Supplier Quality Manual

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The adoption of a Quality Management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, objectives, products, and processes as well as the size of the organization.

It is understood that each supplier is on their own continuous improvement path, however, there are certain requirements in this standard that require compliance regardless of the state of the Supplier's quality system. The word "shall" when used in this document indicates a mandatory requirement.

1 Vision

Our vision is for all Caltherm Suppliers to implement and maintain a quality system that allows them to produce and deliver to Caltherm, globally competitive products and services, clearly seen by our customers as superior in performance and value. Our suppliers shall conduct business with a high degree of integrity in a socially and environmentally responsible manner in accordance with the **Caltherm Supplier Code of Conduct**.

2 Goal

The goal of the Caltherm Supplier Quality Manual is to provide a uniform method for Caltherm to communicate general requirements, expectations, and guidelines to the supply chain.

This supports the Caltherm Achieving Excellence purposes: continuously measuring supplier performance, rewarding improvements, and recognizing suppliers' outstanding efforts; embracing proactive quality planning as a routine part of doing business; and helping suppliers' continuous improvement efforts.

3 Purpose

The Caltherm Supplier Quality Manual has two purposes. First, this manual defines the fundamental quality system activities that Caltherm expect from suppliers and their supply chain to ensure on-going quality planning, control, and improvement. Secondly, suppliers can use this manual as an aide in further developing their own quality systems. In many sections throughout this manual, instructions can be found not only on what the requirements are, but how to meet the requirements.

4 Quality Management System

Caltherm realizes that many suppliers are registered or are currently pursuing registration/compliance to standards audited by third party registrars (such as ISO/TS 16949, Malcolm Baldrige (not a standard), ISO 9001, or one of the various equivalents from other industries, states, or countries). This revision and format of the manual is based on the Quality Systems of ISO/TS 16949:2002 version.

Caltherm encourages our supply chain to become compliant to the International Automotive Management Standard, ISO/TS 16949. This manual represents the minimum requirement that Caltherm may require for registration to more stringent standards. Many of the activities referenced in this manual are further explained in the AIAG (Automotive Industry Action Group) manuals, such as Measurement System Analysis (MSA) and Failure Mode and Effects Analysis (FMEA). It is recommended that suppliers obtain copies of the AIAG manuals. Caltherm units will continue to move towards the requirements of ISO/TS 16949 and further embrace the philosophies of continuous improvement. Through executing the proper quality planning activities, Caltherm and our supply base will be able to install control measures to eliminate the issues that lead to customer dissatisfaction.

To achieve continuous improvement, Caltherm expects our suppliers to embrace a sound quality system and to work with us in a spirit of trust, cooperation, and teamwork. The Caltherm SQM establishes expectations for quality activities, while recognizing that each Caltherm division has unique customer needs. This manual is not intended to replace a supplier's existing quality system. Suppliers should perform a self-evaluation to determine where their quality system aligns with this manual, and should also perform an evaluation of their supply chain. **As included in the terms and conditions, acceptance of a Caltherm purchase order constitutes acceptance of the requirements of this manual.** Suppliers should require similar terms and conditions with their supply chain. Suppliers are expected to discuss and understand the specific applicability of these requirements with their Caltherm representatives and their applicable supply chain in order to make effective business decisions.

4.1 General Requirements

The supplier shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirement of this Caltherm Supplier Quality Manual. The supplier shall:

- Identify the processed needed for the quality management system and its application throughout the organization
- Determine the sequence and interaction of these processes
- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
- Monitor, measure, and analyze these processes
- Implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this Caltherm Supplier Quality Manual
- Adhere to the Caltherm Supplier Code of Conduct

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes, including control of raw material. Control of such outsourced processes shall be identified within the quality management system. Processes needed for the quality management system referred to should include processes for management activities, provision of resources, product realization, and measurement.

4.2 Documentation Requirements

4.2.2 General

The quality management system documentation shall include:

- Documented statements of a quality policy and quality objectives
- A Quality Manual
- Documented procedures as required by this Caltherm Standard
- Documents needed by the organization to ensure the effective planning, operation and control of its processes
- Records required by this Caltherm Standard

4.2.3 Quality Manual

The supplier shall have a Quality Manual that is a controlled document and includes the following:

- The scope of the quality management system
- Documented procedures or reference to them
- A description of the interaction between the processes of the quality management system, such as with a flowchart.

4.2.4 Control of Documents

A supplier shall establish and maintain documented procedures to control all documents and data of external origin such as standards and customer drawings. For specifications referenced within a document, a supplier shall have currently released editions of these documents available at all appropriate manufacturing locations.

A supplier shall have a documented procedure for control and distribution of drawings and/or standards. Obsolete drawings shall be destroyed or appropriately identified as such. When Caltherm is using a supplier-controlled drawing and this drawing is changed, the supplier shall notify Caltherm by furnishing a Change Request and gain approval via a Verification Warrant. (See Section 7.2.3)

4.2.5 Control of Records

All quality records shall be kept for at least three years unless otherwise specified in the supplier's quality manual and agreed to by Caltherm. These records shall be stored in an environment that protects documents from deterioration and are readily accessible upon request by a Caltherm representative. It is also expected that the supply chain's records pertaining to Caltherm products shall be retained in the same manner.

Examples of such records may include, but are not limited to:

- Measurements Data
- Design and Process Failure Modes and Effects Analysis
- Measurement Systems Analysis Data
- Capability and Statistical Process Control Data
- Major Process Change Data
- Production Lot Control Data
- Verification Warrant and Documents
- Corrective Action Requests and Responses
- Gage Calibration and Maintenance Records
- Gage Repeatability & Reproducibility Analysis
- Heat Treatment – Metallurgical Examination Results and Material Composition Data
- Initial Sample Inspection Report
- Quality System Internal Assessments
- Employee Training Records (kept for term of employment)
- Destructive and Non-Destructive Testing Data
- Scrap, Reclaim, and Deviation Records
- Product Verification & Validation Activity Template – (See Template in Section 13)
- Functional and Performance (Laboratory and Field) Test Data
- Quality Plans or Control Plans for Parts and Assemblies (most recent plan only)
- Quality Rejections and Disposition Records
- Quality System Audits, Process Audits, and Corrective Actions
- Appearance Approval Report – (See Section 18)
- Production Part Approval Documents
- Design Review and Design Analysis Documents
- Risk Assessments

5 Management Responsibility

Top management is required to take an active role in the quality management system. This commitment shall address the managerial processes of quality planning, quality control, and quality improvement.

- Develop and maintain quality policies.
- Determine customers and their needs.
- Develop and maintain short- and long-range goals/metrics.
- Support supplier development strategies.
- Support product-feature and manufacturing-process development.
- Develop and maintain training procedures.

Quality Control

- Assure systems adequacy - develop a Quality Control Manual.
- Create information feedback loops.
- Implement mistake-proofing techniques.
- Create an environment for quality and process control by individual workers through procedures and job instructions documentation.
- Monitor cost of quality.
- Develop and maintain Quality Plans and Control Plans.
- Develop and maintain gage calibration system.
- Develop and maintain change notification procedures.
- Adhere to problem containment and traceability procedures.

Quality Improvement

- Formulate continuous improvement policy.
- Integrate controls in problem solutions.
- Identify projects to resolve current problems.
- Communicate corrective action to customers.
- Create continuous improvement teams to complete projects and solve problems using structured problem-solving processes.
- Provide resources and training.
- Provide recognition.

5.1 Management Commitment

A supplier to Caltherm shall demonstrate a top management commitment to continuous improvement. Top management shall provide documented evidence of its commitment to the development and improvement of the quality management system by:

- Communicating to the organization the importance of meeting customer as well as regulatory and legal requirements
- Establishing the quality policy and objectives
- Conducting regularly scheduled management reviews of the quality system and execution
- Ensuring the availability of necessary resources

A sound quality system shall be structured after a proven methodology such as ISO 9001, ISO/TS 16949, the Malcolm Baldrige Criteria for Performance Excellence, the Deming award, or the European Foundation for Quality Management. Each business process should detail the roles of management.

5.2 Customer Focus

Top management shall ensure that customer needs and expectations are determined, converted into requirements, and fulfilled with the aim of achieving customer satisfaction. Needs and expectations of Caltherm include conformance to design and performance specifications, reliability, delivery, cost management, wavelength, and technical support.

5.3 Quality Policy

Top management shall endorse a written quality policy that:

- Is appropriate to the purpose of the organization
- Includes a commitment to meeting customer requirements and to continuous improvement
- Provides a framework for establishing and reviewing quality objectives
- Is communicated and understood at appropriate levels in the organization
- Is reviewed for continued appropriateness

5.4 Planning

Top management shall ensure that quality objectives are established for the appropriate functions and levels. The quality objectives shall be measurable and consistent with the supplier's quality policy.

Caltherm expects the supplier to have a structured quality planning process. This long-term quality plan shall include, but is not limited to:

1. Quality Training
   - Quality planning processes and tools
   - Root cause determination, mistake proofing, and team involvement.
   - Basic statistical concepts identifying and improving variation and control.
   - Inspector and operator training programs in the use of control plans and care of measurement and test equipment.
2. Manufacturing and Tooling Improvements
   - Capability studies and capability objectives for current and new processes, and for approval of new tooling.
   - Assembly team or cell-unit manufacturing concepts
   - Training aids for set-up and operation of equipment
   - Preventive maintenance programs
3. Quality Information Systems
   - Integration of computers to statistically analyze data, to assist corrective action activities, and to provide timely reporting to Caltherm
   - Installation of inspection equipment and gaging to provide improved monitoring of manufacturing processes and quality data collection
4. Quality Budgeting
   - Budget planning for quality and plant improvements such as training, equipment, and program development.
   - A quality plan to shift resources spent on appraisal and correcting internal and external failures to defect prevention, such as: APQP (Advanced Product Quality Planning), PPAP (Production Part Approval Process), Control Plan Checklist and Form, and other continuous improvement methods and activities.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

A quality management system shall be implemented in order to provide confidence that the organization can satisfy the needs of its customers. The system should be consistent with the size, culture, and products of the organization. A supplier shall show evidence of a quality policy emphasizing continuous quality improvement driven by top management through preventive and corrective action. A copy of a long-term quality improvement program shall be available for review by Caltherm personnel. Management shall define specific quality indicators (metrics) and have a system in place to track them and monitor for trends. Improvement activities should be based around these trends.

5.5.2 Management Representative

Top management shall appoint member(s) of management who shall have responsibility and authority for planning, execution, control, and improvement of quality-related activities.

5.5.3 Internal Communication

The organization shall ensure that communication takes place between its various levels and functions regarding the processes of the quality management system and their effectiveness. This communication may take the form of team meetings, bulletin boards, publications, electronic media, or other techniques.

5.6 Management Review

5.6.1 Management Review - General

The supplier's management shall use internal audits to evaluate the degree of compliance and effectiveness of the quality system. The supplier shall have a documented program to perform internal audits. The results of the audits shall be documented and retained for at least three years. These audit records shall be made available to Caltherm personnel for review upon request. A formal corrective action process (See Section 8.5.2) that includes root cause determination shall be used to correct deficiencies. Subsequent audits shall include verification of corrective actions. The supplier shall have internal auditors who are qualified to audit the requirements of this Caltherm Supplier Quality Manual. Trained personnel that are independent of the area being audited shall perform the audits.

5.6.2 Review Input

Inputs to management review shall include current performance and improvement opportunities related to:

- Audit results and schedule
- Customer feedback (such as Achieving Excellence and Warranty)
- Process performance and product conformance
- Status of preventive and corrective actions
- Follow-up actions from earlier management reviews
- Changes that could affect the quality management system

5.6.3 Review Output

The outputs from a management review shall include supporting and leading actions addressing deficiencies relating to:

- Improvement of the system and its processes
- Improvement of product related to customer satisfaction
- Resource needs

6 Resource Management

6.1 Provision of Resources

Employees shall be qualified for the job they perform through education, training, or work experience and be knowledgeable of appropriate quality tools and processes that affect the quality of products and services provided to Caltherm. Further, employees shall be provided with the equipment, facilities and a work environment conducive to producing high quality products and services that consistently meet functional requirements and product specifications and provide genuine value to Caltherm and our customers.

A Supplier shall develop a quality management system and resource management plan that demonstrates a commitment to continuous improvement as described in Section 4 of this manual. The resource management plan shall provide for the evaluation of the resources needed to implement and improve the processes of the quality management system and customer satisfaction. The resource management plan shall also include the evaluation of the skill level of employees to determine their understanding of quality tools and processes and their ability to apply these tools relevant to their job.

6.2 Human Resources

A supplier shall provide a system of ongoing monitoring of each employee's education, training and work experience and provide opportunities for training and continuing education to improve employee's skill level. (Contact your Caltherm Supply Management representative for availability of classes.) The training shall provide employees with an awareness of the relevance and importance of their activities and how they contribute to the achievement of quality objectives in the business plan.

6.3 Infrastructure

A supplier shall provide and maintain facilities, equipment, workspace, hardware, software, and support services to achieve conformity to product specifications and functional requirements.

6.4 Work Environment

A supplier shall provide a work environment that supports quality objectives by identifying and managing human and physical factors that affect the quality of products and services provided to Caltherm.

7 Product Realization – Advanced Product Quality Planning

7.1 Planning of Product Realization

An effective and structured product realization planning process shall result in the determination of:

- The quality objectives for the product or service
- The need to develop specific processes, resources, facilities, and documentation
- Verification and validation activities and the criteria for acceptability

7.1.1 Advanced Product Quality Planning

Advanced Product Quality Planning. Suppliers shall participate in Advanced Product Quality Planning activities, such as Design Reviews, FMEAs, and electronic build events for the purpose of collaboratively planning for product realization and preventing problems during physical builds. Key characteristics (See Section 7.2.1.1) are identified and recorded during the early stages of design and communicated to suppliers. Quality planning activities shall be completed for first physical builds, and updated for subsequent physical builds.

