

Production Part Approval Process

PPAP
Fourth Edition



PRODUCTION PART APPROVAL PROCESS (PPAP)

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FOREWORD TO THE FOURTH EDITION

Effective June 1, 2006, **PPAP** Fourth Edition replaces **PPAP** Third Edition, unless otherwise specified by your customer.

Production Part Approval Process (PPAP) is updated to the 4th edition to incorporate the customer focused process approach associated with ISO/TS 16949:2002 and other changes listed below to update requirements.

PPAP's purpose continues to be to provide the evidence that all customer engineering design record and specification requirements are properly understood by the organization and that the manufacturing process has the potential to produce product consistently meeting these requirements during an actual production run at the quoted production rate.

PPAP 4th Edition includes the following changes:

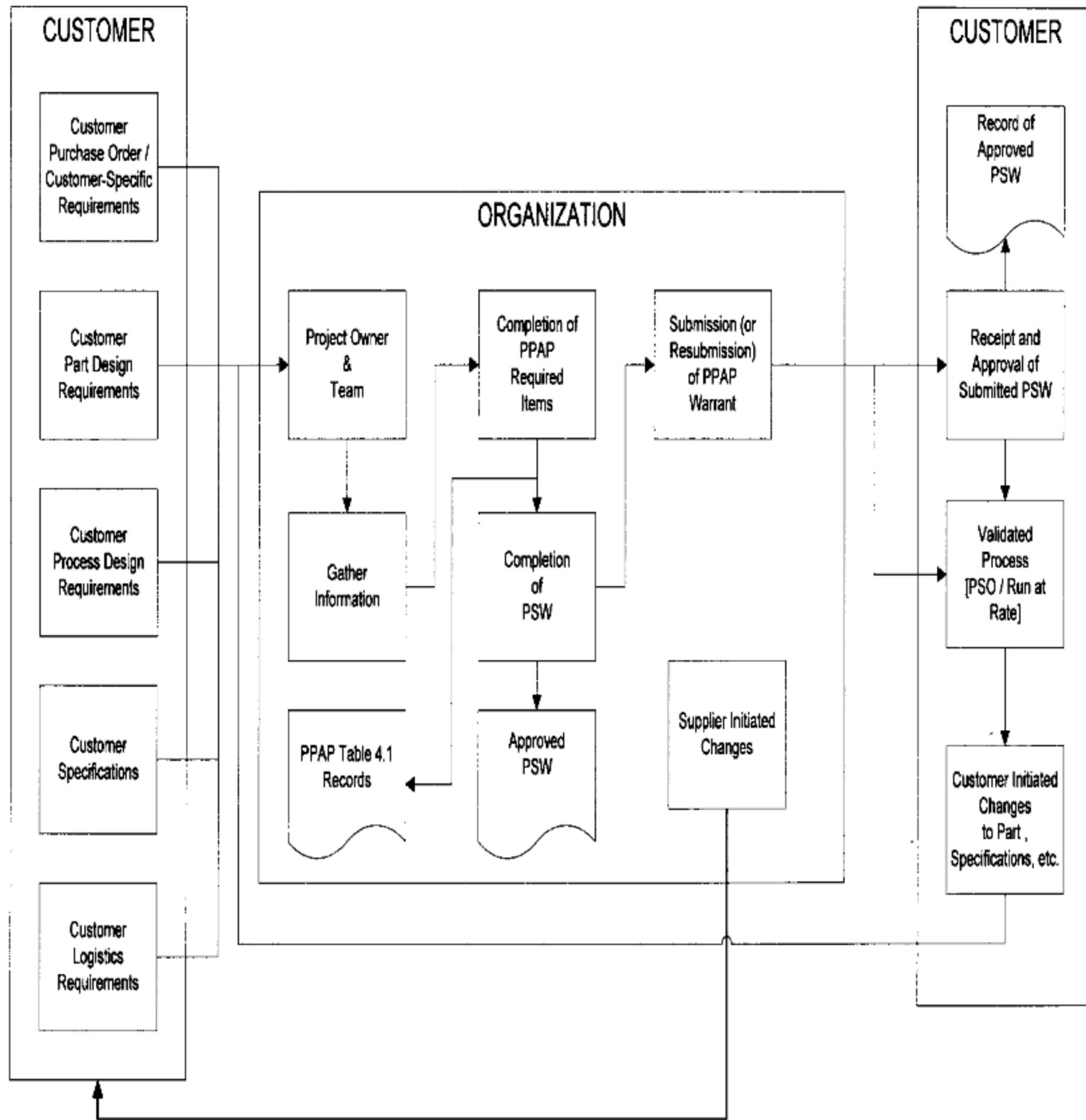
- Alignment of **PPAP** to the ISO/TS 16949:2002 process approach, including:
 - ♦ Aligning the order of the **PPAP** requirements with the automotive product development and manufacturing process
 - ♦ Inclusion of an example process flow for **PPAP**
- Relocation of Customer Specific Instructions to appropriate websites, (e.g. OEM and IAOB, www.iaob.org) to provide current requirements
- Update of Truck OEM requirements and moved to Appendix H
- Revised PSW (Part Submission Warrant) to:
 - ♦ Provide a more logical flow for the part / design description fields
 - ♦ Make the supplier address fields applicable to international locations
 - ♦ Include IMDS materials reporting to indicate reporting status
- Updated specific **PPAP** requirements, including:
 - ♦ Materials reporting and polymeric identification requirements in the design record
 - ♦ Process capability index usage (Cpk and Ppk)
 - ♦ The definition and approval of catalog parts and the definition of black box parts
- Modified customer notification and submission requirements to align with OEM requirements (e.g., I.3.3 from **PPAP** 3rd removed)
- Clarified and commonized Appendices C, D, and E to match the **PPAP** reporting requirements
- Revised Tire Appendix to allow OEM specification of applicability and to eliminate duplications with allowances already provided in the **PPAP** requirements
Note: The Tire Appendix is not applicable to organizations supplying tires to Ford Motor Company.
- Reorganized and updated Appendix F to stress the importance of the Bulk Materials Checklist
Note: Ford Motor Company requires all organizations supplying bulk material to Ford Motor Company to comply with **PPAP**.
- Revised Glossary to be consistent with the updates in the text

PPAP refers to the following reference manuals: **Advanced Product Quality Planning & Control Plan**, **Potential Failure Modes and Effects Analysis**, **Measurement System Analysis**, and **Statistical Process Control**. These manuals are authored by DaimlerChrysler Corporation, Ford Motor Company, and General Motors Corporation and are available through the Automotive Industry Action Group (AIAG) at www.aiag.org.

The Supplier Quality Requirements Task Force gratefully acknowledges the contributions of the many individuals and their respective companies that participated in the revision process.

PPAP Process Flowchart Example

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INTRODUCTION

Purpose

Production Part Approval Process (PPAP) defines generic requirements for production part approval, including production and bulk materials (see Glossary). The purpose of **PPAP** is to determine if all customer engineering design record and specification requirements are properly understood by the organization and that the manufacturing process has the potential to produce product consistently meeting these requirements during an actual production run at the quoted production rate.

Applicability

PPAP shall apply to internal and external organization sites (see Glossary) supplying production parts, service parts, production materials, or bulk materials. For bulk materials, **PPAP** is not required unless specified by the authorized customer representative.

An organization supplying standard catalog production or service parts shall comply with **PPAP** unless formally waived by the authorized customer representative.

NOTE 1: See customer-specific requirements for additional information. All questions about **PPAP** should be addressed to the authorized customer representative.

NOTE 2: A customer can formally waive **PPAP** requirements for an organization. Such waivers can only be issued by an authorized customer representative.

NOTE 3: An organization or supplier requesting a waiver of a **PPAP** requirement should contact the authorized customer representative. The organization or supplier should obtain documentation of waivers from the authorized customer representative.

NOTE 4: Catalog parts (e.g., bolts) are identified and/or ordered by functional specifications or by recognized industry standards.

