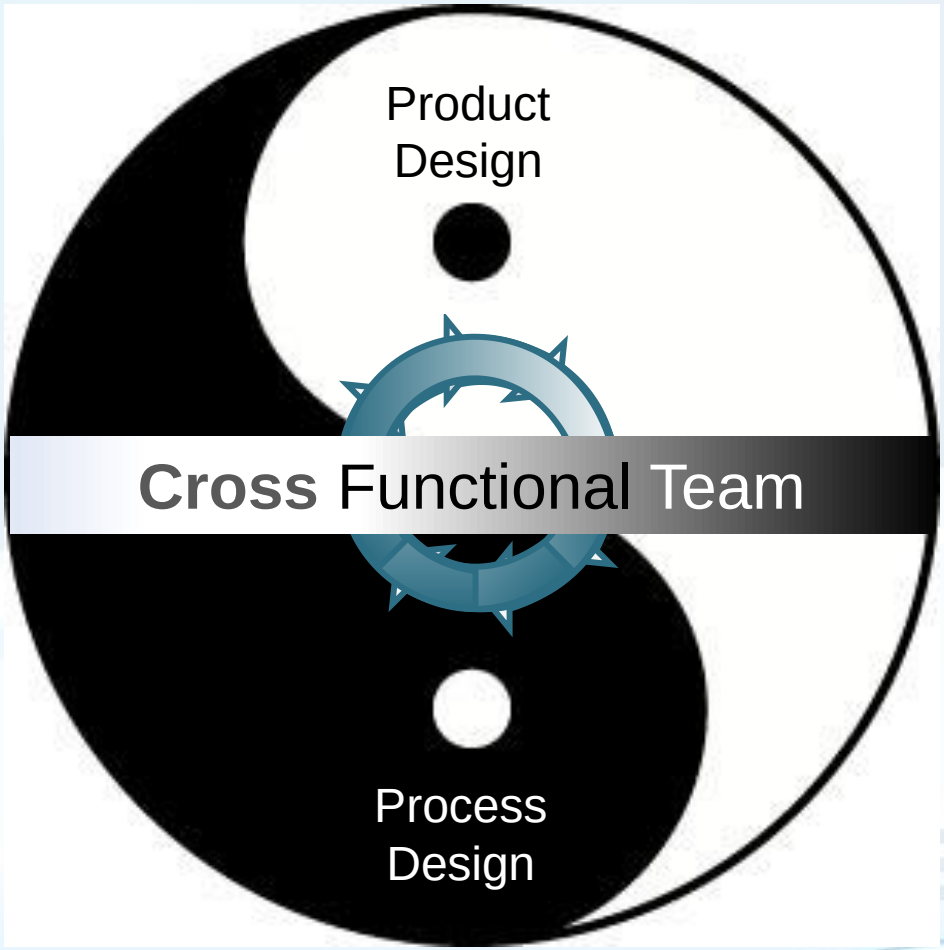
# Concurrent Engineering

**Concurrent (or Simultaneous) Engineering is basic to:**

- Effective knowledge sharing between all key functions to achieve common goals
- Elimination of developmental "*Loop-Backs*"
  - Engineering changes
  - Process re-engineering
  - Tool re-design
- Develop optimal product and process designs
- Minimize product launch time and quality risk
- On-time deliverables

# “Yin/Yang” of Concurrent Engineering

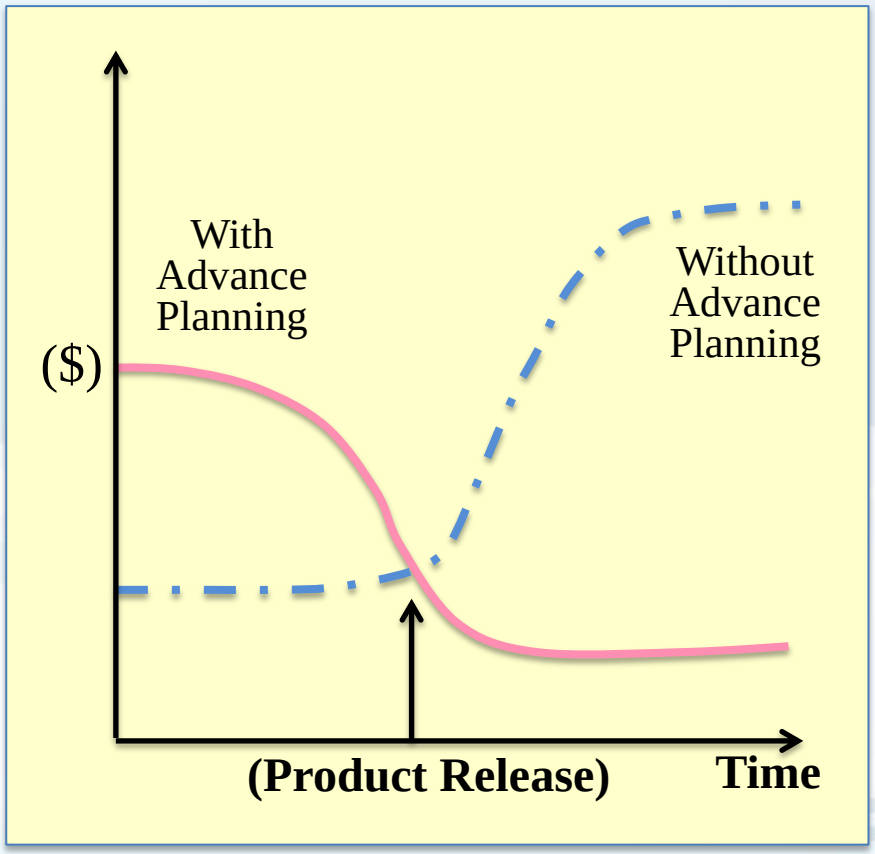
Changes in either development activity may have profound impact on the counterpart development activity—they are two halves of the same process.



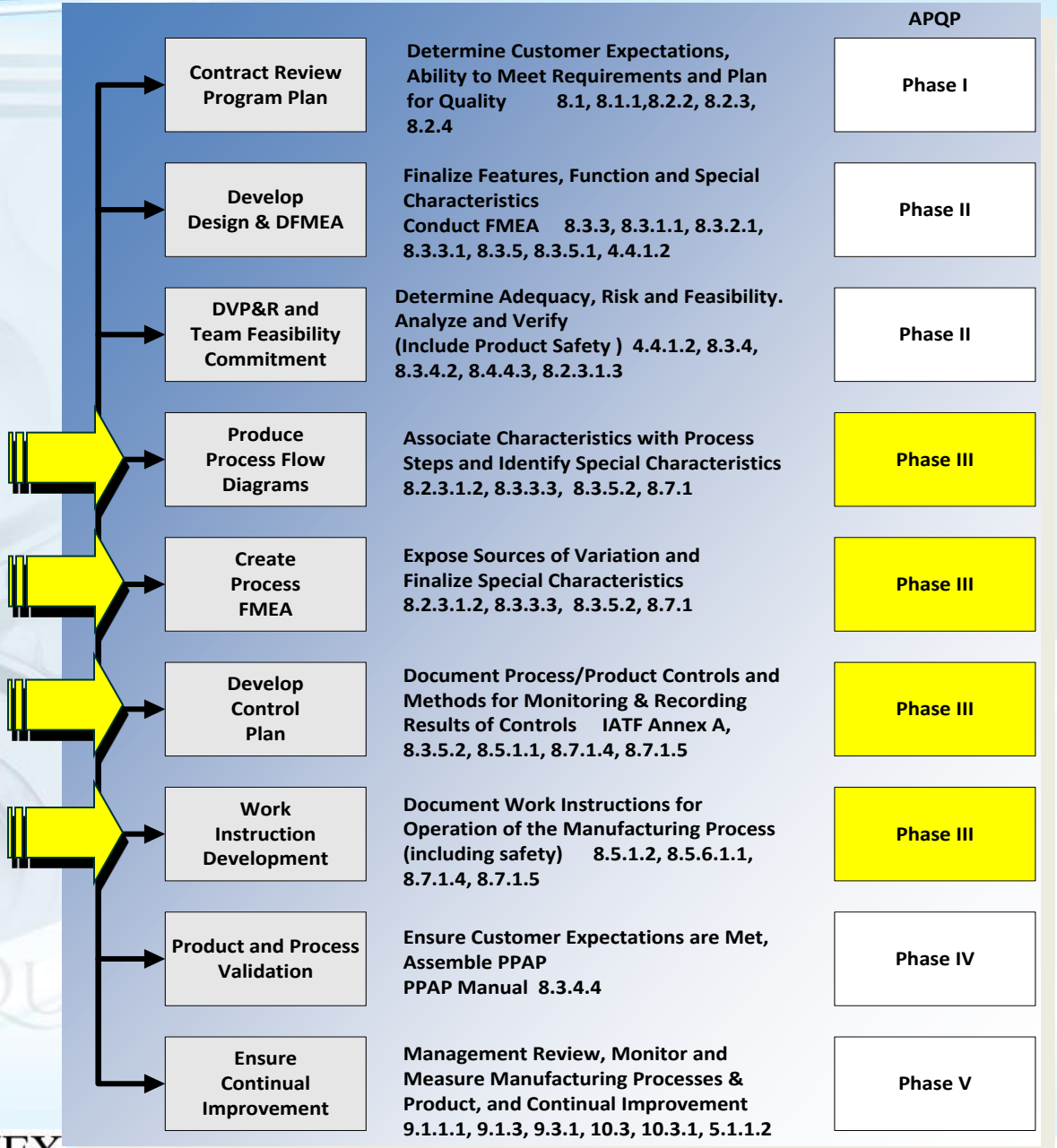
# Advance Planning: Concurrent Engineering

## Benefits

- Resources are focused on customer satisfaction
- Required changes are identified early
- Changes close to or after product launch are avoided
- Process can accommodate unavoidable changes
- Reflects the Yin/Yang reality of development



# Product Development Process Model



# PFMEA

The PFMEA supports manufacturing process development in **reducing the risk of failures** by:

- Identifying and evaluating the process functions and requirements. O.m.n.ex
- Identifying and evaluating potential product and process-related failure modes, and the effects of the potential failures on the process and customers
- Identifying the potential manufacturing or assembly process causes

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# Process FMEA Objectives

- Improved Process → Robust Process
- Improved Process Control
- Identify and Minimize Risk – PFMEA is an analytical technique utilized by a process-responsible engineer/team to:
  - Ensure that potential failure modes and associated causes are considered and addressed
  - Standardize method of identifying, evaluating, and prioritizing risks from process causes
  - Prevent the "**customer**" from experiencing failure modes
  - Meet product expectations
  - Formalize the mental discipline that should be used in planning any manufacturing process

# Requirements

- What **SHOULD** the process 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)?
  - Acceptance criteria

# PFMEA Documents Living Information

**The Process FMEA is a living document and should:**

- Be initiated before or at the feasibility stage (APQP Phase II)
- Be initiated **prior to** producing tooling for production
- Take into account all manufacturing operations, from individual components to assemblies
- Include all processes within the plant that can impact the manufacturing and assembly operations such as shipping, receiving, transporting of material, storage, conveyors, or labeling

# Chapter 1: APQP and PFMEA Introduction – What We Covered

## Learning Objectives

You should now be able to:

- Note the phases in the Advance Product Quality Planning (APQP) process where the FMEA is initiated
- Describe the purpose of the PFMEA

# Chapter 2

## APQP Inputs to the PFMEA, Process Flow Diagram

# Chapter 2: APQP Inputs to the PFMEA — What We Will Cover

## Learning Objectives

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

- Identify key APQP inputs used to develop the PFMEA
- Develop a Process Flow Diagram
- Define the term Special Characteristics

