PFMEAs per the AIAG/VDA FMEA Handbook

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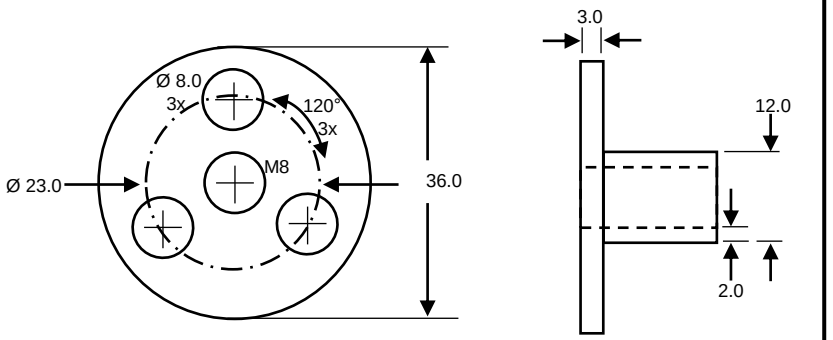
Introduction

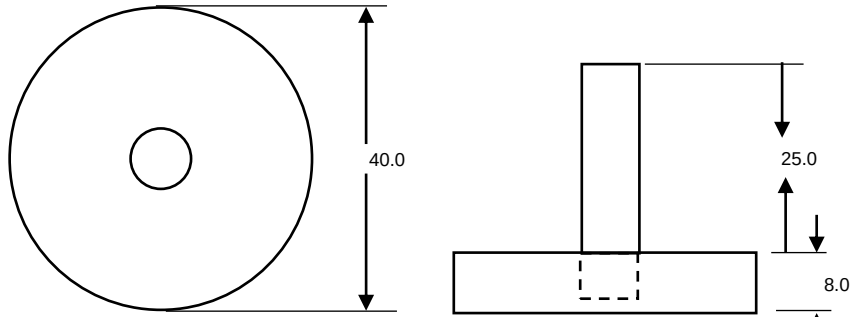
- This workshop will present PFMEAs (Process Failure Modes and Effects Analysis) using the seven steps described in the AIAG/VDA FMEA Handbook
  - The session will consist of both lecture, and a practical example with participants creating a PFMEA for a simple product
  - After completion of this workshop, participants will be able to:
    - List the seven steps in the AIAG/VDA FMEA Handbook
    - Describe the difference between failure causes, failure modes, and failure effects
    - Explain the use of system elements in PFMEAs
    - Rate severity, occurrence, and detection
    - Prioritize using AP (Action Priority)

Introduction

- A hypothetical “adjustable foot” will be used for examples



Mounting Plate
4130 steel with tensile strength minimum 993 Mpa and hardness 31 HRC
Deburr



Foot Subassembly
Polyoxymethylene (POM) base with overmolded 33.0 M8 rod

Adjustable Foot

Failure Modes and Effects Analysis

- According to a poem by Lowe (1980), a kingdom fell due to a lack of a nail

  - Sometimes it is the simple details that matter
    - An FMEA can be performed to identify the “simple details” to ensure action are taken to avoid failures

Failure Modes and Effects Analysis

- FMEAs may be done for the design of a product or the manufacturing / assembly process
  - A DFMEA (Design-Failure Modes and Effects Analysis) is for the design concept
    - A DFMEA may be for a component, assembly, or a complete system
  - A PFMEA is for the manufacturing or assembly process

Failure Modes and Effects Analysis

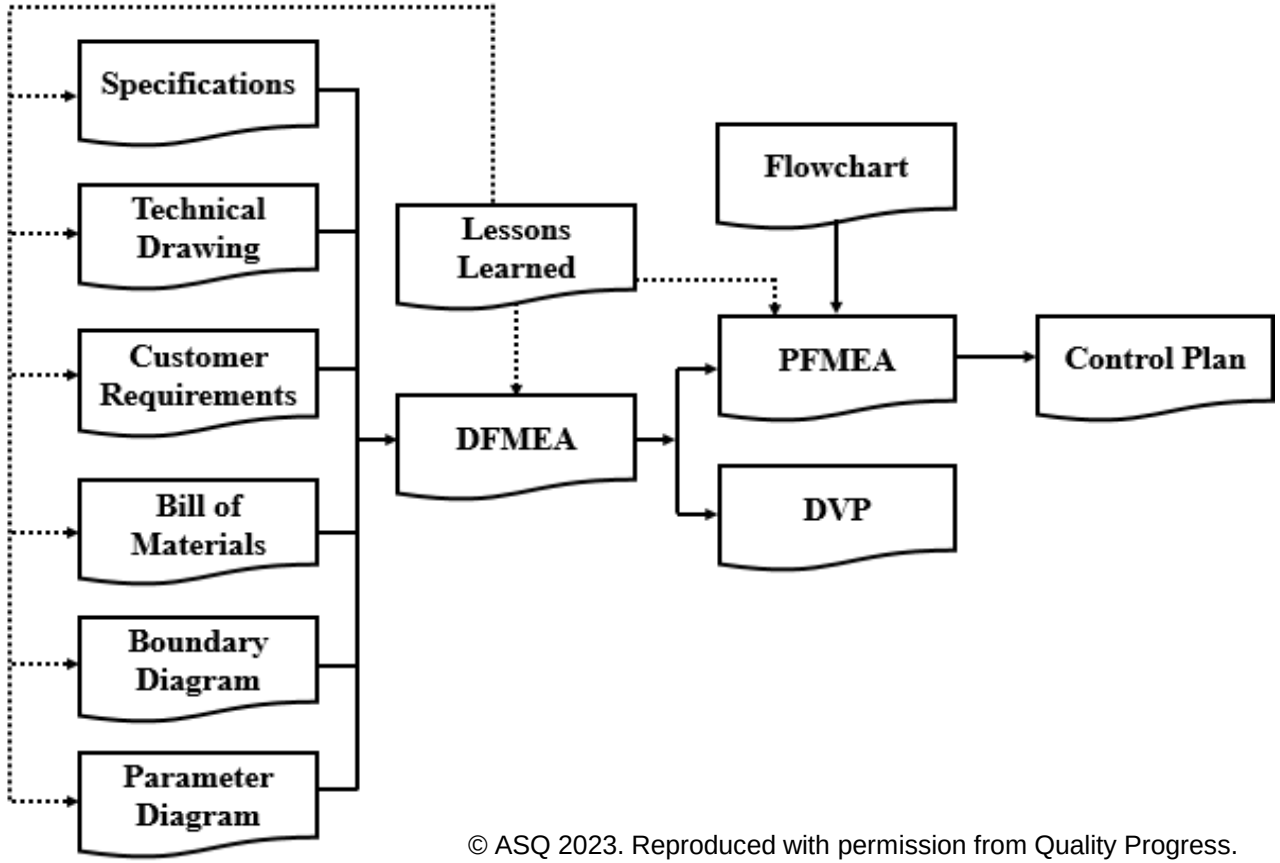
- Advantages of FMEAs include
  - Reduction or elimination of
    - Scrap and rework
    - Customer complaints
    - Safety risks
    - Production stoppages
  - Increases in
    - Yield
  - Repository for organizational lessons learned
  - Identification of risks
  - Conformance with ISO/TS 16949

Risk Identification and Mitigation Landscape

- A PFMEA interacts with other documents
  - Specifications, drawings, requirements, and bills of material are inputs for both the DFMEA and the PFMEA
  - Lessons learned are also inputs for DFMEAs and PFMEAs
  - The DFMEA is an input for the PFMEA
    - A failure cause could be in both the DFMEA and the PFMEA
      - Diameter could be too small due to a too small dimension on the drawing in the DFMEA and too small due to wrong drill used in the PFMEA
      - The failure mode and failure effect could be exactly the same
  - A process flow diagram/flow chart is also used for creating a PFMEA

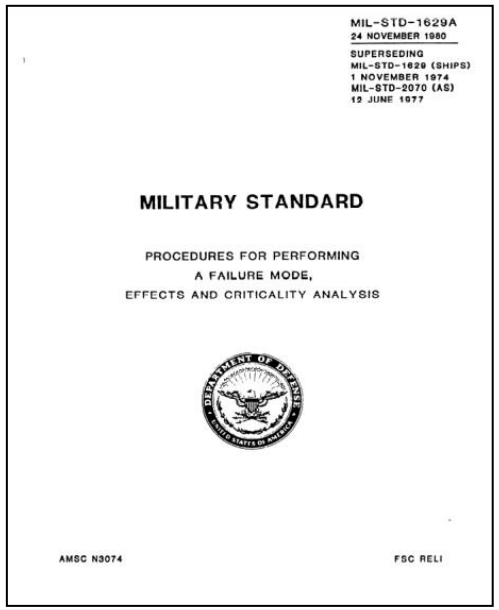
Risk Identification and Mitigation Landscape