Approach

The word “shall” indicates mandatory requirements. The word “should” indicates a recommendation.

Paragraphs marked “NOTE” are for guidance in understanding or clarifying the associated requirement. The word “should” appearing in a NOTE is for guidance only.

For the purposes of **PPAP**, the terms and definitions given in ISO/TS 16949 and the **PPAP** Glossary apply.

SECTION 1 – GENERAL

1.1 Submission of PPAP

The organization shall obtain approval (see 5.2.1) from the authorized customer representative for:

1. a new part or product (e.g., a specific part, material, or color not previously supplied to the specific customer).
2. correction of a discrepancy on a previously submitted part.
3. product modified by an engineering change to design records, specifications, or materials.
4. any situation required by Section 3.

NOTE: If there is any question concerning the need for production part approval, contact the authorized customer representative.

SECTION 2 – PPAP PROCESS REQUIREMENTS

2.1 Significant Production Run

For production parts, product for **PPAP** shall be taken from a significant production run. This significant production run shall be from one hour to eight hours of production, and with the specific production quantity to total a minimum of 300 **consecutive** parts, unless otherwise specified by the authorized customer representative.

This significant production run shall be conducted at the production site, at the production rate (see Glossary) using the production tooling, production gaging, production process, production materials, and production operators. Parts from each unique production process, e.g., duplicate assembly line and/or work cell, each position of a multiple cavity die, mold, tool or pattern, shall be measured and representative parts tested.

For bulk materials: No specific number of “parts” is required. The submitted sample shall be taken in a manner as to assure that it represents “steady-state” operation of the process.

NOTE: For bulk material, production histories of current products may often be used to estimate the initial process capability or performance of new and similar products. In cases where no production history of a similar bulk material product or technology exists, a containment plan may be put into effect until sufficient production has demonstrated capability or performance, unless otherwise specified by the customer.

2.2 PPAP Requirements

The organization shall meet all specified **PPAP** requirements listed below (2.2.1 through 2.2.18). The organization shall also meet all customer-specific **PPAP** requirements.

Production parts shall meet all customer engineering design record and specification requirements (including safety and regulatory requirements).

Bulk Material **PPAP** requirements are defined by a completed Bulk Material Requirements Checklist (see Appendix F).

If any part specifications cannot be met, the organization shall document their problem-solving efforts and shall contact the authorized customer representative for concurrence in determination of appropriate corrective action.

NOTE: Items or records from 2.2.1 through 2.2.18 may not necessarily apply to every customer part number from every organization. For example, some parts do not have appearance requirements, others do not have color requirements, and plastic parts may have polymeric part marking requirements. In order to determine with certainty which items must be included, consult the design record, e.g., part print, the relevant Engineering documents or specifications, and your authorized customer representative.

2.2.1 Design Record

The organization shall have the design record for the saleable product/part, including design records for components or details of the saleable product/part. Where the design record is in electronic format, e.g., CAD/CAM math data, the organization shall produce a hard copy (e.g., pictorial, geometric dimensioning & tolerancing [GD&T] sheets, drawing) to identify measurements taken.

NOTE 1: For any saleable product, part or component, there will only be one design record, regardless of who has design-responsibility. The design record may reference other documents making them part of the design record.

NOTE 2: A single design record can represent multiple part or assembly configurations, e.g., a sub-frame assembly with various hole configurations for different applications.

NOTE 3: For parts identified as black box (see Glossary), the design record specifies the interface and performance requirements.

NOTE 4: For parts identified as catalog parts, the design record may consist only of a functional specification or a reference to a recognized industry standard.

NOTE 5: For bulk materials, the design record may include identification of raw materials, formulations, processing steps and parameters, and final product specifications or acceptance criteria. If dimensional results do not apply, then CAD/CAM requirements are also not applicable.

2.2.1.1 Reporting of Part Material Composition

The organization shall provide evidence that the Material/Substance Composition reporting that is required by the customer has been completed for the part and that the reported data complies with all customer-specific requirements.

NOTE: This materials reporting may be entered into the IMDS (International Materials Data System) or other customer-specified system/method. IMDS is available through <http://www.mdssystem.com/index.jsp>.

2.2.1.2 Marking of Polymeric Parts

Where applicable, the organization shall identify polymeric parts with the ISO symbols such as specified in ISO 11469, "Plastics – Generic Identification and marking of plastic products" and/or ISO 1629, "Rubber and lattices – Nomenclature." The following weight criteria shall determine if the marking requirement is applicable:

- Plastic parts weighing at least 100g (using ISO 11469/1043-1)
- Elastomeric parts weighing at least 200g (using ISO 11469/1629)

NOTE: Nomenclature and abbreviation references to support the use of ISO 11469 are contained in ISO 1043-1 for basic polymers and in ISO 1043-2 for fillers and reinforcements.

2.2.2 Authorized Engineering Change documents

The organization shall have any authorized engineering change documents for those changes not yet recorded in the design record but incorporated in the product, part or tooling.

2.2.3 Customer Engineering Approval

Where specified by the customer, the organization shall have evidence of customer engineering approval.

NOTE: For bulk materials, this requirement is satisfied by a signed 'Engineering Approval' line item on the Bulk Material Requirements Checklist (see Appendix F) and/or inclusion on a customer maintained list of approved materials.

2.2.4 Design Failure Mode and Effects Analysis (Design FMEA) if the organization is product design-responsible

The product design-responsible organization shall develop a Design FMEA in accordance with, and compliant to, customer-specified requirements (e.g., **Potential Failure Mode and Effects Analysis** reference manual).

NOTE 1: A single Design FMEA may be applied to a family of similar parts or materials.

NOTE 2: For bulk materials, see Appendix F.

2.2.5 Process Flow Diagram(s)

The organization shall have a process flow diagram in an organization-specified format that clearly describes the production process steps and sequence, as appropriate, and meets the specified customer needs, requirements and expectations (e.g., **Advanced Product Quality Planning and Control Plan** reference manual). For bulk materials, an equivalent to a Process Flow Diagram is a Process Flow Description.

NOTE: Process flow diagrams for 'families' of similar parts are acceptable if the new parts have been reviewed for commonality by the organization.

2.2.6 Process Failure Mode and Effects Analysis (Process FMEA)

The organization shall develop a Process FMEA in accordance with, and compliant to, customer-specified requirements, (e.g., **Potential Failure Mode and Effects Analysis** reference manual).

NOTE 1: A single Process FMEA may be applied to a process manufacturing a family of similar parts or materials if reviewed for commonality by the organization.

NOTE 2: For bulk materials, see Appendix F.

2.2.7 Control Plan

The organization shall have a Control Plan that defines all methods used for process control and complies with customer-specified requirements (e.g., **Advanced Product Quality Planning and Control Plan** reference manual).

NOTE 1: Control Plans for "families" of parts are acceptable if the new parts have been reviewed for commonality by the organization.

NOTE 2: Control Plan approval may be required by certain customers.

2.2.8 Measurement System Analysis Studies

The organization shall have applicable Measurement System Analysis studies, e.g., gage R&R, bias, linearity, stability, for all new or modified gages, measurement, and test equipment. (see the **Measurement Systems Analysis** reference manual).

NOTE 1: Gage R&R acceptability criteria are defined in the **Measurement Systems Analysis** reference manual.

NOTE 2: For bulk materials, Measurement System Analysis may not apply. Customer agreement should be obtained on actual requirements.

2.2.9 Dimensional Results

The organization shall provide evidence that dimensional verifications required by the design record and the Control Plan have been completed and results indicate compliance with specified requirements. The organization shall have dimensional results for each unique manufacturing process, e.g., cells or production lines and all cavities, molds, patterns or dies (see 2.2.18). The organization shall record, with the actual results: all dimensions (except reference dimensions), characteristics, and specifications as noted on the design record and Control Plan.