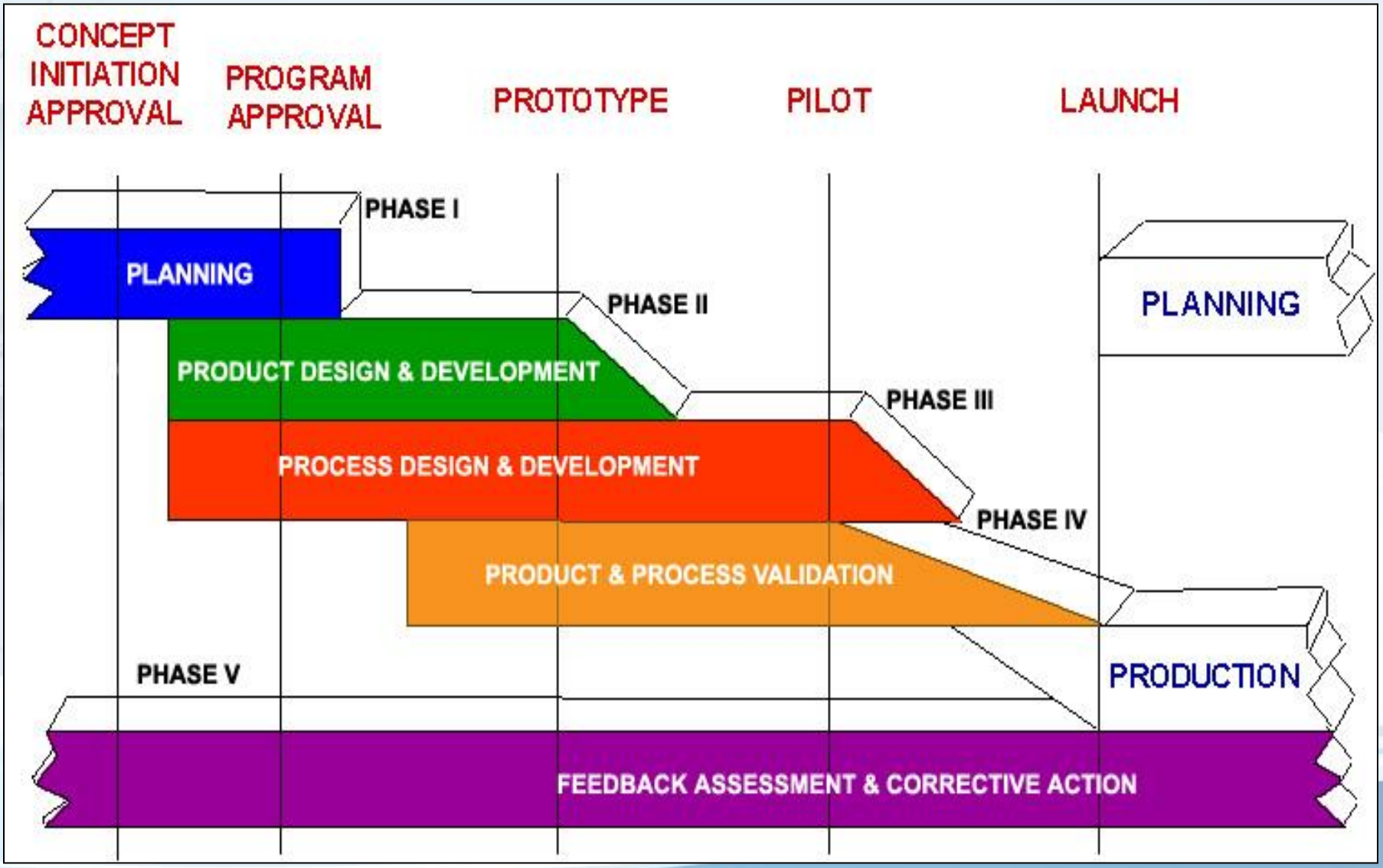
## Chapter Agenda

- Phase II Inputs/Deliverables
- Phase III Deliverables
- Print Preparation
- Process Flow Diagram
  - **Breakout Exercise 1**
- Special Characteristics

# Phase III: Design and Develop the Process

- Development of a comprehensive and effective manufacturing system and production process
- Manufacturing system must assure all customer requirements, needs and expectations are met
- Manufacturing system must support meeting all program goals and objectives

# Alignment of APQP Processes



# Phase III Deliverables — PFMEA Inputs

- Packaging Standards and Specifications
- **Product/Process Quality System Review**
- Floor Plan Layout
- **Process Flow Chart**
- **Characteristics Matrix**
- Process Failure Mode and Effects Analysis (PFMEA)
- Pre-launch Control Plan
- Process Instructions
- Measurement System Analysis Plan
- **Preliminary Process Capability Study Plan**
- Management Support

# Phase III Deliverables — PFMEA Inputs

- **Process Design Feasibility**
- **Manufacturing Process Design**
- **Special Process Characteristics Review**
- **Manufacturing Layout**
- Production Bill of Materials
- **Pre-production Trial Runs**
- Work Instructions
  - Process
  - Operator
  - Inspection
  - Set Up
- Production Control Plan
- Acceptance/Visual Standards

# Team Feasibility Commitment

The APQP team must assess the feasibility of the proposed design.

Customer design ownership does not preclude the supplier's obligation to assess design feasibility.

APQP 2nd Edition Appendix D

| YES | NO | CONSIDERATION |
|---|---|---|
| | | Is product adequately defined (application requirements, etc.) to enable feasibility evaluation? |
| | | Can Engineering Performance Specifications be met as written? |
| | | Can product be manufactured to tolerances specified on drawing? |
| | | Can product be manufactured with Cpk's that meet requirements? |
| | | Is there adequate capacity to produce product? |
| | | Does the design allow the use of efficient material handling techniques? |
| | | Can the product be manufactured without incurring any unusual: |
| | | • Costs for capital equipment? |
| | | • Costs for tooling? |
| | | • Alternative manufacturing methods? |
| | | Is statistical process control required on product? |
| | | Is statistical process control presently used on similar products? |
| | | Where statistical process control is used on similar products: |
| | | • Are the processes in control and stable? |
| | | • Are Cpk's greater than 1.33? |

**Conclusion**

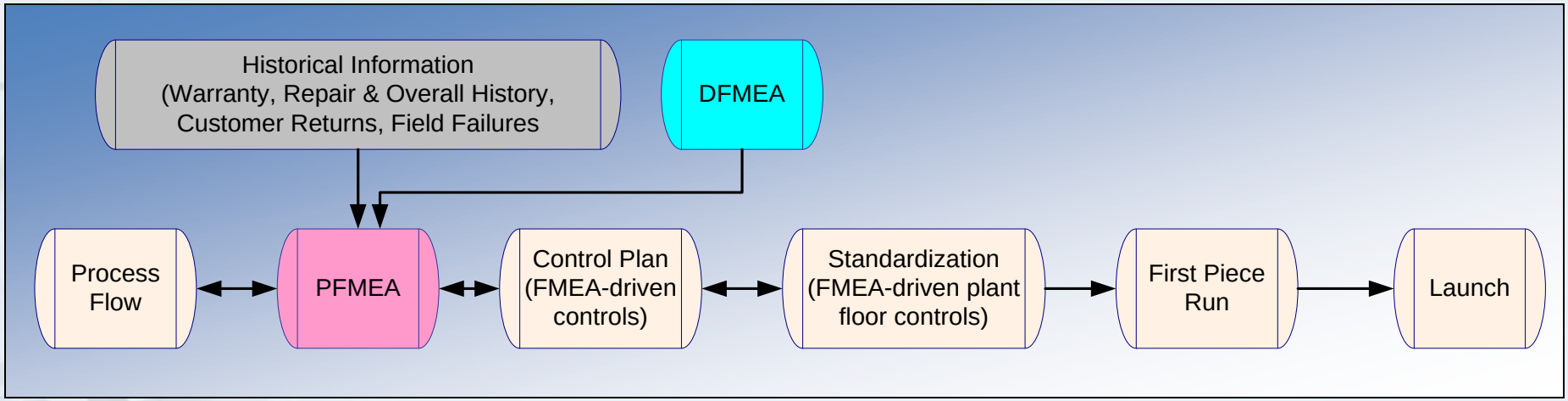
| | | |
|---|---|---|
| ☐ | Feasible | Product can be produced as specified with no revisions. |
| ☐ | Feasible | Changes recommended (see attached). |
| ☐ | Not Feasible | Design revision required to produce product within the specified requirements. |

# Critical Item Assessment

Illustration

| Supplier / | Product Breakdown | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Risk Assessment Checklist** | | | | | | | | | | | | | | | |
| **Critical Item Assessment** | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N | Y/N |
| 1) **Design Novelty** | | | | | | | | | | | | | | | |
| Does an existing design have to be changed/modified? | Y | Y | Y | Y | N | N | N | Y | | Y | N | Y | Y | Y | Y |
| Is this a new design/technology for the engineering team? | N | N | N | Y | N | N | N | N | | Y | N | Y | N | Y | N |
| Is this a new design/technology for the industry? | N | N | N | N | N | N | N | N | | N | N | N | N | N | N |
| 2) **Design Complexity** | | | | | | | | | | | | | | | |
| Is the design a sub-system/component that requires critical / important functional interfaces with others? | Y | Y | Y | Y | Y | Y | Y | Y | | Y | Y | Y | Y | Y | Y |
| Is the design a system made of made of various interfacing sub-systems/components? | | | | | | | | | | Y | N | Y | N | Y | Y |
| Have significant manufacturing and/or field problems been experienced with this design / product? | N | N | Y | Y | N | N | N | N | | Y | N | N | Y | Y | |
| Are regulatory and customer requirements expected to change significantly during the design / project phase? | N | N | N | N | N | N | N | N | | Y | N | N | N | Y | N |
| Will the design goals (weight, materials, functional performance, etc.) and Reliability goals be difficult to achieve? | N | N | Y | Y | Y | N | N | N | | Y | N | Y | Y | Y | N |
| 3) **Experience of the Manufacturing Team** | | | | | | | | | | | | | | | |
| Does the production process require qualifications to meet customer, regulatory or other requirements? | Y | N | N | N | | | | | | N | N | N | N | N | |
| Have new manufacturing personnel to be introduced for the production? | | N | N | N | | | | | | N | N | N | N | N | |
| Has a new or additional production line or facility to be started? | N | N | N | Y | | | | | | N | N | N | N | N | |
| Has a new production technology to be introduced? | N | N | N | N | | | | | | Y | Y | Y | Y | Y | |
| Are key people new to the manufacturing team? | N | N | N | N | | | | | | N | N | N | N | N | |
| 4) **Performance of the Manufacturing Team** | | | | | | | | | | | | | | | |
| Are similar products produced with major quality problems? | | N | N | | | | | | | N | N | N | N | N | |
| Are similar products produced with major logistic problems? | | N | N | N | | | | | | N | N | N | N | N | |
| Have major problems during start-up of project and/or launch of production have been experienced? | | N | N | N | | | | | | N | N | N | N | N | |
| Is this the first project/production launch of a BT project for this manufacturing team? | Y | N | N | N | | | | | | N | N | N | N | N | |
| Will the quality goals (warranty, TGW`s, scrap rates, rework rates, etc.) be difficult to achieve? | N | N | N | N | | | | | | N | N | N | N | N | |
| 5) **Project Management** | | | | | | | | | | | | | | | |
| Is the program timing compressed? | Y | Y | Y | Y | Y | Y | Y | Y | | Y | Y | Y | Y | Y | |
| Are the cost targets aggressive? | Y | Y | Y | Y | Y | Y | Y | Y | | Y | Y | Y | Y | Y | |

# Process Review




- Improve process capability
- Resolve process feasibility issues
- Formulate control strategy based on PFMEA

Links to Design FMEA

- Process technology improvement using Machine FMEA and Process FMEA
- Update design rules
- Increase first time through capability of design
- Improve quality and productivity

# The Process Design is Your Friend

## Get to Know it Well

# FMEA Prerequisites

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

**– Abraham Lincoln**

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# SCOPE OF ANALYSIS

# Scope of the Analysis

**Need to Know:**

- What is included
- What is not included
  - That is, what is the scope of the analysis?

- Tools
  - Process Flow Chart
  - Characteristics Matrix (optional)