- The PFMEA is used to develop the control plan



FMEA Standards

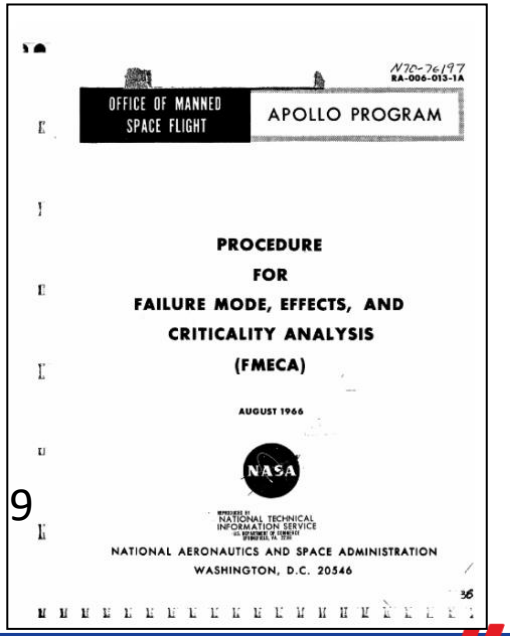
- Failure Modes and Effects Analysis (FMEA) was introduced in the 1949 military standard MIL-P-1629
  - FMEAs were used for NASA's Apollo program in the 1960s
  - Then used by Ford Motor Company in the 1970s
  - Spread across industries by the 1980s


MIL-STD-1629A
24 NOVEMBER 1980
SUPERSEDING
MIL-STD-1629 (SHIPS)
1 NOVEMBER 1974
MIL-STD-2070 (AS)
13 JUNE 1977

MILITARY STANDARD

PROCEDURES FOR PERFORMING
A FAILURE MODE,
EFFECTS AND CRITICALITY ANALYSIS

AMSC N3074 FSC RELI


N70-76197
NASA-006-013-1A

OFFICE OF MANNED SPACE FLIGHT | APOLLO PROGRAM

PROCEDURE
FOR
FAILURE MODE, EFFECTS, AND
CRITICALITY ANALYSIS
(FMECA)

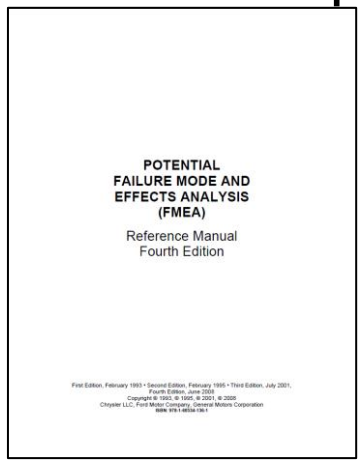
AUGUST 1966

NASA

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
WASHINGTON, D.C. 20546

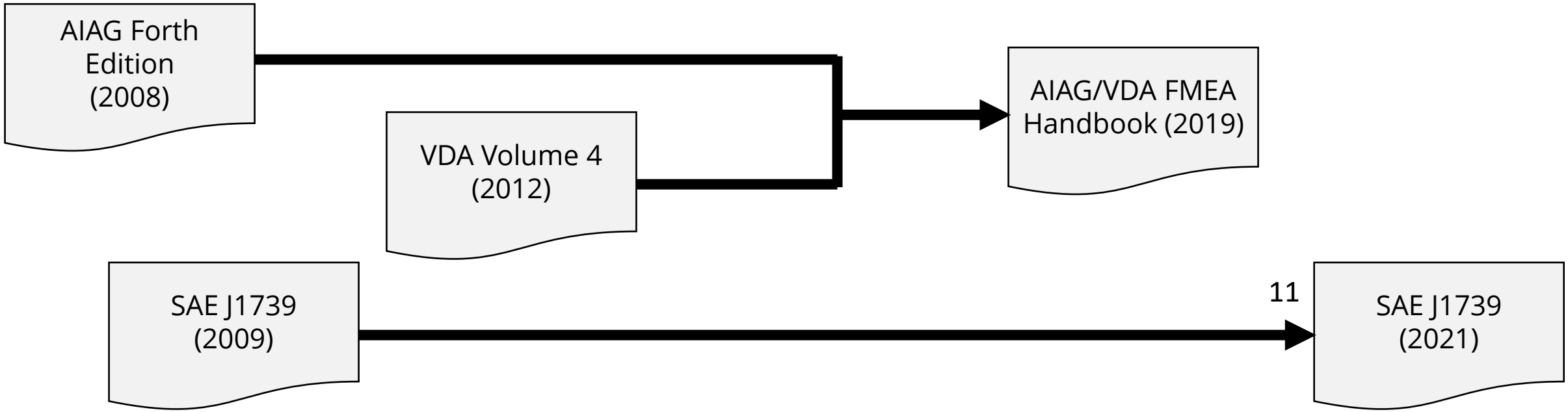
FMEA Standards

- The automotive industry has had many standards including AIAG FMEA Manual 4th ed. and SAE J1739 for American companies and VDA's (Verband der Automobilindustrie) VDA Volume 4: Product and Process FMEA for German companies
  - One supplier may need multiple DFMEAs to meet customer specific requirements
  - AIAG/VDA FMEA Handbook harmonized the approaches used by AIAG and VDA in 2019
  - SAE J1739 updated in 2021



FMEA Standards

- The SAE J1739 update is essentially old style PFMEAs with the option to use RPN (Risk Priority Number) or AP (Action Priority) for prioritization
  - Suggestion: Use AIAG/VDA form sheet with both AP and RPN and remove whichever is not needed



FMEA Standards

- An AIAG/VDA FMEA Handbook Errata sheet was released in June 2020
  - Available at https://www.aiag.org/docs/default-source/product/aiag-vda-fmea-handbook-1---errata-sheet---english---june-2020.pdf?sfvrsn=32f3199d_8
  - A second printing of the AIAG/VDA FMEA Handbook was published in June 2022

PFMEA - Introduction to PFMEAs

- The AIAG/VDA FMEA Handbook has a seven step approach:
  - System analysis:
    - Step 1 - Planning and preparation
    - Step 2 - Structure analysis
    - Step 3 - Function analysis
  - Failure analysis and risk mitigation:
    - Step 4 - Failure analysis
    - Step 5 - Risk analysis
    - Step 6 - Optimization
  - Risk communication:
    - Step 7 - Results documentation

PFMEA - Step 1: Planning and Preparation

- Form a PFMEA team
  - Team should be cross-functional
  - Moderator/facilitator
  - Process owner
  - Process operator(s)
  - Manufacturing engineers
  - SMEs (Subject Matter Experts)
    - Should be invited only when needed

PFMEA - Step 1: Planning and Preparation

- Review relevant documents
  - Drawings
  - Customer requirements
  - Specifications
  - PFD (Process Flow Diagram)
  - DFMEA
  - Previous, comparable PFMEAs
  - Legal requirements

PFMEA - Step 1: Planning and Preparation

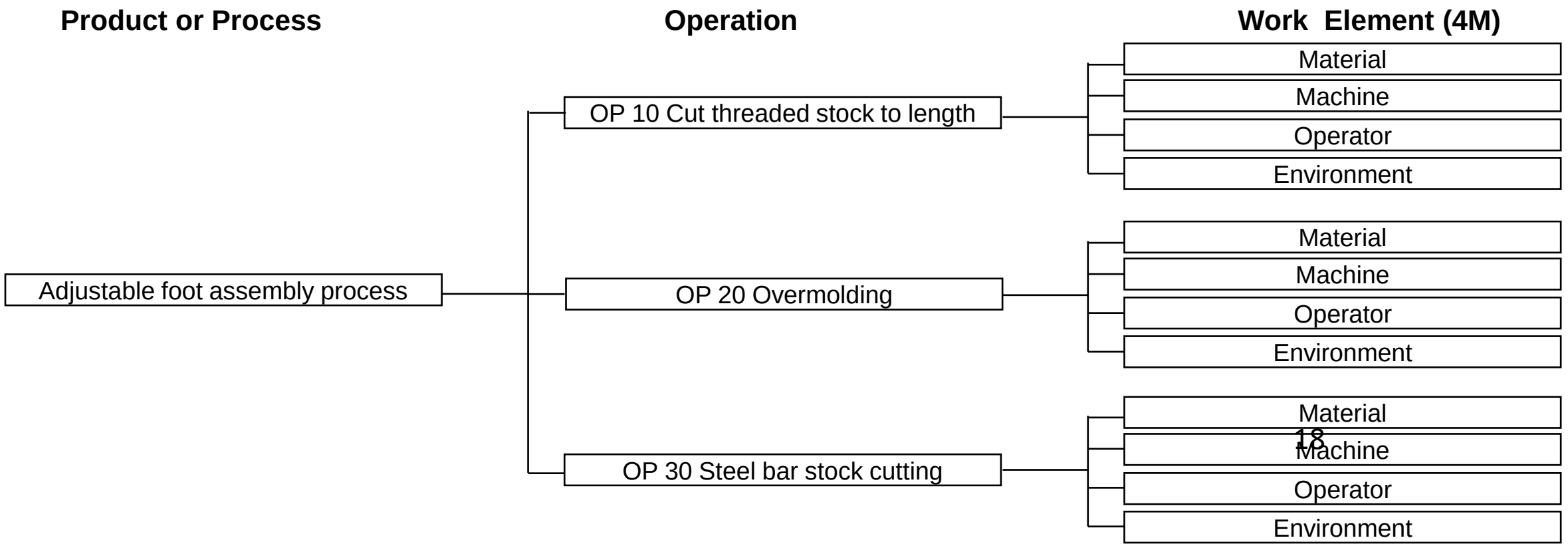
- Establish project plan and timing
  - Schedule PFMEA meetings
    - One hour is not enough time
    - Two hours is ideal
    - Four or more hours may be too much
  - Schedule reviews
    - Could be after completion of each step
    - May be after completion of each major phase
      - System analysis, failure analysis and risk mitigation, and risk communication
    - Can also be part of organizations internal review process