The organization shall indicate the date of the design record, change level, and any authorized engineering change document not yet incorporated in the design record to which the part was made. The organization shall record the change level, drawing date, organization name and part number on all auxiliary documents (e.g., supplementary layout results sheets, sketches, tracings, cross sections, CMM inspection point results, geometric dimensioning and tolerancing sheets, or other auxiliary drawings used in conjunction with the part drawing). Copies of these auxiliary materials shall accompany the dimensional results according to the Retention/Submission Requirements Table. A tracing shall be included when an optical comparator is necessary for inspection.

The organization shall identify one of the parts measured as the master sample (see 2.2.15).

NOTE 1: The Dimensional Results form in Appendix C, a pictorial, geometric dimensioning & tolerancing [GD&T] sheets, or a checked print where the results are legibly written on a part drawing including cross-sections, tracings, or sketches as applicable may be utilized for this purpose.

NOTE 2: Dimensional results typically do not apply to bulk materials.

2.2.10 Records of Material / Performance Test Results

The organization shall have records of material and/or performance test results for tests specified on the design record or Control Plan.

2.2.10.1 Material Test Results

The organization shall perform tests for all parts and product materials when chemical, physical, or metallurgical requirements are specified by the design record or Control Plan.

Material test results shall indicate and include:

- the design record change level of the parts tested;
- any authorized engineering change documents that have not yet been incorporated in the design record;
- the number, date, and change level of the specifications to which the part was tested;
- the date on which the testing took place;
- the quantity tested;

- the actual results;
- the material supplier's name and, when required by the customer, the customer-assigned supplier/vendor code.

NOTE: Material test results may be presented in any convenient format. An example is shown in Appendix D.

For products with customer-developed material specifications and a customer-approved supplier list, the organization shall procure materials and/or services (e.g., painting, plating, heat-treating, welding) from suppliers on that list.

2.2.10.2 Performance Test Results

The organization shall perform tests for all part(s) or product material(s) when performance or functional requirements are specified by the design record or Control Plan.

Performance test results shall indicate and include:

- the design record change level of the parts tested;
- any authorized engineering change documents that have not yet been incorporated in the design record;
- the number, date, and change level of the specifications to which the part was tested;
- the date on which the testing took place;
- the quantity tested;
- the actual results.

NOTE: Performance test results may be presented in any convenient format. An example is shown in Appendix E.

2.2.11 Initial Process Studies

2.2.11.1 General

The level of initial process capability or performance shall be determined to be acceptable prior to submission for all Special Characteristics designated by the customer or organization. The organization shall obtain customer concurrence on the index for estimating initial process capability prior to submission.

The organization shall perform measurement system analysis to understand how measurement error affects the study measurements. (see 2.2.8)

NOTE 1: Where no special characteristics have been identified, the customer reserves the right to require demonstration of initial process capability on other characteristics.

NOTE 2: The purpose of this requirement is to determine if the production process is likely to produce product that will meet the customer's requirements. The initial process study is focused on variables not attribute data. Assembly errors, test failures, surface defects are examples of attribute data, which is important to understand, but is not covered in this initial study. To understand the performance of characteristics monitored by attribute data will require more data collected over time. Unless approved by the authorized customer representative, attribute data are not acceptable for **PPAP** submissions.

NOTE 3: C_{pk} and P_{pk} are described below. Other methods more appropriate for certain processes or products may be substituted with prior approval from an authorized customer representative.

NOTE 4: Initial process studies are short-term and will not predict the effects of time and variation in people, materials, methods, equipment, measurement systems, and environment. Even for these short-term studies, it is important to collect and analyze the data in the order produced using control charts.

NOTE 5: For those characteristics that can be studied using X-bar and R charts, a short-term study should be based on a minimum of 25 subgroups containing at least 100 readings from consecutive parts of the

significant production run (see 2.1). The initial process study data requirements may be replaced by longer-term historical data from the same or similar processes, with customer concurrence. For certain processes, alternative analytical tools such as individual and moving range charts may be appropriate and permitted with prior approval from an authorized customer representative.

2.2.11.2 Quality Indices

Initial process studies shall be summarized with capability or performance indices, if applicable.

NOTE 1: The initial process study results are dependent on the purpose of the study, method of data acquisition, sampling, amount of data, demonstration of statistical control, etc. See the **Statistical Process Control** reference manual for additional information in understanding the basic principles of statistical stability and process measures (indices). For guidance on items listed below, contact the authorized customer representative.

C_{pk} - The capability index for a stable process. The estimate of sigma is based on *within subgroup variation* ($R\text{-bar}/d2$ or $S\text{-bar}/c4$). C_{pk} is an indicator of process capability based on process variation within each subgroup of a set of data. C_{pk} does not include the effect of process variability between the subgroups. C_{pk} is an indicator of how good a process could be if all process variation between subgroups was to be eliminated. Therefore, use of C_{pk} alone may be an incomplete indicator of process performance. For more information, see the **Statistical Process Control** reference manual.

P_{pk} - The performance index. The estimate of sigma is based on *total variation* (all of individual sample data using the standard deviation [root mean square equation], "s"). P_{pk} is an indicator of process performance based on process variation throughout the full set of data. Unlike C_{pk} , P_{pk} is not limited to the variation within subgroups. However, P_{pk} cannot isolate within subgroup variation from between subgroup variation. When calculated from the same data set, C_{pk} and P_{pk} can be compared to analyze the sources of process variation. For more information, see the **Statistical Process Control** reference manual.

Initial Process Studies. The purpose of the initial process study is to understand the process variation, not just to achieve a specific index value. When historical data are available or enough initial data exist to plot a control chart (at least 100 individual samples), C_{pk} can be calculated when the process is stable. Otherwise, for processes with known and predictable special causes and output meeting specifications, P_{pk} should be used. When not enough data are available (< 100 samples) or there are unknown sources of variation, contact the authorized customer representative to develop a suitable plan.

NOTE 2: For Initial Process Studies involving more than one process stream, additional appropriate statistical methods or approaches may be required.

NOTE 3: For bulk material, the organization should obtain customer agreement regarding the appropriate techniques for initial process studies, if required, in order to determine an effective estimate of capability.

2.2.11.3 Acceptance Criteria for Initial Study

The organization shall use the following as acceptance criteria for evaluating initial process study results for processes that appear stable.

<u>Results</u>	<u>Interpretation</u>
Index > 1.67	The process currently meets the acceptance criteria.
$1.33 \leq \text{Index} \leq 1.67$	The process may be acceptable. Contact the authorized customer representative for a review of the study results.
Index < 1.33	The process does not currently meet the acceptance criteria. Contact the authorized customer representative for a review of the study results.

NOTE 1: Meeting the initial process study capability acceptance criteria is *one* of a number of customer requirements that leads to an approved **PPAP** submission.

NOTE 2: See 2.2.11.1 and 2.2.11.2.

2.2.11.4 Unstable Processes

Depending on the nature of the instability, an unstable process may not meet customer requirements. The organization shall identify, evaluate and, wherever possible, eliminate special causes of variation prior to **PPAP** submission. The organization shall notify the authorized customer representative of any unstable processes that exist and shall submit a corrective action plan to the customer **prior to any submission**.

NOTE: For bulk materials, for processes with known and predictable special causes and output meeting specifications, corrective action plans may not be required by the customer.

2.2.11.5 Processes With One-Sided Specifications or Non-Normal Distributions

The organization shall determine with the authorized customer representative alternative acceptance criteria for processes with one-sided specifications or non-normal distributions.

NOTE: The above mentioned acceptance criteria (2.2.11.3) assume normality and a two-sided specification (target in the center). When this is not true, using this analysis may result in unreliable information. These alternate acceptance criteria could require a different type of index or some method of transformation of the data. The focus should be on understanding the reasons for the non-normality (e.g., is it stable over time?) and managing variation. Refer to the **Statistical Process Control** reference manual for further guidance.

