

**62nd ASQ NEQC CONFERENCE**  
OCTOBER 23 – 24, 2018

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# **PROCESS VALIDATION**

## **Production Part Approval Process (PPAP)**

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# Production Part Approval Process (PPAP)



# What is PPAP?

- Production Part Approval Process
- Standard used to formally reduce risks prior to product or service release, in a team oriented manner using well established tools and techniques
- Initially developed by AIAG (Auto Industry Action Group) in 1993 with input from the Big 3 - Ford, Chrysler, and GM
- PPAP has now spread to many different industries beyond automotive

# Production Run

- PPAP data must be submitted from a production run using:
  - Production equipment and tooling
  - Production employees
  - Production rate
  - Production process

**All data shall reflect the actual production process that will be used at start-up!**

# Purpose of PPAP

- Provide evidence that all customer engineering design record and specification requirements are properly understood by the organization
- To demonstrate that the manufacturing process has the potential to produce product that consistently meets all requirements during an actual production run at the quoted production rate

# When is PPAP Required?






- New part
- Engineering change(s)
- Durable Tooling: transfer, replacement, refurbishment, or Tooling inactive > one year
- Correction of discrepancy
- Change to optional construction or material
- Sub-supplier or material source change
- Change in part processing
- Parts produced at a new or additional location

**PPAP is required with any significant change to product or process!**

# Benefits of PPAP Submissions

- Helps to maintain design integrity
- Identifies issues early for resolution
- Reduces warranty charges and prevents cost of poor quality
- Assists with managing supplier changes
- Prevents use of unapproved and nonconforming parts
- Identifies suppliers that need more development
- Improves the overall quality of the product & customer satisfaction

# PPAP Submission Levels

|  |         |  |
|--|---------|--|
|    | Level 1 | Production Warrant and Appearance Approval Report (if applicable) submitted to Customer  |
|    | Level 2 | Production Warrant, product samples, and dimensional results submitted to Customer   |
|    | Level 3 | Production Warrant, product samples, and complete supporting data submitted to Customer  |
|    | Level 4 | Production Warrant and other requirements as defined by Customer   |
|  | Level 5 | Production Warrant, product samples and complete supporting data (a review will be conducted at the supplier's manufacturing location) |



# PPAP Submission Requirements

Any customer specific requests fall under Element # 17

Note: For each level, full APQP is required. The PPAP level simply indicates which elements you submit, and which you retain at your site.

| Requirement  | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|--|---------|---------|---------|---------|---------|
| 1.Design Record  | R       | S       | S       | *       | R       |
| 2.Engineering Change Documents, if any                       | R       | S       | S       | *       | R       |
| 3.Customer Engineering approval, if required                 | R       | R       | S       | *       | R       |
| 4.Design FMEA  | R       | R       | S       | *       | R       |
| 5.Process Flow Diagrams                                      | R       | R       | S       | *       | R       |
| 6.Process FMEA   | R       | R       | S       | *       | R       |
| 7.Control Plan   | R       | R       | S       | *       | R       |
| 8.Measurement System Analysis studies                        | R       | R       | S       | *       | R       |
| 9.Dimensional Results  | R       | S       | S       | *       | R       |
| 10.Material, Performance Test Results                        | R       | S       | S       | *       | R       |
| 11.Initial Process Studies                                   | R       | R       | S       | *       | R       |
| 12.Qualified Laboratory Documentation                        | R       | S       | S       | *       | R       |
| 13.Appearance Approval Report (AAR), if applicable           | S       | S       | S       | *       | R       |
| 14.Sample Product  | R       | S       | S       | *       | R       |
| 15.Master Sample   | R       | R       | R       | *       | R       |
| 16.Checking Aids   | R       | R       | R       | *       | R       |
| 17.Records of Compliance With Customer Specific Requirements | R       | R       | S       | *       | R       |
| 18.Part Submission Warrant                                   | S       | S       | S       | S       | R       |
| 19.Bulk Material Checklist                                   | S       | S       | S       | S       | R       |

S = The organization shall submit to the customer and retain a copy of records or documentation items at appropriate locations

R = The organization shall retain at appropriate locations and make available to the customer upon request

\* = The organization shall retain at the appropriate location and submit to the customer upon request

# PPAP Element 17: Ex. Customer Requirements

- Depending on the specific Customer business, Customer may require:
  - APQP Kickoff - team
  - APQP Timeline Template
  - Action Item Log
  - Production Feasibility Agreement (PFA)
  - Gage Plan
  - Dimensional Correlation Matrix
  - Pass Through Characteristics (PTC)
  - Safe Launch Control Plan
  - AS 9102 Forms (Aerospace Industry)
  - Ramp Up & Down Plan
  - Packaging Specification Data Sheet
  - Submit Bar Code Label Packaging Approval
  - PPAP Interim Recovery Worksheet
  - Capacity R@R Worksheet
  - Production Readiness Review (PRR)

# PPAP Status

- Approved
  - The part meets all Customer requirements
  - Supplier is authorized to ship production quantities of the part
- Interim Approval
  - Permits shipment of part on a limited time or piece quantity basis
- Rejected
  - The part does not meet Customer requirements, based on the production lot from which it was taken and/or accompanying documentation



**Production quantities shall  
not be shipped before  
Customer Approval**

# PPAP Element #1: Design Record

- Includes:
  - Component drawings
  - Assembly drawings
  - Bill of Materials
  - Referenced engineering specifications
  - Material specifications
  - Performance or test specifications
- Ensures manufacturer has the complete design record at the correct revision levels
- This requirement may be satisfied by attaching the “ballooned” design record to the Production Feasibility Agreement (PFA) – located in the PPAP Workbook
  - Some Customer businesses may use an alternate approach

# PPAP Element #2: Authorized Engineering Change Documents

- The supplier shall provide authorized change documents for those changes not yet recorded in the design record, but incorporated in the product, part or tooling, such as:
  - ECNs (must be approved, not pending)
  - Specification changes
  - Supplier change requests
  - Sub-assembly drawings
  - Life or reliability testing requirements

# PPAP Element #3: Customer Engineering Approval

- Written statement from Customer Engineering approving the parts
  - Example: supplier designed components in which we require additional information for validation of designs...for structural integrity
  - The engineering design requires approval
  - Other elements of the PPAP validate the manufacturing process

# PPAP Element #4: Design Failure Mode and Effects Analysis (DFMEA)

- Provide potential cause and effect relationships for the basic design of the product
- Helps to plan design needs for:
  - Materials selection
  - Tolerance stack-up
  - Software
  - Interfaces
  - DVP&R (life cycle tests)
- Employs R.P.N rating system
  - High R.P.N's and Severity > 8 need recommended Corrective Actions (CA)

# Difference between DFMEA and PFMEA

- DFMEA **does not** reference manufacturing controls
  - Design controls include:
    - Tolerance stack-up analysis
    - Simulation
    - Finite Element Analysis
    - Testing
- Recommended actions should be **Design** actions
  - Re-design
  - Testing
  - Analysis



# DFMEA Common Pitfalls

- One time document
  - Must be continuously reviewed and updated
  - What if the latest change or revision has a significant impact?
- Not submitted or reviewed with supplier
- The After Thought
  - Completed after drawing and production release
  - Doesn't help to direct the design effort
- Does not consider all potential failure modes
- Critical and/or Special Characteristics not identified
- Only considers full assembly
  - Not completed to correct level – component, sub assembly, assembly, product
- Family based DFMEA not all inclusive
  - Not reviewed for specific/ custom application/ designs

# PPAP Element #5: Process Flow Diagram(s)

- Step by Step designation of the process flow required to produce the referenced product which meets all customer requirements
  - Provide linkage to PFMEA and Control Plan
  - Traditional block diagram
  - May employ “Family” based diagrams
  - Should cover all steps from Receiving to Shipping

(for additional details reference Advance Product Quality Planning and Control Plan AIAG Manual)

# Process Flow Diagrams

| PROCESS / INSPECTION FLOWCHART |                    |                  |                                   |              |                                 |           |
|--------------------------------|--------------------|------------------|-----------------------------------|--------------|---------------------------------|-----------|
| Product Program                |                    |                  | Issue Date                        |              | ECL                             | ECL       |
| Supplier Name                  |                    | ORGANIZATION     |                                   | Part Name    |                                 | NAME      |
| Supplier Location              |                    | CITY             | STATE                             | Part Number  |                                 | NUMBER    |
| Legend:                        |                    |                  |                                   |              |                                 |           |
| ○ Operation                    |                    | ⇨ Transportation |                                   | □ Inspection |                                 | ⏸ Delay   |
|                                |                    |                  |                                   |              |                                 | ▽ Storage |
| STEP                           | Operation or Event |                  | Description of Operation or Event |              | Evaluation and Analysis Methods |           |
|                                | ○                  | ⇨                | □                                 | ⏸            | ▽                               |           |

**The process flow diagram utilizes these symbols to clearly identify each step in the process**

# PPAP Element #6: Process FMEA (PFMEA)

- What is It?
  - A tool used to identify and prioritize risk areas and their mitigation plans.
- Objective or Purpose
  - Identifies potential failure modes, causes, and effects. Inputs come from the process flow diagram.
  - Identifies key inputs which affect quality, reliability and safety of a product or process.
- When to Use It
  - New product launches
    - After completion of the process flow diagram.
    - Prior to tooling for production
  - When troubleshooting production issues
  - When planning and closing preventive and corrective actions

| POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA) |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|--|------------------------|--------------------------------|----------|------------------------|--------------------------------|------------|-------------------------------------|------------------------------------|-----------|--------------|--|
| Item:  |                        |                                |          | Process Responsibility |                                |            |                                     |                                    |           | ORGANIZATION |  |
| Model Year(s)/Program(s)                                   |                        |                                |          | APPLICATION            |                                | Key Date   |                                     |                                    |           |              |  |
| Core Team:   |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
| Process Step / Function                                    | Potential Failure Mode | Potential Effect(s) of Failure | Severity | Classification         | Potential Causes(s) of Failure | Occurrence | Current Process Controls Prevention | Current Process Controls Detection | Detection | RPN          |  |
| Requirements   |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |
|  |                        |                                |          |                        |                                |            |                                     |                                    |           |              |  |

**IMPORTANT!**  
The PFMEA should be completed using a *cross-functional* team!

# PFMEA - Step 1

| Process Step                                       | Potential Failure Mode   | Potential Failure Effects  | How severe is the effect on the customer? See SEV table. | Classify any special characteristics needing controls. | How often does the cause of the failure mode occur? See OCC table. | Current Controls   |  | DET                                    |   |
|--|--|--|--|--|--|--|--|--|---|
|  |  |  |  |  |  | Prevent  | Detect   |  |   |
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specified requirements?<br>Consider:<br>(A) No Function<br>(B) Partial/Over/Degraded Function<br>(C) Intermittent Function<br>(D) Unintended Function. | What are the effects of the failure on the function as perceived by internal and external customers? |  |  |  | What are the existing process controls to <b>prevent</b> the cause of failure or failure mode from occurring or reduce the rate of occurrence?<br><b>Should include an SOP number.</b> | What are the existing process controls to <b>detect</b> the cause of failure or failure mode and lead to corrective action(s)?<br><b>Should include an SOP number.</b> |  |   |
| Assemble Hardware Kit                              | Wrong and/or missing parts/labeling (B)  | Customer unable to install product   | 8  |  | Operator places wrong hardware and/or label with kit               | 3  | Work Instructions, Pack Positive   | Visual Inspection; Scale to weigh kits | 8 |
| Assemble Hardware Kit                              | Bad seal (B)   | Customer unable to install product, due to missing hardware.   | 8  |  | Bagger error   | 2  | Work Instructions  | Visual Inspection                      | 8 |

**Failure Modes**  
For each Process Input, determine the ways in which the input can go wrong.

Using the completed Process Flow Diagram, enter the process step.

**TIP**

- There should be at least one failure mode for each input.