PFMEA - Step 2: Structure Analysis

- The system is analyzed using a structure tree in software, or a PFD if using a spreadsheet
  - There are typically three system levels, but could be more
    - The name of the product or process is at the top level
      - The failure effect is listed here
    - The process step and operation number are at the second level
      - The failure mode is listed here
    - The process work element is the third level and may be based on the 4Ms of an Ishikawa diagram
      - The failure cause is located here

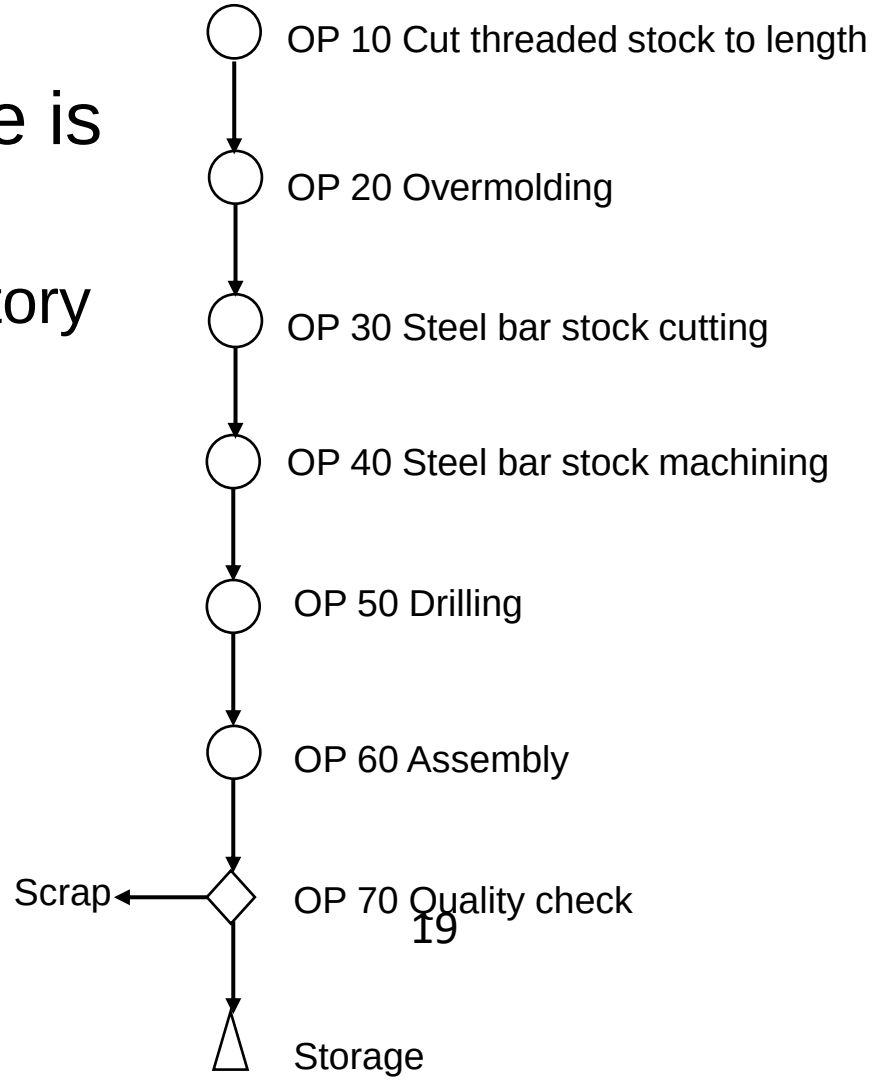
PFMEA - Step 2: Structure Analysis

- The structure tree is created in software



PFMEA - Step 2: Structure Analysis

- A PFD is required if special FMEA software is not used to create a structure tree
  - A PFD should be used even when not mandatory



PFMEA - Step 2: Structure Analysis

- Example of a structure analysis in the form sheet

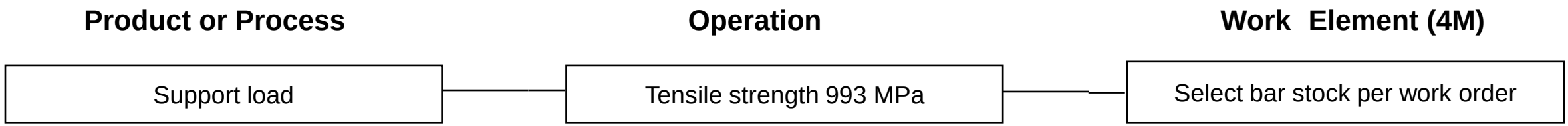
Step 2: Structure Analysis		
Product or process name	**Process step and operation number**	**Process 4M work element**
Adjustable foot assembly	OP 30 Steel bar stock cutting	Operator
Adjustable foot assembly	OP 30 Steel bar stock cutting	Machine

PFMEA - Step 3: Function Analysis

- Functions or requirements are identified during using a function net in software, or in the form sheet
  - Functions describe what is intended to be done using an action verb and a noun in present tense
  - Requirements may be
    - Legal, customer, standards, or internal requirements
      - Requirements that a product must meet, such as “no scrap”
    - Product characteristics
      - Generally defined by drawings and testable on the product
    - Process characteristics
      - Actions taken when producing the product and only testable when they happen

PFMEA - Step 3: Function Analysis

- Function nets link functions together in software
  - May need to be manually created
  - May also be created automatically anytime failures are linked



PFMEA - Step 3: Function Analysis

- Example of a function analysis in a PFMEA form sheet

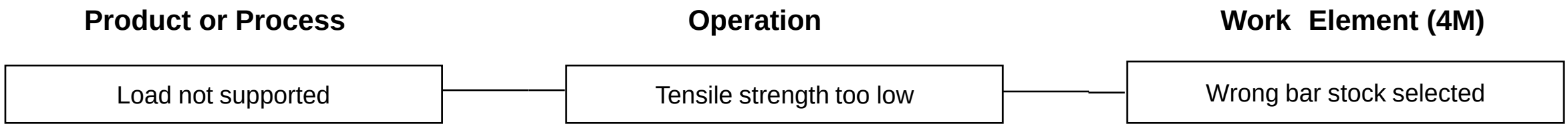
Step 3: Function Analysis		
Function of system, assembly, component, or process	**Function of process step or product characteristic**	**Function of process work element or process characteristic**
Support load	Tensile strength 993 Mpa	Select bar stock per work order
Scrap avoidance	Length 37.0 mm	Saw blade must be sufficiently sharp

PFMEA - Step 4: Failure Analysis

- Failures are the negation of the functions and are identified using an Ishikawa diagram or a failure net in FMEA software
  - Failure effects are the consequence of the failure mode
    - May happen in-house, at the customer, and/or at the end user
  - The failure mode is what has gone wrong with the product
    - Happens at the component, assembly, or system
  - The failure cause results in the failure mode
    - Happens at the process step