2.2.11.6 Actions To Be Taken When Acceptance Criteria Are Not Satisfied

The organization shall contact the authorized customer representative if the acceptance criteria (2.2.11.3) cannot be attained by the required **PPAP** submission date. The organization shall submit to the authorized customer representative for approval a corrective action plan and a modified Control Plan normally providing for 100% inspection. Variation reduction efforts shall continue until the acceptance criteria are met, or until customer approval is received.

NOTE 1: 100% inspection methodologies are subject to review and concurrence by the customer.

NOTE 2: For bulk materials, 100% inspection means an evaluation of a sample(s) of product from a continuous process or homogeneous batch which is representative of the entire production run.

2.2.12 Qualified Laboratory Documentation

Inspection and testing for **PPAP** shall be performed by a qualified laboratory as defined by customer requirements (e.g., an accredited laboratory). The qualified laboratory (internal or external to the organization) shall have a laboratory scope and documentation showing that the laboratory is qualified for the type of measurements or tests conducted.

When an external/commercial laboratory is used, the organization 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.

2.2.13 Appearance Approval Report (AAR)

A separate Appearance Approval Report (AAR) shall be completed for each part or series of parts if the product/part has appearance requirements on the design record.

Upon satisfactory completion of all required criteria, the organization shall record the required information on the AAR. The completed AAR and representative production products/parts shall be submitted to the location specified by the customer to receive disposition. AARs (complete with part disposition and authorized customer representative signature) shall then accompany the PSW at the time of final submission based upon the submission level requested. See customer-specific requirements for any additional requirements.

NOTE 1: AAR typically applies only for parts with color, grain, or surface appearance requirements.

NOTE 2: Certain customers may not require entries in all AAR fields. See Appendix B or customer-specifics for detailed instructions on completing the AAR.

2.2.14 Sample Production Parts

The organization shall provide sample product as specified by the customer.

2.2.15 Master Sample

The organization shall retain a master sample for the same period as the production part approval records, or a) until a new master sample is produced for the same customer part number for customer approval, or b) where a master sample is required by the design record, Control Plan or inspection criteria, as a reference or standard. The master sample shall be identified as such, and shall show the customer approval date on the sample. The organization shall retain a master sample for each position of a multiple cavity die, mold, tool or pattern, or production process unless otherwise specified by the customer.

NOTE 1: When part size, sheer volume of parts, etc. makes storage of a master sample difficult, the sample retention requirements may be modified or waived in writing by the authorized customer representative. The purpose of the master sample is to assist in defining the production standard, especially where data is ambiguous or in insufficient detail to fully replicate the part to its original approved state.

NOTE 2: Many bulk material properties are by their nature time dependent, and if a master sample is required, it may consist of the manufacturing record, test results, and certificate of analysis of key ingredients, for the approved submission sample. (see Appendix F).

2.2.16 Checking Aids

If requested by the customer, the organization shall submit with the **PPAP** submission any part-specific assembly or component checking aid.

The organization shall certify that all aspects of the checking aid agree with part dimensional requirements. The organization shall document all released engineering design changes that have been incorporated in the checking aid at the time of submission. The organization shall provide for preventive maintenance of any checking aids for the life of the part (see Glossary - "Active Part").

Measurement system analysis studies, e.g., gage R & R, accuracy, bias, linearity, stability studies, shall be conducted in compliance with customer requirements. (see 2.2.8 and the **Measurement Systems Analysis** reference manual).

NOTE 1: Checking aids can include fixtures, variable and attribute gages, models, templates, mylars specific to the product being submitted.

NOTE 2: Checking aids, etc. typically do not apply to Bulk Materials. If checking aids are used for bulk materials, the organization should contact the authorized customer representative regarding this requirement.

2.2.17 Customer-Specific Requirements

The organization shall have records of compliance to all applicable customer-specific requirements. For bulk materials, applicable customer-specific requirements shall be documented on the Bulk Material Requirements Checklist.

2.2.18 Part Submission Warrant (PSW)

Upon completion of all **PPAP** requirements, the organization shall complete the Part Submission Warrant (PSW).

A separate PSW shall be completed for each customer part number unless otherwise agreed to by the authorized customer representative.

If production parts will be produced from more than one cavity, mold, tool, die, pattern, or production process, e.g., line or cell, the organization shall complete a dimensional evaluation (see 2.2.9) on one part from each. The specific cavities, molds, line, etc., shall then be identified in the "Mold/Cavity/Production Process" line on a PSW, or in a PSW attachment.

The organization shall verify that all of the measurement and test results show conformance with customer requirements and that all required documentation is available and, for Level 2, 3, and 4, is included in the submission as appropriate. A responsible official of the organization shall approve the PSW and provide contact information.

NOTE 1: One warrant per customer part number can be used to summarize many changes providing that the changes are adequately documented, and the submission is in compliance with customer program timing requirements.

NOTE 2: PSWs may be submitted electronically in compliance with customer requirements.

2.2.18.1 Part Weight (Mass)

The organization shall record on the PSW the part weight of the part as shipped, measured and expressed in kilograms to four decimal places (0.0000) unless otherwise specified by the customer. The weight shall not include shipping protectors, assembly aides, or packaging materials. To determine part weight, the organization shall individually weigh ten randomly selected parts, calculate and report the average weight. At least one part shall be measured from each cavity, tool, line or process to be used in product realization.

NOTE: This weight is used for vehicle weight analysis only and does not affect the approval process. Where there is no production or service requirement for at least ten parts, the organization should use the required number for calculation of the average part weight. For bulk materials, the part weight field is not applicable.

SECTION 3 – CUSTOMER NOTIFICATION AND SUBMISSION REQUIREMENTS

3.1 Customer Notification

The organization shall notify the authorized customer representative of any planned changes to the design, process, or site. Examples are indicated in the table below (see Table 3.1).

NOTE: Organizations are responsible to notify the authorized customer representative of all changes to the part design and/or the manufacturing process.

Upon notification and approval of the proposed change by the authorized customer representative, and after change implementation, **PPAP** submission is required unless otherwise specified.

Table 3.1

Examples of changes requiring notification	Clarifications
1. Use of other construction or material than was used in the previously approved part or product	For example, other construction as documented on a deviation (permit) or included as a note on the design record and not covered by an engineering change as described in Table 3.2, #3.
2. Production from new or modified tools (except perishable tools), dies, molds patterns, etc. including additional or replacement tooling	This requirement only applies to tools, which due to their unique form or function, can be expected to influence the integrity of the final product. It is not meant to describe standard tools (new or repaired), such as standard measuring devices, drivers (manual or power), etc.
3. Production following upgrade or rearrangement of existing tooling or equipment.	Upgrade means the reconstruction and/or modification of a tool or machine or to increase the capacity, performance, or change its existing function. This is not meant to be confused with normal maintenance, repair or replacement of parts, etc., for which no change in performance is to be expected and post repair verification methods have been established. Rearrangement is defined as activity that changes the sequence of product/process flow from that documented in the process flow diagram (including the addition of a new process). Minor adjustments of production equipment may be required to meet safety requirements such as, installation of protective covers, elimination of potential ESD risks, etc.
4. Production from tooling and equipment transferred to a different plant site or from an additional plant site.	Production process tooling and /or equipment transferred between buildings or facilities at one or more sites.
5. Change of supplier for parts, non-equivalent materials, or services (e.g., heat-treating, plating).	The organization is responsible for approval of supplier provided material and services.