# Potential Failure Mode

- List all credible failure modes or ways the process/operation can fail in the PFMEA document before addressing failure effects and failure causes
- In each instance, the assumption is made that the failure could occur, but will not necessarily occur
- The failure mode:
  - “... is the manner in which the process could potentially fail to meet the process requirements and/or design intent.”
  - Is a description of nonconformance
  - Assumes incoming parts are correct
  - Considers subsequent operations
- Typical failure modes could be, but are not limited to:
  - Bent
  - Open circuited
  - Dirty
  - Binding
  - Cracked
  - Improper setup
  - Burred
  - Deformed
  - Tool worn
  - Handling Damage

# PFMEA - Step 2

| Process Step                                       | Potential Failure Mode   | Potential Failure Effects  | SEV   | CLASS  | Potential Cause  | How often does the cause occur? See OCC | How often does the failure occur? See OCC | Should include an SOP number.    | How can we detect the cause of failure mode? See DET table. | DET |
|--|--|--|---|--|--|---|---|----------------------------------|---|-----|
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specified requirements?<br>Consider:<br>(A) No Function<br>(B) Partial/Over/Degraded Function<br>(C) Intermittent Function<br>(D) Unintended Function. | What is the impact on the output variables (customer requirements) or internal requirements?<br><br>What are the effects of the failure on the function as perceived by internal and external customers? | How severe is the effect to the customer?<br>See SEV table. | Classify any special product or process characteristics needing additional controls. | What cause(s) could lead to go wrong?<br><br>What could cause a failure, in something that is corrected or controlled? |   |   | Should include an SOP number.    | How can we detect the cause of failure mode? See DET table. |     |
| Assemble Hardware Kit                              | Wrong and/or missing parts/labeling (B)  | Customer unable to install product   | 8   |  | Operator places wrong hardware and/or label with kit   | 3                                       |   | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits                      | 8   |
| Assemble Hardware Kit                              | Bad seal (B)   | Customer unable to install product, due to missing hardware.   | 8   |  | Bagger error   | 2                                       |   | Work Instructions                | Visual Inspection   | 8   |

**Potential Failure Effects**  
For each Failure Mode, determine what effect the specific failure could have on the process output.

## TIPS

- There should be at least one failure effect for each failure mode.
- Effects should be specific, clear, and leave no doubt to the uninformed reviewer.

# Potential Effect(s) of Failure

- Effect of failure mode based on what customer might notice/experience
- Includes subsequent process operations
- Typical effects may include, but are not limited to:
  - No Function
  - Partial/Over Function/Degraded over time
  - Intermittent Function
  - Unintended Function
  - Erratic operation



# PFMEA – Step 3

| Process Step                                       | Potential Failure Mode  | Potential Failure Effects  | S E V   | C L A S S  | Potential Causes   | O C C  | Current Controls  |   | D E T   |
|--|---|--|---|--|--|--|---|---|---|
|  |   |  |   |  |  |  | Prevent   | Detect  |   |
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specified requirements?<br>Consider:<br>(A) No Function<br>(B) Partial/Over/Degraded Function<br>(C) Intermittent | What is the impact on the output variables (customer requirements) or internal requirements?<br><br>What are the effects of the failure on the function as perceived by internal and external customers? | How severe is the effect to the customer?<br>See SEV table. | Classify any special product or process characteristics needing additional controls. | What causes the input to go wrong?<br><br>What could cause the failure, in terms of something that can be corrected or controlled? | How often does the cause of the failure mode occur? See OCC table. | What are the existing process controls to prevent the cause of failure or failure mode from occurring or reduce the rate of occurrence?<br><b>Should include an SOP number.</b> | What are the existing process controls to detect the cause of failure or failure mode and lead to corrective action(s)?<br><b>Should include an SOP number.</b> | How well can you detect the cause of failure mode? See DET table. |
|  | Missing   | Customer unable to install product   | 8   |  | Operator places wrong hardware and/or label with kit   | 3  | Work Instructions, Pack Positive  | Visual Inspection; Scale to weigh kits  | 8   |
| Assemble Hardware Kit                              | Bad seal (B)  | Customer unable to install product, due to missing hardware.   | 8   |  | Bagger error   | 2  | Work Instructions   | Visual Inspection   | 8   |

**Class**  
Identify special product or process characteristics

# PFMEA - Step 4

| Process Step                                       | Potential Failure Mode   | Potential Failure Effects  | SEV   | CLASS  | Potential Causes   | OCC  | Current Controls   |  | DET   |
|--|--|--|---|--|--|--|--|--|---|
|  |  |  |   |  |  |  | Prevent  | Detect   |   |
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specified requirements?<br>Consider: | What is the impact on the output variables (customer requirements) or internal | How severe is the effect to the customer?<br>See SEV table. | Classify any special product or process characteristics needing additional controls. | What causes the input to go wrong?<br><br>What could cause the failure, in terms of something that can be corrected or controlled? | How often does the cause of the failure mode occur? See OCC table. | What are the existing process controls to <b>prevent</b> the cause of failure or failure mode from occurring or reduce the rate of occurrence?<br><b>Should include an SOP number.</b> | What are the existing process controls to <b>detect</b> the cause of failure or failure mode and lead to corrective action(s)?<br><b>Should include an SOP number.</b> | How well can you detect the cause of failure mode? See DET table. |
| Assemble Hardware Kit                              | Wrong and/or missing parts/labeling (B)  | Customer unable to install product   | 8   |  | Operator places wrong hardware and/or label with kit   | 3  | Work Instructions, Pack Positive   | Visual Inspection; Scale to weigh kits   | 8   |
| Assemble Hardware Kit                              | Bad seal (B)   | Customer unable to install product, due to missing hardware.                   | 8   |  | Bagger error   | 2  | Work Instructions  | Visual Inspection  | 8   |

**Potential Causes**  
For each Failure Mode, determine the possible cause of the failure.

**TIP**

- There should be at least one potential cause for each failure mode.

# Potential Cause(s) of Failure

- “...how the failure could occur.”
- Described in terms of something that can be corrected/controlled
- Requires determination of root cause
- Sources of process variation that cause the failure mode to occur
- Typical failure causes may include, but are not limited to:
  - Improper torque – over, under
  - Improper weld – current, time, pressure
  - Inaccurate gauging
  - Improper heat treat – time, temperature
  - Inadequate gating/venting
  - Part missing or installed incorrectly
  - Thermocouple broken
  - Typographical error

# PFMEA - Step 5

| Process Step                                       | Potential Failure Mode  | Potential Failure Effects   | SEV | CLASS | Potential Causes   | OCC  | Current Controls  |   | DET   |
|--|---|---|-----|-------|--|--|---|---|---|
|  |   |   |     |       |  |  | Prevent   | Detect  |   |
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specified requirements?<br>(A)<br>Partial<br>(C)<br>(D) | What is the impact on the output variables (customer requirements)? |     | Class | What causes the input to go wrong?<br><br>What could cause the failure, in terms of something that can be corrected or controlled? | How often does the cause of the failure mode occur? See OCC table. | What are the existing process controls to prevent the cause of failure or failure mode from occurring or reduce the rate of occurrence?<br><b>Should include an SOP number.</b> | What are the existing process controls to detect the cause of failure or failure mode and lead to corrective action(s)?<br><b>Should include an SOP number.</b> | How well can you detect the cause of failure mode? See DET table. |
| Assemble Hardware Kit                              | Wrong and/or missing parts/labeling (B)   | Customer unable to install product                                  | 8   |       | Operator places wrong hardware and/or label with kit   | 3  | Work Instructions, Pack Positive  | Visual Inspection; Scale to weigh kits  | 8   |
| Assemble Hardware Kit                              | Bad seal (B)  | Customer unable to install product, due to missing hardware.        | 8   |       | Bagger error   | 2  | Work Instructions   | Visual Inspection   | 8   |

Current Controls  
For each potential cause, list the current method used for preventing and/or detecting failure.

**TIPS**

- This step in the FMEA begins to identify initial shortcomings or gaps in the current control plan.
- If a procedure exists, enter the document number.
- If no current control exists, list as "none." There may not be both preventive and detection controls.

# PFMEA - Step 6

| Process Step                            | Potential Failure Mode  | Potential Failure Effects  | S E V   | C L A S S  | Potential Causes   | O C C  | Current Controls  |  | D E T                         |
|---|---|--|---|--|--|--|---|--|-------------------------------|
|   |   |  |   |  |  |  |   |  |                               |
| Wrong and/or missing parts/labeling (B) | Partial/Over/Degraded Function<br>(C) Intermittent Function<br>(D) Unintended Function. | What is the impact on the output variables (customer requirements) or internal requirements?<br><br>What are the effects of the failure on the function as perceived by internal and external customers? | How severe is the effect to the customer?<br>See SEV table. | Classify any special product or process characteristics needing additional controls. | What causes the input to go wrong?<br><br>What could cause the failure, in terms of something that can be corrected or controlled? | How often does the cause of the failure mode occur? See OCC table. | How well can you detect the cause or failure mode? See DET table. | Should include an SOP number.          | Should include an SOP number. |
| Assemble Hardware Kit                   | Wrong and/or missing parts/labeling (B)   | Customer unable to install product   | 8   |  |  | 3  | Work Instructions, Pack Positive                                  | Visual Inspection; Scale to weigh kits | 8                             |
| Assemble Hardware Kit                   | Bad seal (B)  | Customer unable to install product, due to missing hardware.   | 8   |  |  | 2  | Work Instructions   | Visual Inspection                      | 8                             |

**Assign Severity**  
(How serious is the effect if it fails?)

**Assign Detection**  
(How easily can the cause or failure mode be detected?)

**Assign Occurrence**  
(How likely is the cause to occur?)

# PFMEA - Definition of Terms

- **Severity (of Effect)** - severity of the effect on the Customer and other stakeholders (Higher Value = Higher Severity)
- **Occurrence (of Cause)** - frequency with which a given Cause occurs and creates Failure Mode. (Higher Value = Higher Probability of Occurrence)
- **Detection (Capability of Current Controls)** - ability of current control scheme to detect the cause before creating the failure mode and/or the failure mode before suffering the effect (Higher Value = Lower Ability to Detect)

Caution: Notice the scale difference for Detection

# Example: Severity Rating

**Suggested PFMEA Severity Evaluation Criteria**

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

# Example: Occurrence Rating Definitions

| Suggested PFMEA Occurrence Evaluation Criteria |                       |   |
|--|-----------------------|---|
| Rank   | Likelihood of Failure | Criteria:<br>Occurrence of Cause - DFMEA<br>(Incidents per Item / Products) |
| 10   | Very High             | => 100 per Thousand   |
|  |                       | => 1 in 10  |
| 9  | High                  | 50 per Thousand   |
|  |                       | 1 in 20   |
|  |                       | 20 per Thousand   |
|  |                       | 1 in 50   |
|  |                       | 10 per Thousand   |
| 7  |                       | 1 in 100  |
|  |                       |   |
| 6  | Moderate              | 2 per Thousand  |
|  |                       | 1 in 500  |
|  |                       | 0.5 per Thousand  |
|  |                       | 1 in 2,000  |
| 5  |                       | 0.1 per Thousand  |
|  |                       | 1 in 10,000   |
| 4  | Low                   | 0.01 per Thousand   |
|  |                       | 1 in 100,000  |
|  |                       | =< 0.001 per Thousand   |
| 3  |                       | 1 in 1,000,000  |
|  |                       |   |
| 2  |                       |   |
|  |                       |   |
| 1  | Very Low              | Failure is eliminated through preventive control                            |



# Example: Detection Rating

| Suggested PFMEA Prevention / Detection Evaluation Criteria |                         |  |                   |            |            |   |
|--|-------------------------|--|-------------------|------------|------------|---|
| Rank   | Likelihood of Detection | Opportunity for Detection  | Inspection Types  |            |            | Criteria:<br>Likelihood of Detection by Design Control  |
|  |                         |  | A - Error Proofed | B - Gauged | C - Manual |   |
| 10   | Almost Impossible       | No Detection Opportunity   |                   |            | X          | No Current Process Control; Cannot Detect or is not Analyzed  |
| 9  | Very Remote             | Not Likely to Detect at any Stage  |                   |            | X          | Failure Mode and/or Error (Cause) is not easily detected (eg random audits)   |
| 8  | Remote                  | Controls will probably not detect.<br>Problem detection post processing.         |                   |            | X          | Failure Mode detection post processing by operator through visual tactile audible means   |
| 7  | Very Low                | Controls have poor chance of detection<br>Problem detection at source.           |                   | X          | X          | 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.)  |
| 6  | Low                     | Controls might detect.<br>Problem detection post processing.                     |                   | X          | X          | Failure Mode detection post processing by operator through variable gauging or in-station by operator through the use of attribute gauging (go/no go, manual torque check / clicker wrench etc.)  |
| 5  | Moderate                | Controls might detect.<br>Problem detection at source.                           | X                 | X          |            | Failure Mode or Error (Cause) detection in-station by operator through the use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light buzzer etc.). Gauging performed on set-up and first piece check (for set-up causes only) |
| 4  | Moderately High         | Controls may detect.<br>Problem detection post processing.                       | X                 | X          |            | Failure Mode detection post processing by automated controls that will detect discrepant part and lock part to prevent further processing.  |
| 3  | High                    | Controls have a good chance to detect.<br>Problem detection at source.           | X                 |            |            | Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.  |
| 2  | Very High               | Controls almost certain to detect.<br>Error detection and or problem prevention. | X                 |            |            | Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made.  |
| 1  | Almost Certain          | Detection not applicable, error prevention.                                      | X                 |            |            | 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.   |

# PFMEA - Step 7

| Process Step          | Potential Failure Mode                  | Potential Failure Effects                                    | S E V | C L A S S | Potential Causes                                     | O C C | Current Controls                 |  | D E T | R P N |
|-----------------------|---|--|-------|-----------|--|-------|----------------------------------|--|-------|-------|
|                       |   |  |       |           |  |       | Prevent                          | Detect                                 |       |       |
| Assemble Hardware Kit | Wrong and/or missing parts/labeling (B) | Customer unable to install product                           | 8     |           | Operator places wrong hardware and/or label with kit | 3     | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8     | 192   |
| Assemble Hardware Kit | Bad seal (B)                            | Customer unable to install product, due to missing hardware. | 8     |           | Bagger error   | 2     | Work Instructions                | Visual Inspection                      | 8     | 128   |

**Calculate the Risk Priority Number**  
**RPN = Severity x Occurrence x Detection**

## TIPS

- The RPN is used to prioritize the most critical risks
- Higher RPNs are flags to take effort to reduce the calculated risk
  - Continually work to improve highest risk items - don't set an RPN threshold
- In addition to RPN, examine top Severity and Occurrence risks

## PFMEA – Remediation Guidelines

- **Severity** – can only be improved by a design change to the product or process
- **Occurrence** – can only be reduced by a change which removes or controls a cause. Examples are redundancy, substituting a more reliable component or function or mistake-proofing.
- **Detection** – can be improved by deploying better controls. Examples are mistake-proofing, simplification and statistically sound monitoring.