# PROCESS FLOW DIAGRAM

Prerequisite for Developing PFMEA

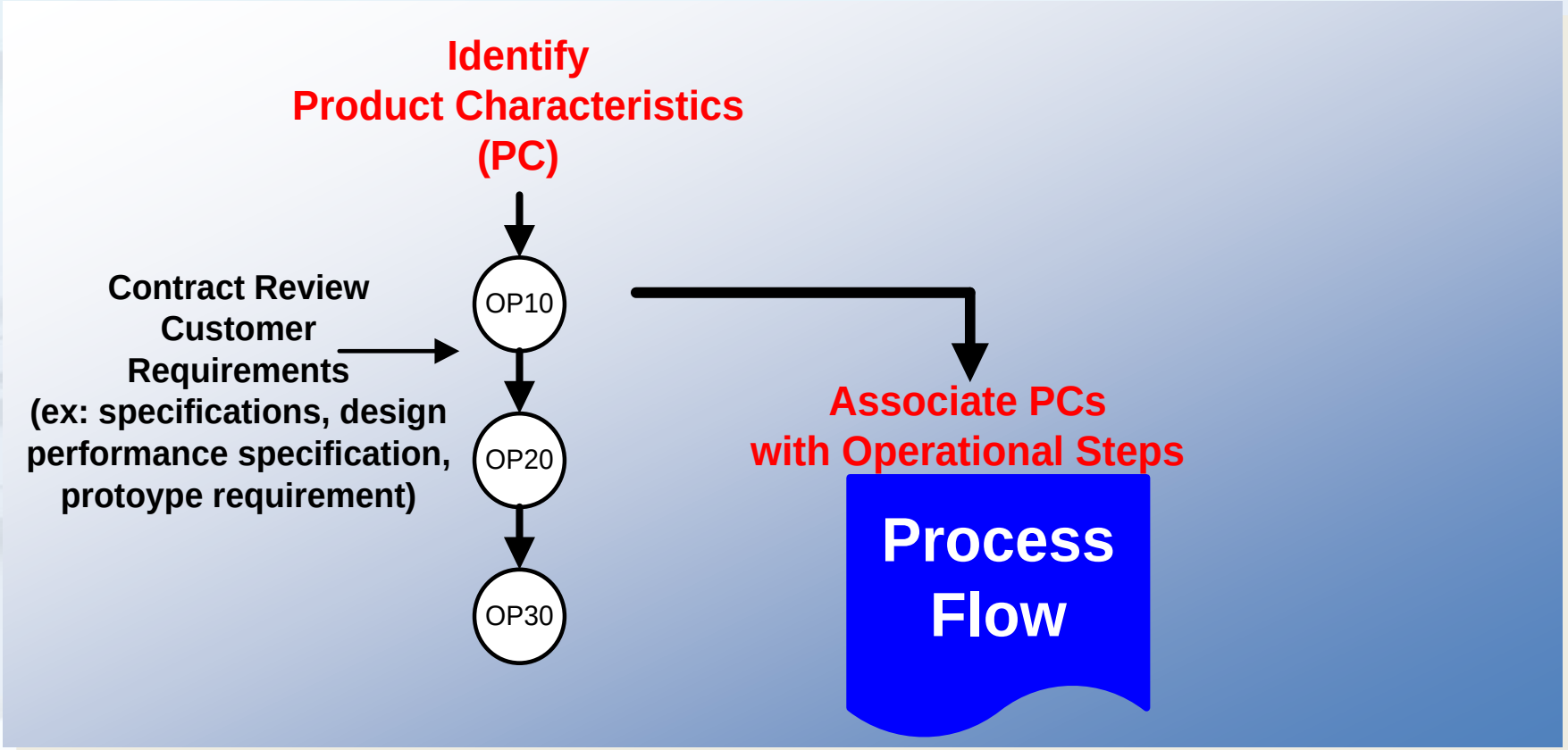
# Process Flow Diagram

## 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.

# System Diagram



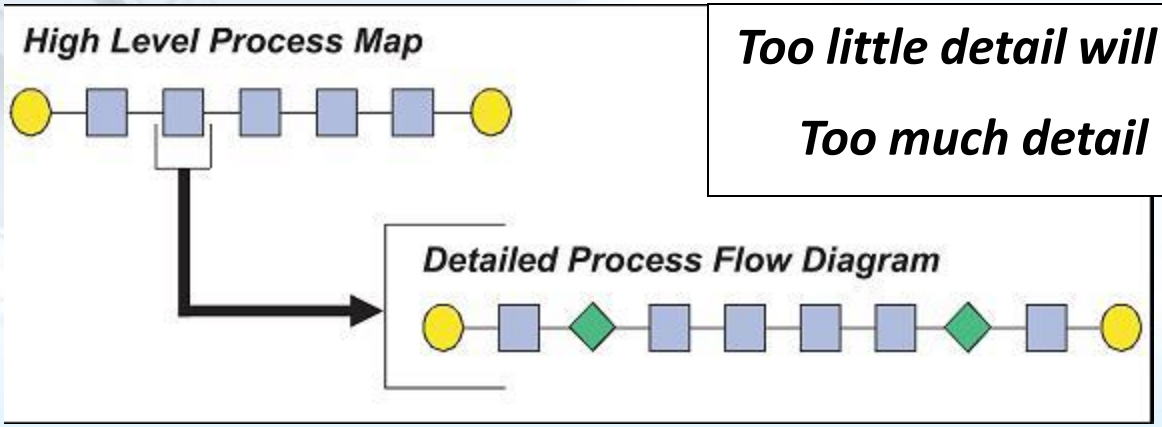
# Elements of Process Flow Document

- Process Step / Process Function (description)
- Incoming Sources of Variation
- Operation Type and/or Symbol
- Product Characteristic I.D. O-M-N-E-X
  - Product characteristic description
- Process Characteristic I.D.
  - Process characteristic description
- Special Characteristics Identified

# Preparing a Process Flow

**Process Step / Process Function (description) recommendations:**

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



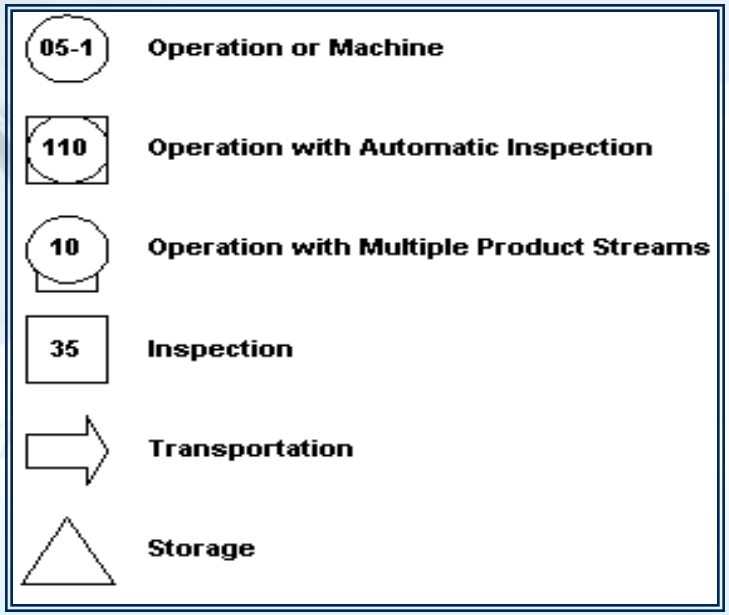

***Too little detail will not expose the problem.***

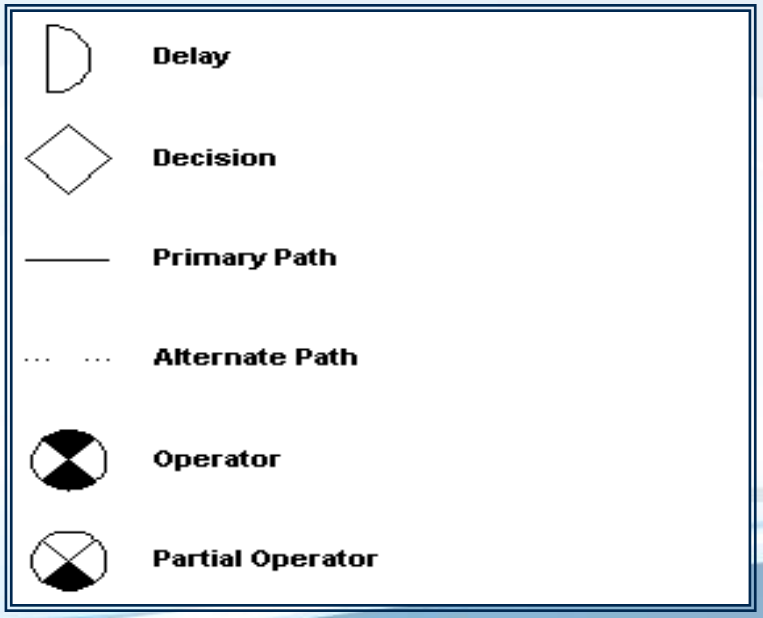
***Too much detail will hide the problem.***

# Preparing a Process Flow

## Process Flow Graphics

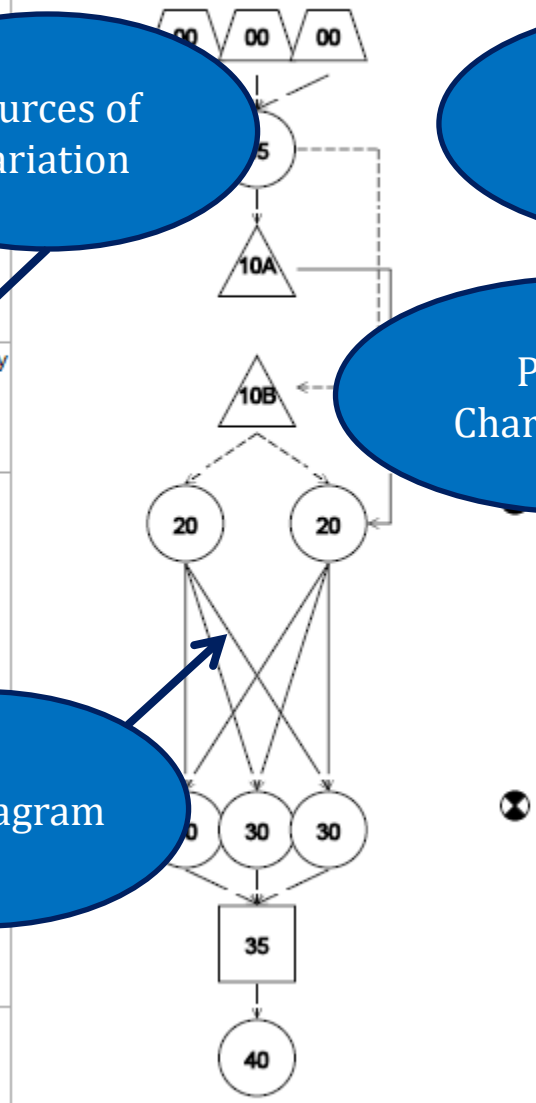
- Each process step should be represented by a symbol (icon)
- Some customers have specified a specific format or graphics but there is no single approach – be consistent
- Example symbols:



# Manufacturing Process Flow Example

| Step | | Experienced Sources of Variations | Process Flow Diagram | Function | Requirement | | | |
|---|---|---|---|---|---|---|---|---|
| Num | Description | | | | ID. | Product | Process | SC |
| 00 | Supplier | | | | | | | |
| 05 | Receive Hot Bars | deli… vari… | | | | | correct decision | |
| 10A | | …e time; …n; humidity | | | | …be surface condition | | |
| | | | | | | | inventory protocal | |
| 10B | | …age time; humidity | | | | …urface …n | | |
| | | | | | | | inventory protocal | |
| 20 | Scre… Machine | machine capbility; operator training; tool variation; setup variation | | | | tube inside diameter | | CS |
| | | | | | 05 | OAL | | |
| | | | | | 06 | Chamfer degree | | |
| | | | | | 07 | Chamfer length | | |
| | | | | | 12 | Spacer inside diameter | | PC |
| | | | | | ND03 | | tool replacement | |
| 30 | Wash | | | | 14 | free of machine oil | | |
| | | | | | ND04 | | Washer Acid concentration | |
| 35 | Inspect -- inside diameter | operat… | | | ND… | | correct decision | |
| 40 | Grind - outside diameter | tool wear variation; setup variation | | | 08 | | | |
| | | | | | 10 | | | |
| | | | | | ND05 | | wheel speed | |
| | | | | | ND06 | | wheel feed rate | |