<p>6. Product produced after the tooling has been inactive for volume production for twelve months or more.</p>	<p>For product that has been produced after tooling has been inactive for twelve months or more: Notification is required when the part has had no change in active purchase order and the existing tooling has been inactive for volume production for twelve months or more. The only exception is when the part has low volume, e.g., service or specialty vehicles. However a customer may specify certain PPAP requirements for service parts.</p>
<p>7. Product and process changes related to components of the production product manufactured internally or manufactured by suppliers.</p>	<p>Any changes, including changes at the suppliers to the organization and their suppliers, that affect customer requirements, e.g., fit, form, function, performance, durability.</p>
<p>8. Change in test/inspection method – new technique (no effect on acceptance criteria)</p>	<p>For change in test method, the organization should have evidence that the new method has measurement capability equivalent to the old method.</p>
<p>Additionally, for bulk materials:</p> <p>9. New source of raw material from new or existing supplier.</p> <p>10. Change in product appearance attributes</p>	<p>These changes would normally be expected to have an effect on the performance of the product.</p>

3.2 Submission to Customer

The organization shall submit for **PPAP** approval prior to the first production shipment in the following situations unless the authorized customer representative has waived this requirement (see Table 3.2).

NOTE: In the situations described below, prior notification to, or communication with, the authorized customer representative is assumed.

The organization shall review and update, as necessary, all applicable items in the **PPAP** file to reflect the production process, regardless of whether or not the customer requests a formal submission. The **PPAP** file shall contain the name of the authorized customer representative granting the waiver and the date.

Table 3.2

Requirement	Clarifications
1. A new part or product (i.e. a specific part, material, or color not previously supplied to the customer)	Submission is required for a new product (initial release) or a previously approved product that has a new or revised product/part number (e.g., suffix) assigned to it. A new part/product or material added to a family may use appropriate PPAP documentation from a previously approved part within the same product family.
2. Correction of a discrepancy on a previously submitted part.	Submission is required to correct any discrepancies on a previously submitted part. A "discrepancy" can be related to: <ul style="list-style-type: none"> • The product performance against the customer requirements • Dimensional or capability issues • Supplier issues • Approval of a part replacing an interim approval • Testing, including material, performance, or engineering validation issues
3. Engineering change to design records, specifications, or materials for production product/part numbers(s).	Submission is required on any engineering change to the production product/part design record, specifications or materials.
Additionally, for Bulk Materials:	
4. Process technology new to the organization, not previously used for this product.	

SECTION 4 – SUBMISSION TO CUSTOMER - LEVELS OF EVIDENCE

4.1 Submission Levels

The organization shall submit the items and/or records specified in the level identified below in Table 4.1:

Table 4.1

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

See Retention/Submission Requirements Table 4.2 for exact retention/submission requirements for each submission level.

The organization shall use level 3 as the default level for all submissions unless otherwise specified by the authorized customer representative.

The minimum submission requirement for bulk materials is the PSW and the Bulk Materials Checklist. For Bulk Material **PPAP** submissions, check "Other" in the Reason for Submission Section on the PSW form and specify "Bulk Material." This indicates that the "Bulk Material Requirements Checklist" was used to specify the **PPAP** requirements for the bulk material and shall be included in the submission packet.

NOTE 1: The authorized customer representative may identify a submission level, different from the default level, that is to be used with each organization, or organization and customer part number combination. Different customer locations may assign different submission levels to the same organization manufacturing location.

NOTE 2: All of the forms referenced in this document may be replaced by computer-generated facsimiles. Acceptability of these facsimiles is to be confirmed with the authorized customer representative prior to the first submission.

Retention/Submission Requirements Table 4.2

(Normative)

[NOTE: Table 4.2 lists submission and retention requirements. Mandatory and applicable requirements for a PPAP record are defined in the PPAP manual and by the customer.]

<u>Requirement</u>	Submission Level				
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>	<u>Level 5</u>
1. Design Record	R	S	S	*	R
- for proprietary components/details	R	R	R	*	R
- for all other components/details	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 (PSW)	S	S	S	S	R
Bulk Material Checklist (see 4.1 above)	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 appropriate locations and submit to the customer upon request.

SECTION 5 – PART SUBMISSION STATUS

5.1 General

Upon approval of the submission, the organization shall assure that future production continues to meet all customer requirements.

NOTE: For those organizations that have been classified as “self certifying” (PPAP submission level 1) by a specific customer, submission of the required organization-approved documentation will be considered as customer approval unless the organization is advised otherwise.

5.2 Customer PPAP Status

5.2.1 Approved

Approved indicates that the part or material, including all sub-components, meets all customer requirements. The organization is therefore authorized to ship production quantities of the product, subject to releases from the customer scheduling activity.

5.2.2 Interim Approval

Interim Approval permits shipment of material for production requirements on a limited time or piece quantity basis. Interim Approval will only be granted when the organization has:

- clearly defined the non-compliances preventing approval; and,
- prepared an action plan agreed upon by the customer. **PPAP** re-submission is required to obtain a status of “approved.”

Note 1: The organization is responsible for implementing containment actions to ensure that only acceptable material is being shipped to the customer.

Note 2: Parts with a status of “Interim Approval” are not to be considered “Approved.”

Material covered by an interim approval that fails to meet the agreed-upon action plan, either by the expiration date or the shipment of the authorized quantity, will be rejected. No additional shipments are authorized unless an extension of the interim approval is granted.

For bulk materials, the organization shall use the “Bulk Material Interim Approval” form, or its equivalent (see Appendix F).

5.2.3 Rejected

Rejected means that the **PPAP** submission does not meet customer requirements, based on the production lot from which it was taken and/or accompanying documentation. In such cases, the submission and/or process, as appropriate, shall be corrected to meet customer requirements. The submission shall be approved before production quantities may be shipped.



SECTION 6 – RECORD RETENTION

PPAP records (see 2.2), regardless of submission level, shall be maintained for the length of time that the part is active (see Glossary) plus one calendar year.

The organization shall ensure that the appropriate **PPAP** records from a superseded part **PPAP** file are included, or referenced in the new part **PPAP** file.

NOTE: An example of an appropriate document/record that should be carried forward from the old file to the new part file would be a material certification from a raw material supplier for a new part that represents only a dimensional change from the old part number. This should be identified by conducting a **PPAP** “gap analysis” between the old and new part numbers.

Appendix A – Completion of the Part Submission Warrant (PSW)

PART INFORMATION

1. **Part Name and 2a. Customer Part Number:** Engineering released finished end item part name and number.
- 2b. **Org, Part Number:** Part number defined by the organization, if any.
3. **Shown on Drawing Number:** The design record that specifies the customer part number being submitted.
4. **Engineering Change Level & Date:** Show the change level and date of the design record.
5. **Additional Engineering Changes & Date:** List all authorized engineering changes not yet incorporated in the design record but which are incorporated in the part.
6. **Safety and/or Government Regulation:** "Yes" if so indicated by the design record, otherwise "No."
7. **Purchase Order Number:** Enter this number as found on the contract/purchase order.
8. **Weight:** Enter the actual weight in kilograms to four decimal places unless otherwise specified by the customer.
- 9./10. **Checking Aid Number, Change Level and Date:** If requested by the customer, enter the checking aid number, its change level and date.

ORGANIZATION MANUFACTURING INFORMATION

11. **Organization Name & Supplier/Vendor Code:** Show the name and code assigned to the manufacturing site on the purchase order/contract.
12. **Street Address, Region, Postal Code, Country:** Show the complete address of the location where the product was manufactured. For "Region," enter state, county, province, etc.

CUSTOMER SUBMITTAL INFORMATION

13. **Customer Name/Division:** Show the corporate name and division or operations group.
14. **Buyer/Buyer Code:** Enter the buyer's name and code.
15. **Application:** Enter the model year, vehicle name, engine, transmission, etc.

MATERIALS REPORTING

16. **Substances of Concern:** Enter "Yes," "No," or "n/a".
IMDS/Other Customer Format: Circle either "IMDS" or "Other Customer Format" as appropriate. If submitted via IMDS include: Module ID #, Version #, and Creation Date. If submitted via other customer format, enter the date customer confirmation was received.
17. **Polymeric Parts Identification:** Enter "Yes," "No," or "n/a".

REASON FOR SUBMISSION

18. Check the appropriate box(es). For bulk materials, in addition to checking the appropriate box, check "Other" and write "Bulk Material" in the space provided.