**In general, reducing the Occurrence is preferable to improving the Detection**

# FMEA – Step 8

| Current Controls                    |   | D<br>E<br>T | R<br>P<br>N | Actions<br>Recommended                    | Responsible | Actions Taken  | S<br>E<br>V | O<br>C<br>C | D<br>E<br>T | R<br>P<br>N |
|-------------------------------------|---|-------------|-------------|---|-------------|--|-------------|-------------|-------------|-------------|
| Prevent                             | Detect                                    |             |             |   |             |  |             |             |             |             |
| Work Instructions,<br>Pack Positive | Visual Inspection;<br>Scale to weigh kits | 8           | 192         | Implement scale to<br>weigh hardware kits | Kolumban    | 7/11/11 - Scale implmented to<br>weigh kits. SK.- <i>Complete</i>  | 8           | 3           | 5           | 120         |
| Work Instructions                   | Visual Inspection                         | 8           | 128         | Repair/replace worn<br>bagger             | Zindler     | 2010 Capital Plan - New HM<br>Autobagger. Follow status on<br>HM 2010 VSM implementation<br>plan.<br>7/11/11 - New Bagger<br>implemented 3Q 2010. APZ -<br><i>Complete</i> | 8           | 1           | 8           | 64          |

For the high risk items,  
determine the  
recommended actions.

# FMEA – Steps 9 and 10

| Current Controls                    |   | D<br>E<br>T | R<br>P<br>N | Actions<br>Recommended                    | Responsible | Actions Taken  | S<br>E<br>V | O<br>C<br>C | D<br>E<br>T | R<br>P<br>N |
|-------------------------------------|---|-------------|-------------|---|-------------|--|-------------|-------------|-------------|-------------|
| Prevent                             | Detect                                    |             |             |   |             |  |             |             |             |             |
| Work Instructions,<br>Pack Positive | Visual Inspection;<br>Scale to weigh kits | 8           | 192         | Implement scale to<br>weigh hardware kits | Kolumban    | 7/11/11 - Scale implmented to<br>weigh kits. SK.- <i>Complete</i>  | 8           | 3           | 5           | 120         |
|                                     |   |             | 128         | Repair/replace worn<br>bagger             | Zindler     | 2010 Capital Plan - New HM<br>Autobagger. Follow status on<br>HM 2010 VSM implementation<br>plan.<br>7/11/11 - New Bagger<br>implemented 3Q 2010. APZ -<br><i>Complete</i> | 8           | 1           | 8           | 64          |

**Resp (responsibility)**  
Assign a specific person  
who will be responsible  
for recommended actions.

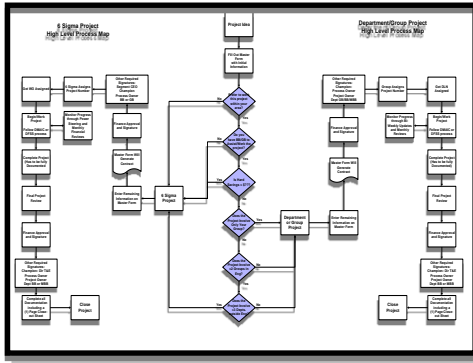
**Actions Taken**  
As actions are identified  
and completed, document  
in the "Actions Taken"  
column.

**SEV, OCC, DET, RPN**  
As actions are complete  
reassess Severity,  
Occurrence, and Detection  
and recalculate RPN.



# Control Plan

## Tool Interaction

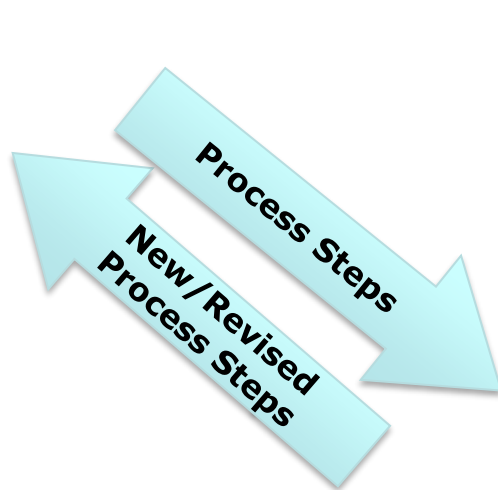


**Process Flowchart**



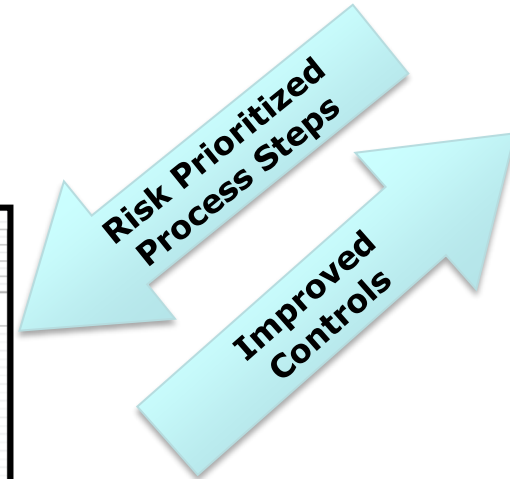
| Process Step      | Key Process Input            | Potential Failure Mode      | Potential Failure Effects                           | SEV | Potential Causes   | OCC | Current Controls  | DET | RPN | EOC |
|-------------------|------------------------------|-----------------------------|---|-----|--|-----|---|-----|-----|-----|
| Receive Payment   | Checks                       | Delay internal mail         | AR balance does not go down                         | 7   | Inadequate staffing in mail room   | 7   | None  | 10  | 490 |     |
| Identify Customer | Wire Transfer reference line | Information not supplied    | AR balance is past due                              | 10  | Customer or bank did not include name and/or account info on wire transfer | 5   | Acct identifies problem when trying to apply payment      | 5   | 250 |     |
| Identify Invoice  | Checks                       | Incorrect invoice supplied  | Invoice shows outstanding (AR balance does go down) | 5   | Customer error   | 5   | Customer might catch it when reviewing the next statement | 10  | 250 |     |
| Identify Invoice  | Checks                       | Invoice number not supplied | Invoice shows outstanding (AR balance does go down) | 5   | Customer error   | 10  | Acct identifies problem when trying to apply payment      | 5   | 250 |     |

**Process FMEA**



| CONTROL PLAN                  |              |                                  |      |                                |                 |                                |                |                                |              |   |              |
|-------------------------------|--------------|----------------------------------|------|--------------------------------|-----------------|--------------------------------|----------------|--------------------------------|--------------|---|--------------|
| Product/Service               |              | Part/Process/Procedure           |      | Date/Version                   |                 | Date/Rev                       |                | Rev. Year                      |              | Customer Engineering Approval Date (If Req'd) |              |
| Part Number/Last Change Level |              | EOL                              |      | 999-999-9999                   |                 | 1/1/2000                       |                | 1/1/2000                       |              | Customer Quality Approval Date (If Req'd)     |              |
| Part Name/Description         |              | Organization/Plant Approval Date |      | Other Approval Date (If Req'd) |                 | Other Approval Date (If Req'd) |                | Other Approval Date (If Req'd) |              | Other Approval Date (If Req'd)                |              |
| REV#                          | PROCESS NAME | REV#                             | DATE | DESCRIPTION                    | CHARACTERISTICS | SPECIAL REQUIREMENTS           | CONTROL METHOD | REACT PLAN                     | CONTROL PLAN | CONTROL PLAN                                  | CONTROL PLAN |
| 1                             | PROCESS NAME | 1                                | DATE | DESCRIPTION                    | CHARACTERISTICS | SPECIAL REQUIREMENTS           | CONTROL METHOD | REACT PLAN                     | CONTROL PLAN | CONTROL PLAN                                  | CONTROL PLAN |

**Control Plan**



# The Control Plan Form

## CONTROL PLAN

Prototype     Pre-Launch     Production

| Control Plan Number<br>FILE.XLS               |   |  | Key Contact/Phone<br>555-555-5555 |         |         |                           | Date (Orig.)<br>1/1/1996                       |   | Date (Rev.)<br>1/1/1996 |  |                   |                  |
|---|---|--|-----------------------------------|---------|---------|---------------------------|--|---|-------------------------|--|-------------------|------------------|
| Part Number/Latest Change Level<br>NUMBER ECL |   |  | Core Team                         |         |         |                           | Customer Engineering Approval/Date (If Req'd.) |   |                         |  |                   |                  |
| Part Name/Description<br>NAME                 |   |  | Organization/Plant Approval/Date  |         |         |                           | Customer Quality Approval/Date (If Req'd.)     |   |                         |  |                   |                  |
| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    | Other Approval/Date (If Req'd.)   |         |         |                           | Other Approval/Date (If Req'd.)                |   |                         |  |                   |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS                   |         |         | SPECIAL<br>CHAR.<br>CLASS | METHODS  |   |                         |  |                   | REACTION<br>PLAN |
|   |   |  | NO.                               | PRODUCT | PROCESS |                           | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE                  |  | CONTROL<br>METHOD |                  |
|   |   |  |                                   |         |         |                           |  | SIZE                                    | FREQ.                   |  |                   |                  |



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|   |   |  | NO.                               | PRODUCT                         | PROCESS |                           | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE                  |  |                  |
|   |   |  |                                   |                                 |         |                           |  | SIZE                                    | FREQ.                   |  |                  |

**Administrative Section**  
Identifies part number and description, supplier, required approval signatures, and dates.

# The Control Plan Form

**CONTROL PLAN**

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| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    |                 | Other Approval/Date (If Req'd.) |  | Other Approval/Date (If Req'd.) |  |   |        |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS |                                 |  | SPECIAL<br>CHAR.<br>CLASS       | METHODS  |   |        |  | REACTION<br>PLAN |
|   |   |  | NO.             | PRODUCT                         | PROCESS  |                                 | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE |  |                  |
|   |   |  |                 |                                 |  |                                 |  | SIZE                                    | FREQ.  |  |                  |

### 3 Distinct Phases

1. **Prototype** – a description of the dimensional measurements and material and performance tests that will occur during Prototype build.
2. **Pre-Launch** – a description of the dimensional measurements and material and performance tests that will occur after Prototype and before full Production.
3. **Production** – a comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems that will occur during mass production

# The Control Plan Form

## CONTROL PLAN

Prototype     Pre-Launch     Production

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| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    |                 | Other Approval/Date (If Req'd.) |         | Other Approval/Date (If Req'd.)                |  |   |        |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS |                                 |         | SPECIAL<br>CHAR.<br>CLASS                      | METHODS  |   |        |  | REACTION<br>PLAN |
|   |   |  | NO.             | PRODUCT                         | PROCESS |  | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE |  |                  |
|   |   |  |                 |                                 |         |  |  | SIZE                                    | FREQ.  |  |                  |

**Each stage of *production and testing*. Can be:**

- Each operation indicated by the process flow
- Each workstation
- Each machine

**Include testing and audits**  
**“Process Number” should cross reference with PFMEA and Process Map**

# The Control Plan Form

## CONTROL PLAN

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| Organization/Plant<br>ORGANIZATION            | Organization Code<br>CODE                 | Other Approval/Date (If Req'd.)              |                 |         | Other Approval/Date (If Req'd.)                |                         |  |   |        |                  |                   |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS |         | SPECIAL<br>CHAR.<br>CLASS                      | METHODS                 |  |   |        | REACTION<br>PLAN |                   |
|   |   |  | NO.             | PRODUCT |  | PROCESS                 | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE |                  | CONTROL<br>METHOD |
|   |   |  |                 |         |  |                         |  | SIZE                                    | FREQ.  |                  |                   |