Parts shall be production intent for physical builds, and should be produced using production tooling in a production process, unless approved by the Caltherm representative. Quality planning steps shall be repeated for parts that are supplied not using production tooling and processes. If there is a tooling or process difference between the actual parts used on the pre-production build versus the tooling or process for the production build, there shall be evidence of conformance to the specification and risk mitigation.

After successful completion of the final phase of APQP, the Order Fulfillment Process will be followed. The Order Fulfillment Process (OFP) at Caltherm is a global process that is designed to deliver the right product at the right place at the right time. It begins with an estimate of retail sales and ends with the retail delivery and payment.

7.1.2 Acceptance Criteria

Acceptance criteria is approved by Caltherm, where required.

7.1.3 Confidentiality

The organization shall ensure the confidentiality of customer-contracted products and projects under development, and related product information.

Suppliers are required to complete a confidentiality and non-disclosure agreement, unless this requirement is specifically waived by Caltherm Management.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Specific quality planning activities are required for every new or revised part or process. At Caltherm the APQP activities help ensure that new products or processes, and changes to existing products or processes, fulfill their intended purposes. APQP provides a consistent, structured, and preventive process for managing risks associated with new or revised parts, assemblies, changes to suppliers and processes.

One of the activities that can be required is the Design, Process, and Assembly Review (DPAR). A DPAR is a meeting which confirms all expectations of the products or services prior to a physical build. Caltherm teams initiate this review as early as possible before tooling release. Multiple DPARs may be required for multiple physical builds, depending on the magnitude of change from one build to the next. DPARs may be conducted in person, or with the use of telephone and electronic communication. Parts or subsystems may be grouped together in a DPAR. Documentation of DPAR events shall be maintained. Production Part Approval Process (PPAP) requirements shall be clearly understood as an output of the DPAR. The PPAP requirements correlated to the QPL are in Section 10. The PPAP requirements shall be documented on a Verification Warrant Form. (See Section 11)

Where the supplier maintains design control of the product, the supplier shall form a team to conduct these reviews with their supply chain. The teams should include Supply Management, Quality Engineering, Design Engineering, Supplier Representatives, and any other personnel necessary to evaluate a supplier's capability to meet product or service requirements. Documentation of DPAR events shall be maintained by the design control entity. Examples of the items covered during this meeting are shown in the Design, Process, and Assembly Review Checklist (See Section 12). Action items shall be documented and tracked.

7.2.1.1 Customer-Designated Special Requirements

A Key Characteristic is a product or process characteristic whose variation or targeting control is necessary to meet customer requirements and that directly or significantly impact customer satisfaction through compliance with government, country or industry standards and/or regulations, ability to perform its intended design requirements (form, fit, function, reliability, appearance), or manufacturability and ability to assemble.

There are two types of Key Characteristics - Product and Process. For minimum process capability on key characteristics, see (See Section 7.5.1). A structured process shall be used to identify Key Characteristics and corresponding controls.

Product key characteristics are those characteristics of a part whose variation within the design tolerance and/or specification can affect customer satisfaction. The selected measurable characteristics require extra control. Product Key Characteristics shall be documented on the Control Plan, the drawing/model, and/or assembly specifications. No deviations are allowed for out-of-tolerance and/or out-of-specification product key characteristics.

Process key characteristics are those characteristics of a process that significantly impact customer satisfaction and that require extra control, such as Process FMEA, Gage R&R, statistical process monitoring, control plans, and capability studies to manage variation and targeting to ensure that the product is within tolerance and/or specification. Process Key Characteristics can exist without corresponding Product Key Characteristics, and are not designated by a special symbol. Process Key Characteristics shall be documented on the Control Plan.

7.2.2 Review of Requirements Related to the Product

Key characteristics for the product and processes are confirmed in the DPAR using information from Design Reviews, FMEAs, and historical information. The supplier shall provide Caltherm a Process Failure Modes and Effects Analysis (PFMEA) for each component with one or more key characteristics prior to the end of Phase 2 of the APQP process. Refer to Preventive Action, (See Section 8.5.3). The supplier's processes, process capabilities, PFMEA, and their supply chain capabilities and requirements should be reviewed during the DPAR. If key characteristics are not identified directly on the drawing, they may be documented in the DPAR Checklist (See Section 12).

Purposes of the DPAR are:

- Confirm the product and process Key Characteristics
- Discuss applicable Caltherm requirements and Caltherm Standards
- Identify revisions to the print or process necessary to manufacture or procure the product or servie to specifications
- Review the quality plan level
- Ensure understanding of the part function and the manufacturing process
- Review the Supplier's processes, process capabilities, and PFMEA
- Review the Supplier's supply chain capabilities and requirements
- Clarify requirements for capability assessment and gage studies on key characteristics, plus other characteristics that are identified by Caltherm
- Clarify Supplier responsibility for PPAP requirements (communicate formally via Verfication Warrant Form (See Section 11))
- Identify and assign preventive action for potential problems in manufacturing or procurement
- Discuss product or service order quantities, delivery schedules, handling, packaging, product preservation, and product or service cost
- Mistake-proof the design and manufacturing process, including assembly, to ensure a low probability of error
- Identify or evaluate potential cost reduction or value improvement opportunities
- Review obligations related to product, including environmental, regulatory and legal requirements
- Review dimensional featuring according to functional requirements
- Review the Bill of Materials (BOM) for accuracy
- Review service requirements
- Determine material products shall not contain any quantities of substances deemed hazardous or toxic in excess of the limits set forth by OSHA or EPA guidelines, or those restricted under international specification of "conflict" material

Effective reviews require supplier participation. It is during this review that the supplier should ask for clarification on any unclear issue. From this meeting the supplier should acquire all of the information required to clearly understand Caltherm requirements. The supplier should be prepared to address questions in this meeting and respond back to any unanswered questions on the date specified during the meeting. The supplier shall communicate to Caltherm any changes that may affect the data documented in this review.

7.2.3 Customer Communication

The supplier shall identify and implement a communication plan with Caltherm and with their supply chain relating to product or service information, contracts or order handling, product or process changes, contract amendments, and customer feedback. Where product requirements are changed, the supplier shall ensure that relevant documentation is revised appropriately. The supplier shall also ensure that personnel involved in the realization of the product or service are made aware of the changed requirements.

Material Control and Communication

The manufacture of equipment and components, based on a worldwide design, has significant material specification challenges. Materials that are commonly available in one geographical region may be difficult or excessively costly to obtain in another. The purpose of the next three paragraphs is to clarify the determination of an equivalent or alternate material and the process for notification and approval.

An **equivalent** material is one whose specifications, in their full range of variation, meet those of the drawing-specified material. Determination that a material is equivalent requires a careful evaluation of all related specifications and characteristics. This review shall only be performed by individuals who are well versed in those particular materials, qualified to make that evaluation, able to provide supporting documentation (e.g. mill certifications), and fully conversant with the relevant Caltherm specifications. Unless specifically authorized by the appropriate Caltherm representative, in writing, only the primary material producer (e.g. steel mill, foundry, warehouse), may make that decision. If material is equivalent, the manufacturing process should not require revision.

An **alternate** material is one whose specifications do not fully meet those of the drawing-specified material, but have been verified as fully meeting the design intent and can be used interchangeably. Alternate materials shall appear on the drawing. Either a print change or a temporary deviation to allow the alternate material is required. Refer to the Engineering Deviation Authorization Checklist and Form. Alternate materials will likely require changes to the manufacturing processes utilized to make or process parts. Processing areas like heat treatment, bending, forming, and welding will likely show the greatest differences when utilizing alternate materials.

The subtleties of detail within the Caltherm material specifications requires specialist training to interpret. Incorrect material substitutions can result in product failures. Any questions relating to the equivalence of two materials should be directed to a qualified Caltherm materials engineer.

Customer Notification

A supplier shall request approval from Caltherm **before** making changes to a specification or process for supplied products or services for any change that may impact safety, fit, form, function, performance, durability, or appearance per the following requirements listed in Table 1.

The supplier shall notify the responsible Caltherm design unit of any design or process changes as indicated in the table below via Change Request. The following tables specify when notification is required, and are taken from AIAG Production Part Approval Process Manual (See Section 21, Reference 11).

Table 1 — Planned Changes Requiring Notification Prior to Implementation

Requirement	Clarification or examples
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.
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 refurbishment or rearrangement of existing tooling or equipment.	Refurbishment 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.

Requirement	Clarification or examples
	Rearrangement is defined as activity which 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 Electro Static Discharge risks, etc. These changes can be made without customer approval unless the process flow is changed as a result of this adjustment.
4. Production from tooling and equipment transferred to a different plant location or from an additional plant location.	Production process tooling and/or equipment transferred between buildings or facilities in one or more locations.
5. Change of supplier for parts, non-equivalent materials, or services (e.g.: heat-treating, painting, plating) that affect customer fit, form, function, durability, or performance requirements.	Suppliers are responsible for approval of subcontracted material and services that do not affect customer fit, form, function, durability, or performance requirements.
6. Product produced after the tooling has been inactive for volume production for twelve months or more.	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 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.
7. Product and process changes related to components of the production product manufactured internally or manufactured by suppliers that impact safety, fit, form, function, performance, durability, and/or appearance of the salable product. Additionally, the supplier shall concur with any requests by a subcontractor before submission to the customer.	Any change that affects customer requirements for safety, fit, form, function, performance, durability, and/or appearance requires notification to the customer. **Note:** The safety, fit, form, function, performance, durability, and/or appearance requirements should be part of Caltherm specifications as agreed on during reviews.
8. For bulk materials only: New source of raw material with special characteristics from new or existing subcontractor. Change in product appearance attributes where there is not appearance specification. Revised parameters in the same process (outside PFMEA parameters of the approved product, includes packaging). Change outside of DFMEA (product composition, ingredient levels) of the approved product.	These changes would normally be expected to have an effect on the performance of the product.
9. Change in test/inspection method – new technique (no effect on acceptance criteria).	For change in test method, supplier should have evidence that the new method provides results equivalent to the old method.

Submission to Customer

The supplier shall obtain PPAP approval **prior** to the first production shipment in the following situations unless the responsible product approval activity has waived this requirement (see Table 2). Conditional Approval may be granted to authorize limited production shipments when there are outstanding PPAP requirements.

The supplier 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 responsible customer product approval activity person granting the waiver and the date.

Table 2 — Changes Requiring PPAP Approval Prior to First Production Shipment

Requirement	Clarification or examples
1. A new part of product (i.e. a specific part, material, or color not previously supplied to the specific customer).	Submission is required for a new product (initial release) or a previously approved product which has a new or revised (e.g. suffix) product/part number assigned to it. A new part/product or material added to a family may use appropriate PPAP documentation from a previously fully 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: • The product performance against the customer requirement • Dimensional or capability issues • Subcontractor issues • Full approval of a part replacing an interim approval • Testing, including material, performance, engineering validation issues
3. Engineering change to design records, specifications, or materials for production product/part number(s).	Submission is required on any engineering change to production product/part design records, specifications or materials.
4. For Bulk Materials only: Process technology new to the supplier, not previously used for this product.	

Changes in any of the above situations (Table 1 and Table 2) require appropriate quality planning and written request with acceptance to proceed from Caltherm prior to implementation. (See Section 7.5.2) **The supplier shall ensure that proper notifications of changes by their supply chain are communicated as well.** See Change Request and Verification Warrant (See Section 11) for additional change request information. PPAP approval is required prior to shipping parts.

7.3 Design and Development

7.3.1 Design and Development Planning

Design Reviews shall be conducted periodically as the product or process is designed, first to identify how the design will work and how the various subsystems will work together, then later when more detail is available. Tools, such as Failure Mode and Effects Analysis, are used to identify problems and are used in an iterative fashion with Design Reviews. Design Reviews take place earlier than the DPAR in the APQP.

Design reviews are typically conducted with Caltherm and supplier team members from areas such as: product engineering, product verification and validation, reliability engineering, marketing, supply management, quality engineering, and materials engineering. Typical areas for discussion are designs, regulations, standards, product support, manufacturing processes, assembly techniques, and personal hazards. The review is documented and corrective action plans are developed and validated for any problems identified.

Design reviews may be conducted at various stages of the design and development process to accomplish the outputs listed below and to periodically review the ability of the supply chain to fulfill requirements. When requested, the supplier shall participate in design reviews. Suppliers shall provide technical leadership for their product, assist in the identification of potential problems, and work with Caltherm in correcting these problems. When design control of the product resides with the supplier, the supplier shall conduct such reviews and include representation from their supply chain and Caltherm, as appropriate.

Important outputs of the design review process are:

- Identification of the design and development processes
- Identification of the verification and validation activities appropriate for each design and development stages
- Identification of responsibilities and authorities for each of the design and development stages
- Determination of the requirements for, and methods of, communication at each stage in the design and development process
- Functional and performance requirements of the product or service
- Identification of criteria for acceptability, including key characteristics plus other characteristics that are identified by Caltherm
- Determination of applicable regulatory and legal requirements
- Identification of applicable information derived from previous similar designs
- Identification of product or service acceptance criteria
- Definition of the characteristics of the product that are essential for safe and proper use
- Special packaging requirements for proper delivery to the customer

7.3.2 Design and Development Inputs

Design verification and validation plans are developed to ensure that the product design shall meet the objectives for performance and reliability that have been established resulting in a product that meets or exceeds defined customer needs. Caltherm and the supplier jointly develop the Product Verification and Validation (PV&V) plan. The PV&V plan should consider component functionality and durability, software function, environmental conditions, anticipated applications, existing and potential failure modes, interfaces with other system components and controls, customer expectations, and key performance characteristics. Laboratory, field, customer, or supplier testing may be used to validate designs.

Product verification and validation plans and results shall be documented using a spreadsheet template provided by the Caltherm representative. The completed form shall be returned to Caltherm.