SUBMISSION LEVEL

19. **SUBMISSION LEVEL:** Identify the submission level requested by the customer.

SUBMISSION RESULTS

20. Check the appropriate boxes for dimensional, material tests, performance tests, appearance evaluation, and statistical data.
21. Check the appropriate box. If "no," enter the explanation in "comments" below.
22. **Molds/Cavities/Production Processes:** For instruction, see 2.2.18.

DECLARATION

23. Enter the number of pieces manufactured during the significant production run.
24. Enter the time (in hours) taken for the significant production run.
25. **EXPLANATION/COMMENTS:** Provide any explanatory comments on the Submission Results or any deviations from the Declaration. Attach additional information as appropriate.
26. **CUSTOMER TOOL TAGGING/NUMBERING:** Are customer-owned tools identified in accord with ISO/TS 16949 and any customer-specific requirements, answer "Yes" or "No." May not be applicable to OEM internal suppliers.
27. **ORGANIZATION AUTHORIZED SIGNATURE:** A responsible organization official, after verifying that the results show conformance to all customer requirements and that all required documentation is available, shall approve the declaration and provide **Title, Phone Number, Fax Number, and E-mail address.**

FOR CUSTOMER USE ONLY

Leave blank.





Part Submission Warrant

Part Name _____ Cust. Part Number _____
 Shown on Drawing No. _____ 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 No. _____ Checking Aid Engineering Change Level _____ Dated _____

ORGANIZATION MANUFACTURING INFORMATION

CUSTOMER SUBMITTAL INFORMATION

Organization 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 n/a

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)

- Initial Submission
- Engineering Change(s)
- Tooling: Transfer, Replacement, Refurbishment, or additional
- Correction of Discrepancy
- Tooling Inactive > than 1 year
- Change to Optional Construction or Material
- Supplier or Material Source Change
- Change in Part Processing
- Parts Produced at Additional Location
- Other – please specify below _____

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 _____

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 review. I have noted any deviations 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) _____

Appendix B – Completion of the Appearance Approval Report

1. **Customer part number:** Engineering released customer part number.
2. **Drawing Number:** Use the number of the drawing on which the part is shown if different from the part number.
3. **Application:** Enter the model year(s) and vehicle or other program on which the part is used.
4. **Part Name:** Use the finished part name on the part drawing.
5. **Buyer Code:** Enter the code for specific buyer of part.
- 6./7. **E/C Level & Date:** Engineering change level and E/C date for this submission.
8. **Organization Name:** Organization responsible for submission (include supplier if applicable).
9. **Manufacturing Location:** Location where part was manufactured or assembled.
10. **Supplier/Vendor Code:** Customer-assigned code for organization location where the part was manufactured or assembled.
11. **Reason for Submission:** Check box(es) explaining the reason for this submission.
12. **Organization Sourcing & Texture Information:** List all first surface tools, graining source(s), grain type(s), and grain and gloss masters used to check part.
13. **Pre-Texture Evaluation:** To be completed by authorized customer representative (not used by GM).
14. **Color Suffix:** Use alphanumeric or numeric color identification.
15. **Tristimulus Data:** List numerical (colorimeter) data of submission part as compared to the customer-authorized master.
16. **Master Number:** Enter alphanumeric master identification (not used by Ford).
17. **Master Date:** Enter the date on which the master was approved.
18. **Material Type:** Identify first surface finish and substrate (e.g., paint/ABS).
19. **Material Source:** Identify first surface and substrate suppliers. Example: Redspot/Dow.
20. **Color Evaluation, Hue, Value, Chroma, Gloss and Metallic Brilliance:** Visual assessment by customer.
21. **Color Shipping Suffix:** Color part number suffix or color number.
22. **Part Disposition:** To be determined by customer (approved or rejected).
23. **Comments:** General comments by the organization or customer (optional).
24. **Organization Signature, Phone No. & Date:** Organization certification that the document information is accurate and meets all requirements specified.
25. **Authorized Customer Representative Signature & Date:** Authorized Customer Representative approval signature.

THE AREAS INSIDE THE BOLD LINES ARE FOR CUSTOMER USE ONLY.



APPEARANCE APPROVAL REPORT

PART NUMBER		DRAWING NUMBER		APPLICATION (VEHICLES)	
PART NAME		BUYER CODE	E/C LEVEL		DATE
SUPPLIER 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 RESUBMIT	
		APPROVED TO ETCH/TOOL/EDM	

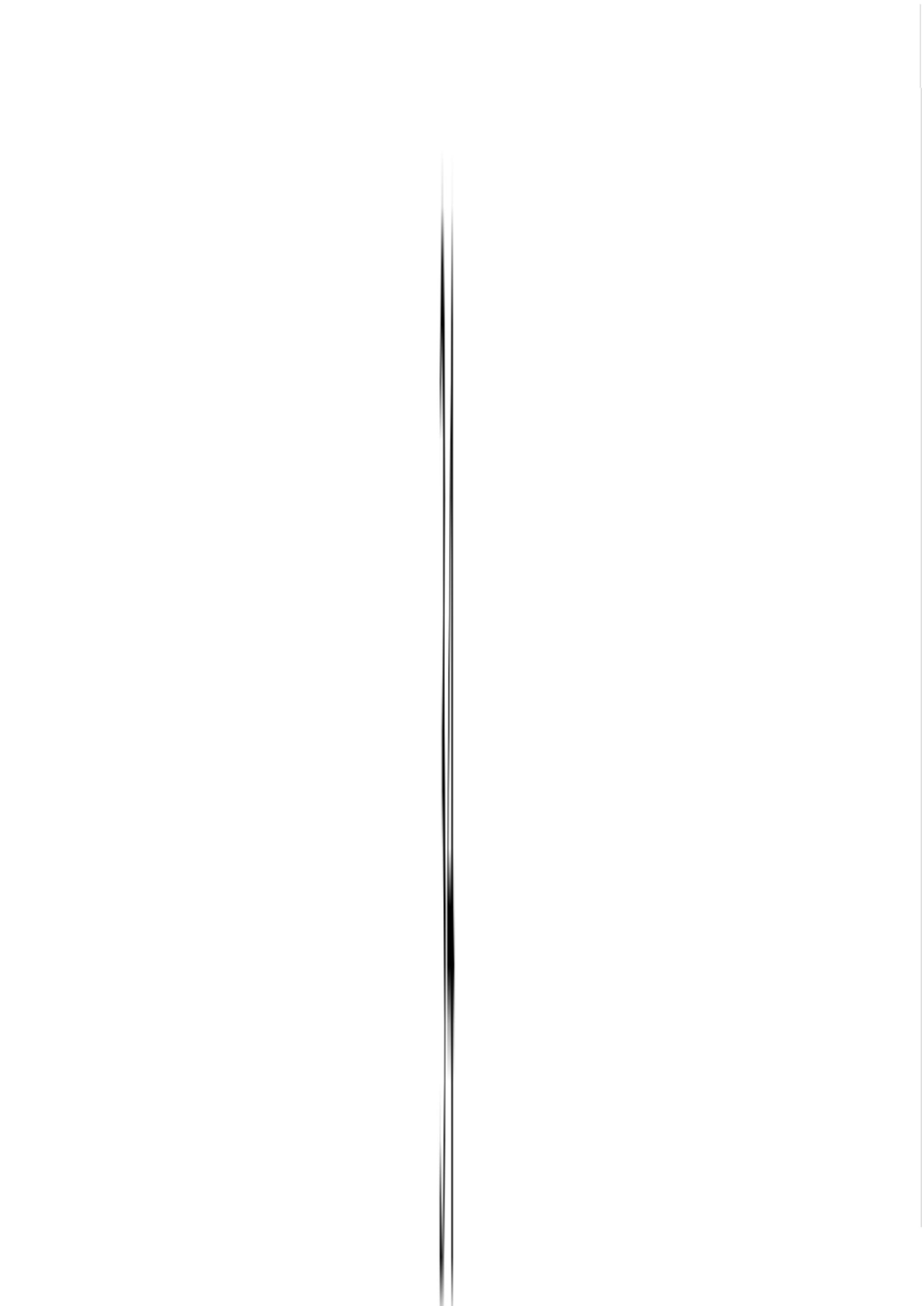
COLOR EVALUATION

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		

COMMENTS

ORGANIZATION SIGNATURE	PHONE NO.	DATE	AUTHORIZED CUSTOMER REPRESENTATIVE SIGNATURE	DATE
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Appendix F – Bulk Material - Specific Requirements

F.1 Introduction

An organization supplying bulk materials shall comply with the requirements in this Appendix or use guidance herein for clarification of **PPAP**. The requirements in this Appendix are minimums and may be supplemented at the discretion of the organization and/or the customer.