**Product characteristics that are important. These can be determined by referencing:**

- ST Dimensions on the drawing
- Customer critical characteristics
- Process critical characteristics

**There may be several for each operation**

**Can be dimensional, performance or visual criteria**

# The Control Plan Form

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|---|---|--|---------------------------------|--------------------|--|--|---|--------|--|------------------|
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| Part Name/Description<br>NAME                 |   | Organization/Plant Approval/Date             |                                 |                    | Customer Quality Approval/Date (If Req'd.)     |  |   |        |  |                  |
| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    | Other Approval/Date (If Req'd.) |                    |  | Other Approval/Date (If Req'd.)                |   |        |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS                 |                    | SPECIAL<br>CHAR.<br>CLASS                      | METHODS  |   |        |  | REACTION<br>PLAN |
|   |   |  | NO.                             | PRODUCT<br>PROCESS |  | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE |  |                  |
|   |   |  |                                 |                    |  |  | SIZE                                    | FREQ.  |  |                  |

**Process parameters that are important. A process parameter is a setting made within a process that effects the variation within the operation. Examples include:**

- Temperature (molding, heat treat, etc.)
- Pressure
- Fixture settings
- Speed
- Torque

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| Part Name/Description<br>NAME                 |   | Organization/Plant Approval/Date             |                 |                                 |         | Customer Quality Approval/Date (If Req'd.)     |  |   |        |  |                  |
| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    |                 | Other Approval/Date (If Req'd.) |         | Other Approval/Date (If Req'd.)                |  |   |        |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS |                                 |         | SPECIAL<br>CHAR.<br>CLASS                      | METHODS  |   |        |  | REACTION<br>PLAN |
|   |   |  | NO.             | PRODUCT                         | PROCESS |  | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE |  |                  |
|   |   |  |                 |                                 |         |  |  | SIZE                                    | FREQ.  |  |                  |

**Class refers to special characteristics – product or process. Should align with FMEA**

# The Control Plan Form

## CONTROL PLAN

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| Control Plan Number<br>FILE.XLS               |   |  | Key Contact/Phone<br>555-555-5555 |         |         |                          | Date (Orig.)<br>1/1/1996                       |   | Date (Rev.)<br>1/1/1996 |  |                  |
|---|---|--|-----------------------------------|---------|---------|--------------------------|--|---|-------------------------|--|------------------|
| Part Number/Latest Change Level<br>NUMBER ECL |   |  | Core Team                         |         |         |                          | Customer Engineering Approval/Date (If Req'd.) |   |                         |  |                  |
| Part Name/Description<br>NAME                 |   |  | Organization/Plant Approval/Date  |         |         |                          | Customer Quality Approval/Date (If Req'd.)     |   |                         |  |                  |
| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    | Other Approval/Date (If Req'd.)   |         |         |                          | Other Approval/Date (If Req'd.)                |   |                         |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS                   |         |         | SPECIAL<br>CHAR<br>CLASS | METHODS  |   |                         |  | REACTION<br>PLAN |
|   |   |  | NO.                               | PRODUCT | PROCESS |                          | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE                  |  |                  |
|   |   |  |                                   |         |         |                          |  | SIZE                                    | FREQ.                   |  |                  |

**This is a specification from the Design Record or a key process parameter**

# The Control Plan Form

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|---|---|--|-----------------|---------------------------------|---------|--|--|---|--------|--|------------------|
| Part Number/Latest Change Level<br>NUMBER ECL |   | Core Team                                    |                 |                                 |         | Customer Engineering Approval/Date (If Req'd.) |  |   |        |  |                  |
| Part Name/Description<br>NAME                 |   | Organization/Plant Approval/Date             |                 |                                 |         | Customer Quality Approval/Date (If Req'd.)     |  |   |        |  |                  |
| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    |                 | Other Approval/Date (If Req'd.) |         | Other Approval/Date (If Req'd.)                |  |   |        |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS |                                 |         | SPECIAL<br>CHAR.<br>CLASS                      | METHODS  |   |        |  | REACTION<br>PLAN |
|   |   |  | NO.             | PRODUCT                         | PROCESS |  | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE |  |                  |
|   |   |  |                 |                                 |         |  |  | SIZE                                    | FREQ.  |  |                  |

**How is the characteristic or parameter going to be measured? Examples include:**

- Caliper
- Attribute gage
- Visual
- Fixture
- Test equipment



# The Control Plan Form

## CONTROL PLAN

Prototype     Pre-Launch     Production

| Control Plan Number<br>FILE.XLS               |   | Key Contact/Phone<br>555-555-5555            |                 |                                 |         | Date (Orig.)<br>1/1/1996                       |  | Date (Rev.)<br>1/1/1996                |        |  |                  |
|---|---|--|-----------------|---------------------------------|---------|--|--|--|--------|--|------------------|
| Part Number/Latest Change Level<br>NUMBER ECL |   | Core Team                                    |                 |                                 |         | Customer Engineering Approval/Date (If Req'd.) |  |  |        |  |                  |
| Part Name/Description<br>NAME                 |   | Organization/Plant Approval/Date             |                 |                                 |         | Customer Quality Approval/Date (If Req'd.)     |  |  |        |  |                  |
| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    |                 | Other Approval/Date (If Req'd.) |         | Other Approval/Date (If Req'd.)                |  |  |        |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS |                                 |         | SPECIAL<br>CHAR.<br>CLASS                      | METHODS  |  |        |  | REACTION<br>PLAN |
|   |   |  | NO.             | PRODUCT                         | PROCESS |  | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION<br>MEASUREMENT<br>TECHNIQUE | SAMPLE |  |                  |
|   |   |  |                 |                                 |         |  |  | SIZE                                   | FREQ.  |  |                  |

**How many parts will be measured and how often.**  
**Examples:**  
**Final testing, visual criteria**  

- 100%

**SPC, Audit,**  

- The sample size and frequency

# The Control Plan Form

## CONTROL PLAN

Prototype     Pre-Launch     Production

| Control Plan Number<br>FILE.XLS               |   |  | Key Contact/Phone<br>555-555-5555 |         |         |                           | Date (Orig.)<br>1/1/1996                       |   | Date (Rev.)<br>1/1/1996 |  |                  |
|---|---|--|-----------------------------------|---------|---------|---------------------------|--|---|-------------------------|--|------------------|
| Part Number/Latest Change Level<br>NUMBER ECL |   |  | Core Team                         |         |         |                           | Customer Engineering Approval/Date (If Req'd.) |   |                         |  |                  |
| Part Name/Description<br>NAME                 |   |  | Organization/Plant Approval/Date  |         |         |                           | Customer Quality Approval/Date (If Req'd.)     |   |                         |  |                  |
| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    | Other Approval/Date (If Req'd.)   |         |         |                           | Other Approval/Date (If Req'd.)                |   |                         |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS                   |         |         | SPECIAL<br>CHAR.<br>CLASS | METHODS  |   |                         |  | REACTION<br>PLAN |
|   |   |  | NO.                               | PRODUCT | PROCESS |                           | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE                  |  |                  |
|   |   |  |                                   |         |         |                           |  | SIZE                                    | FREQ.                   |  |                  |

**How the characteristic or parameter will be controlled (this is the record) Examples include:**

- Xbar/R Chart
- NP Chart
- Pre-control Chart
- Checklist
- Log sheet
- Mistake proofing
- 1st piece inspection
- Lab report

# The Control Plan Form

## CONTROL PLAN

Prototype     Pre-Launch     Production

| Control Plan Number<br>FILE.XLS               |   | Key Contact/Phone<br>555-555-5555            |                 |                                 |         | Date (Orig.)<br>1/1/1996                       |  | Date (Rev.)<br>1/1/1996                 |                         |  |                  |
|---|---|--|-----------------|---------------------------------|---------|--|--|---|-------------------------|--|------------------|
| Part Number/Latest Change Level<br>NUMBER ECL |   | Core Team                                    |                 |                                 |         | Customer Engineering Approval/Date (If Req'd.) |  |   |                         |  |                  |
| Part Name/Description<br>NAME                 |   | Organization/Plant Approval/Date             |                 |                                 |         | Customer Quality Approval/Date (If Req'd.)     |  |   |                         |  |                  |
| Organization/Plant<br>ORGANIZATION            |   | Organization Code<br>CODE                    |                 | Other Approval/Date (If Req'd.) |         | Other Approval/Date (If Req'd.)                |  |   |                         |  |                  |
| PART/<br>PROCESS<br>NUMBER                    | PROCESS NAME/<br>OPERATION<br>DESCRIPTION | MACHINE,<br>DEVICE<br>JIG, TOOLS<br>FOR MFG. | CHARACTERISTICS |                                 |         | SPECIAL<br>CHAR.<br>CLASS                      | METHODS  |   |                         |  | REACTION<br>PLAN |
|   |   |  | NO.             | PRODUCT                         | PROCESS |  | PRODUCT/PROCESS<br>SPECIFICATION/<br>TOLERANCE | EVALUATION/<br>MEASUREMENT<br>TECHNIQUE | SAMPLE<br>SIZE    FREQ. |  |                  |
|   |   |  |                 |                                 |         |  |  |   |                         |  |                  |

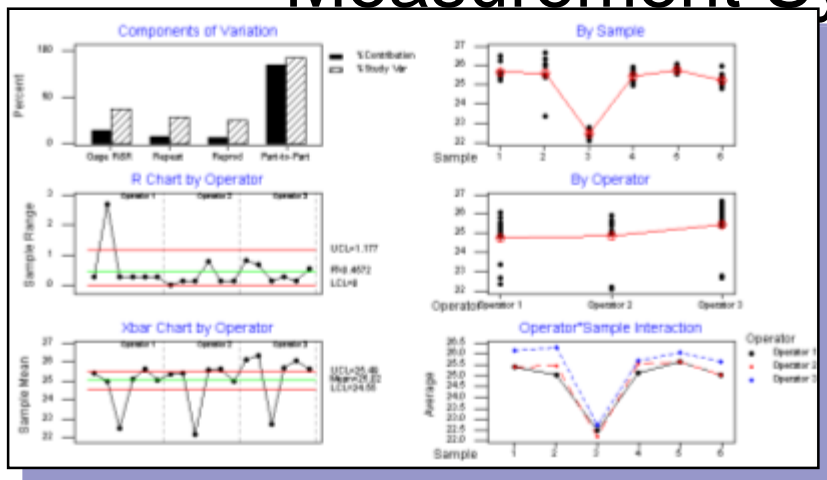
**What happens when the characteristic or parameter is found to be out of control. Must include:**

- Segregation of nonconforming product
- Correction method

**May include (as appropriate):**

- Sorting
- Rework/Repair
- Customer notification

# PPAP Element #8: Measurement System Analysis (MSA)



## What is It?

An MSA is a statistical tool used to determine if a measurement system is capable of precise measurement.

## Objective or Purpose

- To determine how much error is in the measurement due to the measurement process itself.
- Quantifies the variability added by the measurement system.
- Applicable to attribute data and variable data.