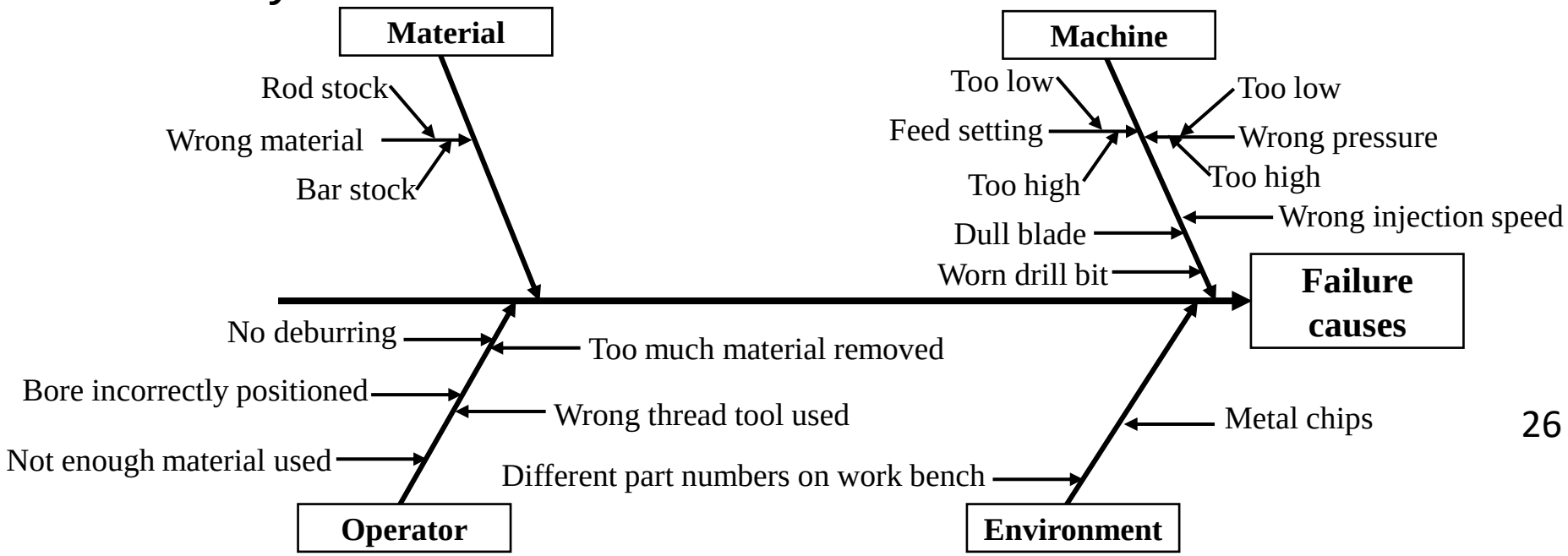
PFMEA - Step 4: Failure Analysis

- Example of a failure net
  - One failure cause could lead to multiple modes
  - One failure mode may lead to multiple failure effects



PFMEA - Step 4: Failure Analysis

- Example of an Ishikawa diagram with the 4Ms for finding failure causes
  - The exact wording of the Ms may vary
  - 6Ms may also be used



PFMEA - Step 4: Failure Analysis

- Example of a failure analysis in the PFMEA form sheet

Step 4: Failure Analysis			
Failure effect(s)	**Severity**	**Failure mode(s)**	**Failure cause(s)**
Load not supported	8	Tensile strength too low	Wrong bar stock selected
Insufficient material for machining -> scrap	7	Length too short	Dull blade

PFMEA - Step 4: Failure Analysis

- Identify failure effects, failure modes, and failure causes
  - Failure effect is the consequence of the failure at the next higher level and/or the end user
  - Failure mode is the way in which the system element fails
  - Failure cause is the reason for the failure and happens at the next lower system element or characteristic

PFMEA - Step 5: Risk Analysis

- Current controls for prevention and detection are identified and the occurrence and detection ratings are assigned
  - The actions are ones that are planned and will be performed
  - Ratings are identified with the help of tables

PFMEA - Step 5: Risk Analysis

- Examples of prevention actions include
  - Visual aids
  - Process instructions
  - Machine maintenance
  - Poke-yoke for prevention
  - Operator training
  - Setup instructions

PFMEA - Step 5: Risk Analysis

- Examples of detection actions include
  - Measuring parts
    - First part, last part, first and last part, random sampling
  - Visual inspection
  - Material testing
  - Function check
  - Camera system
  - Check torque
  - Poke-yoke for detection

PFMEA - Step 5: Risk Analysis

- Severity occurrence, and detection ratings are assigned with the help of tables
  - Severity is the failure effect’s impact
    - Raided at the failure effect
  - Occurrence is the chance of the failure cause occurring
    - Rated at the prevention action
  - Detection is the ability to detect the failure mode or failure cause
    - Rated at the detection action

PFMEA - Step 5: Risk Analysis

S	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 product or operator.	
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.	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance	**Loss** of primary function during expected service life.	
7		Product may have to be sorted and a portion (les than 100%) scrapped; deviation form primary process; decreased line speed or added manpower	Line shutdown from 1 hour up to production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance.	**Degradation** of primary function during expected service life.	
6	**Moderately low**	100% of production run may have to be reworked off line and accepted.	Line shutdown up to one hour.	**Loss** of secondary function.	
5		A portion of 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 function.	
4		100% of production run may have to be reworked in-station before it is processed.	Defective product triggers significant reaction plan; additional effective 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 no 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.	

Severity table © AIAG/VDA Reproduced with permission

PFMEA - Step 5: Risk Analysis

O	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		Best Practices: Behavioral or Technical		
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		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 - Step 5: Risk Analysis

D	Ability to Detect	Detection Method Maturity	Opportunity for Detection	Corporate or Product Line Examples
10	Very Low	No testing or inspection method has been established or is known.	The failure 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 though 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 of 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.	
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 of 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 (automated or 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).	
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 the failure mode **downstream**, prevent further processing or system will identify 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 the failure mode **in-stream**, prevent further processing or system will identify 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.	
2		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 failure mode or failure cause.		

Detection table © AIAG/VDA Reproduced with permission

PFMEA - Step 5: Risk Analysis

- Traditional RPNs (Risk Priority Number) have been replaced by AP (Action Priority) in the AIAG/VDA FMEA Handbook
  - Thee are three possible AP values
    - High: Actions must be implemented or and a reason must be documented if no actions are implemented
    - Medium: Actions should be considered and a reason can be documented if no actions are implemented
    - Low: Actions not necessary

PFMEA - Step 5: Risk Analysis

- AP uses weighted values with emphasis on severity followed by occurrence
  - Severity 3 with occurrence 10 with detection 4 = RPN 120 and AP = L
  - Severity 10 with occurrence 4 with detection 2 = RPN 80 and AP = H

		Severity Rating															
		1	2 - 3		4 - 6				7 - 8				9 - 10				
Ocurrence Rating	8 - 10	Low	Low	Medium	Medium	Medium	High	High	High	High	High	High	High	High	High	High	High
	6 - 7	Low	Low	Low	Low	Medium	Medium	Medium	High	High	High	High	High	High	High	High	High
	4 - 5	Low	Low	Low	Low	Low	Low	Medium	Medium	Medium	Medium	High	Medium	High	High	High	High
	2 - 3	Low	Low	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Low	Low	Medium	High	High
	1	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
		1 - 10	1 -4	5 - 10	1	2 - 4	5 - 6	7 - 10	1	2 - 4	5 - 6	7 - 10	1	2 - 4	5 - 6	7 - 10	
		Detection Rating															

AP matrix. Modified from Barsalou (2022) under CC BY 4.0

PFMEA - Step 5: Risk Analysis

- PFMEAs per SAE J1739 may still use RPN
  - RPN is equal to severity x occurrence x detection
    - 8 x 5 x 6 = 240
    - Used for prioritization
    - Go from highest to lowest
    - “Cutoff scores” are not advisable
    - Also consider criticality, which is severity x occurrence
      - 10 x 5 x 5 = 250 is worse than 8 x 5 x 9 = 360

PFMEA - Step 5: Risk Analysis

- Example of a risk analysis in the PFMEA form sheet

5: Risk Analysis					
Current prevention actions	**Occurrence**	**Current detection actions**	**Detection**	**AP**	**Special Characteristics**
Compare material label to work order	7	Overload test of first and last part	5	H	
Blade change interval per process instruction	5	100% length check with calipers	6	M	

PFMEA - Step 6: Optimization

- Optimization actions are taken to improve the AP (or RPN if used)
  - Prevention and/or detection actions are described and somebody is assigned responsibility and a deadline is given
    - Optimization actions can be taken even if it they have no impact on the AP
  - Actions must be tracked

PFMEA - Step 6: Optimization

- A status must be listed when optimization is needed
  - Open
    - An optimization is needed, but has not been defined
  - Decision pending
    - Optional status for when a decision has not been reached
  - Implementation pending
    - Optional status for when an optimization is in progress
  - Completed
    - Optimization implemented, verified, and documented
  - Not implemented
    - Decision made not to implement an optimization

PFMEA - Step 6: Optimization

- Example of a optimization in a PFMEA form sheet

Step 6: Optimization									
Planned improvement actions	**Responsible**	**Due date**	**Status**	**Implemented improvement actions**	**Completion date**	**Severity**	**Occurrence**	**Detection**	**AP**
P: Implement bar code scanning	J. Schmidt	22 May	Impl. pending			8	(3)	5	AP

PFMEA - Step 7: Results Documentation

- Results are communicated and improvements are documented
  - A company specific document should be created to communicate:
    - Purpose and scope of the PFMEA
    - Timing and team members
    - An explanation of how functions were identified
    - A summary of high risk failures together with actions taken to address them
    - Timing for continuing actions
    - Commitment to review and update the PFMEA during mass production and when failures occur

PFMEA - Afterwards

- PFMEAs are a “living document”
  - Update with lessons learned
    - Examples:
      - Causes of scrap or rework
      - Customer complaints
  - When the product or process changes