If requested, the supplier shall assist in conducting the PV&V activities either at Caltherm or the supplier's facility. The supplier shall provide information about standardized tests such as SAE, ISO, DIN, ASTM, or others that are routinely conducted for the supplied product. The supplier shall understand appropriate engineering standards (See Section 19). Also, Caltherm may conduct a Product Engineering Assessment for components with Quality Plan Level: 3 when the supplier has component or subsystem design control. This assessment is normally done as part of a Supplier Quality System Audit.

Higher component reliability is vital to improved profitability and customer satisfaction. A reliable machine starts with reliable components. To achieve component reliability, Caltherm may provide suppliers a component reliability goal. In this case, the supplier shall provide statistical evidence that the component goal is met.

The Major Component Reliability Assessment Process assures component reliability goals are set and plans are created and executed to validate and demonstrate the ability to meet the goals. The Major Component Reliability Assessment Process shall be used when directed by Caltherm. Typically, the process will be used for components with a Quality Plan Level 3: (See Section 7.2.1) when the supplier has design control of a new component or when there are plans to use an existing component in a more severe application

If requested, the supplier shall complete and submit the Component Performance & Reliability Assurance Form to Caltherm. The supplier and Caltherm shall sign this form when the component meets or exceeds its requirement(s), including reliability. This form should be signed before any components are provided for Caltherm's physical build of machines for field durability testing.

7.3.3 Design and Development Outputs

The output of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall; a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangement; a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and purpose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the reviews and any necessary actions shall be maintained.

7.3.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements (See Section 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (See Section 4.2.4).

7.3.6 Design and Development Validation

Design and development validation shall be performed in accordance with planned arrangements (See Section 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Whenever practical, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (See Section 4.2.4).

7.3.7 Control of Design and Development Changes

Changes to the design of a product or service shall be identified, documented, communicated and controlled. In cases where design control resides with the supplier, the supplier shall take appropriate measures to communicate all their proposed changes and their supply chain proposed changes, via the Change Request and Verification Warrant to Caltherm. The supplier shall evaluate the effect of any proposed changes to all constituent parts and completed products. This may be accomplished through a design review, failure modes and effects analysis, lab or field-testing, or other means, as determined jointly by Caltherm and the supplier. The changes shall be approved by Caltherm prior to implementation, see Customer Communication (See Section 7.2.3). The results of the review of changes and subsequent follow-up actions shall be documented.

7.4 Purchasing

7.4.1 Purchasing Process

As a primary supplier to Caltherm, the supplier is responsible for the quality of the products and services provided by their supply chain.

The requirements of this document should be extended to the supplier's supply chain. A supplier shall have a documented system to properly select suppliers with the capability to meet this standard and other applicable Caltherm Standards. The initial supplier selection process for providers of products or services for Caltherm shall include an on-site assessment. Assessments shall determine the supply chain's capability to meet the requirements of this standard. Suppliers shall monitor their supply chain's performance.

At times, it may be appropriate for the supplier to have their supplier(s) participate in Caltherm initiated Design, Process, and Assembly Reviews and other quality activities. A supplier shall have a communication plan to notify their supply chain of the latest specifications and to verify the product on an ongoing basis. A change in the supply chain, or any process change by the supply chain that produces the Caltherm product, requires appropriate quality planning, and Caltherm's notification prior to implementation. Caltherm requires documented approval before implementation (See Section 7.2.3).

7.4.1.1 Regulatory Conformity

The supplier shall own the patent or copyright that allows it to lawfully manufacture the product, or utilize the manufacturing process, the Company desires to purchase.

The supplier shall be properly licensed by the holder of the patent or copyright to produce or utilize the manufacturing process.

The supplier shall have documentation to substantiate that it owns the requisite Intellectual Property rights, or that it is properly licensed to use the requisite Intellectual Property Rights.

The Intellectual Property rights are effective and legally enforceable in the country where the supplier will produce the product or utilize the manufacturing process, and the documentation to substantiate that its Intellectual Property Rights are effective in the country where it will produce or utilize the manufacturing process. The duration of the requisite Intellectual Property shall be sufficient to cover the term of the proposed supply agreement.

The supplier shall identify any third party Intellectual Property Rights that could interfere with the proposed supply agreement.

Through discussion and physical testing verify that supplied products do not contain substances in excess of the amounts set forth on Caltherm's Restricted Materials List (e.g., asbestos or lead in paint) and/or other substances restricted by applicable laws.

7.4.2 Purchasing Information

Purchasing documents of Caltherm's suppliers shall contain information describing the requirements for approval of the product and the qualification of the procedures, processes, specifications, equipment and personnel necessary to produce the product.

7.4.3 Verification of Purchased Product

Verification of purchased product shall be conducted using a documented quality assessment methodology. The primary supplier to Caltherm is fully responsible for the quality of the products and services they provide, including that of the supplier's supply chain. Supplier shall verify that all materials supplied to Caltherm are free of hazardous or toxic materials beyond the permissible limits set forth by OSHA and EPA guidelines, and minerals or materials from "conflict" sources as defined by the SEC in this document: http://www.sec.gov/rules/final/2012/34-67716.pdf . Further, Caltherm recommends that suppliers should employ the iPoint Conflict Minerals Platform or the iGSM to aid in data collection and reporting to help ensure that there are no omissions in their submissions of certification of compliance.

7.4.4 Material Certifications

Material certification requirements will be outlined in the Caltherm Inspection Plan which will be provided to the supplier during the PPAP acceptance process. If a material certificate is required then it is the supplier's responsibility to submit the material certificate to the Caltherm Quality Department via one of the methods outlined below:

1. The Supplier should include the material certification with the packing slip for the shipment.
2. If for some reason it is not feasible to include the material certifications with the packing slip, the Supplier should submit via email to the materialcerts@caltherm.com email address within 24 hours of shipment of product.
3. If Supplier lacks email capacity, material certifications may be faxed to (812) 376-8305 within 24 hours of shipment of product.

7.4.5 Delivery Requirements

Suppliers will be required to meet the terms outlined on Caltherm purchase orders in regard to dock date and on time delivery. Evaluation of supplier delivery performance will be monitored through the criteria set forth in the Supplier Performance (See Section 8.6).

Supplier activity that results in an unsatisfactory on time delivery score or effects Caltherm's operational schedule may result in immediate corrective action requirements and/or financial penalties. Suppliers may be assessed charges for impact to productivity, such as "line down" conditions, up to and including the full rate of $2000 per hour during the time period in which productivity is impacted or halted all together.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Process control is needed to ensure that the manufacturing process is performed under stable conditions. Documentation shall be provided to assure quality of products at initial production and is used to maintain ongoing acceptable quality levels. Examples of process control documents are process sheets, inspection and test instructions, test procedures, standard operating procedures, preventive maintenance instructions, and specific part control plans.

Process control documents shall be in place prior to initial production and be readily available to the employees responsible for the operation of the process. The key processing parameters, process and product key characteristics identified during Design Reviews, FMEA's, and DPARs shall be addressed in the process control documents, including a Control Plan. Process control documentation or Control Plans shall be available for review by Caltherm. Minimum process capability for a key characteristic is a P_{pK} >1.33 or C_{pK} >1.33. Higher process capability requirements may be specified by the Caltherm

representative. If minimum process capability for a key characteristic has not been demonstrated the Continuous Process Monitoring Matrix shall be used to determine required activities, refer to Process Evaluation (See Section 15), unless otherwise agreed to by Caltherm.

7.5.2 Validation of Processes for Production and Service Provision

The Supplier shall validate any special process for production and service where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered. Examples of special processes are welding, heat treatment, plating, and coating.

Validation shall demonstrate the ability of the processes to achieve planned results.

The supplier shall define arrangements for validation that shall include the following, as applicable:

- Qualification of processes
- Qualification of equipment and personnel
- Use of defined methodologies and procedures
- Requirements for records
- Re-validation

After PPAP documents have been submitted, Caltherm reviews the submissions and approves or rejects the Verification Warrant (See Section 11). Approval is required prior to shipping production parts. Conditional Approval may be granted to authorize limited production shipments when there are outstanding PPAP requirements. PPAP requirements shall be completed prior to full production.

7.5.3 Identification and Traceability

A supplier shall establish and maintain documented procedures for product identification. The supplier shall have product traceability to the extent required so that if a discrepancy is found, product can be contained and corrective action initiated.

Identification is a process to identify product during all stages of production. Traceability allows for parts to be matched to a certain time frame, processes, and specific lots of material. Should a problem arise, Caltherm and the suppliers shall identify suspect parts.

7.5.4 Customer Property

The supplier shall exercise care with all Caltherm property, including intellectual property, while it is under the supplier's control or being used by the supplier. The supplier shall identify, verify, protect and maintain Caltherm property provided for use or incorporation into product. Occurrence of any Caltherm property that is lost, damaged or otherwise found to be unsuitable for use shall be recorded and reported to Caltherm. Processing equipment, tooling, and measuring equipment / fixtures owned by Caltherm are covered under this section.

7.5.5 Preservation of Product

The supplier shall preserve conformity of product with customer requirements during internal processing and delivery to the intended destination. This shall include identification, handling, packaging, storage, and protection. This also applies to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Devices

Gaging Selection

In selecting measuring equipment, Caltherm is concerned with the capability of the measurement system to detect and indicate even small changes of the measured characteristic. The measuring

equipment selected should have a discrimination of less than one-tenth of the total product tolerance being measured.

Calibration

A supplier shall establish and maintain documented procedures for the calibration, control, and maintenance of measuring, inspection, and test equipment used to assure that products and processes conform to applicable requirements. A supplier shall calibrate these devices at consistent periodic intervals against applicable standards with known traceability, and safeguard them against adjustments that would invalidate the calibration. Whenever a gage is found out of calibration and it has been used to verify parts for Caltherm, the supplier shall notify Caltherm of the suspect parts.

For certain applications Caltherm will send gages, test fixtures, and test machines to a supplier. They remain the property of Caltherm, who shall provide a gage drawing with the gage for the supplier's records. After the receipt of Caltherm gages, a supplier shall calibrate, repair, and replacement of nonconforming gages. A supplier shall review gages to assure proper function and application.

Gage Repeatability and Reproducibility

A gage repeatability and reproducibility (R&R) study measures the total repeatability and reproducibility of a gage system as a percentage of the total specification. The personnel who will be using the measuring instrument in production should always conduct the Gage R&R study. Caltherm recommends that Gage R&R studies be performed whenever production personnel using the measuring instrument are changed. The method for performing the Gage R&R study is either the Range Method or the ANOVA method, with three or more operators.

Gage R&R studies apply to variable gages. Attribute gages (such as ring or plug gages) do not require gage R&R studies unless otherwise specified by Caltherm. Attribute gages shall be checked periodically for accuracy. For non-dedicated gages such as coordinate measuring machines, a repeatability and reproducibility analysis shall be conducted utilizing specific part programs on all key characteristics plus other characteristics that are identified by Caltherm.

Gage R&R studies are required for each unique variable gage used to monitor key product or process characteristics. Studies on families of gages or equipment are not acceptable, unless the study uses an industry-approved methodology such as found in Concepts for R&R Studies (See Section 21, Reference 4). Some types of equipment, such as flow meters and hardness testers do not lend themselves to Measuring System Analysis. This type of equipment shall be identified in the calibration program and verified at a specified frequency using traceable standards.

Total variation is the ratio of the uncertainty of the repeatability and reproducibility of the gaging system to the tolerance range of the characteristic to be measured. If the total variation of the repeatability and reproducibility of the gage system (gage and operator) is less than 10 percent of the total tolerance range, the gaging system is acceptable for use. A gage demonstrating a variation of the repeatability and reproducibility of the gage system between 10 percent and 30 percent should trigger a recommendation and action plan for an improvement to the process or measurement apparatus. If the supplier uses a gage with a total variation greater than 30 percent, Caltherm shall be contacted for approval. A gage shall be proven repeatable and reproducible before it can be used in a capability study or is used to accept or reject parts. If the gage system fails, the supplier shall take corrective action to make the gage measurements repeatable and reproducible.

8 Measurement, Analysis and Improvement

8.1 General

Measurement, analysis and improvement is the process of planning, defining, and using performance metrics in processes and products critical to Caltherm. These performance metrics are used to determine the current level of performance, drive continuous improvement activities, and monitor long-

term performance levels.

Critical to the use of these performance metrics are statistical tools. These statistical tools are not only used on processes and products, but also measure customer satisfaction and supply chain performance.

A supplier shall define, plan, and implement measurements where processes affect the quality of products or services Caltherm receives.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

A supplier shall include a customer satisfaction metric in the review of its quality management system. This metric shall be included in the management review process. Trends in customer satisfaction performance should be reviewed and improvement activities developed around the data. Customer satisfaction improvement activities should utilize a structured process improvement technique.

Caltherm will use a formal review process, associated metrics and warranty data to measure our satisfaction with the supplier's performance. Suppliers shall use this data to drive improvements in Caltherm's satisfaction metrics.

8.2.2 Internal Auditing

Suppliers shall conduct their own internal audits per Section 5.6.1, Management Review – General.

Caltherm reserves the right to conduct a quality system assessment at the supplier's facility. When performing this assessment, Caltherm would expect access to a supplier's personnel, documentation, gaging, and test facilities. At the close of the assessment, Caltherm will share findings in a debriefing meeting and issue a report to the supplier summarizing the results. Any items requiring corrective action shall be clearly noted, and the supplier should submit a corrective action plan to address these issues within the agreed upon target date. Caltherm will use the Supplier Quality System Audit to complete the supplier quality system assessment. Caltherm may conduct a Product Engineering Assessment for components with Quality Plan Level: 3 when the supplier has component or subsystem design control. Caltherm may ask the supplier to complete a Supplier Information Survey prior to the on-site quality system assessment.

8.2.2.1 Quality Management System Audit

The supplier shall audit its quality management system to verify compliance with this standard and any additional quality management system requirements.

8.2.2.2 Manufacturing Process Audit

The organization shall audit each manufacturing process to determine its effectiveness.