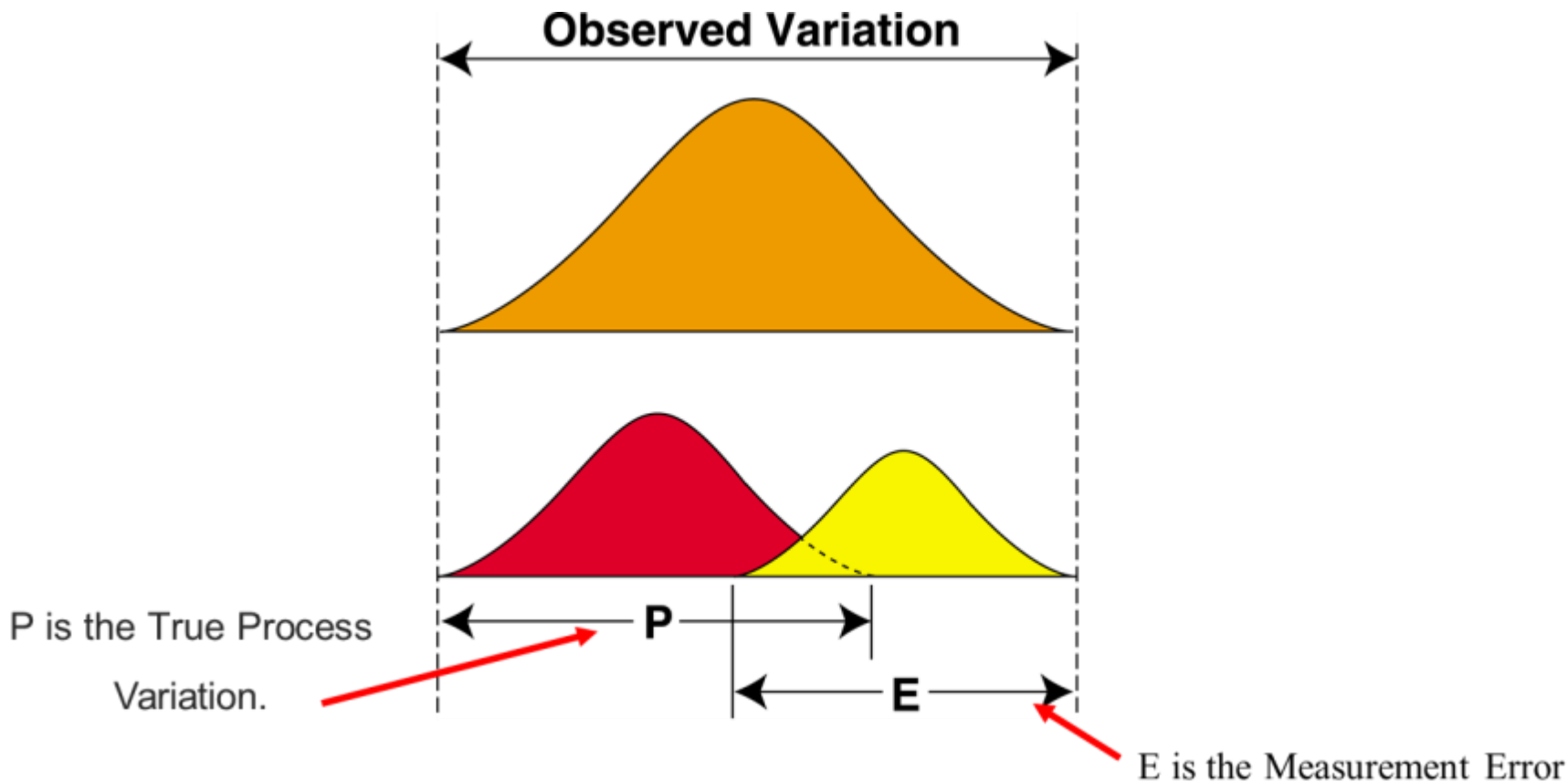
## When to Use It

- On systems measuring critical inputs and outputs prior to collecting data for analysis.
- For any new or modified process in order to ensure the quality of the data.

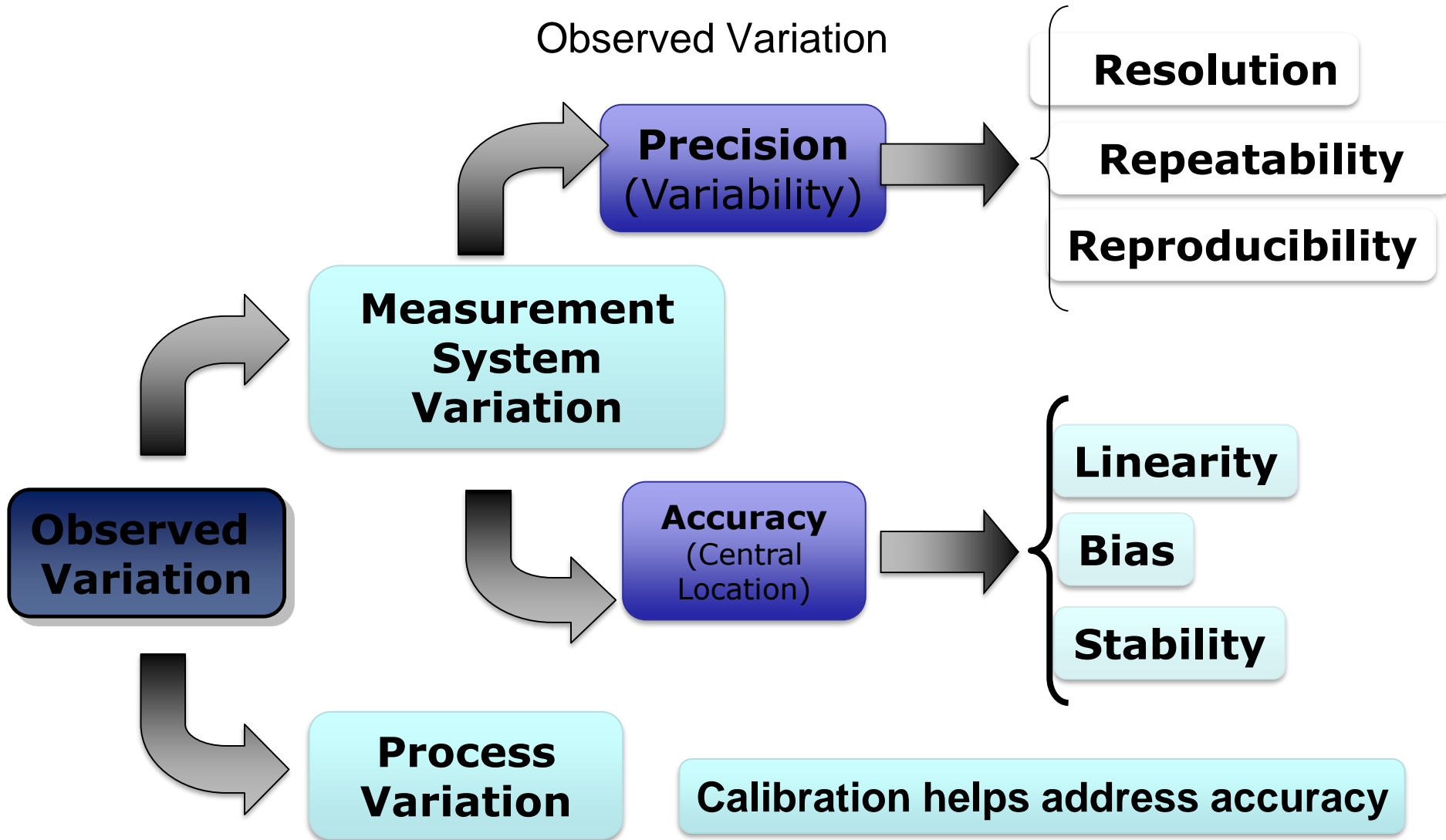
## IMPORTANT!

**Measurement System Analysis is an analysis of the measurement process, *not* an analysis of the people!!**

# Inspection – what do you really see?



# Measurement System Analysis (MSA)



# Measurement System Analysis (MSA)

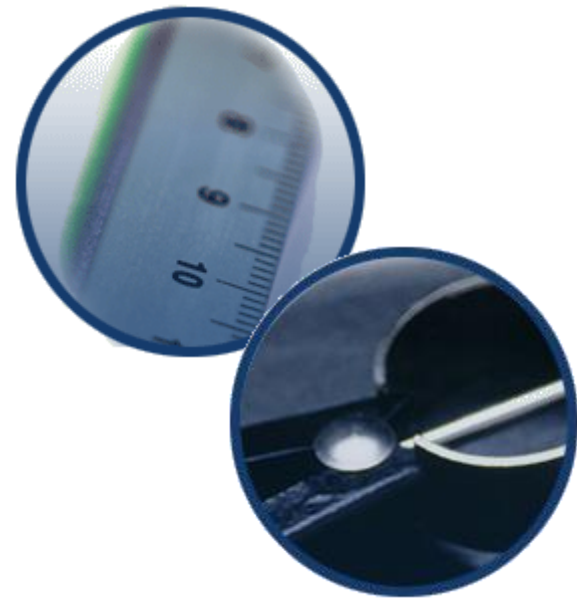
## Resolution

### Error in Resolution

**The inability to detect small changes.**

### Possible Cause

**Wrong measurement device selected - divisions on scale not fine enough to detect changes.**



# Measurement System Analysis (MSA)

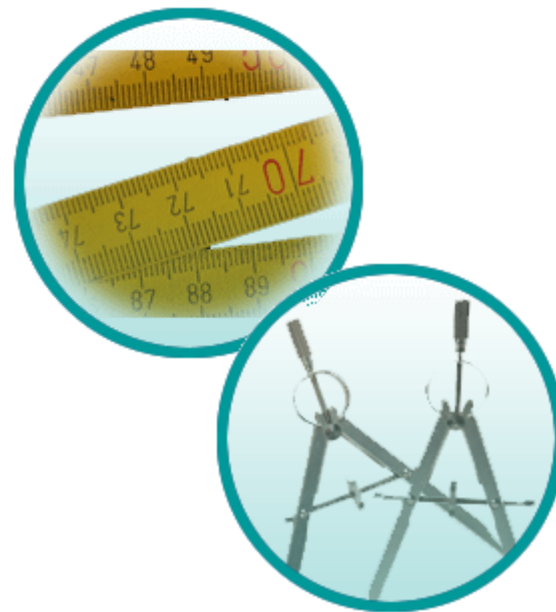
## Repeatability

### Error in Repeatability

**The inability to get the same answer from repeated measurements made of the same item under absolutely identical conditions.**

### Possible Cause

**Lack of standard operating procedures (SOP), lack of training, measuring system variability.**



## Equipment Variation



# Measurement System Analysis (MSA)

## Reproducibility

### Error in Reproducibility

**The inability to get the same answer from repeated measurements made under various conditions from different inspectors.**

### Possible Cause

**Lack of SOP, lack of training.**



**Appraiser Variation**

# Variable MSA – AIAG GR&R VAR(Tol)

**GAGE REPEATABILITY AND REPRODUCIBILITY DATA SHEET  
VARIABLE DATA RESULTS**

**GAGE REPEATABILITY AND REPRODUCIBILITY DATA SHEET  
VARIABLE DATA RESULTS**

|   |             |             |            |                |                               |             |             |            |                |
|---|-------------|-------------|------------|----------------|-------------------------------|-------------|-------------|------------|----------------|
| Part Number<br>NUMBER                                 | Gage Name   | Appraiser A |            |                | Part Number<br>NUMBER         | Gage Name   | Appraiser A |            |                |
| Part Name<br>NAME                                     | Gage Number | Appraiser B |            |                | Part Name<br>NAME             | Gage Number | Appraiser B |            |                |
| Characteristic<br>Specification<br><i>Lower Upper</i> | Gage Type   | Appraiser C |            |                | Characteristic                | Gage Type   | Appraiser C |            |                |
| Characteristic Classification                         | Trials      | Parts       | Appraisers | Date Performed | Characteristic Classification | Trials      | Parts       | Appraisers | Date Performed |