PFMEA - Afterwards

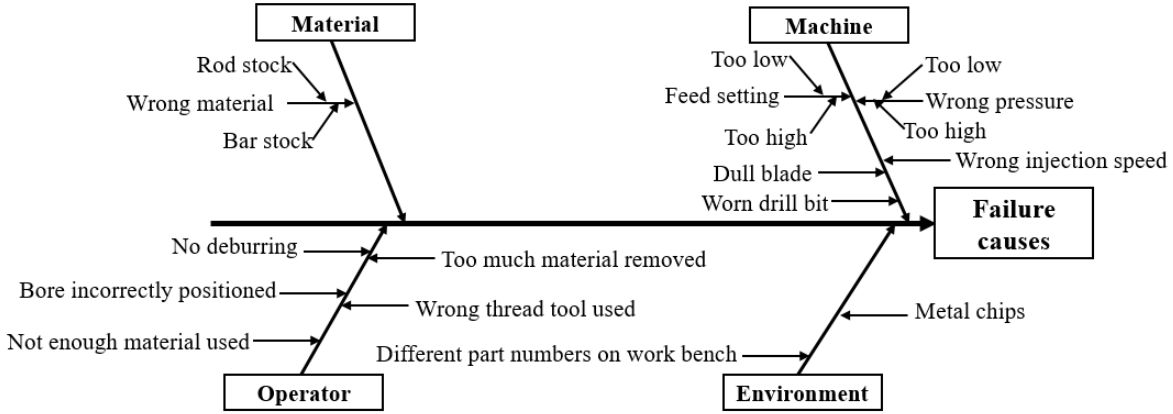
- A completed PFMEA can be used as a basis for future PFMEAs
  - May be known as a template, corporate PFMEA, baseline PFMEA, foundation PFMEA, gold standard PFMEA, best practice PFMEA
  - The template should be updated based on lessons learned from individual PFMEAs
  - When using a PFMEA as a template, consider moving competed optimization actions to current actions

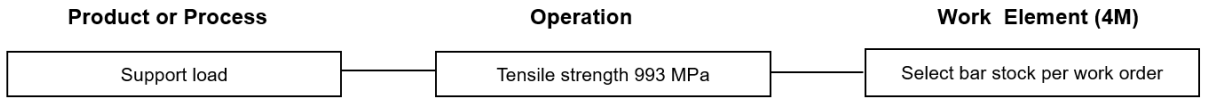
PFMEA - Review Questions

- Which of the following is not a PFMEA input?
  - A. DFMEA
  - B. Control plan
  - C. Process Flow Diagram
  - D. Technical drawing

PFMEA - Review Questions

- Is an Ishikawa diagram mandatory when using a failure net in FMEA software?
  - A. Yes
  - B. No



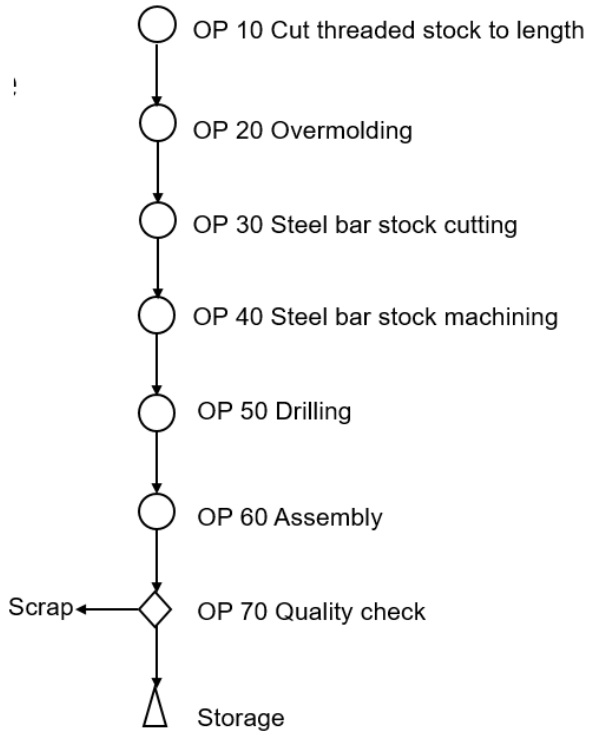


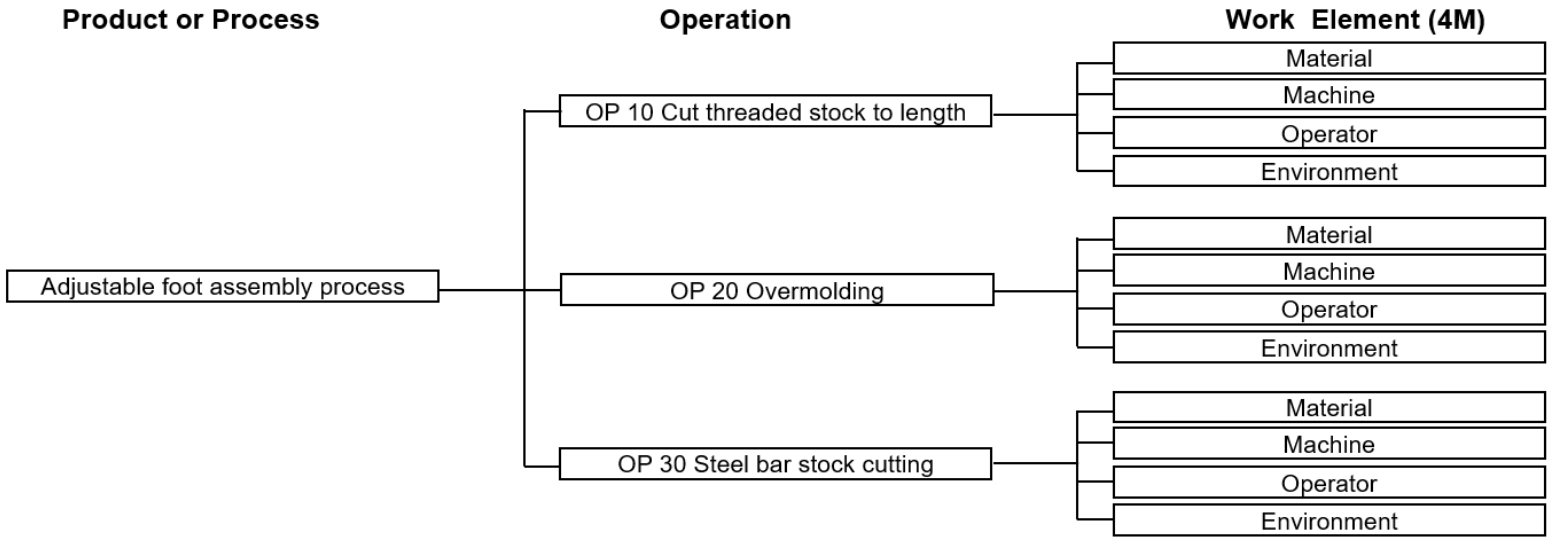
PFMEA - Review Questions

- Which of the following is the earliest FMEA standard?
  - A. AIAG FMEA Reference Manual, 4th ed.
  - B. AIAG/VDA FMEA Handbook
  - C. MIL-P-1629 Procedure for Failure Mode, Effects, and Criticality Analysis
  - D. SAE J1739 from 2009

PFMEA - Review Questions

- Is a PFD mandatory when using a structure tree in FMEA software?
  - A. Yes
  - B. No





PFMEA - Review Questions

- Which of the following is an example of a product characteristic?
  - A. Diameter 8.1 +/- 0.05
  - B. Diameter too big
  - C. Hardness test
  - D. Use correct drill bit

PFMEA - Review Questions

- Which of the following is an example of a detection control?
  - A. Check first and last part
  - B. CNC machine
  - C. Oil level too low
  - D. Use calibrated equipment

PFMEA - Review Questions

- Which of the following is an example of a function?
  - A. Length 44.4 +/- 0.5 mm
  - B. Provide a secure connection
  - C. Test the first part produced
  - D. Work instruction for machine setup

PFMEA - Review Questions

- What should be prioritized first when using AP?
  - A. S = 8, O = 2, D = 4
  - B. S = 7, O = 5, D = 6
  - C. S = 6, O = 8, D = 5
  - D. S = 6, O = 7, D = 2

		Severity Rating														
		1	2 - 3		4 - 6				7 - 8				9 - 10			
Ocurrence Rating	8 - 10	Low	Low	Medium	Medium	Medium	High	High	High	High	High	High	High	High	High	High
	6 - 7	Low	Low	Low	Low	Medium	Medium	Medium	High	High	High	High	High	High	High	High
	4 - 5	Low	Low	Low	Low	Low	Low	Medium	Medium	Medium	Medium	High	Medium	High	High	High
	2 - 3	Low	Low	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Low	Low	Medium	High
	1	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
		1 - 10	1 -4	5 - 10	1	2 - 4	5 - 6	7 - 10	1	2 - 4	5 - 6	7 - 10	1	2 - 4	5 - 6	7 - 10
		Detection Rating														

AP matrix. Modified from Barsalou (2022) under CC BY 4.0

PFMEA - Review Questions

- Which of the following is an example of a prevention control?
  - A. Inspection
  - B. Dimensional deviation
  - C. Work instruction for machine setup
  - D. Wrong part used

PFMEA - Review Questions

- What should be prioritized first when using criticality?
  - A. S = 8, O = 3, D = 7
  - B. S = 8, O = 5, D = 4
  - C. S = 7, O = 2, D = 4
  - D. S = 6, O = 6, D = 3

PFMEA - Review Questions

- Which of the following is an example of a process characteristic?
  - A. All parts 100% checked
  - B. Calibration
  - C. Leak
  - D. Set required turning speed

Create a PFMEA for an Adjustable Foot Assy.