F.2 Applicability

Organizations are responsible for applying **PPAP** to their suppliers of ingredients which have organization-designated special characteristics.

Where OEM **PPAP** approval of a bulk material exists, evidence of that approval is sufficient as the **PPAP** submission at other levels in the supply chain.

Examples of bulk material include, but are not limited to: adhesives and sealants (solders, elastomers); chemicals (rinses, polishes, additives, treatments, colors/pigments, solvents); coatings (top coats, undercoats, primers, phosphates, surface treatments); engine coolants (antifreeze); fabrics; film and film laminates; ferrous and non-ferrous metals (bulk steel, aluminum, coils, ingots); foundry (sand/silica, alloying materials, other minerals/ores); fuels and fuel components; glass and glass components; lubricants (oils, greases, etc.); monomers, pre-polymers and polymers (rubbers, plastics, resins and their precursors); and performance fluids (transmission, power steering, brake, refrigerant).

F.3 Bulk Materials Requirements Checklist (see 2.2)

For bulk material, the **PPAP** elements required are defined by the Bulk Materials Requirements Checklist. Any customer-specific requirements shall be documented on the Bulk Materials Requirements Checklist.

Use the Bulk Materials Requirements Checklist as follows:

- **Required / Target Date:** For each item listed in the checklist either enter a target date for completion of the element or enter “NR” for Not Required.
- **Primary Responsibility - Customer:** Identify by name or function the individual who will review and approve the element.
- **Primary Responsibility - Organization:** Identify by name or function the individual who will assemble and assure the completeness of the element to be reviewed.
- **Comments / Conditions:** Identify any qualifying information or references to attached documents that provide specific information regarding the element. For example, this may include specific formats to be used for the Design Matrix or acceptable tolerances for Measurement System Analysis (MSA) studies.
- **Approved by:** Enter the initials of the authorized customer representative who has reviewed and accepted the element.
- **Plan agreed to by:** Identify the individuals (and their functions) who made and agreed upon the project plan.

Bulk Materials Requirements Checklist

Project:

	Required / Target Date	Primary Responsibility		Comments/ Conditions	Approved by / date
		Customer	Organization		
Product Design and Development Verification					
Design Matrix					
Design FMEA					
Special Product Characteristics					
Design Records					
Prototype Control Plan					
Appearance Approval Report					
Master Sample					
Test Results					
Dimensional Results					
Checking Aids					
Engineering Approval					
Process Design and Development Verification					
Process Flow Diagrams					
Process FMEA					
Special Process Characteristics					
Pre-launch Control Plan					
Production Control Plan					
Measurement System Analysis					
Interim Approval					
Product and Process Validation					
Initial Process Studies					
Part Submission Warrant					
Elements to be completed as needed					
Customer Plant Connection					
Customer-Specific Requirements					
Change Documentation					
Supplier Considerations					
Plan Agreed to by: Name / Function			Company / Title / Date		

F.4 Design Matrix

F.4.1 Introduction

Organizations supplying bulk material generally deal with the chemistry and functionality of the product being designed. Use of these suggestions will arrive at the same end point of a completed Design FMEA, but with greater applicability to bulk materials. For bulk materials, a Design Matrix, when required, shall be prepared prior to developing the Design FMEA. The Design Matrix determines the complex interactions of formula ingredients, ingredient characteristics, product characteristics, process constraints, and conditions for customer use. High impact items can then be effectively analyzed in the Design FMEA.

F.4.2 Design Matrix – Elaboration

This matrix correlates customer expectations with the product design items.

Construct the Design Matrix referring to the example which will follow:

1. Along the horizontal axis, list the Functions (Desired Attributes/Potential Failure Modes).
2. Along the vertical axis, list the design items as Potential Causes (Category/Characteristics) :
 - Formula Ingredients
 - Ingredient Characteristics
 - Product Characteristics
 - Process Constraints
 - Conditions for Use (customer process constraints)
3. For each design item, enter the current robust threshold range levels and units.
4. Correlate the potential causes to the potential failure modes using a number, letter, or symbol representing the impact or strength of the relationship. Ask what would happen if a potential cause item is allowed to go under or over its robust minimum or maximum, respectively.
5. After completion of the rankings in the Design Matrix, review the category/characteristics for a preliminary assessment of Special Characteristics. Designate any Special Characteristics in column 1.
6. The high negative impact potential causes are transferred to the Design FMEA for analysis.

F.5 Design FMEA (see 2.2.4)

F.5.1 Effects of Failure and Severity Rankings

The following two steps provide an alternative method for identifying the Potential Effects of Failure and assigning a Severity Ranking.

List Effects of Failure

- Consumer Effects - General terms identifying the loss experienced by the ultimate user of the product (e.g., the vehicle buyer).
- Customer Effects - General terms identifying the loss experienced by the intermediate user of your product (e.g., the vehicle manufacturer).

Assign a Severity Ranking to each Effect

- See the Severity Definition and Evaluation Criteria in the Potential Failure Mode and Effects Analysis reference manual.
- The goal for each of the items that multiply to arrive at the Risk Priority Number is to differentiate between the items in that category. The following figure provides a guideline for severity rankings. If your situation only uses a small portion of the scale then develop your own scale to improve the differentiation. If your situation is greater than two tiers back from the final consumer, then the guideline figure should be adjusted to reflect the effects that will be felt by your customer's customer.

Effects of Failure and Severity Ranking Table

Stakeholder	Effects of Failure	Severity
Consumer (e.g., vehicle buyer)	Owner Safety Problem	10
	Major Owner Dissatisfaction (Loss of Owner Loyalty)	8
	Moderate Owner Dissatisfaction (Inconvenience)	6
	Minor Owner Dissatisfaction (Annoyance)	4
Customer (e.g., vehicle manufacturer)	Plant Safety Problem	10
	Possible Recall	9
	Line Stoppage	8
	Warranty Costs	7
	Scrap	7
	Regulatory Penalty	7
	Moderate Rework (e.g., < 20% or moderate repair)	5
	Plant Dissatisfaction	4
	Minor Rework (e.g., < 10% or simple repair)	3

F.5.2 Potential Cause(s)/Mechanisms of Failure and Design Matrix

From the Design Matrix (if used), list the high negative impact characteristics as the Potential Causes/Mechanisms of Failure which are associated with Potential Failure Modes.

Mechanisms are generally described as over or under a certain threshold. These thresholds define the boundaries of the product approval and subsequent requirements for change notification.

F.5.3 Likelihood of Occurrence Rankings

The following step provides an alternate method for assigning Occurrence ratings.

Rank Occurrence - the ranking scale in the **Potential Failure Mode and Effects Analysis** manual is difficult to relate to bulk materials and generally results in very low numbers with little differentiation in the ultimate risk. The following matrix is recommended as a replacement. It evaluates the frequency of occurrence based upon observed evidence the formulator has in the design.

Occurrence Matrix

Formulation Occurrence Ranking <u>Type of Evidence</u>	FREQUENCY		
	<u>LOW</u>	<u>MODERATE</u>	<u>HIGH</u>
Actual Experience	1	4	7
Similar Experience	2	5	8
Assumption	3	6	9
No Background			10

Actual Experience: Obtained from appropriate experimentation on the specific final product and the potential failure mode.