**Included in PPAP Workbook**

**Automatically calculates %GRR, %PV, ndc**

| AVERAGE  |                |        |  | Measurement Unit Analysis   |  |  |  | % Tolerance (Tol)     |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
|--|----------------|--------|--|---|--|--|--|-----------------------|----------------|---|----------------|--------|--------|---|--------|---|--------|---|--------|---|--------|----|--------|---|--|
| Repeatability - Equipment Variation (EV)   |                |        |  | EV = $R \times K_1$   |  |  |  | % EV = 100 (EV/Tol)   |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
|  |                |        |  | <table border="1"> <tr> <td>Trials</td> <td>K<sub>1</sub></td> </tr> <tr> <td>2</td> <td>0.8862</td> </tr> <tr> <td>3</td> <td>0.5908</td> </tr> </table>   |  |  |  | Trials                | K <sub>1</sub> | 2 | 0.8862         | 3      | 0.5908 | = |        |   |        |   |        |   |        |    |        |   |  |
| Trials   | K <sub>1</sub> |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 2  | 0.8862         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 3  | 0.5908         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| Reproducibility - Appraiser Variation (AV)   |                |        |  | AV = $\{(X_{DIFF} \times K_2)^2 - (EV^2/nr)\}^{1/2}$  |  |  |  | % AV = 100 (AV/Tol)   |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
|  |                |        |  | <table border="1"> <tr> <td>Appraisers</td> <td>2</td> <td>3</td> </tr> <tr> <td>K<sub>2</sub></td> <td>0.7071</td> <td>0.5231</td> </tr> </table>  |  |  |  | Appraisers            | 2              | 3 | K <sub>2</sub> | 0.7071 | 0.5231 | = |        |   |        |   |        |   |        |    |        |   |  |
| Appraisers   | 2              | 3      |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| K <sub>2</sub>   | 0.7071         | 0.5231 |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| Repeatability & Reproducibility (GRR)  |                |        |  | GRR = $\{(EV^2 + AV^2)\}^{1/2}$   |  |  |  | % GRR = 100 (GRR/Tol) |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
|  |                |        |  | <table border="1"> <tr> <td>Parts</td> <td>K<sub>3</sub></td> </tr> <tr> <td>2</td> <td>0.7071</td> </tr> <tr> <td>3</td> <td>0.5231</td> </tr> </table>  |  |  |  | Parts                 | K <sub>3</sub> | 2 | 0.7071         | 3      | 0.5231 | = |        |   |        |   |        |   |        |    |        |   |  |
| Parts  | K <sub>3</sub> |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 2  | 0.7071         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 3  | 0.5231         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| Part Variation (PV)  |                |        |  | PV = $R_p \times K_3$   |  |  |  | % PV = 100 (PV/Tol)   |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
|  |                |        |  | <table border="1"> <tr> <td>Parts</td> <td>K<sub>3</sub></td> </tr> <tr> <td>4</td> <td>0.5774</td> </tr> <tr> <td>5</td> <td>0.4030</td> </tr> <tr> <td>6</td> <td>0.3742</td> </tr> <tr> <td>7</td> <td>0.3534</td> </tr> <tr> <td>8</td> <td>0.3375</td> </tr> <tr> <td>9</td> <td>0.3249</td> </tr> <tr> <td>10</td> <td>0.3146</td> </tr> </table> |  |  |  | Parts                 | K <sub>3</sub> | 4 | 0.5774         | 5      | 0.4030 | 6 | 0.3742 | 7 | 0.3534 | 8 | 0.3375 | 9 | 0.3249 | 10 | 0.3146 | = |  |
| Parts  | K <sub>3</sub> |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 4  | 0.5774         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 5  | 0.4030         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 6  | 0.3742         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 7  | 0.3534         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 8  | 0.3375         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 9  | 0.3249         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 10   | 0.3146         |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| Tolerance (Tol)  |                |        |  | Tol = Upper - Lower / 6   |  |  |  | ndc = 1.41(PV/GRR)    |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
|  |                |        |  | = (Upper - Lower) / 6   |  |  |  | =                     |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
|  |                |        |  | =   |  |  |  | =                     |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 17. $(r_a + r_b + r_c) / (\# \text{ OF APPRAISERS}) =$   |                |        |  | R =   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 18. $X_{DIFF} = (\text{Max X} - \text{Min X}) =$   |                |        |  | X <sub>DIFF</sub> =   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| 19. $* UCL_R = R \times D_4 =$   |                |        |  | UCL <sub>R</sub> =  |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| <p>* D<sub>4</sub> = 3.27 for 2 trials and 2.58 for 3 trials. UCL<sub>R</sub> represents the limit of individual R's. Circle those that are beyond this limit. Identify the cause and correct. Repeat these readings using the same appraiser and unit as originally used or discard values and re-average and recompute R and the limiting value from the remaining observations.</p> |                |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| Notes: _____   |                |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |
| For information on the theory and constants used in the form see <i>MSA Reference Manual</i> , Fourth edition.   |                |        |  |   |  |  |  |                       |                |   |                |        |        |   |        |   |        |   |        |   |        |    |        |   |  |

# PPAP Element #9: Dimensional Results

## Production Part Approval / Dimensional Test Results

Corporate SCM Form-XX (Rev. A, 2014)

| Supplier               |                           |                        |           |             | 0                  |  |  |                                     |    | Part Number                 |  |  | 0 |  |  |
|------------------------|---------------------------|------------------------|-----------|-------------|--------------------|--|--|-------------------------------------|----|-----------------------------|--|--|---|--|--|
| Supplier / Vender Code |                           |                        |           |             |                    |  |  |                                     |    | Part Name                   |  |  |   |  |  |
| Inspection Facility    |                           |                        |           |             |                    |  |  |                                     |    | Design Record Change Level  |  |  | 0 |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    | Engineering Change Document |  |  |   |  |  |
| Item                   | Dimension / Specification | Specification / Limits | Test Date | Qty. Tested | Measurement Method |  |  | Supplier Measurement Results (DATA) | OK | Not OK                      |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |
|                        |                           |                        |           |             |                    |  |  |                                     |    |                             |  |  |   |  |  |

### What is It?

Evidence that dimensional verifications have been completed and results indicate compliance with specified requirements

### Objective or Purpose

- To show conformance to the customer part print on dimensions and all other noted requirements

### When to Use It

- For each unique manufacturing process (e.g., cells or production lines and all molds, patterns, or dies)

# PPAP Element #10: Records of Material/Performance Test Results

- Material Test Results
  - The supplier shall perform tests for all parts and product materials when chemical, physical, or metallurgical requirements are specified by the design record or Control Plan
  - For products with Customer-developed material specifications and/or an Customer-approved supplier list, the supplier shall procure materials and/or services from suppliers on that list
- Performance Test Results
  - The supplier shall perform tests for all parts or product materials when performance or functional requirements are specified by the design record or Control Plan

# Material Results

## Production Part Approval Material Test Results

| ORGANIZATION:<br>SUPPLIER / VENDOR CODE:  |                        |           | PART NUMBER:<br>PART NAME:                                   |                              |    |        |
|---|------------------------|-----------|--|------------------------------|----|--------|
| MATERIAL SUPPLIER:<br>*CUSTOMER SPECIFIED SUPPLIER / VENDOR CODE:                     |                        |           | DESIGN RECORD CHANGE LEVEL:<br>ENGINEERING CHANGE DOCUMENTS: |                              |    |        |
| *If source approval is req'd, include the Supplier (Source) & Customer assigned code. |                        |           | NAME of LABORATORY:  |                              |    |        |
| MATERIAL SPEC. NO. / REV / DATE   | SPECIFICATION / LIMITS | TEST DATE | QTY. TESTED  | SUPPLIER TEST RESULTS (DATA) | OK | NOT OK |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |
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|   |                        |           |  |                              |    |        |
|   |                        |           |  |                              |    |        |

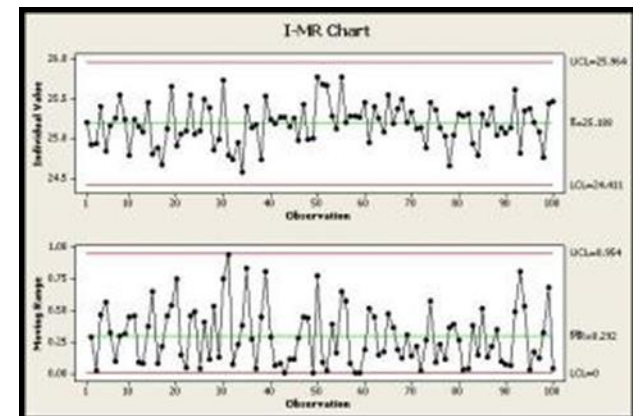
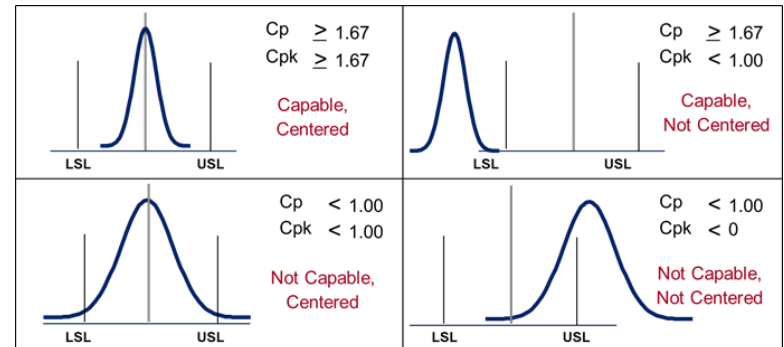
Material Results shall include:

- ✓ The name of the laboratory that conducted the test
- ✓ The type of test that was conducted
- ✓ The number, date, and specification to which the part was tested
- ✓ The actual test results



# PPAP Element #11: Initial Process Studies

- Capability studies are measures of how well the process is meeting the design requirements.
  - Is the process employed Stable and Capable?
- MSA before Cpk
  - MSA must be acceptable and should represent tools/process used for Initial Process Studies
- >1.67 Cpk for SCs, >1.33 for other characteristics
- Cpk & Ppk minimums are higher for initial release vs. ongoing



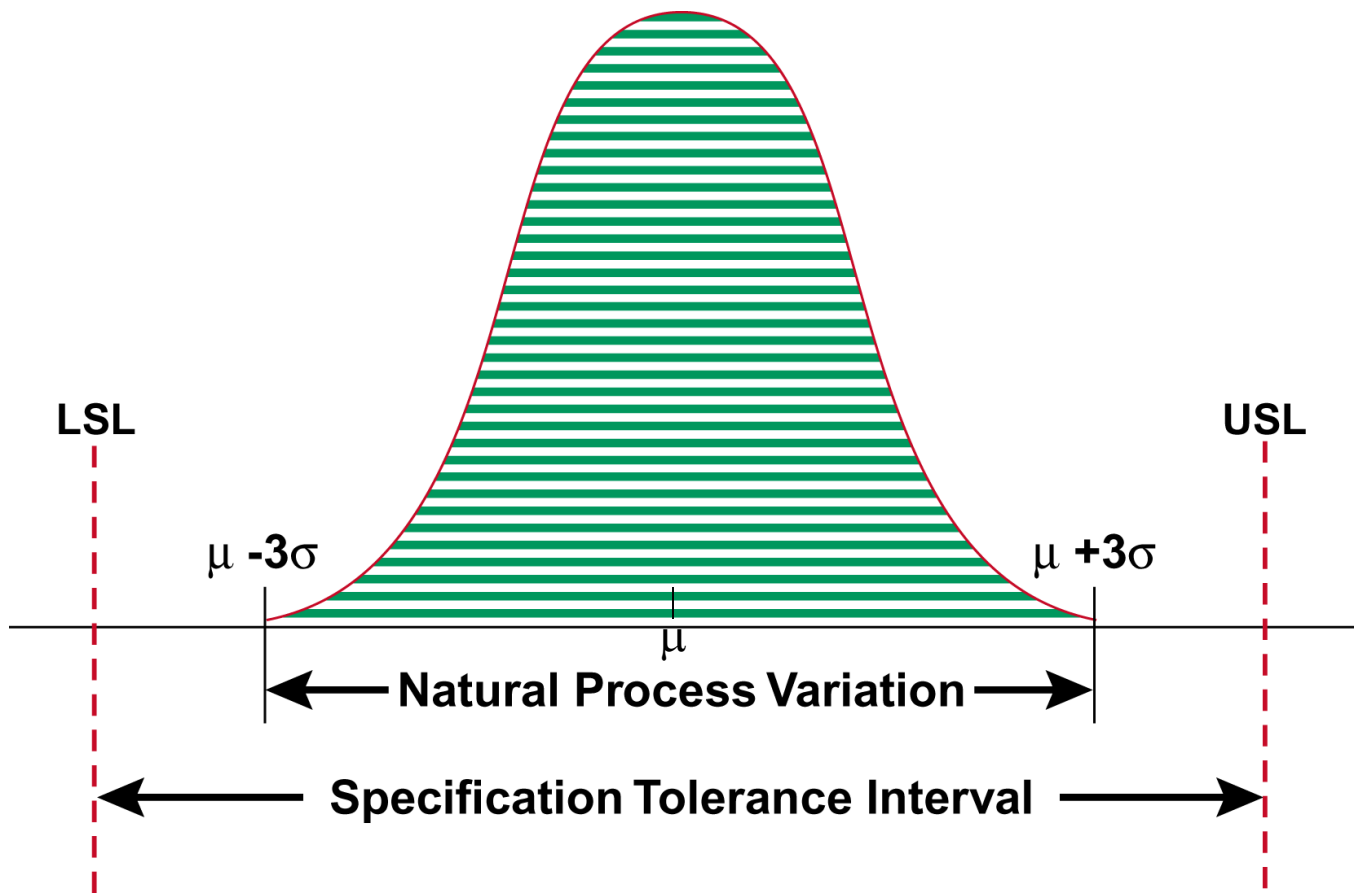
# PPAP Element #11: Initial Process Study

## Purposes of Initial Process Study

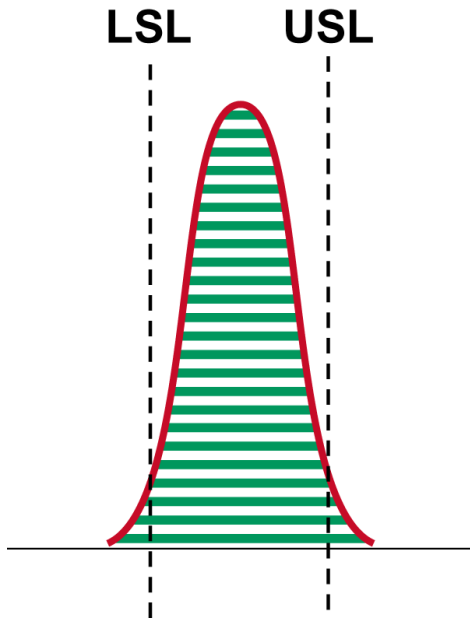
- To evaluate how well a process can produce product that meets specifications
- To provide guidance about how to improve capability
  - better process centering
  - reduced variation
- Capability studies can be used to identify a problem or to verify permanent corrective actions in the problem solving process.