OP 10 Cut threaded stock to length
Rod stock taken form storage and to cut length per drawing

OP 20 Overmolding
Rod placed in tooling, tooling placed in machine, granulate holder filled, machine set to 230°C, mold heated to 105°C, pressure set to 120 MPa, injection speed set to high

OP 30 Steel bar stock cutting
Diameter 39 mm bar stock cut to length 37mm

OP 40 Steel bar stock machining
Length cut per drawing and outer and middle diameters reduced per drawing with speed 890 Vc and feed 0.255 Fs, and burrs removed

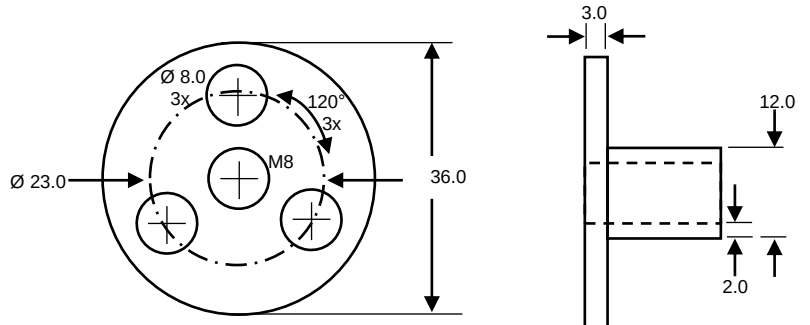
OP 50 Drilling
Four diameters drilled and M8 diameter threaded

OP 60 Assembly
Foot assembly screwed onto mounting plate to an overall length of 35.0 mm +/- 1.0 mm

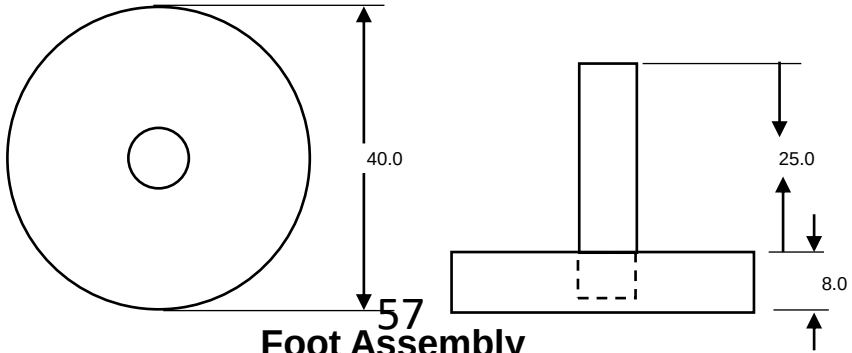
Scrap ← **OP 70 Quality check**

Storage
Required quality checks performed

Adjustable Foot



Mounting Plate
4130 steel with tensile strength minimum 993 Mpa and hardness 31 HRC
Deburr



Foot Assembly
Polyoxymethylene (POM) with overmolded 33.0 mm M8 rod

Rate PFMEA Severity

S	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 product or operator.	
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.	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance	**Loss** of primary function during expected service life.	
7		Product may have to be sorted and a portion (les than 100%) scrapped; deviation form primary process; decreased line speed or added manpower	Line shutdown from 1 hour up to production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance.	**Degradation** of primary function during expected service life.	
6	**Moderately low**	100% of production run may have to be reworked off line and accepted.	Line shutdown up to one hour.	**Loss** of secondary function.	
5		A portion of 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 function.	
4		100% of production run may have to be reworked in-station before it is processed.	Defective product triggers significant reaction plan; additional effective 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 no 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.	

Rate PFMEA Occurrence

O	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		Best Practices: Behavioral or Technical		
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		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.	

Rate PFMEA Detection

D	Ability to Detect	Detection Method Maturity	Opportunity for Detection	Corporate or Product Line Examples
10	Very Low	No testing or inspection method has been established or is known.	The failure 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 though 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 of 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.	
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 of 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 (automated or 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).	
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 the failure mode **downstream**, prevent further processing or system will identify 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 the failure mode **in-stream**, prevent further processing or system will identify 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.	
2		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 failure mode or failure cause.		

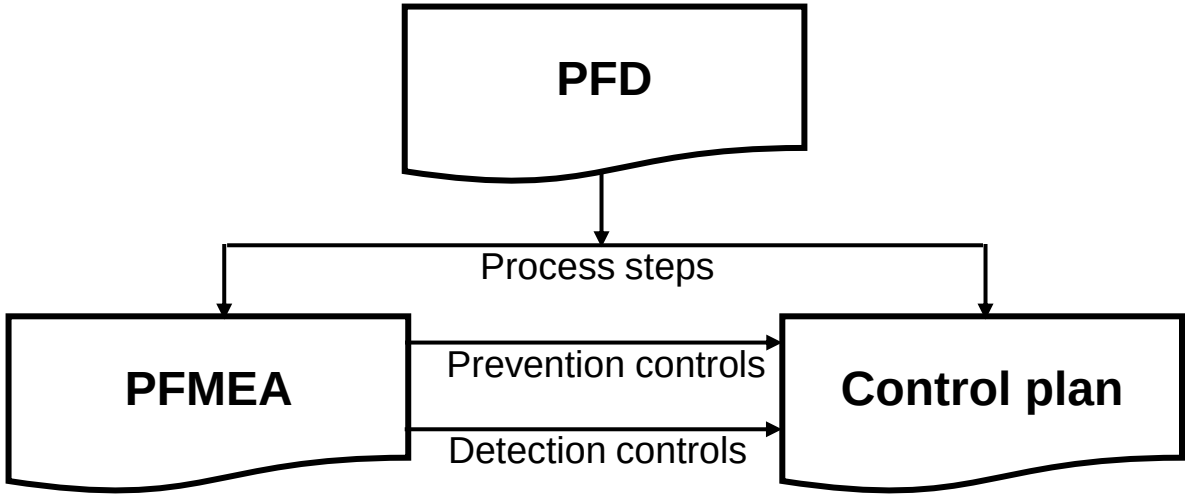
Rate PFMEA Action Priority

		Severity Rating															
		1	2 - 3		4 - 6				7 - 8				9 - 10				
Ocurrence Rating	8 - 10	Low	Low	Medium	Medium	Medium	High	High	High	High	High	High	High	High	High	High	High
	6 - 7	Low	Low	Low	Low	Medium	Medium	Medium	High	High	High	High	High	High	High	High	High
	4 - 5	Low	Low	Low	Low	Low	Low	Medium	Medium	Medium	Medium	High	Medium	High	High	High	High
	2 - 3	Low	Low	Low	Low	Low	Low	Low	Low	Low	Medium	Medium	Low	Low	Medium	High	High
	1	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
		1 - 10	1 -4	5 - 10	1	2 - 4	5 - 6	7 - 10	1	2 - 4	5 - 6	7 - 10	1	2 - 4	5 - 6	7 - 10	
		Detection Rating															

AP matrix. Modified from Barsalou (2022) under CC BY 4.0

Control Plan Overview

- Control plans document inspection actions
  - Developed based on the PFD
  - Prevention and detection controls from the PFMEA can be copied to the control plan



Control Plan Overview - Product, Process, and Equipment

- The name of the product or process is listed in the control plan
  - The product name should be used when all product-related operations are in one control plan
  - The process name is more suitable when the control plan is based on process type and not the individual product

Control Plan Overview - Product, Process, and Equipment

- The process operation step and operation number (when used) are listed
  - The process step is the name of the operation, or a description of what happens at the process step
  - The operation number is often listed as “OP”

Control Plan Overview - Product, Process, and Equipment

- Example of product/process name, process step and operation number, and the equipment used listed in the control plan

Product or process name	Process step and operation number	Machine, devise, jig, or tool
Adjustable foot assembly	OP 30 Steel bar stick cutting	Saw
Adjustable foot assembly	OP 30 Steel bar stick cutting	Saw

Control Plan Overview - Characteristics

- Characteristics describe what is being checked
  - A characteristic number can be listed
    - Optional: Not needed if characteristics are not assigned a unique number

Control Plan Overview - Characteristics

- A product characteristic is on the process
  - Can be assessed after production of the part
  - If the PFMEA control is “measure diameter of five parts,” the diameter could be the product characteristic
  - The product characteristic must be clearly identifiable
    - Listing only “Diameter” is only acceptable if the specific diameter can be identified, such as by looking at the tolerance listed in the control plan

Control Plan Overview - Characteristics

- A product process characteristic is at the process
  - Can be only be assessed when the process happens
    - An exception may be when data is automatically recorded
  - If the PFMEA control is “Setup per work instruction,” the setup per work instruction could be the process characteristic

Control Plan Overview - Characteristics

- Example of characteristics in the control plan

Characteristics		
Number	**Product characteristic**	**Process characteristic**
17	Tensile strength	
22		Select bar stock