Sources of Variation

Process Characteristics

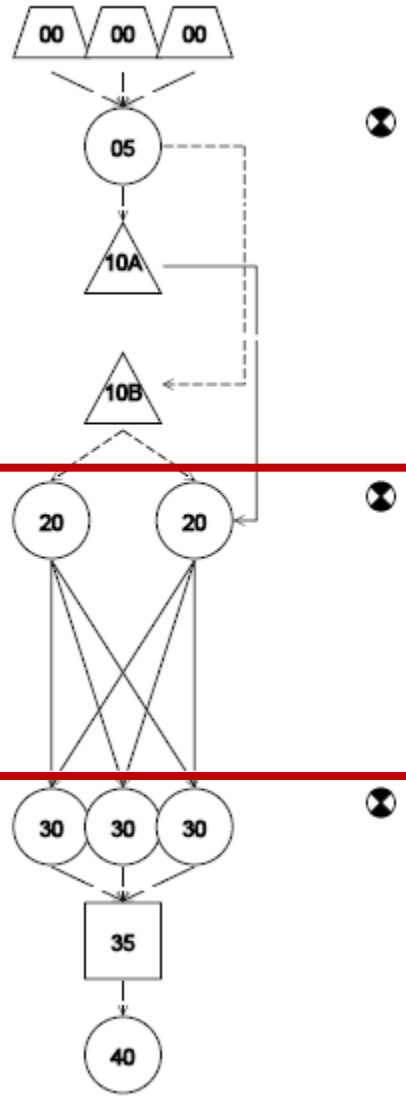
Operation # & Description

Product Characteristics

Flow Diagram

Best-In-Class Approach

# Process Flow as an Analytical Tool

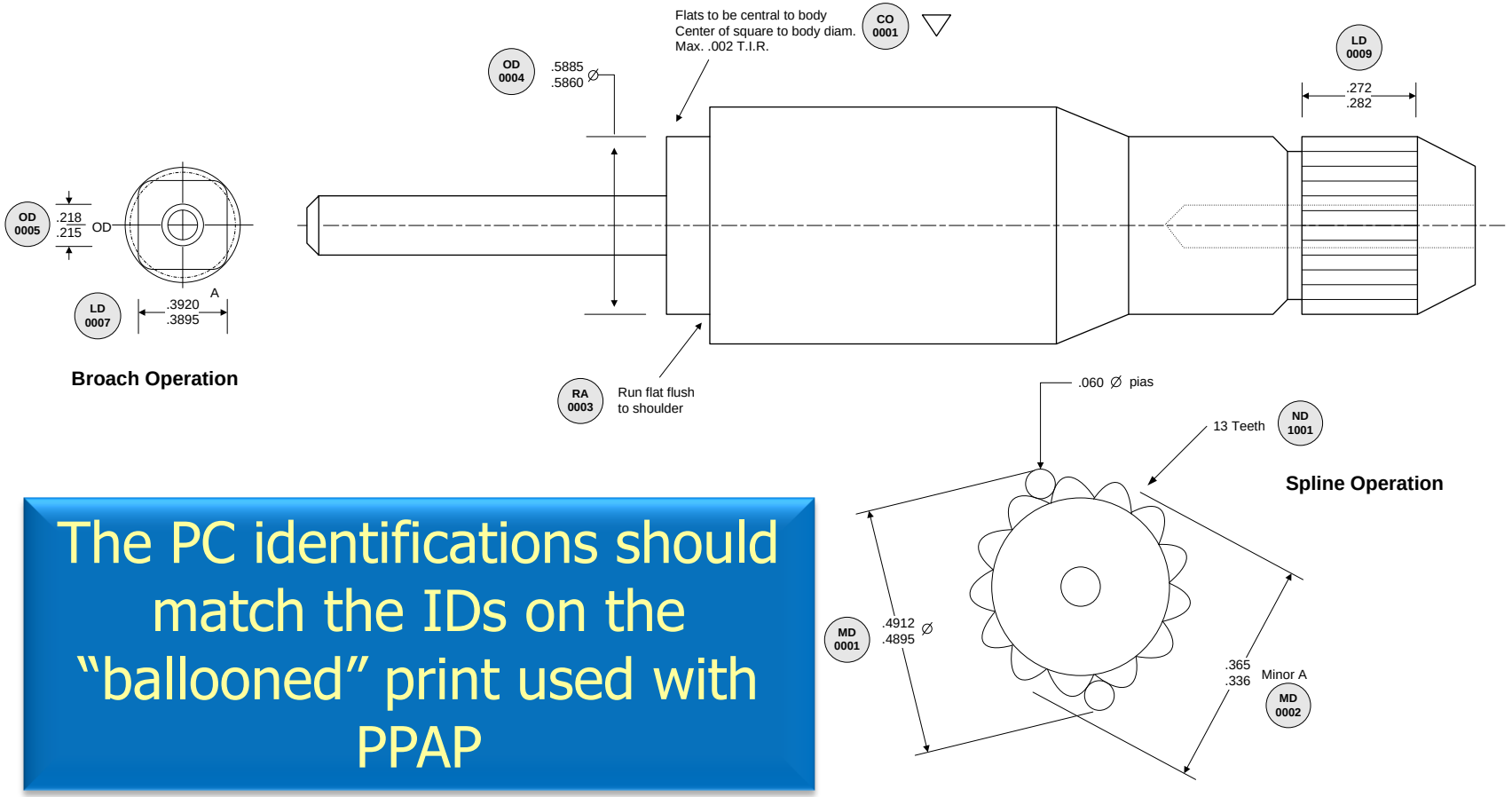
| Step | | Experienced Sources of Variations | Process Flow Diagram | Function | Requirement | | | |
|---|---|---|---|---|---|---|---|---|
| Num | Description | | | | ID. | Product | Process | SC |
| 00 | Supplier | |  | | | | | |
| 05 | Receive Hot Bars | delivery timing variation | | | ND01 | | correct 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 | |

# 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




The PC identifications should match the IDs on the "ballooned" print used with PPAP

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

# Special Characteristics

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 are defined by IATF 16949

# Special Characteristics — IATF 16949

**Special Characteristics** are **product characteristics or manufacturing process parameters** that can affect safety or compliance with regulations, fit, function, performance, requirements, or subsequent processing of product. (IATF 16949)

In Phase II the customer/APQP team affirm a **Preliminary List of Special Characteristics** for both the product and planned process that is used to create the product.

# Special Characteristics — IATF 16949

**Special Characteristics** are **product characteristics or manufacturing process parameters** that can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.
(IATF 16949)

Also see:

- 4.4.1.2 Product Safety
- 5.3.1 Organization Roles, Responsibilities and Authorities — Supplemental
- 7.1.5.1.1 Measurement System Analysis
- 8.2.3.1.2 Customer-designated Special Characteristics
- 8.3.3.1 Product Design Input
- 8.3.3.3 Special Characteristics
- 8.3.5.1 Design and Development Outputs — Supplemental
- 8.3.5.2 Manufacturing Process Design Output
- 8.4.3.1 Information for External Providers — Supplemental
- 8.5.1.1 Control Plan
- 9.1.11 Monitoring and Measurement of Manufacturing Processes
- Appendix A: Control Plan A.2 Elements of the Control Plan

# Special Characteristics — IATF 16949

## 8.3.3.3 Special Characteristics

The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization…

- Include all special characteristics in the Control Plan.
- Include those designated by the customer.
- Comply with customer-specified definitions and symbols.
- Identify special characteristics on process control documents:
  - Drawings
  - FMEA (Risk Analyses)
  - Control Plan
  - Standard Work/Operator Instructions

# Preparing a Process Flow

**Experienced Sources of Variation** (aka Incoming Sources of Variation)

- This column is used to identify those sources of variation that can affect the process step
- It is not intended to be a collecting 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

# Breakout Exercise 1

## Process Flow Diagram

# Breakout Exercise 1: Process Flow Diagram

## Handouts

- Description of a manufacturing process.

## Instructions

1) Draw a Process Flow Diagram using the proposed manufacturing path.
   - Emphasize Blueprint IDs (ID) numbers 01, 02, 05 and 014. Do not spend much time on the other characteristics.
   - Use the enlarged 11x17 Process Flow sheet or flip chart.
   - Be prepare to present your team's Process Flow Diagram to the class; rotate the team spokesperson.
   - Recommend improvements to the proposed flow.

**Be prepared to share and discuss your output with the class**

# 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

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

# Chapter 2: APQP Inputs to the PFMEA — What We Covered

## Learning Objectives

You should now be able to:

- Identify key APQP inputs used to develop the PFMEA
- Develop a Process Flow Diagram
- Define the term Special Characteristics

# Chapter 3

## Developing a Process FMEA

# Chapter 3: Developing a PFMEA — What We Will Cover

## Learning Objectives

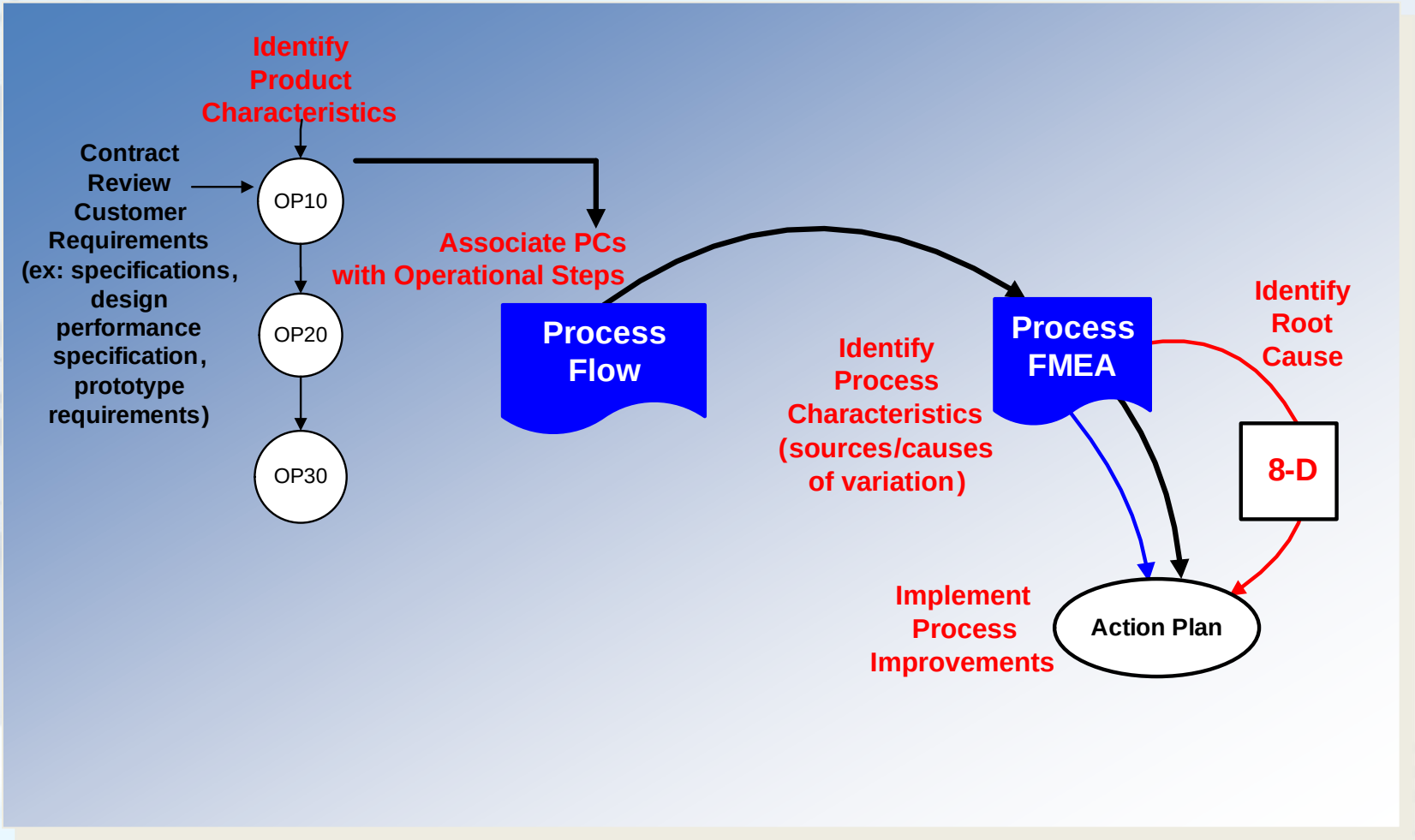
At the end of this chapter, you will be able to:

- Populate a basic PFMEA template
- Distinguish between Product and Process Characteristics
- Describe controls for prevention and detection

## Chapter Agenda

- PFMEA Analytical Sequence
- Preparing the PFMEA
- Failure Mode and Effects
  - **Breakout Exercise 2**
  - **Breakout Exercise 3**
- Controls Prevent / Detect
  - **Breakout Exercise 4**
- Risk Priority Number
- Classification Column
  - **Breakout Exercise 5**

# System Diagram



# Process FMEA: Sample Form

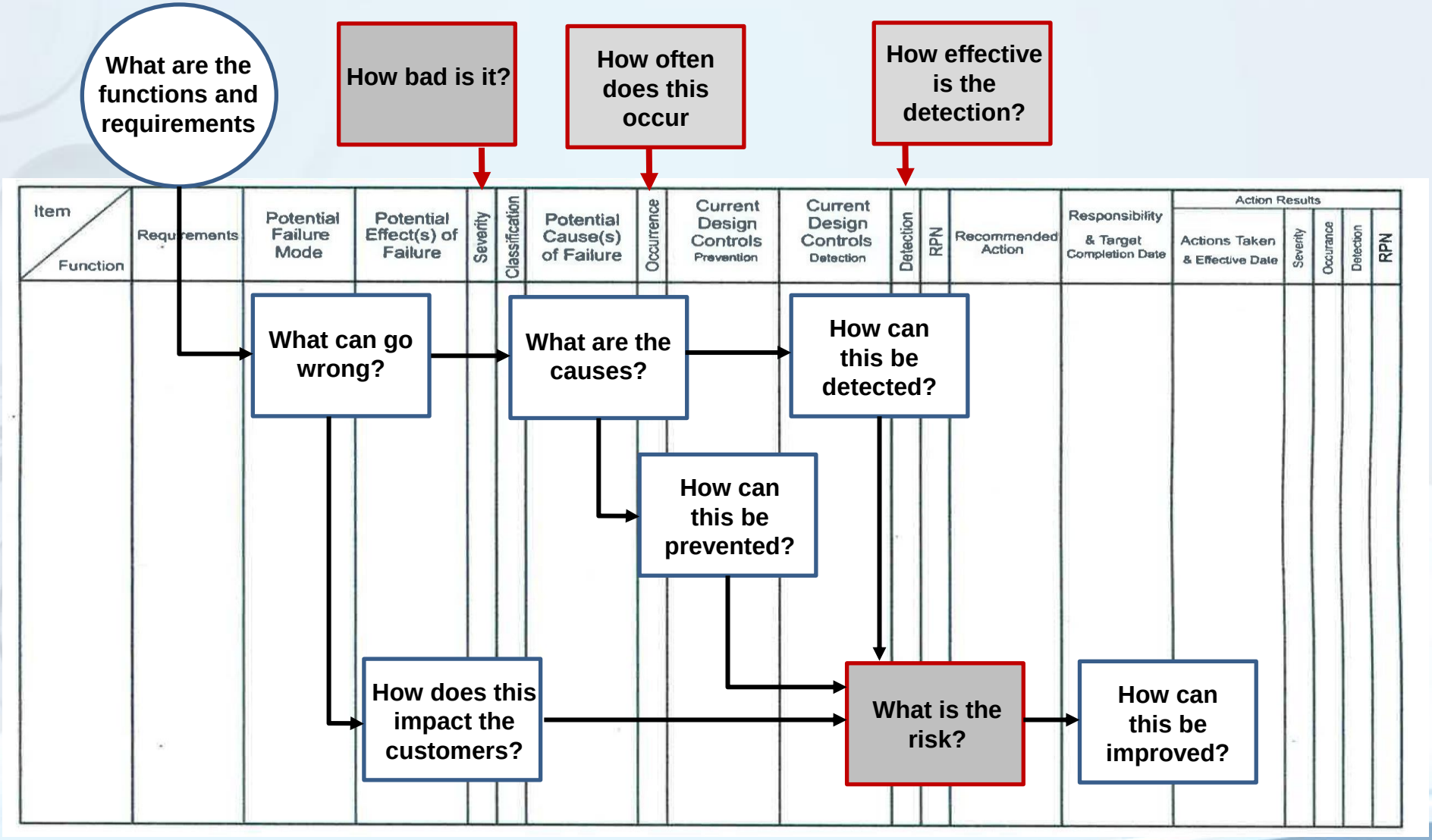
**POTENTIAL**
**FAILURE MODE AND EFFECTS ANALYSIS**
**(PROCESS FMEA)**