Similar Experience: Based upon similar products or processes and the potential failure model.

Assumption: Based upon a clear understanding of the chemical impact of the material and the potential failure mode.

Frequency ranking clarifications:

- High is defined as – Repeated failures
- Moderate is defined as – Occasional failures
- Low is defined as – Relatively few failures

F.5.4 Current Design Controls

Design Control: Supplementing the **Failure Mode Effects and Analysis** manual, bulk material design controls may also include:

- Designed Experiments (DOE's) - List experiment #'s
- Customer validation tests and trial runs - e.g., gravelometer panels, fender sprayouts (list customer reference #'s).
- Test protocols - list Test Methods, Standard Operating Procedures, etc.
- Variation of supplier specifications.
- Formulating practice robust ranges.

Design controls identified by a number should be available so that the relevant content of that control can be understood.

F.5.5 Likelihood of Detection Rankings

The next step provides an alternate method for assigning Detection rankings.

Rank Detection - the ranking scale in the **Potential Failure Mode and Effects Analysis** manual is difficult to relate to bulk materials and generally results in very low numbers with little differentiation in the ultimate risk. The following matrix may be used. It evaluates the Detection as the ability of the current Design Control to actually detect a cause of failure and/or failure mode based upon the assessed

Testing Method R&R's percent of specification range (see the **Measurement System Analysis** reference manual) and the quality of evidence.

Detection Matrix:

Detection by Design Control	Testing Method R&R		
	<30%	30% - 100%	>100%
DOE (Response Surface Analysis)	1	2	7
Screening Experiments	3	4	8
Assumption/Experience	5	6	9
No Evidence			10

DOE (Response Surface Analysis): Symmetric design space analyzed with appropriate statistical tools.

Screening Experiments: Screening design or ladder evaluation strategically set to develop DOE.

Assumption/Experience: Information/data based upon similar products or processes.

Note: The above R&R limits are suggested unless otherwise agreed upon by the customer and organization. R&R calculations can initially be based using design matrix thresholds.

F.6 Process FMEA (see 2.2.6)

Process FMEA Ranking Tables

Severity Rankings

Severity of Effect	Ranking
Very High: Potential failure mode may result in a field failure (9), or constitute a safety hazard or noncompliance with a government regulation (10).	9-10
High: High degree of customer dissatisfaction due to the nature of the failure. May cause serious disruption to subsequent processing of the product or result in the product failing to meet its sales specifications. Will result in a customer complaint and product return. Failure is likely to be detected during the customer's final product testing.	7-8
Moderate: Failure causes some customer dissatisfaction and may result in a customer complaint or limitation on shelf life. The customer may need to make modifications or adjustments to their process to accommodate the material. The problem is likely to be detected as part of an incoming inspection or prior to use (4). The problem will be detected during processing (5). The problem will be detected in subsequent processing steps (6).	4-6
Low: Failure causing only a slight customer annoyance. Customer will notice only a slight deterioration or inconvenience with the product or processing of the product.	2-3
Minor: Reasonable to expect that the minor nature of this failure would not cause any real effect on the product or its processing by the customer. Customer will probably not even notice the failure.	1

Occurrence Rankings

Frequency of Failure	Ranking
Very High: Failure is almost inevitable. Additional process steps are developed to deal with the failures.	9 - 10
High: Similar processes have experienced repeated failures. The process is not in statistical control.	7 - 8
Moderate: Similar processes have experienced occasional failures, but not in major proportions. Process is in statistical control.	4 - 6
Low: Similar processes have experienced isolated failures.	3
Very Low: Almost identical processes have experienced only isolated failures.	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes. The process is in statistical control.	1

Detection Rankings

Likelihood and Location In the Process the Defect Is Detected	Ranking
Absolute Certainty of Non-Detection: Controls will not or cannot detect the existence of the defect.	10
Very Low: Organization controls probably will not detect the existence of the defect, but the defect may be detected by the customer.	9
Low: Controls may detect the existence of the defect, but detection may not occur until packaging is underway.	7 - 8
Moderate: Controls likely to detect the existence of the failure, but not until lot acceptance testing has been completed. Tests with a higher degree of variability will have the higher ranking.	5 - 6
High: Controls have a good chance of detecting the existence of the defect before the manufacturing process has been completed. In-Process testing is used to monitor the manufacturing process.	3 - 4
Very High/Early: Controls will almost certainly detect the existence of the defect before the product moves onto the next step in its manufacturing process. Important raw materials are controlled via organization specifications.	1-2

F.7 Special Characteristics

F.7.1 Introduction

If product characteristics/attributes can have normal variation resulting in movement outside their design-intended robust range which results in significant impact, they are designated special, and must be controlled by special controls.

Special Characteristics - Clarification Table

		Clarification	Example
1	Special Characteristics	<p>For Bulk Materials, a frequent occurrence is a transformation from bulk material to final product.</p> <p>The differences between bulk product characteristics (features of the supplied product) and the final attributes (features of the transformed product) should be understood.</p> <p>During the design phase, the product characteristics can be controls for final product attributes. (This does not imply that they are control characteristics). During manufacture of the bulk material, process parameters are the control characteristics.</p> <p>During transformation from bulk product to final product, both bulk product characteristics and final product attributes can be controlled by customer process control characteristics.</p>	<p>Illustrations of the flow of materials through final product follow (e.g., % solids Resin A, % UVA intended). These are not necessarily intended to be Special Characteristics.</p> <p>Examples of product characteristics are: viscosity, % NV Solids, % Resin "A". Examples of final product attributes are: appearance, film build, FMVSS safety, durability.</p> <p>Examples of manufacturing process parameters (control characteristics) are: temperature, pressure, mix rate, test protocol.</p> <p>Examples of customer transformation process parameters (control characteristics) are: fluid flow, temperature/humidity, air pressure.</p>
2	Symbols for customer-identified Special Characteristics	<p>Organizations may designate their own internal symbols to designate Special Characteristics in their working documents.</p> <p>For customer-designated/identified Special Characteristics, the customer-specific symbols will be used for required customer documentation and required shipping labels.</p>	<p>The organization may choose to use "S" (Safety), or "sp" (special), or "K" (Key), etc.</p> <p>The customer designated shield, inverted delta, diamond, etc. will be used when required per customer identification.</p>

F.7.2 Special Characteristics - Elaboration

For clarification purposes, the following figure is intended to demonstrate the flow of potential special characteristics through the supply chain.

Illustration of the Flow of Materials through Final Product:

Item A (Paint)	Item B (Paint)	Item C (Sealant)
Supplier (Tier II) Bulk Product Characteristic (Raw Material) % Solids Resin "A"	Supplier (Tier II) Bulk Product Characteristic (Raw Material) Purity Assay of UVA	Supplier (Tier II) Bulk Product Characteristic (Raw Material) Polymer Viscosity
Supplier (Tier II) Mfg. Control Characteristic Resin Synthesis Temperature	Supplier (Tier II) Mfg. Control Characteristic Final Reaction Hold Time	Supplier (Tier II) Mfg. Control Characteristic End-Blocker Feed Rate
Organization (Tier I) Bulk Product Characteristic Paint Viscosity	Organization (Tier I) Bulk Product Characteristic % UVA Intended	Organization (Tier I) Bulk Product Characteristic % Polymer In Sealant
Organization (Tier I) Mfg. Control Characteristic Tank Mix Rate	Organization (Tier I) Mfg. Control Characteristic Scale Calibration	Organization (Tier I) Mfg. Control Characteristic Polymer Feed Rate
Customer Transformation Control Characteristic % Solvent Reduction	Customer Transformation Control Characteristic Fluid Flow (for film build)	Customer Transformation Control Characteristic Extruder Bead Size
Final Product Attribute Film Build: Free of Sags	Final Product Attribute Excellent Durability	Final Product Attribute Leak Free Sealant