Caltherm may perform Process Verification Audits on selected components using the Process Verification Audit Questionnaire. This on-site supplier quality audit is intended for parts with a high level of criticality to determine the effectiveness and conformance of process controls when performing work for Caltherm. The work performed can include manufacturing operations at the supplier's facility or operations sub-contracted to the supplier's supply chain. This audit may also be performed on similar parts when the work has not yet been sourced, or when preparing for full production.

Caltherm may perform Special Process Audits for special processes.

8.2.2.3 Product Audit

The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labeling, at a

defined frequency.

8.2.3 Monitoring and Measurement of Processes

A supplier shall determine and implement measurements necessary to monitor processes critical to customer satisfaction. Mistake proofing activities should be the first method of control considered. If mistake proofing is not feasible, statistical techniques shall be used to monitor the process.

Where indicated by the Continuous Process Monitoring Matrix in Section 15, Statistical Process Control charting should be used on key process control variables in order to eliminate the possibility of producing deficiencies. The charting of the monitored variables should be completed by the person(s) able to take action on the process. A written procedure describing actions to take when out-of-control conditions exist shall be present. Documentation shall exist showing evidence that proper techniques were followed by the owner(s) of the process(es). Review of process monitoring techniques shall be made available to Caltherm personnel upon request. This section not only applies to manufacturing processes, but also to business processes that are critical to customer satisfaction.

8.2.4 Monitoring and Measurement of Product

Product measurements and monitors are required to confirm the products are being produced properly and remain stable over time. Included in product measurement and monitoring are capability studies.

Capability / variability studies shall be conducted on all key characteristics plus other characteristics that are identified by Caltherm and the supplier in the quality planning process (for example, during Design Reviews, Failure Modes and Effects Analysis, and/or Design, Process, and Assembly Reviews.)

Process capability studies are conducted to provide insight into how well a process performs in regard to a customer specification. The understanding and quantification of process centering and variation is necessary to understand product quality. Two popular measures titled “capability index” are Cp and Cpk. When calculating a capability index, it is imperative that (1) process stability is demonstrated by a statistical control chart, and (2) the normal distribution model adequately describes the measured characteristic. If these assumptions are violated the capability index is of little value. Refer to AIAG SPC Manual (See Section 21, Reference 15) states on page 132: “Cpk and Cp should always be evaluated together. A Cp value significantly greater than the corresponding Cpk, indicates an opportunity for improvement by simply centering the process.”

It is recommended that capability studies use a minimum of 30 pieces taken from a stable, in control process unless Caltherm specifies otherwise. However, because of sampling variation in the standard deviation it is recommended that when possible, sample sizes of 50 to 75 be used for better estimates of stability and normality assumptions. The data for these studies should be obtained using variable gaging meeting Gage R&R requirements. Caltherm approval is needed for the use of attribute gaging on key characteristics. Key characteristics measured with attribute gages are not required to have Attribute Gage Studies performed unless required by the Caltherm representative. If an Attribute Gage Study is required, reference AIAG Statistical Process Control manual (See Section 21, Reference 15).

The supplier shall perform the following activities to assure Caltherm that the product being supplied is to specification:

- A supplier shall submit an AIAG CFG-1003 Dimensional Report verifying all features of the part, and that parts are produced from production tooling and processes.
- A supplier shall provide capabilities on all key product and process characteristics, plus other characteristics that are identified by Caltherm, whether produced internally or by the supply chain. Documentation requirements are listed in Section 10. The verification process prior to shipping products is documented in the quality plan.
- A supplier shall verify products according to the Control Plan (See Section 13) unless Caltherm does not require it. The control method called out in the Control Plan shall be determined from the capability of the process as specified in the Continuous Process Monitoring Matrix (See Section 15). For Process Control Methods (See Section 17). Control

plans shall be available for all Caltherm components with product and process key characteristics.

- A supplier shall track the material certification for Caltherm part numbers, including: chemical and mechanical properties, hardness, plating, heat number and source mill, if appropriate.
- Caltherm requires release inspection anytime the capability of the Supplier's processes is in question. Documentation of conformance to this section shall be made available to Caltherm personnel upon request.
- At a minimum the supplier shall submit an annual verification of all critical/major characteristics deemed necessary by the Caltherm inspection plan. Failure to submit this annual verification within 12 months of the previous submission may result in delay of processing receipt or invoicing activity. If the inspection plan is not supplied to the Supplier along with PPAP acceptance it is the Suppliers responsibility to contact their Caltherm representative and request this document.

The following steps are recommended for a minimum sample size of a 30 continuous-piece study. Refer to the Process Control Flowchart (See Section 9). The circumflex (^) over a value indicates a sample statistic, such as $\hat{C}pk$ or $\hat{P}pk$.

1. Perform a Gage R&R study.
2. Check to see if the process is in a "state of statistical control" by using the chart for Individuals and Moving Ranges (X-MR). A state of statistical control exists when a process is performing as consistently as it can perform. (See AIAG SPC-3: Statistical Process Control (See Section 21, Reference 15)). Use the (Average MR)/d_2 as an estimate of sigma and plot the Individuals chart.
3. Draw a histogram and estimate the fraction nonconforming from the 30-piece study.
4. Graphically represent the 30 data points with a normal probability plot to see if the bell curve adequately describes the data.
5. If the data passes steps 2 and 4 then calculate a $\hat{P}pk$.
6. Calculate an appropriate one-sided 90% lower confidence limit for the $\hat{P}pk$. See Statistical Quality Assurance Methods for Engineers, by Vardeman and Jobe, p. 213 (See Section 21, Reference 16).

   An approximate 100(1-a) confidence limit for $\hat{P}pk$ or $\hat{C}pk$ is:

$$\hat{C}_{pk} - Z_{oc}\sqrt{\frac{1}{9n} + \frac{\hat{C}_{pk}^{\,2}}{2n-2}}$$

Table 4 — Confidence Limit Z_a Values

Percent of Confidence	Z_a Value
90%	1.28
95%	1.64
99%	2.33

Table 5 — Lower & upper confidence limits on Ppk or Cpk at two levels for various sample sizes.

	Ppk or Cpk = 1.00		Ppk or Cpk = 1.33	
Sample Size (n)	-95% Confidence	+95% Confidence	-95% Confidence	+95% Confidence
5	0.37	1.63	0.52	2.14
10	0.58	1.42	0.79	1.87
20	0.71	1.29	0.95	1.71
30	0.76	1.24	1.03	1.63
50	0.82	1.18	1.10	1.56

The only way to know if a capability target is met is to (1) make an X-MR chart, (2) graphically check for the normal distribution, and (3) use a lower confidence limit for the $\hat{P}pk$. Caltherm is moving toward six sigma processes, reference Section 16. You can convert the into the approximate six sigma scale

$$\hat{P}_{pk} = Min\left\{\frac{USL - \bar{\bar{X}}}{3\hat{\sigma}}, \frac{\bar{\bar{X}} - LSL}{3\hat{\sigma}}\right\}$$

$$\hat{\sigma} = \sqrt{\sum \frac{(X_i - \bar{X})^2}{n-1}}$$

$$\hat{C}_{pk} = Min\left\{\frac{USL - \bar{\bar{X}}}{3s}, \frac{\bar{\bar{X}} - LSL}{3s}\right\}$$

$$s = \frac{\bar{R}}{d_2}$$

$\hat{P}pk$

by multiplying $\hat{P}pk$ by 3 and adding 1.5. A $\hat{P}pk$ of 1.33 is minimal, with a desired $\hat{P}pk$ of 1.5 being the ultimate goal, for Caltherm suppliers to assure a high level of defect free product. The following formulas are commonly used for performance and capability indices.

At Caltherm, world-class capability is defined as “on target with minimum variance.” Conformance to specifications is merely the starting point, not the finish line.

If the process does not follow a normal distribution, a Caltherm quality representative should be contacted. The capability study shall be documented, and a Capability Study Checklist and Form should be included. Examples of inherently non-normal process measures include flatness, concentricity, tensile strength, casting hardness, and parallelism. Of the four indices described above, only Cp and Pp are robust with respect to non-normality. For non-normal process analysis refer to page 140 of the AIAG Statistical Process Control Manual (See Section 21, Reference 15) and page 260 of Process Quality Control by Ott (See Section 21, Reference 10).

Some characteristics specified with geometric dimensioning and tolerancing (GD&T) do not lend themselves to standard methods of calculating capability. If this is the case and assistance is needed, the Caltherm Quality Services group can be used as a resource. Reference page 144 of AIAG Statistical Process Control Manual (Reference 15).

Preliminary process performance $\hat{P}pk$ should be conducted in the early stages of the Product Development Process. The Preliminary Process Capability uses a process standard deviation ($\hat{\sigma}$ or $\frac{\bar{R}}{d_2}$).

Both $\hat{C}pk$ and $\hat{P}pk$ estimates of population capability and process performance assume the data come from a normal (bell-shaped) distribution with specification limit(s) about the target. These point estimates are subject to variation over time. The larger the sample used to estimate them, the smaller the uncertainty in that estimate. The difference between $\hat{C}pk$ and $\hat{P}pk$ is the calculation of the sample standard deviation ($\hat{\sigma}$). $\hat{C}pk$ is calculated by taking the Average Range and dividing by a constant d2 ($\frac{\bar{R}}{d_2}$), which gives only a “within subgroup” estimate of the standard deviation.

For the $\hat{P}pk$ calculation use at least 30 pieces and find an overall standard deviation, which will be larger than the one using the Average Range.

Process measures should be used to align the "voice of the process" with the demands from the "voice of the customer." It is never appropriate to average capability or performance indices for several processes into one index.

Production Sample Size Considerations

Caltherm requests that the supplier use a sampling plan for measurement data that insures no more than one day's production would go undetected. Use the spreadsheet titled "Sample Size & Control Limit Design" which can be provided by your Caltherm representative. The Average Production Length to detection would be less than or equal to one day's consumption at Caltherm. See "Statistical Process Control Scheme Design", by Keats, Miskulin & Runger, Journal of Quality Technology, Vol. 27, No. 3, July 1995.

For example, assume it is economical for a supplier to check no more than 2% of production for control purposes. The process is known to have a mean of 100 mm with a standard deviation of 0.1 mm, and a Cpk equal to 1.33. Caltherm consumes 250 pieces per day. Therefore, we want to detect a one sigma process shift before producing 250 pieces.

To use the Sample Size & Control Limit Design spreadsheet for control limits and sampling frequency, enter in cell B3 the value of "1" for the sigma shift, and enter 2% in B4 which is the sampling rate. The spreadsheet tells us to measure 6 pieces every 294 pieces, and set the control chart limits at:

$$100 \pm (1.667)(\ cr)/(..6) = 100 \pm (1.667)(0.1)/\ ..6 = 100 \pm\ 0.07mm.$$

If the process sigma changes by one unit, the control chart will indicate a significant change before 239 parts are produced for Caltherm. Since 239 are fewer than 250 the plan provides the protection that Caltherm requires.

8.3 Control of Nonconforming Product

The supplier shall establish and maintain documented procedures to ensure that proven or suspected nonconforming products are prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, isolation, disposition of nonconforming products, and for notification to the departments concerned (both internal and external).

If parts are found to be nonconforming at Caltherm, the supplier shall provide the resources necessary to evaluate, contain, sort, reclaim, and/or scrap the nonconforming product. The supplier shall have a representative establish containment at the Caltherm factory, material in transit, and at the supplier within 24 hours. Quicker response may be required based on the severity of the situation.

If nonconforming products get into Caltherm products or become a warranty problem, it shall be the supplier's responsibility to aid Caltherm in evaluating and correcting the problem. Caltherm shall be entitled to recover from the supplier all costs and expenses reasonably incurred in taking corrective action per the terms and conditions.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

8.3.1 Control of Nonconforming Product – Supplemental

Product with unidentified or suspect status shall be classified as nonconforming product.

8.3.2 Control of Reworked Product

Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by appropriate personnel.

8.3.3 Customer Information

Caltherm shall be informed promptly in the event that nonconforming product has been shipped.

8.3.4 Customer Waiver

If a supplier wants to ship a product not meeting the specified requirements, written approval shall be obtained from Caltherm prior to shipment of the product. This request can be made using the Supplier Request for Deviation. This applies equally to products or services purchased from the supply chain. The supplier shall concur with any requests from their supply chain before submission to Caltherm. The supplier shall maintain a record of the expiration date and quantity authorized. The supplier shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. **Each** shipping container of deviated product shall be properly identified with the deviation number.

8.4 Analysis of Data

Caltherm expects our suppliers to obtain appropriate data and apply statistical and problem solving techniques to solve specific problems and to drive continuous improvement activities in a timely manner.

At a minimum, the supplier shall analyze the following:

- Caltherm satisfaction review results
- Internal and external product failures (including warranty)
- Process or product quality trends
- Supply chain (including the Supplier's supply chain) quality performance

Summarized quality performance should be made available to all of the supplier's employees. Quality performance data shall be made available at the request of Caltherm personnel.

When a product or process does not meet customer specifications, or is not performing adequately, one suggested methodology is DMAIC.

Define: Define the project goals and customer (internal and external) deliverables
Measure: Measure the process to determine current performance
Analyze: Analyze and determine the root cause(s) of the defects
Improve: Improve the process by eliminating defects
Control: Control future process performance

8.5 Improvement

8.5.1. Continual Improvement

Evidence shall demonstrate the use of data, past experience, and lessons learned to show continuous improvement of the quality management system.

8.5.2. Corrective Action

Corrective action eliminates the cause(s) of nonconformities in order to prevent recurrence. Suppliers shall investigate resolution to nonconformities using eight Corrective Action steps or Resolution Phases. The supplier shall document Corrective Action in each Resolution Phase.

The **Eight Corrective Action Disciplines (8D)** or Resolution Phases required:

1. **D1 Establish the Corrective Action Team**
   Purpose: To define the members of the team that can successfully resolve the problem.

2. **D2 Problem Identification**
   Purpose: To document all facts, research and field information that would quantify or describe the problem in detail.