FMEA Number: A
Page _____ of _____
Item: B
Process Responsibility: C
Prepared By: H
Model Year(s)/Program(s): D
Key Date: E
FMEA Date (Orig.): F
Core Team: G

| Process Step | | Requirements | | | | | | | | | | | | | | | Action Results | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ID | Description | ID | Product | Process | Potential Failure Mode | Potential Effect(s) of Failure | Severity | Classification | Potential Cause(s) of Failure | Current Process Controls Prevention | Occurrence | Current Process Controls Detection | Detection | RPN | Recommended Action | Responsibility | Target Completion Date | Actions Taken | Effective Date | Severity | Occurance | Detection | RPN |
| Op 70: | Manual application of wax inside door panel | LD 09 | Cover inner door, lower surfaces with wax to specification thickness | | Insufficient wax coverage over specified surface | Allows integrity breach of inner door panel<br>Corroded interior lower door panels<br>Deteriorated life of door leading to:<br>•Unsatisfactory appearance due to rust through paint over time.<br>• Impaired function of interior door hardware | 7 | | Manually inserted spray head not inserted far enough | None | 8 | Variables check for film thickness at start up<br>Visual check for coverage. | 5 | 280 | Add positive depth stop to sprayer | Bob Tate Mfg Eng | 0X 10 15 | Stop added sprayer checked online, | 0X 10 15 | 7 | 2 | 5 | 70 |
| | | | | | | | | | | | | | | | Automate spraying | Bob Tate Mfg Eng | 0X 12 15 | Rejected due to complexity of different doors on same line | | | | | |
| | | | | | | | | | Spray head clogged<br>- Viscosity too high<br>- Temperature too low<br>- Pressure too low | Test spray at start-up and after idle periods and preventative maintenance program to clean heads | 5 | Variables check for film thickness at start up<br>Visual check for coverage. | 5 | 175 | Use Design of experiments (DOE) on viscosity vs. temperature vs. pressure | D Cherry Mfg Eng | 0X 10 15 | Temp and Press Limits were determined<br>Control charts show process is in control Cpk =1.85 | 0X 11 15 | 7 | 1 | 5 | 35 |
| | | | | | | | | | Spray head deformed due to impact | Preventative maintenance programs to maintain heads | 2 | Variables check for film thickness at start up<br>Visual check for coverage. | 5 | 70 | None | | | | | | | | |
| | | | | | | | | | Spray time insufficient | None | 5 | Lot sampling (visual) check coverage of critical areas | 7 | 245 | Install Spray timer. | C Czymak Maint | 0X 11 15 | Automatic spray timer installed<br>Control charts show process is in control Cpk =2.05 | 0X 11 15 | 7 | 2 | 7 | 98 |
| | | | | | | Excessive wax coverage over specified surface | | | | | | | | | | | | | | | | | |
| a1 | a2 | | a3 | | b | c | d | e | f | g | h | i | j | k | -------- l | ---------- | | — m | --- | — | n | — | |

**SAMPLE**

# FMEA Analytical Sequence



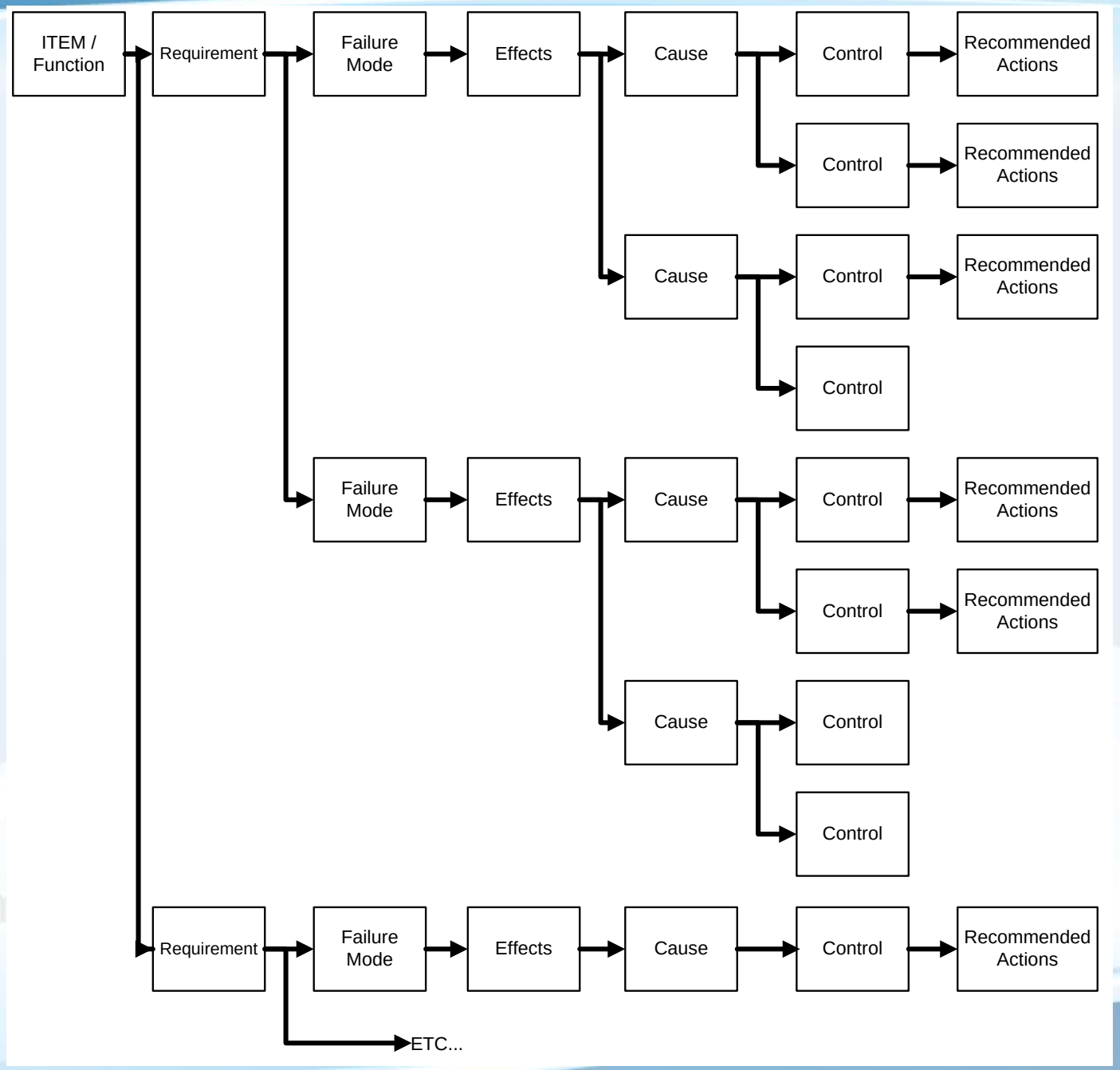
# Standard PFMEA Form

| Process Step | Function | Requirements | | | Potential Failure Mode | Potential Effect(s) of Failure | Severity | Classification | Potential Cause(s) of Failure | Current Process Controls Prevention | Occurrence | Current Process Controls Detection | Detection | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ID | Product | Process | | | | | | | | | | |

**Recommended**

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

# FMEA Structure



# Process Step/Function Requirements

- For each step identified in the Process Flow chart include all **deliverables** (Product and Process Characteristic) as separate branches
- **Best-in-Class:** include the PC ID identifier for each deliverable

# Preparing a Process FMEA

1. List all known, obligatory and implied requirements – from the Process Flow Chart
   - Requirements are Product Related
   - Requirements are Process Related
2. For each requirement **identify potential process related failure modes**

How will the product fail to meet design intent if the requirement is not satisfied?

# Process Failure Mode

- **For each requirement** – How could the process fail to operate as defined in the requirement?
- ***The opposite of the requirement***
- **For product requirements** – non-conformance at the specific operation:
  - Why would the item be rejected?
  - How would the item not conform to the specification?
  - How would the process not conform to the specification?
  - What would the customer consider unacceptable?
  - How does the item fail to meet regulatory compliance?

# Header Information

A. FMEA Number
B. System, Subsystem, or Component Name and Number
**C. Design Responsibility**
D. Model Year(s)/Program(s)
E. Key Date
   – The initial FMEA due date, which should not exceed the scheduled production design release date
**F. FMEA Dates**
   – **The date the original FMEA was completed and the latest revision date**
G. Core Team
H. Prepared By

# 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 |

Typical But Not Recommended

# Potential Failure Mode(s)

- **Recommended — BIC:** Analyze the requirements and use subject matter expertise to determine the failure modes.
- Failure mode is the opposite of the requirement. O$M$$N$E$X
- 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:<br><br>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 Mode is the opposite/absence of the requirement

# Breakout Exercise 2

## Starting the PFMEA Form

# Breakout Exercise 2: Starting the PFMEA Form

## Handouts

- Description of a manufacturing process.

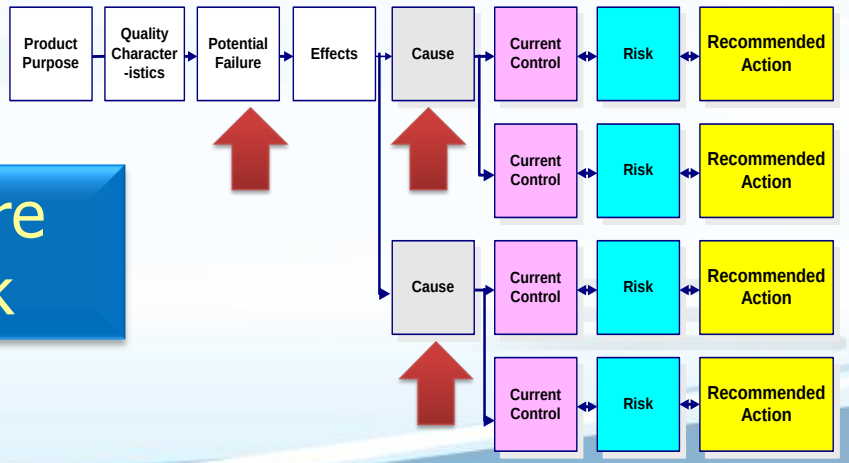
## Instructions

1) Complete the first six columns of the PFMEA, up to and including the Failure Mode column:
   - Do not complete any columns to the right of the Failure Mode column.
   - Include the process steps 20 and 50 and focus on the characteristics (ID) numbers 01, 02, 05 and 14.
   - Include any process characteristics identified in the Process Flow Diagram.
   - Use the recommended format or the Excel workbook provided by the instructor.

**Be prepared to share and discuss your output with the class**

# Potential Cause(s)

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 (later)*
   - *Identify the Cause(s)*

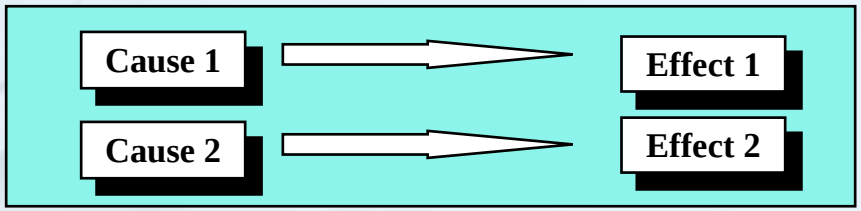



We will return to Effects of Failure at the end, when evaluating Risk

# Potential Cause(s) of Failure

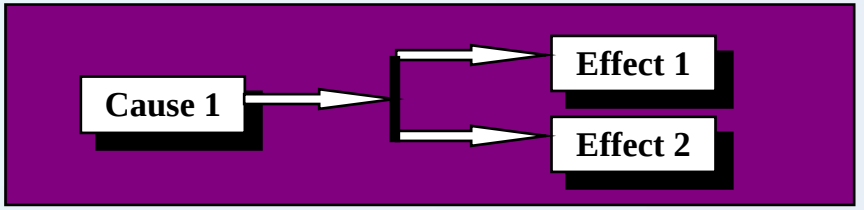
- Potential cause of failure is defined as how the failure mode could occur, described in terms of something that can be **corrected or controlled**
- The cause of failure is an "*Error State*" in a process parameter/characteristic (a "special cause")
- Each cause assignable to a failure mode should be listed and considered separately

# Cause & Effect Relationships

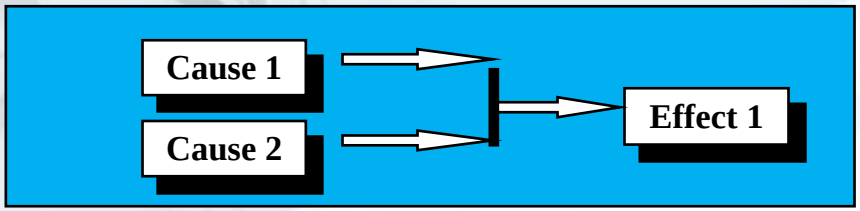


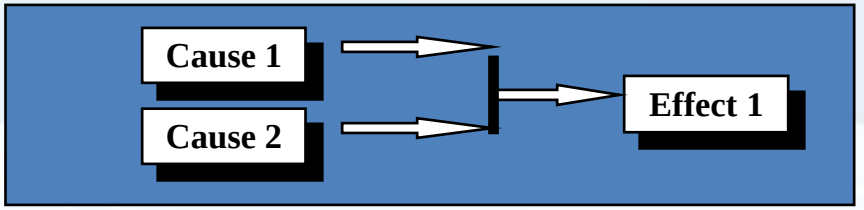

1 Cause to 1 Effect

1 cause with multiple effects




Multiple causes leading to 1 effect "and"