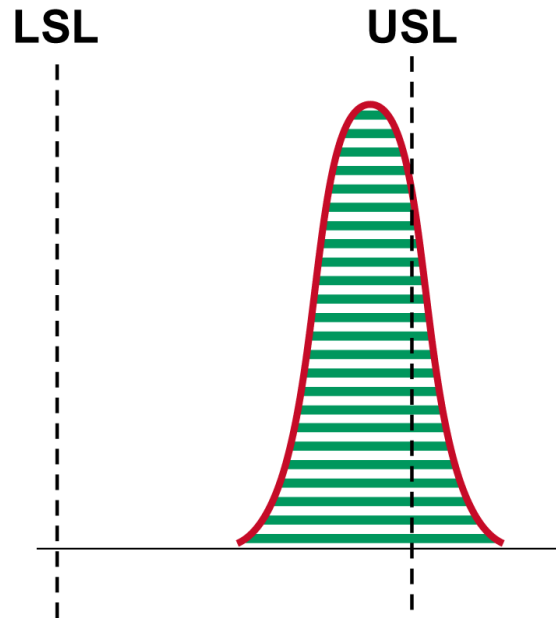
# Process Capability: The Two Voices



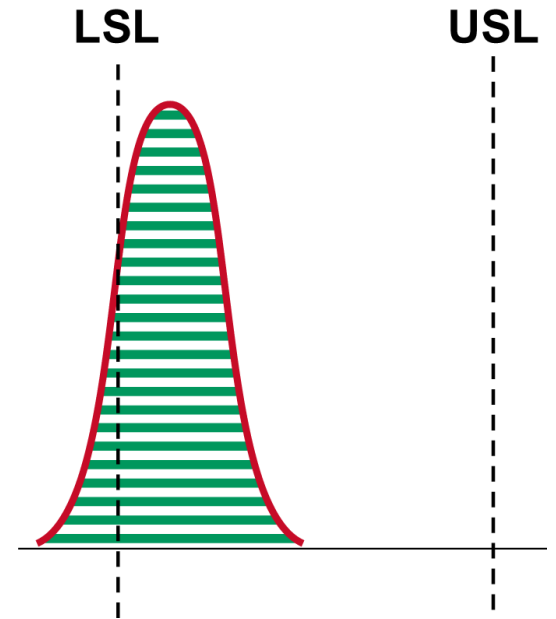
# Examples of *Non-Capable* Processes



**Product produced  
beyond both  
Upper and Lower  
Spec Limits.**



**Product produced  
above the  
Upper Spec Limit.**



**Product produced  
below the  
Lower Spec Limit.**

# PPAP Element #12:

## Qualified Laboratory Documentation

- Inspection and testing for PPAP shall be performed by a qualified laboratory (e.g., an accredited laboratory).
- The qualified laboratory (internal or external to the supplier) shall have a laboratory scope and documentation showing that the laboratory is qualified for the type of measurements or tests conducted
  - When an external laboratory is used, the supplier shall submit the test results on the laboratory letterhead or the normal laboratory report format
  - The name of the laboratory that performed the tests, the date(s) of the tests, and the standards used to run the tests shall be identified.
  - Customer to validate results to specifications.

# PPAP Element #13: Appearance Approval Report

## APPEARANCE APPROVAL REPORT

|                       |  |  |   |                        |                        |
|-----------------------|--|--|---|------------------------|------------------------|
| PART NUMBER           |  | DRAWING NUMBER                                     |   | APPLICATION (VEHICLES) |                        |
| PART NAME             |  | BUYER CODE   | E/C LEVEL                                   |                        | DATE                   |
| ORGANIZATION NAME     |  | MANUFACTURING LOCATION                             |   |                        | SUPPLIER / VENDOR CODE |
| REASON FOR SUBMISSION | <input type="checkbox"/> PART SUBMISSION WARRANT | <input type="checkbox"/> SPECIAL SAMPLE            | <input type="checkbox"/> RE-SUBMISSION      |                        | OTHER                  |
|                       | <input type="checkbox"/> PRE TEXTURE             | <input type="checkbox"/> FIRST PRODUCTION SHIPMENT | <input type="checkbox"/> ENGINEERING CHANGE |                        |                        |

## APPEARANCE EVALUATION

|   |  |  |                           |   |
|---|--|--|---------------------------|---|
| ORGANIZATION SOURCING AND TEXTURE INFORMATION |  |  | PRE-TEXTURE EVALUATION    | AUTHORIZED CUSTOMER REPRESENTATIVE SIGNATURE AND DATE |
|   |  |  | CORRECT AND PROCEED       |   |
|   |  |  | CORRECT AND PROCEED       |   |
|   |  |  | APPROVED TO ETCH/TOOL/EDM |   |

## COLOR EVALUATION

| COLOR SUFFIX | TRISTIMULUS DATA |     |     |     |     | MASTER NUMBER | MASTER DATE | MATERIAL TYPE | MATERIAL SOURCE | HUE |     |     |     |       | VALUE |      |       |      | CHROMA |      | GLOSS |      | METALLIC BRILLIANCE |  | COLOR SHIPPING SUFFIX | PART DISPOSITION |
|--------------|------------------|-----|-----|-----|-----|---------------|-------------|---------------|-----------------|-----|-----|-----|-----|-------|-------|------|-------|------|--------|------|-------|------|---------------------|--|-----------------------|------------------|
|              | DL*              | Da* | Db* | DE* | CMC |               |             |               |                 | RED | YEL | GRN | BLU | LIGHT | DARK  | GRAY | CLEAN | HIGH | LOW    | HIGH | LOW   | HIGH | LOW                 |  |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |       |      |       |      |        |      |       |      |                     |  |                       |                  |

### What is It?

- A report completed by the supplier containing appearance and color criteria

### Objective or Purpose

- To demonstrate that the part has met the appearance requirements on the design record

### When to Use It

- Prior to tooling for production

### IMPORTANT!

Only applies for parts with color, grain, or surface appearance requirements

# PPAP Element #14: Sample Production Parts



## What is It?

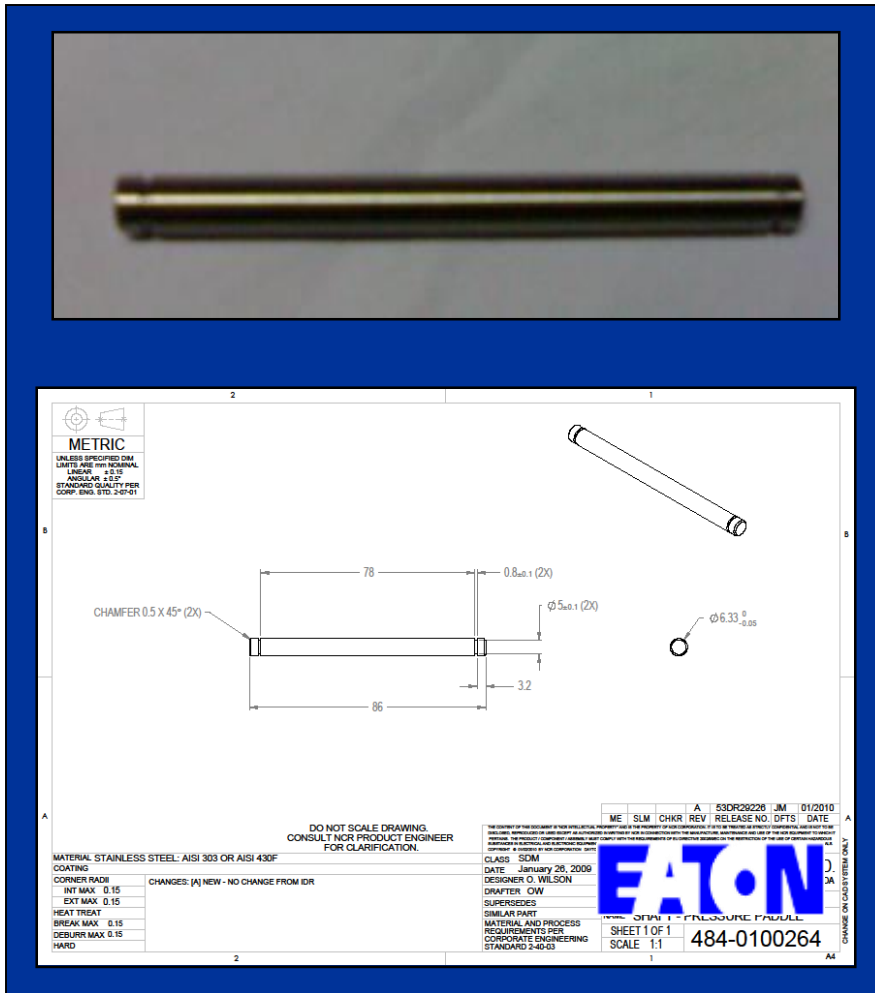
Actual samples that reflect the parts documented in the PPAP.

## Objective or Purpose

- Confirm cosmetic or functional part approval.

## When to Use It

- Sample parts should be delivered WITH the PPAP submission



# Sample Production Parts

- The sample parts provided should be the same parts measured for the dimensional results
- PPAP sample quantity is based on needs from Customer Engineering, Manufacturing and Quality

# Sample Production Parts

Sample production parts **MUST** be properly identified

Include the following information on the part label:

- Date parts were packed
- Customer part number
- Quantity
- Serial number
- Supplier part number (optional)
- Part description
- Country of origin
- Indication of regulatory compliance where applicable (RoHS, REACH, Conflict Minerals, etc.)
- Approval markings (UL, CE, etc.) where applicable

# PPAP Element #15: Master Samples

## PPAP Element #16: Checking Aids

- Master Sample (PPAP Element #15)
  - The “perfect” or “golden” sample that subsequent parts can be compared against
  - Often the first good part off a new tool for injection molding or stamping
  - Is sometimes used to verify testing equipment and measurement systems
  - Master samples are not normal for every product or manufacturing process
- Checking aid (PPAP Element #16)
  - Tools, gages, or test equipment, used to inspect production parts
  - Examples include:
    - Visual standards for color or appearance
    - Shadow boards or templates used to verify general shape or presence of required features
    - Custom gages



# PPAP Element #17: Customer Requirements

- APQP Kickoff - team
- APQP Timeline Template
- Action Item Log
- Production Feasibility Agreement (PFA)
- Gage Plan
- Dimensional Correlation Matrix
- Pass Through Characteristics (PTC)
- Safe Launch Control Plan
- AS 9102 Forms (Aerospace Industry)
- Ramp Up & Down Plan
- Packaging Specification Data Sheet
- Submit Bar Code Label Packaging Approval
- PPAP Interim Recovery Worksheet
- Capacity R@R Worksheet
- Production Readiness Review (PRR)

These items all have templates in the PPAP Workbook – many of which are self-explanatory

Items in blue have additional instructions embedded in the PPAP Workbook

Let's take a closer look at the items in red...

# PPAP Element #18: Part Submission Warrant (PSW)

**Part Submission Warrant**

---

Part Name \_\_\_\_\_ Cust. Part Number \_\_\_\_\_  
 Show n on Drawing Number \_\_\_\_\_ Org. Part Number \_\_\_\_\_  
 Engineering Change Level \_\_\_\_\_ Dated \_\_\_\_\_  
 Additional Engineering Changes \_\_\_\_\_ Dated \_\_\_\_\_  
 Safety and/or Government Regulation  Yes  No Purchase Order No. \_\_\_\_\_ Weight (kg) \_\_\_\_\_  
 Checking Aid Number \_\_\_\_\_ Checking Aid Eng. Change Level \_\_\_\_\_ Dated \_\_\_\_\_

**ORGANIZATION MANUFACTURING INFORMATION      CUSTOMER SUBMITTAL INFORMATION**

Supplier Name & Supplier/Vendor Code \_\_\_\_\_ Customer Name/Division \_\_\_\_\_  
 Street Address \_\_\_\_\_ Buyer/Buyer Code \_\_\_\_\_  
 City \_\_\_\_\_ Region \_\_\_\_\_ Postal Code \_\_\_\_\_ Country \_\_\_\_\_ Application \_\_\_\_\_

**MATERIALS REPORTING**

Has customer-required Substances of Concern information been reported?  Yes  No  
 Submitted by IMDS or other customer format: \_\_\_\_\_

Are polymeric parts identified w with appropriate ISO marking codes?  Yes  No  n/a

**REASON FOR SUBMISSION (Check at least one)**

|   |  |
|---|--|
| <input type="checkbox"/> Initial submission   | <input type="checkbox"/> Change to Optional Construction or Material |
| <input type="checkbox"/> Engineering Change(s)  | <input type="checkbox"/> Sub-Supplier or Material Source Change      |
| <input type="checkbox"/> Tooling; Transfer, Replacement, Refurbishment, or additional | <input type="checkbox"/> Change in Part Processing                   |
| <input type="checkbox"/> Correction of Discrepancy                                    | <input type="checkbox"/> Parts produced at Additional Location       |
| <input type="checkbox"/> Tooling Inactive > than 1 year                               | <input type="checkbox"/> Other - please specify _____                |

**REQUESTED SUBMISSION LEVEL (Check one)**

Level 1 - Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.  
 Level 2 - Warrant with product samples and limited supporting data submitted to customer.  
 Level 3 - Warrant with product samples and complete supporting data submitted to customer.  
 Level 4 - Warrant and other requirements as defined by customer.  
 Level 5 - Warrant with product samples and complete supporting data reviewed at organization's manufacturing location.