3. **D3 Containment Action & Short Term Corrective Action**
   Purpose: Actions to isolate the effect of the problem from any customer until corrective action is implemented. To minimize the effect of any nonconforming product by containment, re-inspection, rework, etc., to verify conformance of current product. Identify and contain nonconforming product at all locations including, but not limited to; in-house at supplier facility, in-transit material, material located at various Caltherm sites (including Parts Depots), dealers and end-use customer. Containment shall be completed within 24 hours of problem notification.

   Production & Experimental/Pilot Build Problems:
   What you did to stop the problem today.
   Customer / Warranty Problems:
   Interim customer solution used to quickly restore customer acceptance.

4. **D4 Define and Verify Root Cause**
   Purpose: Scientific, complete breakdown of the Direct Cause, Contributing Causes and Root Causes of the problem.

5. **D5 Choose and Verify Solution**
   Purpose: Identification of solutions or actions that will eliminate the Root Causes as well as the Contributing Causes. Quantitative results confirming that the selected corrective actions will resolve the issue for the customer.

6. **D6 Implement Permanent Corrective Action**
   Purpose: Action taken in this phase will correct the root cause of the problem and prevent its recurrence. Implementation includes listing action steps, identifying responsible people and target dates for each action. This action shall be completed within 30 days unless Caltherm Approved Date.

7. **D7 Prevent Recurrence**
   Purpose: Modifications to Management Systems, Operating Systems, practices, and procedures such as Process Control Plans, DFMEAs, PFMEAs, Work Instructions, Training Plans, Training Performed, Engineering Documentation to prevent recurrence of this and all similar problems. The responsible person or 8D team reviews all activity performed through resolution phases and confirms that all steps have been completed. It is recommended that the improvements resulting from the Eight Step Problem Resolution Process be replicated to like processes or products to assure the problem has been solved.

8. **D8 Team Recognition**
   Purpose: Acknowledgement from management of the good work done by the 8D team. This set is to recognize extra effort and reinforce successful behavior.

A status report shall be submitted to the originator of a Caltherm initiated corrective action request within one day from the date of receipt, unless otherwise specified by the Caltherm investigator. Each corrective action D-step shall be completed by the target date.

8.5.3. Preventive Action

Preventive action eliminates the cause(s) of potential nonconformities in order to prevent their occurrence. Preventive action focuses on building good quality into the product and processes to ensure that nonconforming products never reach the customer. Processes should be developed so employees can do the job right every time. The processes include, but are not limited to: data collection systems, process control plans, mistake proofing techniques, training, continuous improvement actions, design FMEAs, and process FMEAs. Preventive action activities shall be a part of the management review process.

At a minimum, FMEA items with Risk Priority Number value > 100, or the severity is: 9, require follow-up actions. See AIAG FMEA Manual (See Section 21, Reference 9).

A supplier shall take a systematic approach to defining and implementing preventive action activities. The systematic process improvement approach should include five basic steps:

Define: Define the project goals and customer (internal and external) deliverables

Measure: Measure and determine customer needs and specifications

Analyze: Analyze the process or product options to meet customer needs

Design: Design the process or product to meet customer needs

Verify: Verify the design performance and ability to meet customer needs

8.6 Supplier Performance

Caltherm's evaluation system uses a number of factors, such as Quality, Delivery, and Process Continuous Improvement (PCI) to develop an overall Supplier performance rating. This rating serves as an objective measure to determine whether Caltherm expectations are being met. At Caltherm's discretion, the Caltherm representative may determine that to address the Suppliers performance deficiencies, a meeting with Supplier's management is necessary and a Supplier documented corrective action and improvement plan is required.

8.6.1. Performance Measures

8.6.1.1. Quality

This metric defines the Rejected Parts Per Million (RPPM) shipped using the following formula. The definition of "rejected parts" is the total number of parts returned to the Supplier for any valid quality reason (including those caused by shipping and administrative errors.)

RPPM = (Number of Parts Rejected / Number of Parts Received) x 1,000,000

Based on Caltherm's current expectations, the following table describes the resulting actions for varying RPPM performance levels:

- **Premiere – (< 400 PPM)** – No action required and eligible for Premiere Supplier status.
- **Preferred / Satisfactory – (> 400 PPM & < 900 PPM)** – Corrective action may be required.
- **Marginal Systemic – (> 900 PPM & < 1500 PPM)** – Corrective action shall be required.
- **Unacceptable – (> 1500 PPM)** – Systemic corrective action is required and may require Supplier to meet with Caltherm management representatives.

8.6.1.2. Delivery

This metric defines the delivery performance rating using the following formula:
"On Time" is defined as material arriving on or within **five** days prior to the dock date listed on the purchase order release transmitted by Caltherm to the Supplier.

Delivery = (Number of Parts Received On Time / Number of Parts Received) x 100

Based on Caltherm's current expectations, the following table describes the resulting actions for varying delivery performance levels:

- **Premiere – (>99.9%)** – No action required and eligible for Premiere Supplier status.
- **Preferred / Satisfactory – (> 97% & < 99.8%)** – No action required and meets Caltherm Requirements
- **Marginal Systemic – (> 95% & < 96.9%)** – Corrective action may be required.
- **Unacceptable – (< 94.9%)** – Systemic corrective action is required and may require Supplier to meet with Caltherm management representatives.

8.6.1.3. Preventive Action

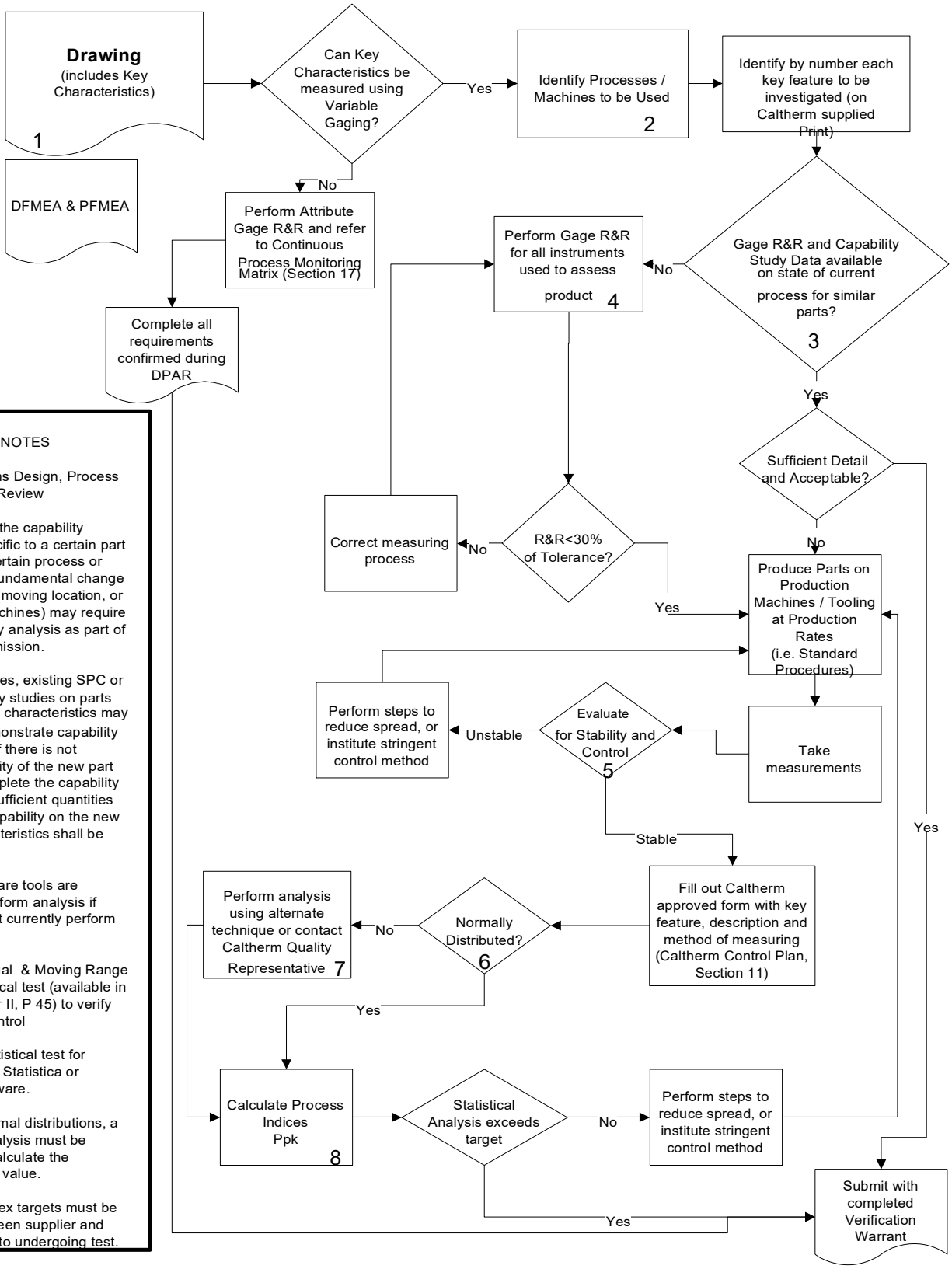
This metric is the percent of savings to annual spend. Spend is defined as the dollar amount Caltherm purchased from the Supplier. The following formula defines the calculation:

% Savings = (Dollar Value of Ideas Submitted / Total Dollar Spend)

Based on Caltherm's current expectations, the following table describes the resulting actions for varying continual improvement performance levels:

- **Premiere – (8.0% or greater)** – Exceeds criteria established for fiscal year by Caltherm Purchasing group and eligible for Premiere Supplier status.
- **Preferred / Satisfactory – (> 4.0% & < 7.9%)** – No action required and meets Caltherm Requirements
- **Marginal Systemic – (> 0% & < 3.9%)** – Corrective action may be required.
- **Unacceptable – (0%)** – Systemic corrective action is required and may require Supplier to meet with Caltherm management representatives.

9. Process Control Flow Chart – PDP and Initial Production



NOTES

1. DPAR means Design, Process and Assembly Review

2. Approval of the capability analysis is specific to a certain part number on a certain process or machine. Any fundamental change to the process (moving location, or substituting machines) may require a new capability analysis as part of the PPAP submission.

3. In some cases, existing SPC or recent capability studies on parts with similar key characteristics may be used to demonstrate capability for a new part if there is not sufficient quantity of the new part ordered to complete the capability study. When sufficient quantities are ordered, capability on the new part key characteristics shall be demonstrated.

4. Some software tools are available to perform analysis if supplier doesn't currently perform R&R

5. Use Individual & Moving Range with mathematical test (available in Memory Jogger II, P 45) to verify stability and control

6. Perform statistical test for normality using Statistica or equivalent software.

7. For non-normal distributions, a non-normal analysis must be performed to calculate the appropriate P_{pk} value.

8. Process Index targets must be agreed to between supplier and Caltherm prior to undergoing test.

10. Production Part Approval Process (PPAP) Requirements

The required Production Part Approval activities and documents will be specified by the Caltherm representative. The requirements are determined by the Quality Plan Level (See Section 7.2.1). Table 10.1 lists submission and retention requirements. Unless otherwise specified, Caltherm requires Section 4.2 Level 2 of the AIAG PPAP (See Section 21, Reference 11) to include the requirements listed in the table below. Ongoing requirements for verification of control processes are outlined in section (See Section 8.2.4)

After the PPAP documents have been submitted, Caltherm reviews the data and either Approves or Rejects the Verification Warrant. Approval is required prior to shipping production parts including all builds. Conditional Approval may be granted to authorize limited production shipments when there are outstanding PPAP requirements.

Production Part Approval Requirements by Quality Plan Level

	Requirement	AIAG Level	Caltherm Quality Plan Level					Complete By
		2	0	1	2	3	4	
1.	Design Record	S						
	- for proprietary components / details	R						Prior to production
	- for all other components / details	S						Prior to production
2.	Engineering Change Documents, if any	S						First production
3.	Customer Engineering approval, if Required	R						Prior to production
4.	Design FMEA (Failure Modes and Effects Analysis)	R					S	Prior to complete design
5.	Design Review						S	Prior to complete design
6.	Design, Process, & Assembly Review (DPAR) – Initiated by Caltherm				S	S	S	Prior to production
7.	Functional Geometry Review					S	S	Prior to production
8.	Process Flow Diagrams / Process Map	R				S	S	Prior to production
9.	Process FMEA	S				S	S	Prior to control plan
10.	Control Plan (including Checking Aids)	S			S	S	S	Prior to production
11.	Measurement System Analysis Studies – Gage R & R Studies for Key Characteristics	R			S	S	S	Prior to use
12.	Initial Sample Inspection Report - ISIR (Dimensional Results)	S		S	S	S	S	Prior to production
13.	Material / Metallurgical / Functional / Performance Results (as appropriate)	S		S	S	S	S	Prior to production
14.	Initial Process Studies – Capability Studies	R			S	S	S	Prior to control plan
15.	* Qualified Laboratory Documentation	S						Prior to production
16.	Appearance Approval Report, if applicable (for Class A parts)	S				S	S	Prior to production
17.	Verification Warrant	S		S	S	S	S	Prior to production
18.	Experimental Part Inspection (Engineering)				S	S	S	Prior to production
19.	Supplier Functional Verification Testing Results					S	S	Prior to production
20.	* Sample Product	S						
21.	* Master Sample	R						
22.	* Records of Compliance With Customer-Specific Requirements	R						
23.	Receipt of Caltherm Inspection Plan	R	R	R	R	R	R	

S = The supplier shall submit to Caltherm and retain a copy of records or documentation items at appropriate locations.
R = The supplier shall retain at appropriate locations and make available to Caltherm upon request.
* If requested by Caltherm, provide documentation.

11. Change Request and Verification Warrant Form

Caltherm requires the following information to be included in the Warrant.