"or" many to 1.

e.g. Vehicle Inoperable due to flat tire, out of gas, alternator fails, No drive-shaft

C & E's may be related in different ways

# Potential Causes of Failure

- Determined by the FMEA team using subject matter knowledge and experiences
- Potential causes can be determined directly or by understanding the Mechanisms of Failure:

| | |
|---|---|
| Excessive Torque Applied | Inaccurate Measurement/Gage |
| Cold Weld | Worn Locator |
| Worn Tool | Missing Locator |
| Wrong Tool | Wrong Material Used |
| Inadequate Venting Lubrication | No Standard Instructions |
| No Preventive Maintenance | Fatigue |
| Programming does not handle interactions | Inadequate Lighting |
| Inconsistent Set-up | Cracked Mold |

Not "Operator Error"

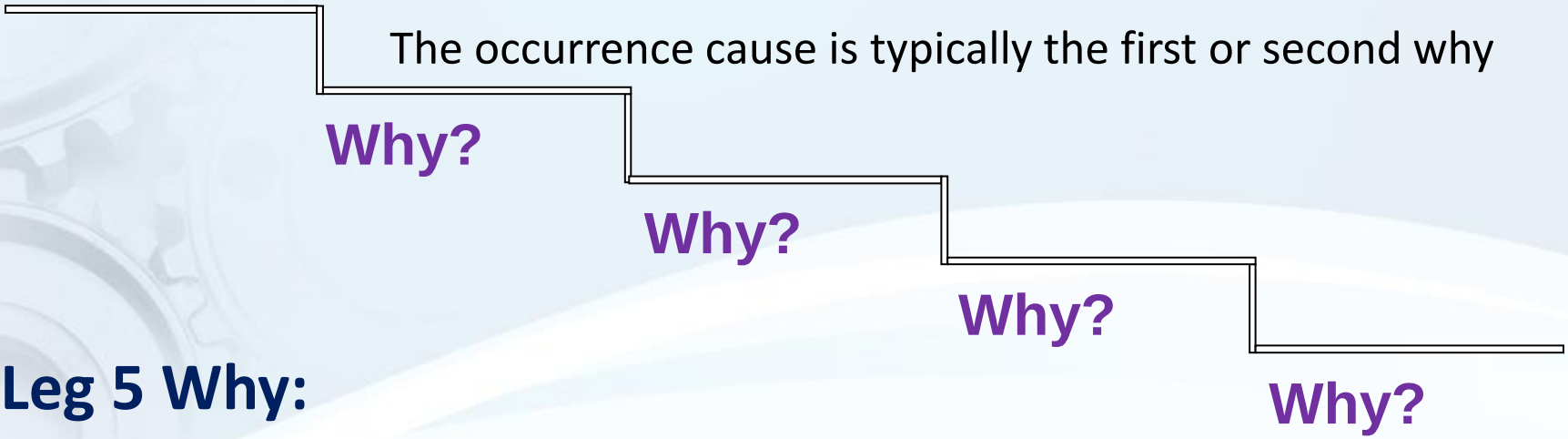
# Cause Analysis Tools

## Why Ladder/5-Why

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

**Failure Mode**

The occurrence cause is typically the first or second why

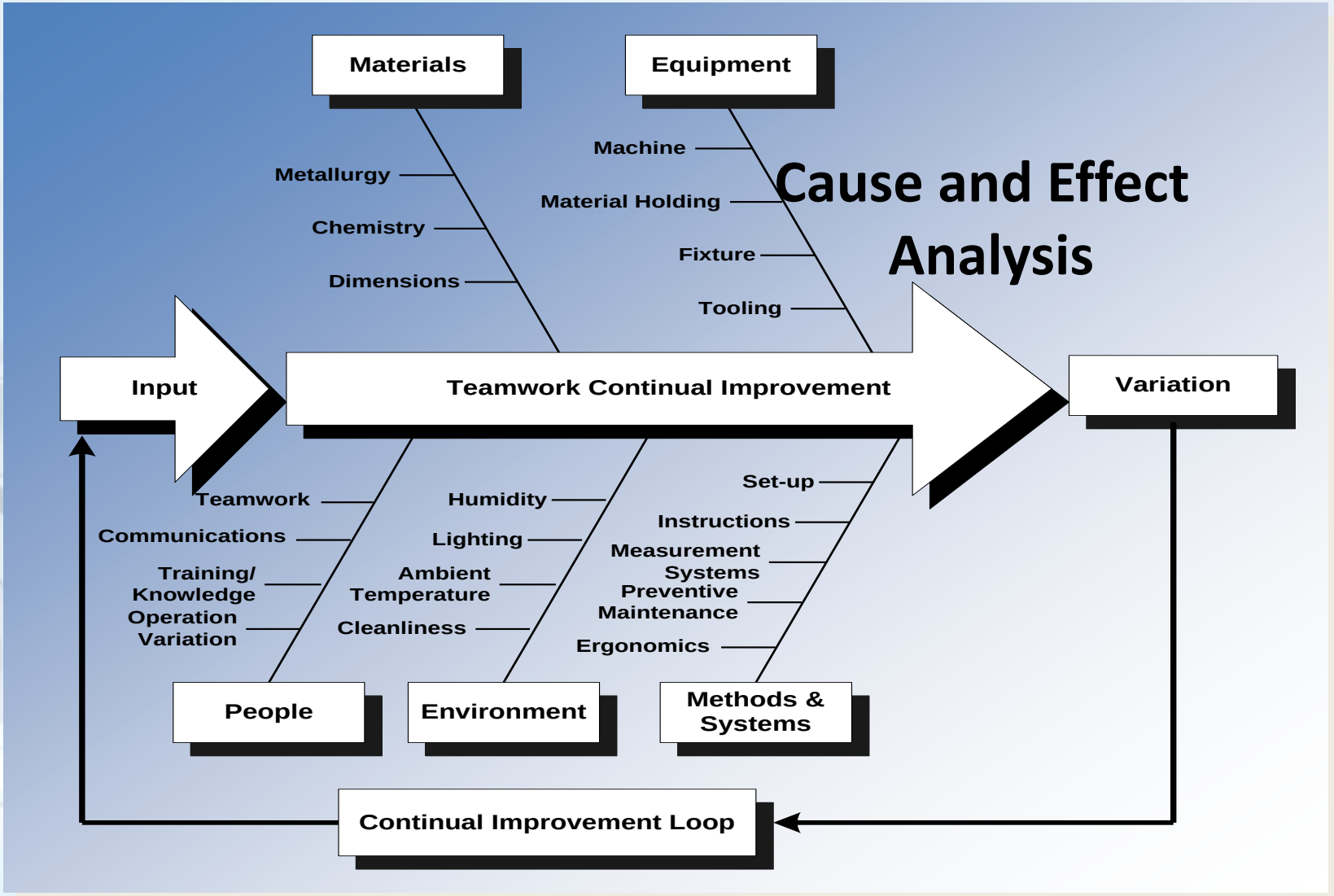



**3 Leg 5 Why:**

1. Why was the error made and or a defect produced?
2. Why did the error/defective escape the current controls?
3. What in our system failed? How did we let it happen?

Do not confuse a causal chain with multiple causes

# Cause Analysis Tools



# Breakout Exercise 3

## Potential Causes

# Breakout Exercise 3: Potential Causes

## Instructions

1) For each failure mode, determine potential causes of failure.
   - Since there may be more than one cause for each failure mode, create a separate branch for each cause identified.
   - Where data is lacking, use your personal experience, knowledge, and imagination to come up with potential causes, effects.

**Be prepared to share and discuss your output with the class**

# 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
- **M**achine/Equipment
- Maintenance
- Components and **M**aterials
- **M**an/Operator Competence
- Standardized **M**ethods
- Fixture/pallet
- Tooling
- **M**easurement System
- **E**nvironment in which the process operates

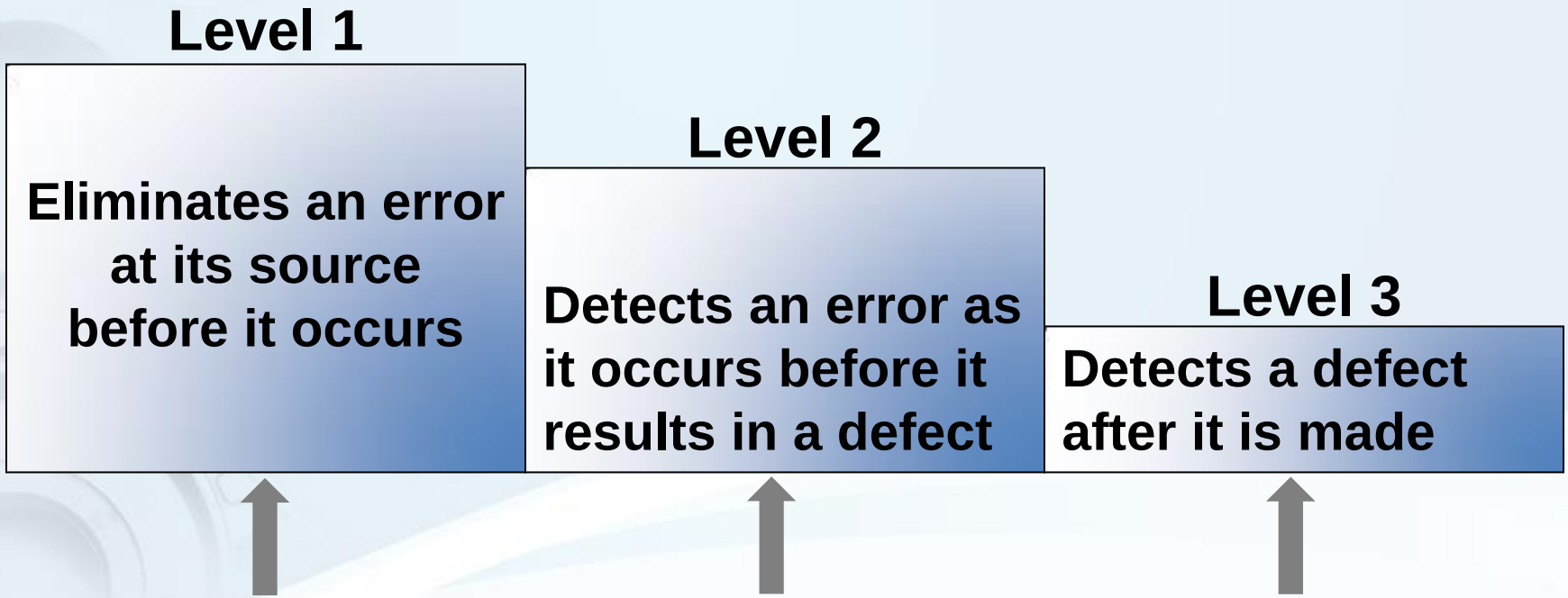
5M&E

# Error and Mistake Proofing is Designed in…

| Lvl | Type | P or D | Action | Result |
|---|---|---|---|---|
| 1 | Error Proofing | Prevention | Eliminates the factors that cause an error – by design | Control in design; zero defects are made |
| 2 | Poka-Yoke 100% Inspection | Cause Detection | Detects a mistake/error cause in-station before it becomes a defect | 100% Inspection – mistake proofing |
| 3 | Poka-Yoke 100% Inspection | Mistake Detection | Error/mistake is detected before leaving station / process | Auto stop when a mistake is detected |

**Design in controls and implementation: Prevention is the key.**

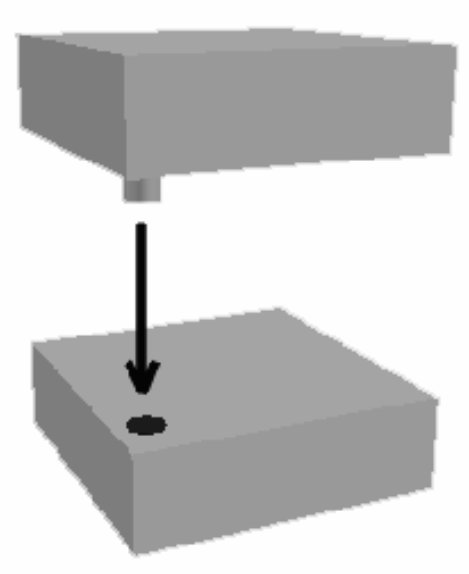
# Control Levels



# PFMEA Process Control Columns

## Prevent the Cause

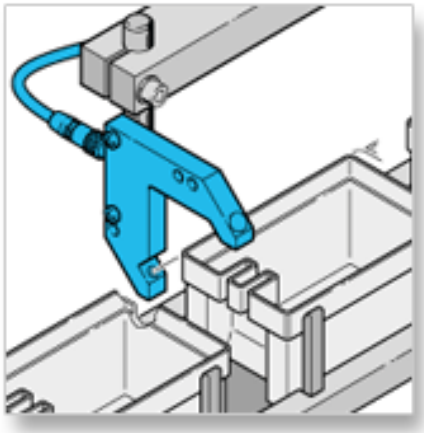
**Error proofing in design**



Prevent the cause of the failure mode

## Detect the Cause

**In line auto part detection**



Detect the cause / mechanism of failure

# Types of Mistake Proofing Devices

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.