**SUBMISSION RESULTS**

The results for  dimensional measurement  material and functional tests  appearance criteria  statistical process package  
 These results meet all design record requirements:  Yes  NO (If "NO" - Explanation Required)  
 Mold / Cavity / Production Process \_\_\_\_\_

**DECLARATION**

I affirm that the samples represented by this warrant are representative of our parts, which were made by a process that meets all Production Part Approval Process Manual 4th Edition Requirements. I further affirm that these samples were produced at the production rate of \_\_\_\_/\_\_\_\_ hours. I also certify that documented evidence of such compliance is on file and available for your review. I have noted any deviation from this declaration below.

EXPLANATION/COMMENTS: \_\_\_\_\_

Is each Customer Tool properly tagged and numbered?  Yes  No  n/a

Organization Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_  
 Print Name \_\_\_\_\_ Phone No. \_\_\_\_\_ Fax No. \_\_\_\_\_  
 Title \_\_\_\_\_ E-mail \_\_\_\_\_

**FOR CUSTOMER USE ONLY (IF APPLICABLE)**

PPAP Warrant Disposition:  Approved  Rejected  Other \_\_\_\_\_  
 Customer Signature \_\_\_\_\_ Date \_\_\_\_\_  
 Print Name \_\_\_\_\_ Customer Tracking Number (optional) \_\_\_\_\_

## What is It?

- Required document in which the supplier confirms the design and validation of manufacturing processes that will produce parts to specification at a specific rate

## Objective or Purpose

- Used to :
  - document part approval
  - provide key information
  - declare that the parts meet specification

## When to Use It

- Prior to shipping production parts

# Part Submission Warrant (PSW)

## Part Submission Warrant

Part Name \_\_\_\_\_ Cust. Part Number \_\_\_\_\_

Show n on Drawing Number \_\_\_\_\_ Org. Part Number \_\_\_\_\_

Engineering Change Level \_\_\_\_\_ Dated \_\_\_\_\_

Additional Engineering Changes \_\_\_\_\_ Dated \_\_\_\_\_

Safety and/or Government Regulation  Yes  No Purchase Order No. \_\_\_\_\_ Weight (kg) \_\_\_\_\_

Checking Aid Number \_\_\_\_\_ Checking Aid Eng. Change Level \_\_\_\_\_ Dated \_\_\_\_\_

### ORGANIZATION MANUFACTURING INFORMATION

### CUSTOMER SUBMITTAL INFORMATION

Supplier Name & Supplier/Vendor Code \_\_\_\_\_

Customer Name/Division \_\_\_\_\_

Street Address \_\_\_\_\_

Buyer/Buyer Code \_\_\_\_\_

City \_\_\_\_\_

Region \_\_\_\_\_

Administrative section containing basic part information, including Part Number and Revision

# Part Submission Warrant (PSW)

## Part Submission Warrant

Part Name \_\_\_\_\_

Shown on Drawing Number \_\_\_\_\_

Engineering Change Level \_\_\_\_\_

Additional Engineering Changes \_\_\_\_\_

Safety and/or Government Regulation

Yes

No

Purchase Order No. \_\_\_\_\_

Weight (kg) \_\_\_\_\_

Checking Aid Number \_\_\_\_\_

Checking Aid Eng. Change Level \_\_\_\_\_

Dated \_\_\_\_\_

Administrative section identifying  
supplier location and customer location

### ORGANIZATION MANUFACTURING INFORMATION

Supplier Name & Supplier/Vendor Code \_\_\_\_\_

Street Address \_\_\_\_\_

City \_\_\_\_\_

Region \_\_\_\_\_

Postal Code \_\_\_\_\_

Country \_\_\_\_\_

### CUSTOMER SUBMITTAL INFORMATION

Customer Name/Division \_\_\_\_\_

Buyer/Buyer Code \_\_\_\_\_

Application \_\_\_\_\_

# Part Submission Warrant (PSW)

## MATERIALS REPORTING

Has customer-required Substances of Concern information been reported?  Yes  No

Submitted by IMDS or other customer format: \_\_\_\_\_

Are polymeric parts identified with appropriate ISO marking codes?  Yes  No  n/a

## REASON FOR SUBMISSION (Check at least one)

- |   |  |
|---|--|
| <input type="checkbox"/> Initial submission   | <input type="checkbox"/> Change to Optional Construction or Material |
| <input type="checkbox"/> Engineering Change(s)  | <input type="checkbox"/> Sub-Supplier or Material Source Change      |
| <input type="checkbox"/> Tooling: Transfer, Replacement, Refurbishment, or additional | <input type="checkbox"/> Change in Part Processing                   |
| <input type="checkbox"/> Correction of Discrepancy                                    | <input type="checkbox"/> Parts produced at Additional Location       |
| <input type="checkbox"/> Tooling Inactive > than 1 year                               | <input type="checkbox"/> Other - please specify _____                |

## REQUESTED SUBMISSION LEVEL (Check one)

- Level 1 - Warrant only (and for designated processes items as Appendix A Annual Report) submitted to customer.
- Level 2 - Warrant only (and for designated processes items as Appendix A Annual Report) submitted to customer.
- Level 3 - Warrant only (and for designated processes items as Appendix A Annual Report) submitted to customer.
- Level 4 - Warrant only (and for designated processes items as Appendix A Annual Report) submitted to customer.
- Level 5 - Warrant only (and for designated processes items as Appendix A Annual Report) submitted to customer.

Here the supplier is required to identify how it has reported Substances of Concern:

- IMDS, RoHS, REACH, Conflict Minerals, etc.

## SUBMISSION RESULT

The results for  dimensions  material  statistical process package

These results meet all design record requirements:  Yes  NO (If "NO" - Explanation Required)

Mold / Cavity / Production Process \_\_\_\_\_

# Part Submission Warrant (PSW)

## MATERIALS REPORTING

Has customer-required Substances of Concern information been reported?  Yes  No

Submitted by IMDS or other customer format: \_\_\_\_\_  
\_\_\_\_\_

Are polymeric parts identified with appropriate ISO marking codes?  Yes  No  n/a

## REASON FOR SUBMISSION (Check at least one)

- |   |  |
|---|--|
| <input type="checkbox"/> Initial submission   | <input type="checkbox"/> Change to Optional Construction or Material |
| <input type="checkbox"/> Engineering Change(s)  | <input type="checkbox"/> Sub-Supplier or Material Source Change      |
| <input type="checkbox"/> Tooling: Transfer, Replacement, Refurbishment, or additional | <input type="checkbox"/> Change in Part Processing                   |
| <input type="checkbox"/> Correction of Discrepancy                                    | <input type="checkbox"/> Parts produced at Additional Location       |
| <input type="checkbox"/> Tooling Inactive > than 1 year                               | <input type="checkbox"/> Other - please specify _____                |

## REQUESTED SUBMISSION LEVEL (Check one)

- Level 1 - Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.
- Level 2 - Warrant with product samples and limited supporting data submitted to customer.
- Level 3 - Warrant with product samples and complete supporting data submitted to customer.
- Level 4 - Warrant with product samples and complete supporting data submitted to customer.
- Level 5 - Warrant with product samples and complete supporting data submitted to customer. \_\_\_\_\_'s manufacturing location.

## SUBMISSION RESULTS

The results for  dimension  
These results meet all de  
Mold / Cavity / Production

The supplier indicates the reason for the PPAP submission

statistical process package (required)

# Part Submission Warrant (PSW)

## MATERIALS REPORTING

Has customer-required S...  
Submitted

- The supplier indicates the PPAP level and certifies that the validation results meet all design specifications.

Are polymeric parts ident...

- This certification is by cavity, production line, etc.

n/a

## REASON FOR SUBMISSION

- |   |  |
|---|--|
| <input type="checkbox"/> Initial submission   | <input type="checkbox"/> Change to Optional Construction or Material |
| <input type="checkbox"/> Engineering Change(s)  | <input type="checkbox"/> Sub-Supplier or Material Source Change      |
| <input type="checkbox"/> Tooling: Transfer, Replacement, Refurbishment, or additional | <input type="checkbox"/> Change in Part Processing                   |
| <input type="checkbox"/> Correction of Discrepancy                                    | <input type="checkbox"/> Parts produced at Additional Location       |
| <input type="checkbox"/> Tooling Inactive > than 1 year                               | <input type="checkbox"/> Other - please specify                      |

## REQUESTED SUBMISSION LEVEL (Check one)

- Level 1 - Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.
- Level 2 - Warrant with product samples and limited supporting data submitted to customer.
- Level 3 - Warrant with product samples and complete supporting data submitted to customer.
- Level 4 - Warrant and other requirements as defined by customer.
- Level 5 - Warrant with product samples and complete supporting data reviewed at organization's manufacturing location.

## SUBMISSION RESULTS

The results for  dimensional measurements  material and functional tests  appearance criteria  statistical process package

These results meet all design record requirements:  Yes  NO (If "NO" - Explanation Required)

Mold / Cavity / Production Process \_\_\_\_\_

# Part Submission Warrant (PSW)

**DECLARATION**

I affirm that the samples represented by this warrant are representative of our parts, which were made by a process that meets all Production Part Approval Process Manual 4th Edition Requirements. I further affirm that these samples were produced at the production rate of \_\_\_/\_\_\_ hours. I also certify that documented evidence of such compliance is on file and available for your review. I have noted any deviation from this declaration below.

EXPLANATION/COMMENTS: \_\_\_\_\_  
\_\_\_\_\_

Is each Customer Tool properly tagged and numbered?  Yes  No  n/a

Organization Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Print Name \_\_\_\_\_ Phone No. \_\_\_\_\_ 555-555-5555 Fax No. \_\_\_\_\_

Title \_\_\_\_\_ E-mail \_\_\_\_\_

FOR CUSTOMER USE ONLY (IF APPLICABLE)

PPAP Warrant Disposition \_\_\_\_\_

Customer Signature \_\_\_\_\_

Print Name \_\_\_\_\_

- The supplier declares that the PPAP submission is based on production processes run at a normal or planned production rate.
- The supplier states the production rate.
- The supplier indicates that any customer owned tooling is properly identified



# Part Submission Warrant (PSW)

- Prior to submitting the PPAP, the supplier representative signs the warrant, indicating the part meets Customer requirements
- The customer then approves or rejects the PPAP and signs to confirm the decision
- The customer approved PSW is a prerequisite for production shipments

**DECLARATION**

I affirm that the samples  
all Production Part App  
production rate of \_\_\_\_  
review. I have noted a

by a process that meets  
s were produced at the  
e and available for your

EXPLANATION/COMMENT

Is each Customer Tool properly tagged and numbered?  Yes  No  n/a

Organization Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Print Name \_\_\_\_\_ Phone No. 555-555-5555 Fax No. \_\_\_\_\_

Title \_\_\_\_\_ E-mail \_\_\_\_\_

FOR CUSTOMER USE ONLY (IF APPLICABLE)

PPAP Warrant Disposition:  Approved  Rejected  Other \_\_\_\_\_

Customer Signature \_\_\_\_\_ Date \_\_\_\_\_

Print Name \_\_\_\_\_ Customer Tracking Number (optional) \_\_\_\_\_

# PPAP Summary

- PPAP checks that any process changes have been properly designed and validated, and the resulting process is capable of repeatedly producing parts to specification
- The PPAP elements should be part of your Quality Management System. PPAP shouldn't require much extra effort, because you've already done the work internally to manage your changes.
- Reacting to later issues with the product or process can be expensive and time-consuming!

# Questions?