Part and Supplier information

- Part Number or Numbers
- Part Name
- Decision Number
- Revision Level
- Supplier Name
- Supplier Number
- Address

Reason for submitting request for manufacturing process and product change authorization

- Design/Material Change
- Process Change
- Location Change
- Tooling Change
- Supplier Change
- Other

Reason for proposed change

- Improve Product Quality
- Increase Manufacturing Efficiency
- Reduce Lead Time
- Other
- Describe proposed change and the quality plan to ensure the quality of product will not be adversely affected. Attach all supporting information.
- Proposed implementation date.
- Changes that deviate from drawings or specifications
- Explanation
- Supplier Signature and Title
- Date

Supplier not to proceed until it receives authorization from Caltherm.

This authorization to proceed is granted upon the understanding that it is advisory in nature and in no manner changes the Supplier's original responsibility for ensuring that all characteristics, designated in the applicable engineering specifications, and/or inherent in the samples as originally tested and approved, are maintained. Supplier accepts full responsibility for the types of changes listed above; and should such changes result in failure to meet customer requirements, Supplier shall be expected to fully reimburse Caltherm for all expenses incurred to correct the deficiency.

Submission of Change Request should be submitted electronically to your Caltherm Quality representative.

Caltherm is responsible for providing a follow up date for any conditional approvals.

12. DPAR CHECKLIST AND STRUCTURE

The list of items below should be considered when conducting a DPAR. Documentation of the DPAR results shall be recorded. C = Complete; I = In Process; N = Not Applicable

C/I/	#	DESCRIPTION	COMMENT
1. DESIGN REVIEW (Print or Model)			
	1.1	Review material requirements	
	1.2	Review geometric dimensioning and tolerancing	
	1.3	Review drawing / model format for clarity and completeness	
	1.4	Review design and functional requirements	
	1.5	Review Caltherm / Supplier test plan and test results	
	1.6	Review tolerances for manufacturability	
	1.7	Review all applicable specifications & standards	
	1.8	Identify key design characteristics from Design Reviews & other sources	
	1.9	Determine requirements for Gage R & R studies on measuring equipment	
	1.10	Determine method to measure key design characteristics	
	1.11	Determine capability study or control plan requirements on key characteristics plus other characteristics defined by Caltherm or the supplier.	
	1.12	Review preferred methods for capability assessment	
	1.13	Determine method for capability studies on key characteristics plus other characteristics defined by Caltherm	
	1.14	Review guidelines for control methods after capability assessment	
	1.15	Review procedure and requirements for initial sample inspection	
	1.16	Review Appearance / Paint requirements	
	1.17	Review requirements for cleanliness and deburring	
	1.18	Identify cost reduction opportunities	
	1.19	Determine potential cost impacts of any changes identified	
2. PROCESS REVIEW			
	2.1	Review all processes required to produce the part / assembly, e.g. machining, grinding, stamping, welding, assembly, plating, heat treatment, bonding, painting	
	2.2	Review manufacturing process for completeness	
	2.3	Review specifications related to these processes	
	2.4	Review key process characteristics from Design Reviews, Process Failure Modes & Effects Analysis (PFMEA's) & other sources	
	2.5	Determine method to measure key process characteristics	
	2.6	Determine requirements for Gage R & R studies on measuring equipment	
	2.7	Determine capability study or control plan requirements on key characteristics plus other characteristics defined by Caltherm	
	2.8	Review preferred methods for capability assessment	
	2.9	Determine method for capability studies on key characteristics plus other characteristics defined by Caltherm	
	2.10	Review guidelines for control methods after capability assessment	
	2.11	Review requirements for cleanliness, debarring, packaging, rust preventives etc.	
	2.12	Review Operator Method Sheets (OMS)	
	2.13	Review Sequence of Events (SOE)	
	2.14	Review machining instruction requirements	
	2.15	Review training needs	
	2.16	Review Mistake Proofing opportunities	
	2.17	Review ergonomics for material handling, tools, processes, etc.	
	2.18	Identify cost reduction opportunities	
	2.19	Determine potential cost impacts of any changes identified	
3. GAGING REVIEW			
	3.1	Determine what measuring equipment gages, test fixtures etc. are required	
	3.2	Determine availability of measuring equipment gages, test fixtures, etc.	
	3.3	Determine quality or control plan requirements	
	3.4	Review procedures for drawings and inventory of gages and test fixtures	
	3.5	Determine how many gages and test fixtures are required	

	3.6	Determine who will design and build gages and test fixtures	
	3.7	Review policy for ongoing gage maintenance and calibration	
	3.8	Identify cost reduction opportunities	
	3.9	Determine potential cost impacts of any changes identified	

4. ASSEMBLY REVIEW

	4.1	Review systems listed for Design Reviews in PDP Phase 2 & 3	
	4.2	Review cleanliness requirements & possible contamination problems	
	4.3	Review critical product systems	
	4.4	Review hose, line, and wiring routing	
	4.5	Review appearance, fit, and finish process requirements	
	4.6	Review linkage adjustment capabilities	
	4.7	Review fasteners	
	4.8	Review potential leak, vibration, and noise problems	
	4.9	Review fit & finish requirements	
	4.10	Review Operator Method Sheets (OMS)	
	4.11	Review Sequence of Events (SOE)	
	4.12	Review assembly instruction requirements	
	4.13	Review needs for assembly gages and aids	
	4.14	Review training needs for key assembly characteristic	
	4.15	Review process for Mistake Proofing opportunities	
	4.16	Review material handling systems that prevent part damage	
	4.17	Review torque requirements for key joints	
	4.18	Review ease of access for assembly	
	4.19	Review need for assembly fixtures	
	4.20	Review plans for assembly tools	
	4.21	Review ability for fluid systems to reach steady state levels	
	4.22	Review trial installation requirements	
	4.23	Review special process requirements (bonding, painting, etc.)	
	4.24	Review performance testing requirements in assembly	
	4.25	Review and verify specification	
	4.26	Review ergonomics for material handling, tools, processes, etc.	
	4.27	Identify cost reduction opportunities	
	4.28	Determine potential cost impacts of any changes identified	

5. PACKAGING REVIEW

	5.1	Review requirements for component packaging / returnable containers	
	5.2	Review the need for temporary sealing for the wash or paint process	
	5.3	Review packaging & shipping requirements for finished goods, including the need for rust protection	
	5.4	Identify cost reduction opportunities	
	5.5	Determine potential cost impacts of any changes identified	

6. MISCELLANEOUS ITEMS REVIEW

	6.1	Review cost targets	
	6.2	Verify service requirements complete	
	6.3	Review engineering Bill of Material (BOM)	
	6.4	Review to ensure the part or assembly does NOT contain substances in excess of the amounts set forth on Caltherm's Restricted Materials List (e.g., asbestos or lead in paint) and or other substances restricted by applicable laws	
	6.5	Review all software requirement specifications	
	6.6	Review Design Review, FMEA results	
	6.7	Print release date	
	6.8	Production tooling Purchase Order ready date	
	6.9	Lead times for tooling	
	6.10	Production Part Approval Process (PPAP) requirements	
	6.11	Supplier audit / visit	
	6.12	Completion of Verification Warrant	
	6.13	Sign off of attendees	

13. Control Plan Checklist

Control Plan Elements (BOLD items are required.)		
#	**Item**	**Description**
1	**Control Plan Category: Prototype, Pre-Launch, or Production**	Indicate the appropriate category. Prototype: Build for verification of design Pre-launch: Build prior to normal production for verification of processes Production: Build or product that Caltherm will offer for sale to customers
2	Control Plan Number	Enter the control plan document number used for tracking, if applicable.
3	**Part Number**	Enter the Caltherm part number (and supplier part number, if Applicable.)
4	**Part Name / Description**	Name and description of the part and/or process being controlled.
5	**Supplier / Plant**	Enter the name of the company (supplier) and the appropriate division or manufacturing plant preparing the Control Plan.
6	Supplier ID / Code	Enter the identification number as requested by the procuring organization (e. g. Corporate Supplier ID or factory department).
7	Core Team Members	Enter the name(s) and telephone number(s) of the individual(s) responsible for preparing the Control Plan to the latest revision.
8	**Preparer**	Name(s) of the individual(s) responsible for preparing the Control Plan or the primary contact responsible for the Control Plan.
9	Responsible Person	Indicates who is responsible for completing the control method.
10	Supplier / Plant Approval / Date	Obtain the responsible manufacturing plant approval (if required).
11	**Engineering Change Level / Revision Level**	Latest engineering design level and/or issue date from the drawing specification.
12	**Decision / Engineering Change Number**	Caltherm number assigned to the engineering change.
13	**Date**	Date the original Control Plan was compiled.
14	**Revision Date**	Date the latest Control Plan was updated.
15	Page	For multiple Control Plan pages, indicate the page numbers (page _ of _).
16	Customer Engineering Approval / Date	Obtain the responsible engineering approval (if required).
17	Customer Quality Approval / Date	Obtain the responsible quality representative (if required).
18	Other Approval / Date	Obtain any other agreed upon approval (if required).
19	**Part / Process Number**	Enter the part number. If multiple part numbers exist (assembly), list the individual part numbers and their processes accordingly.
20	**Process Name / Operation Description**	Description of the generating process/operation which produces the characteristic.
21	**Machine, Device, Jig, Tools for Manufacturing**	For each operation that is described, identify the processing equipment, as appropriate.
CHARACTERISTIC		A distinguishing feature, dimension or property of a process or its output (product) on which variable or attribute data can be collected. Use visual aids where applicable.
22	No.	Number: Enter a cross reference number from all applicable documents such as, but not limited to, process flow diagram, numbered print, FMEAs, and sketches, if required.

23	**Product**	Enter the applicable Product Characteristic. Product Characteristics are the features or properties of a part, component, or assembly that are described on drawings or other primary engineering information. All Key Product Characteristics must be listed on the Control Plan. In addition, the manufacturer my list other Product Characteristics for which process controls are routinely tracked during normal operations.
24	**Process**	Enter the applicable Process Characteristic. Process Characteristics are the process variables (input variables) that have a cause and effect relationship with the identified Product Characteristic. A Process Characteristic can only be measured at the time it occurs. Process Characteristics for which variation must be controlled to minimize product variation must be identified. There could be one or more Process Characteristics listed for each Product Characteristic. In some processes one Process Characteristic may affect several Product Characteristics.
25	**Key Characteristic**	Indicate if the characteristic is designated as a Key Characteristic. A Key Characteristic is a product or process characteristic whose variation or targeting control is necessary to meet customer requirements and that directly or significantly impact customer satisfaction through compliance with government, country or industry standards and/or regulations, ability to perform its intended design requirements (form, fit, function, reliability, appearance), or manufacturability and ability to assemble. Key Characteristics may be the Product or Process type. (See Section 7.2.1.1)
METHODS		A systemic plan using procedures and other tools to control a process.
26	**Product / Process Specification / Tolerance**	Specifications / tolerances may be obtained from various engineering documents, such as, but not limited to, drawings, design reviews, material standard, computer aided design data, manufacturing and / or assembly requirements.
27	**Evaluation / Measurement Technique**	Identify the measurement system being used. This could include gages, fixtures, tools, and / or test equipment required to measure the part / process / manufacturing equipment. An analysis of the reproducibility, repeatability, stability, and accuracy of the measurement system should be done prior to relying on a measurement system and improvements made accordingly.
28	**Sample Size / Frequency**	When sampling is required, enter the sample size and frequency.
29	**Control Method**	Enter a brief description of how the operation will be controlled; include procedure numbers, where applicable. Operations may be controlled by, but are not limited to, Statistical Process Control, inspection, attribute data, mistake-proofing, and sampling plans. The method of control should be continually evaluated for effectiveness.
30	**Reaction Plan**	Enter the corrective actions necessary to avoid producing nonconforming products or operating out of control. The actions should normally be the responsibility of the people closest to the process (operator, set up person, supervisor) and should be clearly designated in the plan. Provisions should be made for documenting. In all cases, suspect and nonconforming products must be clearing identified, quarantined, and disposition made by the responsible person designated in the reaction plan. This column may also refer to a specific reaction plan number and identify the person responsible for the reaction plan.

14. Engineering Deviation Authorization Checklist

Caltherm will accept supplier's deviation forms containing, at a minimum, the following information:

- Date
- Caltherm Part Number and Description
- Quantity Affected
- Proposed Deviation (Use As Is or Reclaim)
- Description of Proposed Deviation
- Reason for Deviation
- Supplier Name and ID Number
- Supplier Contact
- Telephone Number
- Email Address
- Corrective Action
- Implementation Date for Corrective Action (30 day max. unless Caltherm Approved Date)

REPLY from CALTHERM

- Accept
- Reject
- Deviation Number
- Approval Signatures
- Special Instructions (if any)

The assigned deviation number shall accompany all parts shipped to Caltherm covered by this deviation. The assigned deviation shall be referenced in any future correspondence concerning these parts. The supplier shall produce parts to Caltherm print specifications. This deviation does not allow for any additional print changes, other than specified in the assigned deviation.

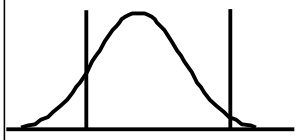
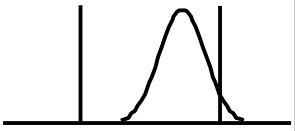
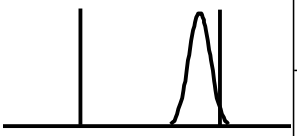
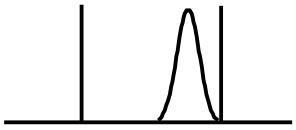
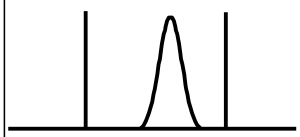
15. Process Evaluation - Continuous Process Monitoring Matrix

CONTINUOUS PROCESS MONITORING MATRIX

		Process Potential – Pp or C_p		
		C_p < 1.0 or Unknown	**1.0 : Cp < 1.33**	**C_p 2 1.33**
Process Capability – Ppk or Cpk	**Cpk < 1.0 or Unknown**	Mean and Variability, See Case 1 *100% inspection and corrective action required*	Mean and/or Variability, See Case 2 *100% inspection and corrective action required*	Mean Only, See Case 3 *100% inspection and corrective action required*
	1.0 :: Cpk < 1.33	*Not Possible*	Mean and/or Variability, See Case 4 *Control charting and sampling required*	Mean Only, See Case 5 *Control charting required*
	Cpk 2 1.33	*Not Possible*	*Not Possible*	Auditing of Both, See Case 6 *Routine audits required*

The goal for each process is to produce parts at the nominal specification value. If a process is not targeted, and/or has excessive variation, quality tools and techniques should be used to determine the cause(s). The first attempt should be to target the process on the nominal specification, and then reduce the overall process variation to improve the process capability.