# Other Examples of Preventive Controls

| Type | Control Methods |
|---|---|
| Preventive Maintenance | Cycle based<br>Time based |
| Error Proofing | Product design<br>Process design<br>Fixture design<br>Tooling sensing<br>Equipment sensing |
| Other | Off-line set-up<br>Set-up verification with SPC<br>Process Control (SPC) |

# 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.
  - Process capability ($C_p$, $C_{pk}$) is only valid for **stable** processes.
- **Best-in-Class:** identify whether the index is based on…
  - Consensus
  - Historical data on the same or similar processes
  - Process study (e.g. DOE) on the process

**Preventing Controls** have a direct impact on the **Occurrence**

# PFMEA Occurrence Table – Example

| Likelihood of Failure | Criteria: Occurrence of Cause – PFMEA (Incidents per items/vehicles) | Rank |
|---|---|---|
| **Very High** | ≥ 100 per thousand \| ≥ 1 in 10 | **10** |
| **High** | 50 per thousand \| 1 in 20 | **9** |
| | 20 per thousand \| 1 in 50 | **8** |
| | 10 per thousand \| 1 in 100 | **7** |
| **Moderate** | 2 per thousand \| 1 in 500 | **6** |
| | .5 per thousand \| 1 in 2,000 | **5** |
| | .1 per thousand \| 1 in 10,000 | **4** |
| **Low** | .01 per thousand \| 1 in 100,000 | **3** |
| | ≤ .001 per thousand \| 1 in 1,000,000 | **2** |
| **Very Low** | Cause is eliminated through preventive control | **1** |

# Detection

**Detection is the index associated with the best detection control shown in the current control 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.**

# Examples of Detection Controls

| Type | Control Methods |
|---|---|
| Audits | Dock Audits<br>Process Parameter |
| Checking | Operator checks<br>100% automatic gauging<br>Visual Inspection |
| Inspection | In-process<br>Final (dimension, functional) |
| Other | Mistake proofing<br>Set-up validation (SPC)<br>Lab test<br>Alarms |

| Opportunity for Detection | Criteria: Likelihood of Detection by Process Control | | Rank | Likelihood of Detection |
|---|---|---|---|---|
| **No detection opportunity** | No current process control; Cannot detect or is no analyzed. | | **10** | **Almost Impossible** |
| **Not likely to detect at any stage** | Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits). | | **9** | **Very Remote** |
| **Problem Detection Post-Processing** | Failure Mode detection post-processing by operator through visual/tactile/audible means. | | **8** | **Remote** |
| **Problem Detection at Source** | Failure Mode detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.) | | **7** | **Very Low** |
| **Problem Detection Post-Processing** | Failure Mode detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.) | | **6** | **Low** |

| Opportunity for Detection | Criteria: Likelihood of Detection by Process Control | | Rank | Likelihood of Detection |
|---|---|---|---|---|
| **Problem Detection at Source** | Failure Mode or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for set-up causes only). | | **5** | **Moderate** |
| **Problem Detection Post-Processing** | Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing. | | **4** | **Moderately High** |
| **Problem Detection at Source** | Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing. | | **3** | **High** |
| **Error Detection and/or Problem Prevention** | Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made. | | **2** | **Very High** |
| **Detection not Applicable; Error Prevention** | Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been error-proofed by process/product design. | | **1** | **Almost Certain** |

# Example

| Process Function | Requirement | Failure Mode |
|---|---|---|
| Operation 20:<br><br>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 Mode is the opposite/absence of the requirement

| 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 | Angle sensor included in nut runner 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 |
| | | | Settings added to set-up instructions | |
| | 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 |
| | | | Settings added to set-up instructions | |
| | | | | |

# Breakout Exercise 4

## Process Controls

# Breakout Exercise 4: Process Controls

## Instructions

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

**Be prepared to share and discuss your output with the class**

# Breakout Exercise 4: Process Controls

**Referring to the previous index tables:**

1) 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.

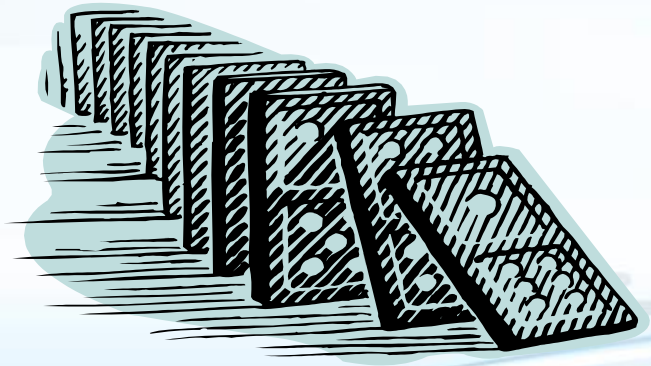
2) Rate each Detection control in the control column. Select the rating for the most effective (lowest number) control.
   - Note that the same controls may operate for different causes or failure modes, and are repeated.

# RISK ANALYSIS

# Risk Analysis

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)*

Let's go back and get the severity for the Risk Analysis



# EFFECTS OF FAILURE

# 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

# Typical Effects – Customer Dissatisfaction

- Inconsistent Appearance
- Gear Noise – “Singing gears”
- Customer Vision Impaired
- Cannot Fasten
- Discoloration
- Delay in presenting information
- Water Enters Vehicle
- Loses Power
- Fading
- Will Not Lock or Hold
- Cannot Read Sensor
- Uneven Fit
- Sticks in Mold
- Squeaks, Rattle, Noise

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

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

| Requirement | Failure Mode | Effect |
|---|---|---|
| **Four screws** | Fewer than four screws | *End User:* Loose seat cushion and noise.<br>*Manufacturing and Assembly:* Stop shipment and additional sort and rework due to affected portion. |
| **Specified screws** | Wrong screw used (larger dia.) | *Manufacturing and Assembly:* Unable to install screw in station. |
| **Assembly sequence: First screw in right front hole** | Screw placed in any other hole | *Manufacturing and Assembly:* Difficult to install remaining screws in station. |
| **Screws fully seated** | Screw not fully seated | *End User:* Loose seat cushion and noise.<br>*Manufacturing and Assembly:* Sort and rework due to affected portion. |

# Severity of Effect

**Severity is the rank associated with the most serious effect of the failure mode on the external (Product) and internal (Process) customer:**

- Assess the severity of each effect by team consensus using the ranking table, in the Effects column
- Consider **Customer Effect** and **Manufacturing/Assembly Effects**

Recommendation: Enter a severity for each effect; place highest rating in the Severity column

| Effect | Criteria: Severity of Effect on Product (Customer Effect) | Rank | Effect | Criteria: Severity of Effect on Process (Manufacturing/Assembly Effect) |
|---|---|---|---|---|
| Failure to Meet Safety and/or Regulatory Requirements | Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning. | 10 | Failure to Meet Safety and/or Regulatory Requirements | May endanger operator (machine or assembly) without warning. |
| | Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning. | 9 | | May endanger operator (machine or assembly) with warning. |
| Loss or Degradation of Primary Function | Loss of primary function (vehicle inoperable, does not affect safe vehicle operation). | 8 | Major Disruption | 100% of product may have to be scrapped. Line shutdown or stop ship. |
| | Degradation of primary function (vehicle operable, but at reduced level of performance). | 7 | Significant Disruption | A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower. |
| Loss or Degradation of Secondary Function | Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable). | 6 | Moderate Disruption | 100% of production run may have to be reworked off line and accepted. |
| | Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance). | 5 | | A portion of the production run may have to be reworked off line and accepted. |
| Annoyance | Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (> 75%). | 4 | Moderate Disruption | 100% of production run may have to be reworked in station before it is processed. |
| | Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%). | 3 | | A portion of the production run may have to be reworked in-station before it is processed. |
| | Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (< 25%). | 2 | Minor Disruption | Slight inconvenience to process, operation, or operator. |
| No effect | No discernible effect. | 1 | No effect | No discernible effect. |

**RPN = severity X occurrence X detection**

# 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 must 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.

# Risk Evaluation

## 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).

# RPN Assessment Weighting

| S | O | D | RPN |
|---|---|---|---|
| 7 | 2 | 5 | 70 |
| 2 | 7 | 5 | 70 |
| 5 | 7 | 2 | 70 |
| 7 | 5 | 2 | 70 |
| 2 | 5 | 7 | 70 |

| S | O | D | RPN |
|---|---|---|---|
| 10 | 2 | 2 | 40 |
| 3 | 10 | 4 | 120 |
| 2 | 5 | 10 | 100 |

# Alternatives / Additions

- SO (S x O) … defined as **RISK**
- SOD
- SD

| S | O | D | RPN | SxO | SOD | SO | SD |
|---|---|---|---|---|---|---|---|
| 7 | 7 | 3 | 147 | 49 | 70703 | 707 | 703 |
| 7 | 3 | 7 | 147 | 21 | 70307 | 703 | 707 |
| 3 | 7 | 7 | 147 | 21 | 30707 | 307 | 307 |

**Very Different Scenarios**

**Equal RPN Values**

# Recommended Actions

- Recommended Actions
  - Determining Actions
    - Creative Process
    - Provide Solution to Cause of Failure
- Responsibility and Completion Date
- Actions Taken
- Resulting RPN

If no action is currently planned, enter "*none at this time*"

# Recommended Actions

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

| To Reduce: | Consider This Action: | To Accomplish this: |
|---|---|---|
| Severity | Change the design (product or process) | Eliminate or reduce the severity of the failure mode |
| Occurrence | Change the process | Prevent the cause or failure and its effect from occurring |
| Detection | Add to or improve evaluation techniques | Detect that the cause has occurred and take corrective action<br>Detect that the failure mode has occurred and correct |

If no actions are recommended, indicate "*none at this time*"

# 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

# Classification – Very Important

- This column is used to classify any **special product or process characteristics** and to tie them to **CONTROLS**.
- This column may also notify the design team of high priority failure modes for engineering assessment.
- Indicate the differences between product characteristics and final product attributes.
- Uses customer and company-designated special characteristics.
- Suppliers may use their own identification designation.

# Breakout Exercise 5

## Effects, Severity and Action Plans

# Breakout Exercise 5: Effects, Severity and Action Plans

## Instructions

1) For each failure mode identified:
   - List the most probable likely effects.
   - Referring to the Severity index table, determine an appropriate severity rating for each effect.
   - In the S column, for each failure mode enter the highest (most severe) effect from among those identified.
   - Identify what logical action plans should be initiated and what the resultant indices would be after the action was completed.

**Be prepared to share and discuss your output with the class**

# Chapter 3: Developing a PFMEA — What We Covered

## Learning Objectives

You should now be able to:

- Populate a basic PFMEA template
- Distinguish between Product and Process Characteristics
- Describe controls for prevention and detection

## Chapter Agenda

- PFMEA Analytical Sequence
- Preparing the PFMEA
- Failure Mode and Effects
  - **Breakout Exercise 2**
  - **Breakout Exercise 3**
- Controls Prevent / Detect
  - **Breakout Exercise 4**
- Risk Priority Number
- Classification Column
  - **Breakout Exercise 5**

# Chapter 4

## Developing a Control Plan

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# Chapter 4: Developing a Control Plan — What We Will Cover

## Learning Objectives

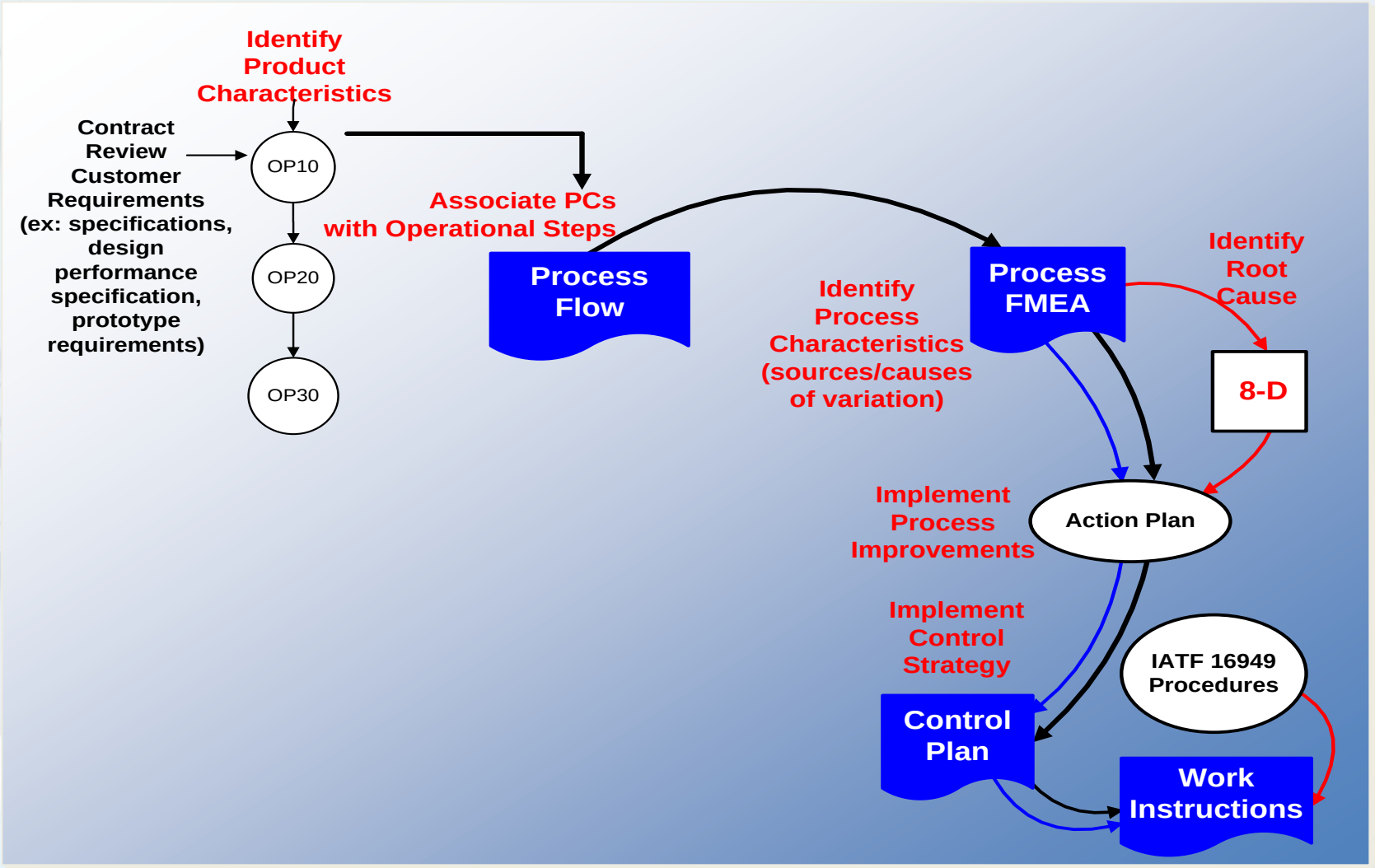
At the end of this chapter, you will be able to:O*M*N*E*X*