Control Plan Overview - Characteristics

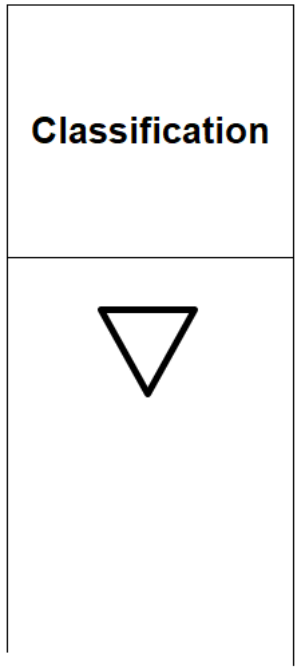
- The classification column is for special characteristics (if used)
  - Special characteristics are mandated by ISO 16949 for the automobile industry and should be considered for when non-mandatory
  - Special characteristics are characteristics that require additional attention due to potential impact on safety or functionality
    - The symbols used are optional, unless customer driven

Control Plan Overview - Characteristics

- Typical symbols include
  - ∇
    - Critical characteristic PFMEA severity = 9 - 10
  - SC
    - Significant characteristic with PFMEA severity = 5 – 8 and concurrence = 4-10
  - HI
    - High impact with PFMEA severity = 5- 8 and occurrence = 4 – 10
  - OS
    - Operator safety with PFMEA severity = 9 – 10

Control Plan Overview - Characteristics

- Example of a special characteristic in the classification field of the control plan



Control Plan Overview - Methods

- The methods section of the control plan contains the details necessary for performing inspections and checks
  - Provides an overview in one document
    - However, references to external documents may be used in place of details in the control plan
      - Example: “See WI 6453”

Control Plan Overview - Methods

- The specification is the criteria used for judging the results oif the assessment
  - Examples include
    - Dimension and tolerance
    - Requirement
    - Reference to external document

Control Plan Overview - Methods

- The inspection equipment used must be listed in the control plan
  - Examples include
    - Calipers
    - Hardness tester
    - “Visual” in cases where the operator makes a visual observation

Control Plan Overview - Methods

- The person responsible for performing the inspection, must be defined
  - An individual may be listed by name, or a role may be listed
    - Recommendation: List roles such as “Operator” and “Quality Engineer”

Control Plan Overview - Methods

- The number of checks to perform is defined in the sample size column
  - Only one check may be necessary when ensuring correct machine settings are used
  - For measurements, more parts will be needed if control charts with subgroups are being used

Control Plan Overview - Methods

- The frequency of checks needs to be listed
  - Examples include
    - First part
    - Last part
    - First and last part
    - Random sampling
    - Continuous

Control Plan Overview - Methods

- The control method defines the way in which the results are documented
  - Examples include
    - xBar and S chart
    - Xbar and R chart
    - Check sheets
    - Machine logs

Control Plan Overview - Methods

- Actions to take if a problem is encountered are described in a reaction plan
  - A document with detailed instructions may be referenced
  - The actions may be listed directly in the control plan
    - Examples include
      - Inspect all parts since last past inspection
      - Scrap or rework part(s)
      - Adjust setting on machine
      - Notify Quality Department

Control Plan Overview - Methods

- Example of the methods section of a control plan

Methods						
Specification	**Inspection equipment**	**Person responsible**	**Sample size**	**Sample frequency**	**Control method**	**Reaction plan**
993 Mpa Minimum	Overload test machine	Quality technician	1	Every 100 parts	Individual and moving range chart	Stop process and scrap all parts since last check
Per work order	Visual	Operator	1	Start of work order	Check sheet	Select correct bar stock

Control Plan - Review Questions

- Which type of characteristic can usually only be checked when it happens?
  - A. Product characteristic
  - B. Process characteristic

Control Plan - Review Questions

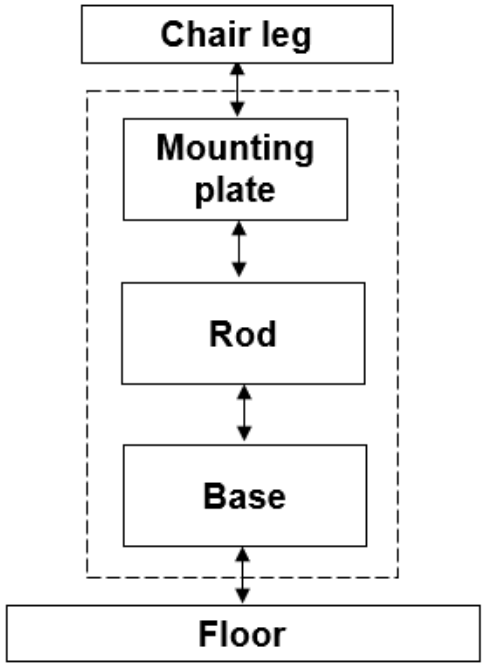
- Which type of the following are inputs for a control plan?
  - A. Drawing and DVP
  - B. DFMEA and DVP
  - C. PFMEA and PFD

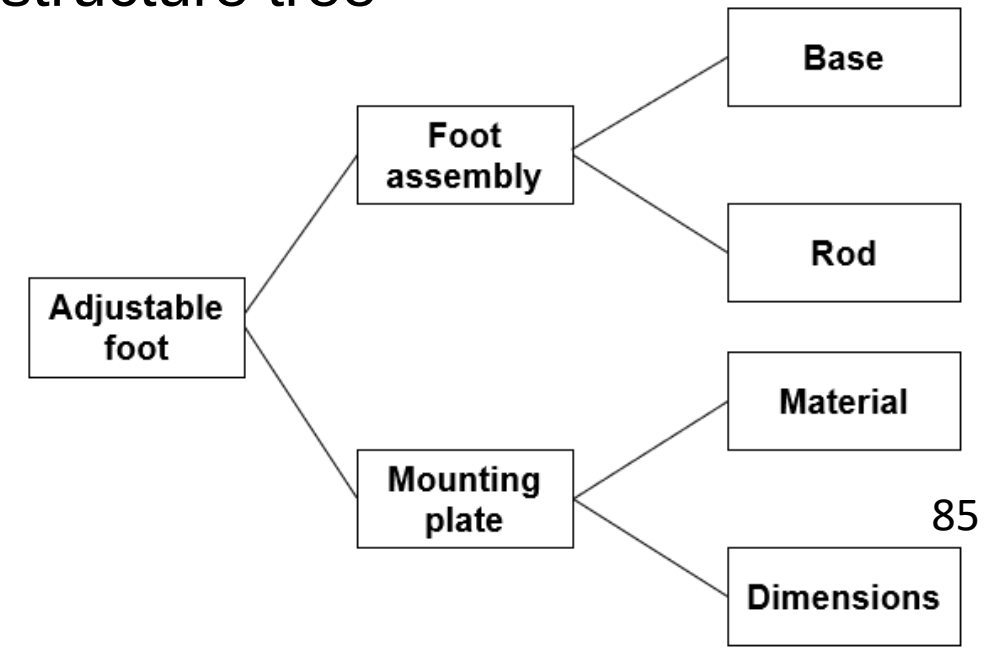
DFMEA Overview - Step 1: Planning and Preparation

- Form a DFMEA team
  - Team should be cross-functional
- Review relevant documents
  - Drawings
  - Customer requirements
  - Specifications
  - Previous, comparable DFMEAs
  - Legal requirements
- Establish project plan and timing
  - Schedule reviews

DFMEA Overview - Step 2: Structure Analysis

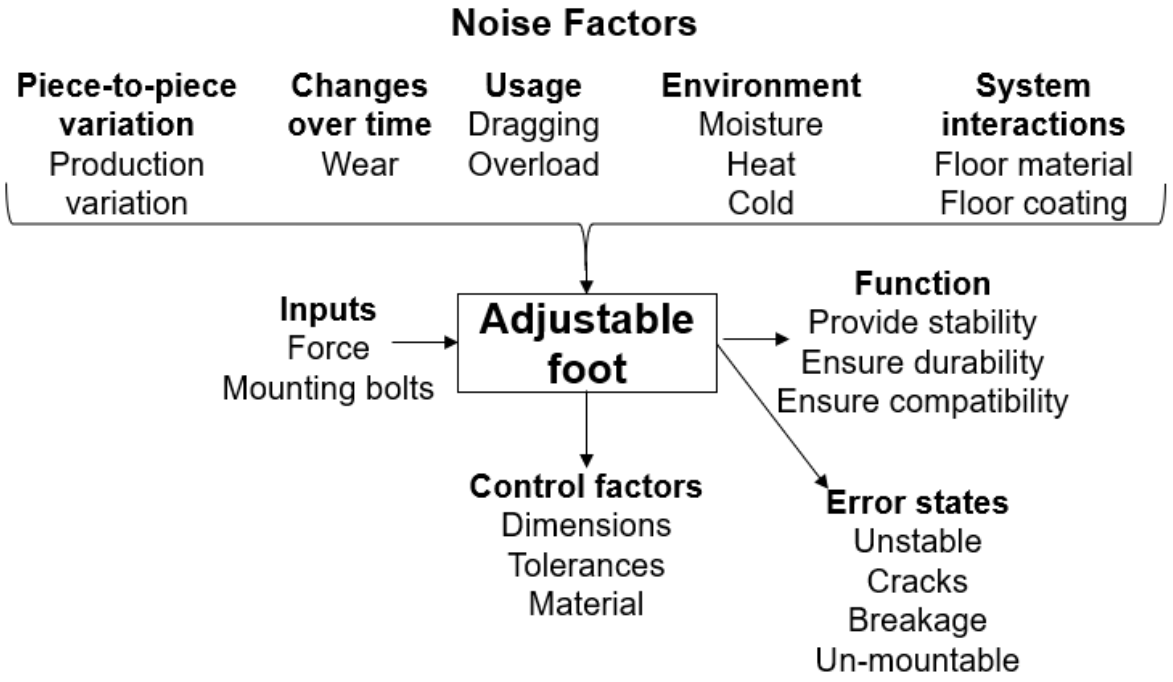
- Create a structure tree or equivalent (boundary diagram, model, parts) to identify interfaces and interactions
  - A boundary diagram was used in AIAG and SAE style DFMEAs
  - VDA style DFMEAs used a structure tree