Case	Action Plans
1,2,3	Nonconforming product is known to occur; these cases imply rework or scrap conditions. 100% inspection and a corrective action plan are required. Reduce the tolerance by half of the Gage R&R (expressed as a percent of the tolerance applied.) Case 1 – The first priority is reduction of variability. Reduce the variability until the process potential is approximately one. Targeting the mean is the second priority. Case 2 – The first priority is targeting the mean. Variability reduction is the second priority when Process Potential nears Process Capability. Case 3 – The first priority is targeting the mean. Variability reduction is unnecessary if properly targeted.
4	Improvement of targeting and reduction of variability is required. First, target the process using EMWA and/or CuSum. Once Process Potential equals Process Capability, switch the priority to using traditional SPC for variability audits and variability reduction. The goal is to get to Case 5.
5	Improvement of targeting is required. First, target the process using EWMA and/or CuSum – Means Testing. Once Process Potential equals Process Capability, Case 6 is achieved.
6	The process is targeted, capable, and in control. Conduct routine audits and infrequent capability studies (using R / d_2 from traditional SPC methods). Audit frequency is determined based on the ability to recall nonconforming material if audits result in finding such material.

CASE	GRAPHICAL REPRESENTATION	DESCRIPTION REQUIREMENTS
CASE 1 Cp < 1.0 Cpk < 1.0 or Unknown		This process is not able to continuously produce parts conforming to specifications. Typical SPC won't help until the process is fixed for both the mean and the variability. If the process capability is unknown, data collection is required to determine the capability of the process. These conditions require 100% inspection and a corrective action plan to improve the process. Caltherm written approval is needed prior to shipping parts.
CASE 2 1.0: Cp < 1.33 Cpk < 1.0		This process is not able to continuously produce parts conforming to specifications. The primary issue is targeting. Mean control is the primary goal. This condition requires 100% inspection and a corrective action plan to improve the process. Caltherm written approval is needed prior to shipping parts.
CASE 3 Cp 2 1.33 Cpk < 1.0		This process is not able to continuously produce parts conforming to specifications. Caltherm written approval is needed prior to shipping parts. The primary issue is targeting. Mean control is the primary goal. This condition requires 100% inspection and a corrective action plan to improve the process. Caltherm written approval is needed prior to shipping parts. Audit variance using SPC.
CASE 4 1.0: Cp < 1.33 1.0: Cpk < 1.33		This process is capable of producing parts that conform to specifications, but may or may not be targeted at the nominal specification value. An attempt should be made to determine the special cause(s) that are prohibiting the process from being centered or are creating excess variation. The primary issue is targeting. Variance shall be monitored and reduced. Charting (SPC, Pre-Control, or run charting) to verify the parts being produced conform to design specifications, and a sampling plan to inspect parts per a frequency interval shall be executed. The interval is determined by the Cp value – the greater the Cp value, the less frequent the parts have to be checked. Evidence of less than .0027% defective is required.
CASE 5 Cp 2 1.33 1.0: Cpk < 1.33		This process is capable of producing parts that conform to specifications, but may or may not be targeted at the nominal specification value. An attempt should be made to determine the special cause(s) that are prohibiting the process from being centered or are creating excess variation. The primary issue is targeting. Variance shall be monitored. Charting (SPC, Pre-Control, or run charting) shall be used to verify the parts being produced conform to design specifications. Evidence of < .0027% defective is required.
CASE 6 Cp 2 1.33 Cpk 2 1.33		This process is capable, well centered, and in control. Parts produced are conforming. There is little concern of nonconforming product. At a minimum, such a process should be verified as appropriate by inspecting the parts being produced, such as during the quartile marks for each run (first, 25%, 50%, 75%, and last piece).

A shift or drift in the process can happen, and depending on the process control technique being used, it may not be detected. The column at the far right shows the corresponding defective PPM if the process average moves 1.5cr from the target (also known as the quality or six sigma level). Suppliers need to be aware of this and shall measure their process capability at least annually. The matrix below further shows the effect off-centering due to a process shifting has on the defective PPM.

When this has been exhausted, a review of the product design should be done to determine if the drawing requirements could be changed. Any action other than that listed in the Continuous Process Monitoring Matrix shall be approved by Caltherm.

QUALITY LEVEL - DEFECTIVE PPM DUE TO PROCESS SHIFTING

Process Shift	3cr	3.5cr	4cr	4.5cr	5cr	5.5cr	6cr
0	2700	465	63	6.8	0.57	0.034	0.002
0.25cr	3577	666	99	12.8	1.02	0.1056	0.0063
0.50cr	6440	1382	236	32	3.4	0.71	0.019
0.75cr	12288	3011	665	88.5	11	1.02	0.1
1.00cr	22832	6433	1350	233	32	3.4	0.39
1.25cr	40111	12201	3000	577	88.5	10.7	1
1.50cr	66803	22800	6200	1350	233	32	3.4
1.75cr	105601	40100	12200	3000	577	88.4	11
2.00cr	158700	66800	22800	6200	1300	233	32

(See Section 21, Reference 17: Table 14.6 from The Management and Control of Quality, 3rd Edition, by Evans and Lindsay, West Publishing Company)

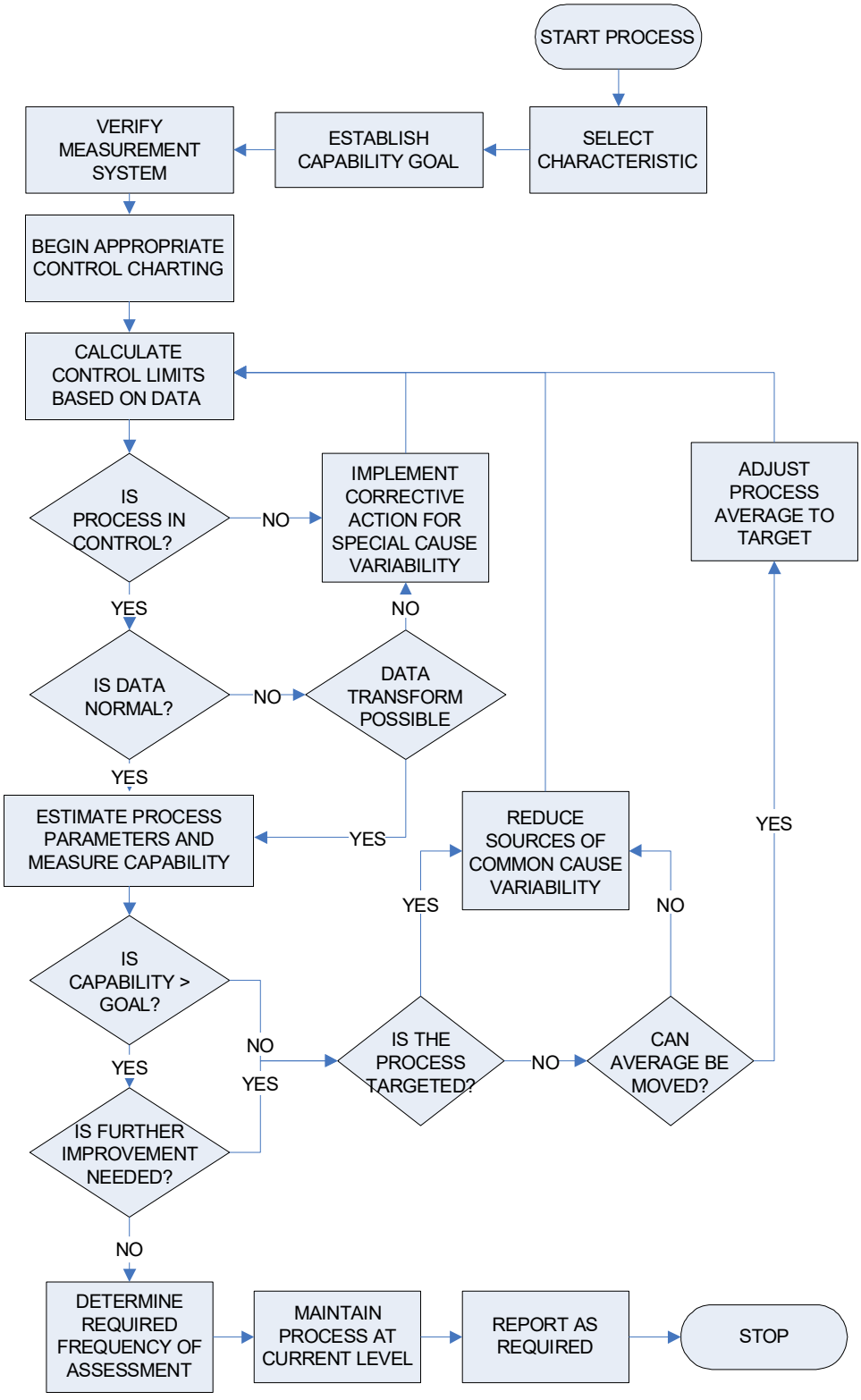


Figure 4.21 – Flowchart for process capability studies. D.R. Bothe, 'Measuring Process Capability', Copyright 2001

16. Six Sigma Conversion Table for Variable Data

This chart is used to determine Six Sigma equivalents for variable data based on the process being in statistical control and normally distributed.

Cpk	Sigma Level	Probability Good	Probability of a Defect	Defects Per Million Opportunities
-0.50	0.00	0.0000	1.0000	1000000.0000
-0.42	0.25	0.0656	0.9344	934409.3832
-0.33	0.50	0.1359	0.8641	864094.8780
-0.25	0.75	0.2144	0.7856	785597.1203
-0.17	1.00	0.3023	0.6977	697672.1266
-0.08	1.25	0.3983	0.6017	601686.0889
0.00	1.50	0.4987	0.5013	501349.8980
0.08	1.75	0.5981	0.4019	401870.6994
0.17	2.00	0.6912	0.3088	308770.1678
0.25	2.25	0.7733	0.2267	226715.7697
0.33	2.50	0.8413	0.1587	158686.9252
0.42	2.75	0.8943	0.1057	105660.4622
0.50	3.00	0.9332	0.0668	66810.5989
0.58	3.25	0.9599	0.0401	40060.1739
0.67	3.50	0.9772	0.0228	22750.4186
0.75	3.75	0.9878	0.0122	12224.5487
0.83	4.00	0.9938	0.0062	6209.6843
0.92	4.25	0.9970	0.0030	2979.7677
1.00	4.50	0.9987	0.0013	1349.8990
1.08	4.75	0.9994	0.0006	577.0252
1.17	5.00	0.9998	0.0002	232.6291
1.25	5.25	0.9999	0.0001	88.4173
1.33	5.50	1.0000	0.0000	31.6712
1.42	5.75	1.0000	0.0000	10.6885
1.50	6.00	1.0000	0.0000	3.3977
1.58	6.25	1.0000	0.0000	1.0171
1.67	6.50	1.0000	0.0000	0.2867
1.75	6.75	1.0000	0.0000	0.0760
1.83	7.00	1.0000	0.0000	0.0190
2.00	7.50	1.0000	0.0000	0.0010

17. Process Control Methods

Process control methods may include, but are not limited to, the following methods.

CONTROL METHOD	DEFINITION
Acceptance Sampling	A sampling technique where units of product are drawn from a specific lot. The information from these samples is used as a basis for making acceptance decisions concerning parts or processes. This could be applicable for large numbers of parts from discreet batches. (See Section 21, Reference 2: ASQ Glossary and Tables for Statistical Quality Control.)
Continuous Sampling	This method requires that a consecutive number of pieces pass inspection before starting normal sampling cycles. This method can be used when the product stream is continuous such as painting, welding, assembly, and machining.
Modified SPC	Modified control charts have control limits that are not established by conventional, control limit-setting techniques. They are sometimes referred to as Acceptance Control Charts. They can establish whether, or not, a process can satisfy product or service tolerances, and is “in a state of statistical control.” It is generally assumed that assignable causes will create shifts in the process level. These shifts should be small enough, in relation to tolerance requirements, to be considered uneconomical to control with conventional SPC Charts. (See Section 21, Reference 2: ASQ Glossary and Tables for Statistical Quality Control.)
Pre-Control	Pre-Control is effective for any process where the quality characteristic of interest can be adjusted. The process can have either a continuous output, (e.g., heat-treat furnace data) or a discrete output (e.g., machine parts). There are no additional requirements and no underlying assumptions concerning capability, or normality of the quality characteristic. This method can be used temporarily, as a precursor to a conventional SPC chart, or as a permanent control method. (See Section 21, Reference 7: Juran’s Quality Control Handbook, 5th Edition.)
Restudy	Measurement data is used to verify process capability and C_{pk} on a periodic basis.
Setup Check	Part characteristics are checked whenever the process is set-up and at periodic intervals. Examples are: CMM checks, roundness checks, and gear geometry checks.
Short-Run SPC	Short Run SPC is used for small lot sizes of parts with characteristics common to a process. Each characteristic is transformed and plotted with other characteristics on the same chart. (See Section 21, Reference 5: International Quality Institute, Inc., SPC for Short Runs Curriculum.)
SPC Control Charts	SPC Control Charts are used as a basis to make decisions about a process. Control determinations are made by comparing the values of statistical measures of an ordered series of samples, or subgroups, with control limits. Examples are: (p, np, c, u, Xbar & s, Xbar & R, and IXMR). SPC Control Charts demonstrate whether, or not, the process is "in control". SPC Control Charts can be used in an acceptance sense, calling for action or investigation when a process shifts from its standard level. SPC Control Charts can be used with variable or attribute data. These continuous control methods are appropriate for mistake-proofing when abnormal process variations are not present. (See Section 21, Reference 3: ASTM Manual on Presentation of Data and Control Chart Analysis, 7th Edition)
Tool Control	A control method where the first part is checked after a new tool is installed. If the part checks OK, the process is run for the expected life of the tool. The last part produced with the old tool is then checked. If it is OK, then all the parts are OK.