- Explain the purpose of a Control Plan
- Populate a generic Control Plan

## Chapter Agenda

- What is a Control Plan?
- Control Plan Header Information
- Control Plan Fields
  - **Breakout Exercise 6**

# 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.

# Production Control Plan: Inputs

**The data or inputs that will be used to develop the Control Plan may include some or all of the following. This data will be reviewed by the multidisciplinary team during their meeting.**

**Primary Source**

- **Process FMEA**
- **Pre-launch Control Plan**
- **Production Trial Run**

**Supporting Information**

- APQP and Control Plan AIAG Reference Manual
- Customer Prints
- In-Process Prints
- Customer and Internal Specifications
- Inspection Plans and Sampling Frequency
- Work Instructions for similar parts or processes
- List of Special Characteristics
- List of Machines, Tools, Jigs or Fixtures
- List of Gauging or Equipment for each measurement, test or inspection
- Performance Testing Requirements
- Design Reviews
- Optimization Data
- **Process Flow Chart**
- System and/or Design FMEA

# 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 | | |
| | | | | | | | | | | | | |

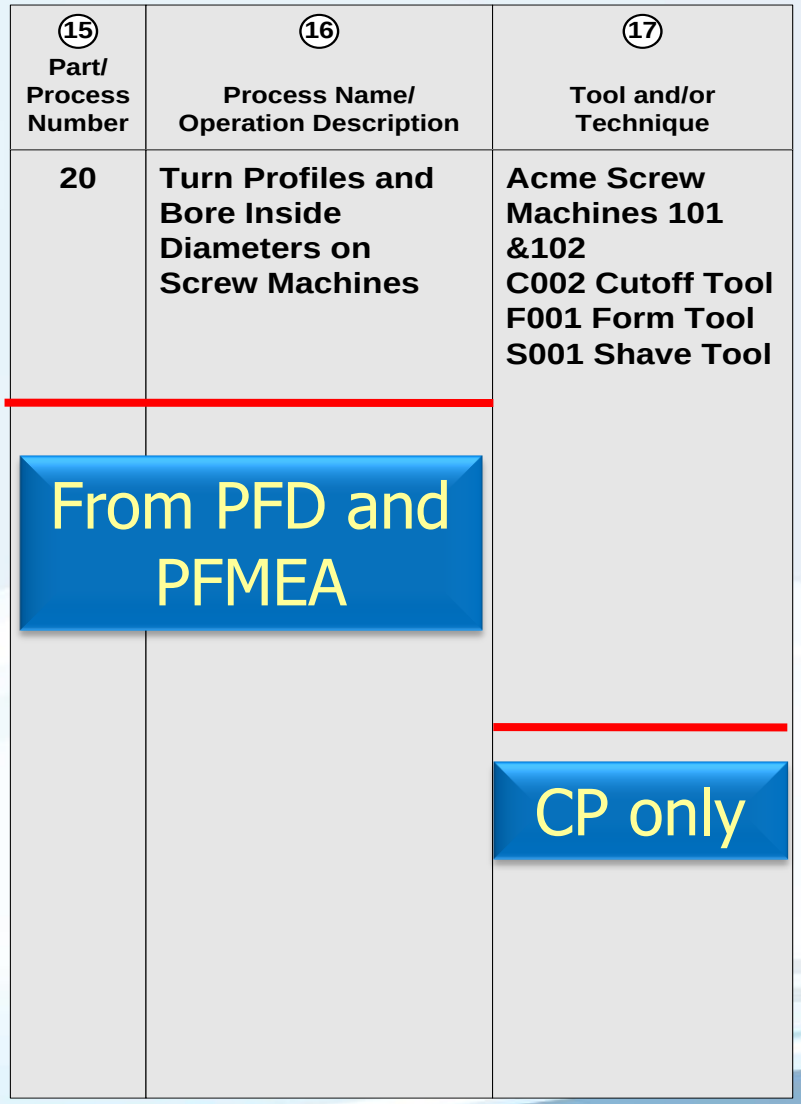
*"An alternate format may be used as long as it contains the same information, as a minimum"—APQP 2nd Edition*

# 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

# Identification of Special Characteristics: Is Action Required?

| Classification | To Indicate | Criteria | Designation |
|---|---|---|---|
| CC | Critical Characteristic | Severity = 9 or 10 | Required |
| SC | Significant Characteristic | Severity = 5 to 8 and Occurrence = 4 to 10 | Candidate |
| OS | Operator Safety | Severity = 9 or10 | Required |

Use customer specific symbols/designations as required

# 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 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
  - Statistical validity of sampling plan

**Control Method must be consistent with PFMEA "Current Controls"**

# Process Capability Studies: Indices

## Robustness of Control Strategy is Based on Risk and Capability

| Results | Interpretation | Control Intensity |
|---|---|---|
| Index Value > 1.67 | The process currently meets customer requirements. After approval, begin production and follow Control Plan. | Low |
| $1.33 \leq$ (Index Value) $\leq 1.67$ | The process is currently acceptable but may require some improvement. Contact your customer and review results of the study. This will require changes to the Control Plan, if not improved prior to the start of volume production. | High |
| Index Value < 1.33 | The process does not currently meet the acceptance criteria. Contact the appropriate customer representative for a review of the study results. | Fix |

**Note: Indices can only be used for stable processes**

# 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

# Nonconforming Outputs – IATF 16949

**The following clauses from IATF 16949:2016 reference control of nonconforming outputs:**

- 8.7 Control of Nonconforming Outputs
  - 8.7.1 [No Title]
  - 8.7.1.1 Customer Authorization for Concessions
  - 8.7.1.2 Control of Nonconforming Product — Customer-specified Process
  - 8.7.1.3 Control of Suspect Product
  - 8.7.1.4 Control of Reworked Product
  - 8.7.1.5 Control of Repaired Product
  - 8.7.1.6 Customer Notification
  - 8.7.1.7 Nonconforming Product Disposition

# Breakout Exercise 6

## Creating a Control Plan

# Breakout Exercise 6: 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 4: Developing a Control Plan — What We Covered

## Learning Objectives

You should now be able to:

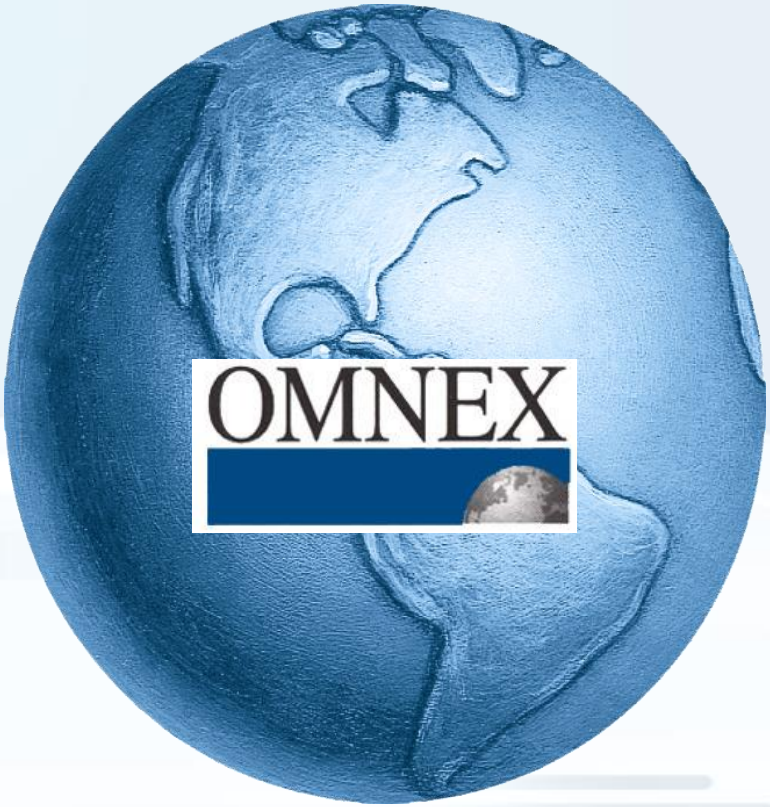
- Explain the purpose of a Control Plan
- Populate a generic Control Plan

## Chapter Agenda

- What is a Control Plan?
- Control Plan Header Information
- Control Plan Fields
  - **Breakout Exercise 6**

# *Thank You!*

## *Questions?*

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# Appendix

## Tables

| Effect | Criteria: Severity of Effect on Product (Customer Effect) | Rank | Effect | Criteria: Severity of Effect on Process (Manufacturing/Assembly Effect) |
|---|---|---|---|---|
| Failure to Meet Safety and/or Regulatory Requirements | Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning. | 10 | Failure to Meet Safety and/or Regulatory Requirements | May endanger operator (machine or assembly) without warning. |
| | Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning. | 9 | | May endanger operator (machine or assembly) with warning. |
| Loss or Degradation of Primary Function | Loss of primary function (vehicle inoperable, does not affect safe vehicle operation). | 8 | Major Disruption | 100% of product may have to be scrapped. Line shutdown or stop ship. |
| | Degradation of primary function (vehicle operable, but at reduced level of performance). | 7 | Significant Disruption | A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower. |
| Loss or Degradation of Secondary Function | Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable). | 6 | Moderate Disruption | 100% of production run may have to be reworked off line and accepted. |
| | Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance). | 5 | | A portion of the production run may have to be reworked off line and accepted. |
| Annoyance | Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (> 75%). | 4 | Moderate Disruption | 100% of production run may have to be reworked in station before it is processed. |
| | Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%). | 3 | | A portion of the production run may have to be reworked in-station before it is processed. |
| | Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (< 25%). | 2 | Minor Disruption | Slight inconvenience to process, operation, or operator. |
| No effect | No discernible effect. | 1 | No effect | No discernible effect. |

**RPN = severity X occurrence X detection**

# PFMEA Occurrence Table – Example

| Likelihood of Failure | Criteria: Occurrence of Cause – PFMEA (Incidents per items/vehicles) | Rank |
|---|---|---|
| **Very High** | ≥ 100 per thousand \| ≥ 1 in 10 | **10** |
| **High** | 50 per thousand \| 1 in 20 | **9** |
| | 20 per thousand \| 1 in 50 | **8** |
| | 10 per thousand \| 1 in 100 | **7** |
| **Moderate** | 2 per thousand \| 1 in 500 | **6** |
| | .5 per thousand \| 1 in 2,000 | **5** |
| | .1 per thousand \| 1 in 10,000 | **4** |
| **Low** | .01 per thousand \| 1 in 100,000 | **3** |
| | ≤ .001 per thousand \| 1 in 1,000,000 | **2** |
| **Very Low** | Cause is eliminated through preventive control | **1** |

| Opportunity for Detection | Criteria: Likelihood of Detection by Process Control | | Rank | Likelihood of Detection |
|---|---|---|---|---|
| **No detection opportunity** | No current process control; Cannot detect or is no analyzed. | | **10** | **Almost Impossible** |
| **Not likely to detect at any stage** | Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits). | | **9** | **Very Remote** |
| **Problem Detection Post-Processing** | Failure Mode detection post-processing by operator through visual/tactile/audible means. | | **8** | **Remote** |
| **Problem Detection at Source** | Failure Mode detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.) | | **7** | **Very Low** |
| **Problem Detection Post-Processing** | Failure Mode detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.) | | **6** | **Low** |

| Opportunity for Detection | Criteria: Likelihood of Detection by Process Control | | Rank | Likelihood of Detection |
|---|---|---|---|---|
| **Problem Detection at Source** | Failure Mode or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for set-up causes only). | | **5** | **Moderate** |
| **Problem Detection Post-Processing** | Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing. | | **4** | **Moderately High** |
| **Problem Detection at Source** | Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing. | | **3** | **High** |
| **Error Detection and/or Problem Prevention** | Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made. | | **2** | **Very High** |
| **Detection not Applicable; Error Prevention** | Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been error-proofed by process/product design. | | **1** | **Almost Certain** |