DFMEA Overview - Step 3: Function Analysis

- Use a function tree or function analysis in DFMEA form together with p-diagram to identify functions
  - A p-diagram was used in AIAG and SAE style DFMEAs
  - VDA style DFMEAs used a function tree



DFMEA Overview - Step 4: Failure Analysis

- Identify failure effects, failure modes, and failure causes
  - Failure mode is the way in which the system element fails
  - Failure cause is the reason for the failure and happens at the next lower system element or characteristic
    - Generally, a cause on the drawing or related to a noise factor
  - Failure effect is the consequence of the failure at the next higher level and/or the end user

DFMEA Overview - Step 5: Risk Analysis

- Current controls for prevention and detection are identified and the occurrence and detection ratings are assigned
  - The controls are ones that are planned and will be performed
    - Detection controls can be transferred to a DVP (Design Validation Plan)
  - Ratings are identified with the help of tables

DFMEA Overview - Step 5: Risk Analysis

- Severity occurrence, and detection ratings are signed with the help of tables
  - Severity is the failure effect’s impact from the customer’s view
  - Occurrence is the chance of the failure cause occurring
  - Detection is the ability to detect the failure mode or failure cause

DFMEA Overview - Step 6: Optimization

- Optimization actions are taken to improve the AP (or RPN if used)
  - Prevention and/or detection actions are described and somebody is assigned responsibility and a deadline is given

DFMEA Overview - Step 7: Results Documentation

- Results are communicated and improvements are documented
  - Purpose and scope of the DFMEA
  - Timing and team members
  - An explanation of how functions were identified
  - A summary of high risk failures together with actions taken to address them
  - Timing for continuing actions
  - Commitment to review and update the DFMEA during mass production and when failures occur

DFMEA - Review Questions

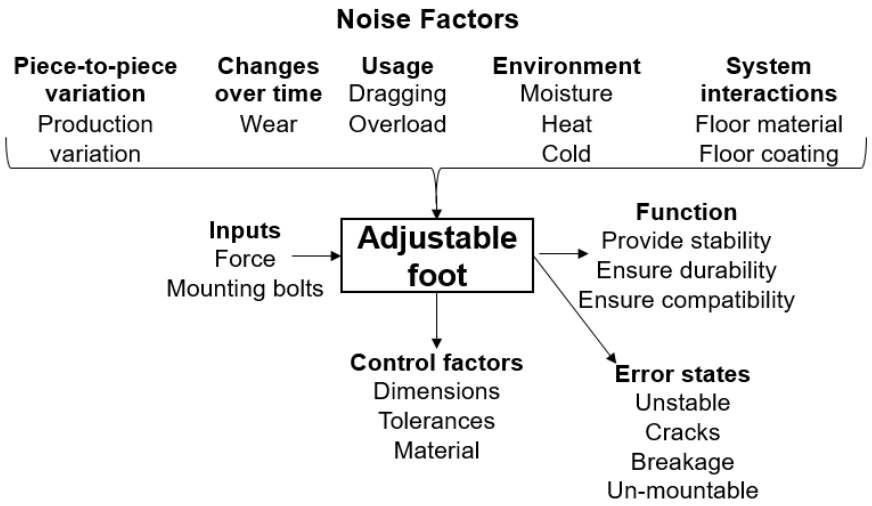
- Which of the following is an example an output of a DFMEA?
  - A. Drawings
  - B. Customer requirements
  - C. DVP
  - D. Specifications

DFMEA - Review Questions

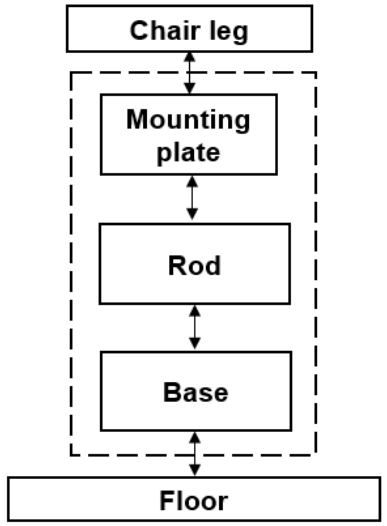
- Which of the following is not an example a DFMEA failure cause?
  - A. Defined surface roughness too high
  - B. Diameter on drawing too wide
  - C. Specified material incorrect for use
  - D. Worn tool on ABC machine

DFMEA - Review Questions

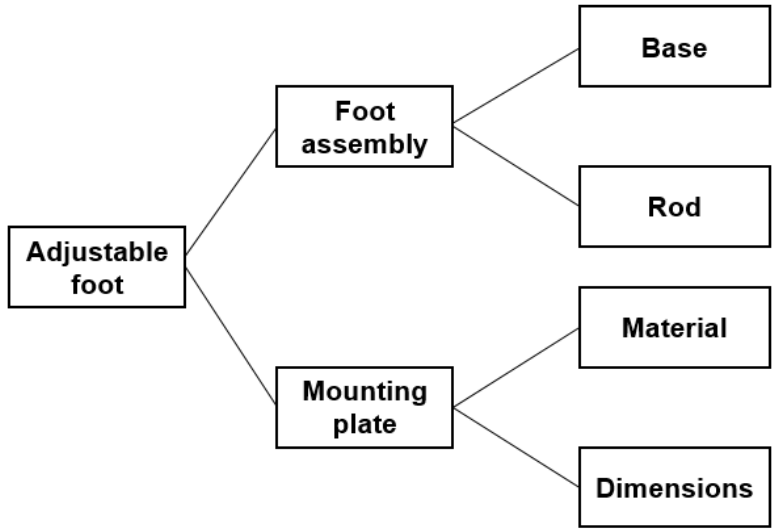
- Which of the following is an example of a boundary diagram?



• A



• B



• C

Link to Templates

- https://docs.google.com/spreadsheets/d/11Eje3DGowVC6ZNpcBbyxAEw7hA8JUEtr/edit?usp=sharing&ouid=104215169443068771470&rtpof=true&sd=true

DFMEA	Organization:	Project:	Project or product owner:	DFMEA number:
	Location:	Product:	DFMEA moderator:	Start and revision date:
	Product line:	System element:	Team:	Revision number:

Step 2: Structure Analysis			Step 3: Function Analysis			Step 4: Failure Analysis				Step 5: Risk Analysis						Step 6: Optimization										
Higher level system element	System element in focus	Lower level system element	Higher level function and requirement	Function and requirement in focus	Lower level function and requirement	Failure effect(s)	Severity	Failure mode(s)	Failure cause(s)	Current prevention actions	Occurrence	Current detection actions	Detection	AP	RPN	Special Characteristics	Planned improvement actions	Responsible	Due date	Status	Implemented improvement actions	Completion date	Severity	Occurrence	Detection	AP	RPN

PFMEA	Organization:	Process:	Process owner:	PFMEA number:
	Location:	Product:	PFMEA moderator:	Start and revision date:
	Product line:	System element:	Team:	Revision number:

Step 2: Structure Analysis			Step 3: Function Analysis			Step 4: Failure Analysis				Step 5: Risk Analysis						Step 6: Optimization									
Product or process name	Process step and operation number	Process 4M work element	Function of system, assembly, component, or process	Function of process step or product characteristic	Function of process work element or process characteristic	Failure effect(s)	Severity	Failure mode(s)	Failure cause(s)	Current prevention actions	Occurrence	Current detection actions	Detection	AP	Special Characteristic	Planned improvement actions	Responsible	Due date	Status	Implemented improvement actions	Completion date	Severity	Occurrence	Detection	AP

Control Plan	Organization:	Process:	Process owner:	Control plan number:
	Location:	Product:	Control plan team leader:	Start and revision date:
	Product line:	System element:	Team:	Revision number:

			Characteristics				Methods						
Product or process name	Process step and operation number	Machine, devise, jig, or tool	Number	Product characteristic	Process characteristic	Classification	Specification	Inspection equipment	Person responsible	Sample size	Sample frequency	Control method	Reaction plan

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Thank You

Thank You