DESCRIPTION OF QUALITY TOOLS

Affinity Diagram	Method for generating large numbers of ideas and then organizing and summarizing into groups.
Box Plot	Pictorial display of data distribution - shows variation in data for easier analysis.
Brainstorming	For creatively generating a high volume of ideas.
Capability Studies	Statistical measurement of the ability of manufacturing process(es) to consistently meet specifications/tolerances.
Cause & Effect Diagram	Graphically display, in detail, possible causes related to a problem.
Control Chart	Charts to monitor control and improve process performance.
Control Plan	Documents significant process or part characteristics that require monitoring for capability levels.
Data Collection	Systematic approach to ensure the data/information gathered is accurate and meaningful.
Design of Experiments	A method for analyzing multiple variables at one time, and determining if there is interaction between any of the variables.
Flow Chart	Identifies the flow or sequence of events in a process (also called Process Mapping).
FMEA - design	Failure Modes and Effects Analysis is an analytical method for determining the risk level of designs.
FMEA - process	Failure Modes and Effects Analysis is an analytical method for determining the risk level of designs.
Force Field Analysis	Identifies the forces and factors in place that support or work against the solution.
Gage R & R	Gage Repeatability and Reproducibility measures the repeatability and reproducibility of gages to ensure that the gage meets the design intent.
Histogram	A graphical representation of the process data.
Mistake - Proofing	A method to eliminate potential operator error from the process.
Pareto Chart	Pictorially shows where to focus effort for greatest improvement potential.
PPAP (1st piece / lot certification)	Production Part Approval Process that is used to assure that a new or changed product or process meets specifications.
Problem Solving	A common model that creates a common language for continuous improvement.
Process Mapping	A group of activities that together define what is being done to provide a service of product for the customer.
QFD	Quality Function Deployment is a structured approach for determining customer needs and translating those needs into the organization's language.
Run Chart	Method to study data for trends or patterns over time.
Scatter Diagram	Visual analysis to determine if relationships between two sets of variables.
Tree Diagram	Breaks any broad goal, graphically, into increasing levels of detailed actions that could be done to achieve the stated goals.
Root Cause Analysis	An effective process for finding the cause(s) of an event. This tool enables more thorough corrective actions.

18. GLOSSARY

Cp	The capability index defined as the ratio of the specification width to the natural variation of the process. C_p indicates if the process is capable of producing parts within specification. The process must be normally distributed and in control when calculating this index. The standard deviation is calculated as R / d_2.
Cpk	The capability index is similar to C_p, but it takes into account the centering of the process. It does this by taking the ratio of the difference between the process average and the lower specification (or higher specification, whichever is less) to one-half of the natural variation limit. The goal for Cpk is to achieve a value of 1.33 or greater. The process must be normally distributed and in control when calculating this index. The standard deviation is calculated as R / d_2.
Change Request	Request for acceptance from Caltherm prior to making changes to a specification, process, location, supply base, or any change that may impact fit, form, function, performance or durability. An approved Verification Warrant is required prior to shipment of production parts.
Control Plan	A Control Plan is a written description of the system for controlling parts and processes. The Control Plan describes the actions that are required at each phase of the process, from receiving to shipping, to assure that all process outputs remain in a state of control. The Control Plan reflects a strategy that is responsive to changing process conditions, and is maintained and used throughout the product life cycle.
Corrective Action	Action taken to eliminate the cause of nonconformities in order to prevent recurrence.
d_2	Constant used to estimate the sample standard deviation based on the sample size and average range value.
Design Process and Assembly Review (DPAR)	A simultaneous engineering process designed to optimize the relationship between design function, manufacturability, and ease of assembly. This may also be referred to as Design for Manufacturability and Assembly.
Design Verification	The process by which a product, through objective evidence, is proven to meet its specification.
Deviation	When part characteristics do not comply with engineering specifications, an Engineering Deviation Authorization (EDA) is required, prior to shipment, to record and control the use of the product, and to provide a means to document corrective action.
Discrimination	Sometimes referred to resolution, is the ability of the gage or measuring equipment to detect and indicate small changes in the measured characteristic. The one-tenth of total variation allows the gage or measuring system to group measurements into 10 data categories.
Documents	Records of the results of the procedures and job instructions that show the system is operating.
Advanced Production Quality Planning (APQP)	Caltherm's product realization process is called the Advanced Production Quality Planning or APQP. It is the sequence of processes required to successfully produce a product or service that meets or exceeds the expectations of Caltherm and our customers. The APQP consists of four phases.
Flow chart	Chart showing the recommended steps needed for controlling a process.
Gage Repeatability	Repeatability is the variation in measurements obtained with one measurement instrument, when used several times by one appraiser, while measuring the identical characteristic on the same part.
Gage Reproducibility	Reproducibility is the variation in the average of the measurements made by different appraisers, using the same measurement instrument, used several times by each appraiser, while measuring the identical characteristic on the same part.

Intellectual Property	Creative ideas and expressions of the human mind that have commercial value and receive the legal protection of a property right. It includes ideas, inventions, business methods and manufacturing processes. The major legal mechanisms for protecting intellectual property rights are copyrights, patents, and trademarks.
Job instructions	Define how the employees accomplish the procedures.
Key Characteristic	A Key Characteristic is a product or process characteristic whose variation or targeting control is necessary to meet customer requirements and that directly or significantly impact customer satisfaction through compliance with government, country or industry standards and/or regulations, ability to perform its intended design requirements (form, fit, function, reliability, appearance), or manufacturability and ability to assemble.
Manuals	Often thought of as the top level documentation, defining what management has committed to address and achieve with their quality system.
Material, alternate	An **alternate** material is one whose specifications do not fully meet those of the drawing- specified material; but, have been verified as fully meeting the design intent and can be used interchangeably. Alternate materials shall appear on the drawing.
Material, equivalent	Determination that a material is **equivalent** requires a careful evaluation of all related specifications and characteristics. This review shall only be performed by individuals who are well versed in those particular materials, qualified to make that evaluation, able to provide supporting documentation (e.g. mill certifications), and fully conversant with the relevant Caltherm specifications. Unless specifically authorized by the appropriate Caltherm representative, in writing, only the primary material producer (e.g. steel mill, foundry, warehouse), may make that decision.
Order Fulfillment Process (OFP)	A global process at Caltherm that is designed to deliver the right product at the right place at the right time. It begins with an estimate of retail sales and ends with the retail delivery and payment.
Physical Build	Term used in the Enterprise Product Delivery Process to indicate a physical model which is used to evaluate the complete product, processes and tooling.
Ppk	Referred to as a performance index, it is a term used to predict the process capability of a new process. The process must be normally distributed and in control when making this calculation. Ppk is based off of the total variation and uses the sample standard deviation value in its calculation. Typically, a much higher value is required for Ppk as opposed to the Cpk due to the amount of uncertainty in the process. The sample standard deviation is calculated by using all the data points.
Preventive Action	Action to eliminate the causes of potential nonconformities in order to prevent their occurrence.
Procedures	A particular method for performing a task. Documentation of who, what, and when of the manual's requirements.
Process Capability	Process capability is the range over which the natural variation of a process occurs as determined by the system of common causes. Process capability has three important components: the design specification, the centering of the natural variation, and the range or spread of the variation. The importance of process capability is in assessing the relationship between the natural variation of a process and the design specifications. This relationship is often quantified by measures known as process capability indices. The most common of these are C_p and C_{pk}. It is recommended that both of these be used when determining what corrective action is needed to make a process capable.
Process Control	Monitoring of characteristics for capability to produce a feature under stable conditions to maintain ongoing acceptable quality levels. Examples of process control documents are process sheets, inspection and test instructions, test procedures, standard operating procedures, preventive maintenance instructions, and specific part control plans.
Product Validation	The process by which a product is confirmed by objective evidence to function properly in the total environment (i.e. features and performance meet customer needs and expectations.)

Product Verification	Ensures the adequacy of design per the product performance and functionality specification (i.e. the product will properly function in its intended application over its design life).
PV&V	Product Verification and Validation. Also referred to as Design Verification and Validation (AIAG) and Design and Development Verification and Validation (ISO).
Risk Priority Number	The product of Severity, Detection, and Occurrence in a Failure Modes and Effects Analysis.
Shall	Indicates mandatory requirements.
Should	Indicates a mandatory requirement with some flexibility allowed in compliance methodology.
Special Process	A *special process* is any production or service delivery process that can generate outputs that cannot be measured, monitored, or verified until it's too late. It's often too late because deficiencies may not be obvious until after the resulting products have been used or services have been delivered. In order to prevent output deficiencies, these *special processes* shall be validated in order to prove that they can generate planned results. (e.g. welding, painting, heat treat, plating)
R	Range which is defined as the difference between the high and low values.
$\bar{R}$	Average Range which is defined as the sum of all ranges divided by the number of ranges.
Supplier	Providers of production and service parts, finishing services (plating, painting, heat treating, etc) both inter-unit and external to Caltherm. In some cases this may include providers of engineering and production services.
Supply Management	All activities relative to procuring products needed to build the finished product.
Sub contractor	Suppliers that supply our primary suppliers, also referred to as second and third tier suppliers, sub tier suppliers, or the supplier's supply chain.
Quality Plan Level (QPL)	A Caltherm measure of part risk based on three categories: cost, severity, and complexity. Each category affects a part or component's overall risk to Caltherm. Quality Plan Levels range from 0 to 4, with 4 representing the greatest risk. The required quality activities are identified based on the Quality Plan Level.
Quality Record	Historical evidence that the quality system is functioning, and is operating at its current level of effectiveness.
Warrant	A Verification Warrant (part submission warrant) is the cover page for the PPAP documents and requires Caltherm approval prior to shipping production parts.

19. Engineering Standards

Understanding Drawings

Caltherm expects suppliers to understand Geometric Dimensioning and Tolerancing (GD&T), and provide drawings incorporating GD&T principles for Caltherm to the latest ASME Standard Y14.5M.

Location of Standards

Caltherm Standards can be obtained by contacting your Caltherm Engineering representative.

Industry standards can be obtained through other means such as Global Engineering Documents.

http://global.ihs.com/

20. ASSESSMENT MATERIAL (to be available for an audit):

a. Caltherm requires copies of the following certifications, if available:
   i. Quality System Certification, Registrar, and Date of Certificate Expiration (IS), QS, etc.)
   ii. Environmental System Certification, Registrar & Date of Expiration (ISO 14001)
   iii. Health & Safety System Certification, Registrar, and Date of Certificate Expiration (ISO 18001)
b. Current Quality Manual
c. Quality Procedure Manual(s)
d. Corrective Action files for the last six months
e. Internal Audit reports for the last twelve months
f. External Quality System Audit reports for the last twelve months
g. Minutes and Quality metrics used for management reviews from the last six months
h. Training Records

21. References

The following books, publications, and web sites are referenced in this manual:

1. *Advanced Topics in Statistical Process Control* ©, Donald J. Wheeler, SPC Press, 1-800-545-8620, http://www.spcpress.com
2. *ASQ Glossary and Tables for Statistical Quality,* American Society for Quality, 1-800-248-1946, http://www.asq.org
3. *ASTM Manual on Presentation of Data and Control Chart Analysis, 7th Edition* ©, http://www.astm.org
4. *Concepts for R&R Studies, Second Edition ©,* Larry B. Barrentine, ASQ Quality Press, Milwaukee, Wisconsin, http://qualitypress.asq.org
5. *International Quality Institute, Inc., SPC for Short Runs curriculum,* GOAL/QPC, 13 Branch Street, Methuen, MA 01844, 1-800-643-4316, http://www.goalqpc.com
6. *ISO/TS 16949, Implementation Guide,* Automotive Industry Action Group, 26200 Lahser Rd Suite 200, Southfield, MI 48034 (248)-358-3003, http://www.aiag.org
7. *Juran's Quality Control Handbook, 5th Edition,* McGraw Hill
8. *Measurement Systems Analysis,* Automotive Industry Action Group, 26200 Lahser Rd Suite 200, Southfield, MI 48034, 1-248-358-3003, Web site: http://www.aiag.org
9. *Potential Failure Modes and Effects Analysis, Third Edition,* Automotive Industry Action Group, 26200 Lahser Rd Suite 200, Southfield, MI 48034, 1-248-358-3003, Web site: http://www.aiag.org
10. *Process Quality Control, 4th Edition ©,* Ellis R. Ott, Edward G. Schilling and Dean V. Neubaurer, American Society fro Quality, Quality Press, Milwaukee
11. *Production Part Approval Process, Fourth Edition,* Automotive Industry Action Group, 26200 Lahser Rd Suite 200, Southfield, MI 48034, 1-248-358-3003, http://www.aiag.org
12. *Quality Improvement Pocket Guide,* Juran Institute, Wilton, Connecticut, 1-800-338-7726
13. *Quality Planning Pocket Reference,* Juran Institute, Wilton, Connecticut, 1-800-338-7726
14. *ASME B89,* American Society of Mechanical Engineers, http://www.asme.org/
15. *Statistical Process Control Second Edition ©,* Automotive Industry Action Group, 26200 Lahser Rd Suite 200, Southfield, MI 48034, 1-248-358-3003, http://www.aiag.org
16. *Statistical Quality Assurance Methods for Engineers* ©, Vardeman and Jobe, John Wiley
17. *The Management and Control of Quality, 3rd Edition ©,* Evans & Lindsay, West Publishing Company
18. *The Memory Jogger II,* GOAL/QPC, 13 Branch Street, Methuen, MA 01844, 1-800-643-4316, http://www.goalqpc.com