REVISION HISTORY

REV	DATE	ORIGIN	REASON FOR CHANGE(S)
A	13Dec16	Jorge Irizarry	Initial Release
B	5/04/18	Daniel Crouse	Added PCN language
C	27Sep19	Scott Ubl	Corrected typo from QVA1 to QV1A

Q-CODE QV1A QUALITY REQUIREMENTS

Supplier's Manufacturing Process Qualification (SMPQ)

The following are the quality requirements for product purchased under the Q-code QV1A. All requirements must be submitted for Part, Process and Tooling approval prior to delivery of product. Please reference the Plexus Supplier Quality Manual DCS # 10503 for additional details. The supplier agrees to abide by all the requirements listed below and resubmit appropriately for any product or process change, unless a written waiver is received from Plexus. These requirements will be supported with additional information such as customer designated characteristics, sampling sizes/plans and processes for IQ, OQ and PQ validation which will be determined by the Plexus SQE with cooperation and input from the supplier.

These requirements will be supported with specifics for each part number that are compiled in a QV1A risk analysis list to be validated. The list will be completed by the supplier with approval and cooperation by Plexus SQE. The list will be used to document the agreement of the customer characteristics, special processes and control characteristics used in the qualification.

Pre-1st Shipment - Before a product will be released for production the supplier will be required to demonstrate control of variation in order to reliability produce good product. A pre-production run will be utilized to understand process variation requiring control, determine and define how to control it and demonstrate capability. The following steps and deliverables are required of the supplier:

A. Manufacturing Process Flow - The supplier must submit a process routing or flowchart which describes the manufacturing process. This will align with and tie into the Quality Control Plan and Process FMEA. (*For Maxon due to the content of company specific intellectual property one shall show the details of the control plan and the standard process description during Plexus visit. The control plan is generated in the CAQ-system. All values and scope of inspections are defined in the CAQ based control plan. The results are stored also in CAQ and can be looked into. "SPB" means standard process description. This specification is a detailed work instruction and contains all specific information (tooling numbers, references to further instructions …) for assembling the product.*)

B. Process FMEA - A Process Failure Modes and Effects Analysis will be completed and reviewable by submission or at supplier site (*due to proprietary information*) which addresses the potential failure modes of each process step. The process FMEA shall document that potential failure modes and their associated effects they have on the process have been considered, addressed or eliminated.

C. Quality Control Plan (QCP) - The supplier must submit a detailed QCP describing how all process, quality and inspection steps will be executed and monitored throughout the process. The QCP is a map of the systems, tools, gages and equipment used to control the quality of the part minimizing process and product variation. All control characteristics (e.g., critical, major, minor, significant, circled, etc.) and validation activity must be identified and addressed on the QCP.

The QCP must be utilized and updated with Plexus approvals before release and to reflect changes over the life of the product.

D. Measurement System Analysis – 100% controlled and CTQ characteristics designated as requiring a capability study or characteristics designated by the supplier as a critical or process control characteristic is covered in the IQ, OQ, PQ.

E. Pre-Production Run - The supplier will manufacture product from the production tooling and processes. The preproduction run must be representative of a stable and repeatable process. During the manufacture of the parts the supplier will employ comparable method to the X-bar and R Charts to monitor the process and all CTQ and validation characteristics specified.

F. Capability Study - During the pre-production run, the supplier will sample an appropriate number of pieces to characterize the distribution (minimum of 30 pieces). From these pieces the supplier will perform a capability study on all CTQ characteristics (Critical, Major and Minor) and supplier chosen process control characteristic; calculating Ppk values. All of the associated data can be reviewed by Plexus.

G. First Article Inspection Report - the supplier will perform a first article inspection including a measurement and acceptance of every characteristic, requirement and/or drawing note in accordance to the master drawing. This will be documented and submitted in a report for a minimum of 3 pieces. The FAIR will be PPAP(Production Part Approval Process) Report according VDA 2.4(German Association of the Automotive Industry).

H. Material Certification - must include a list/BOM of all raw materials used with material certification or test. If product is designated to comply with RoHS, REACH or similar material substance requirement, the appropriate certificate must also be included.

I. Validation for Special Processes using an IQ, OQ and PQ methodology – The supplier is required to validate all processes that produce any CTQ characteristics specified as Critical or Major that are not able to be verified or measured. All protocols require Plexus approval prior to execution. The execution of the validation shal result in an approved result with appropriate ongoing process controls. Documentation of such must be represented in the Quality Control Plan. Please see Appendix 1 for additional definition of process validation.

J. Validation for Test Methods using IQ and OQ methodology - The supplier is required to validate all test methods used in the process validation. The Test Method Validation shall result in an approved result before execution of OQ and PQ process validation. Please see the Appendix 1 for additional definition of process validation.

K. Packaging and labeling documentation – The supplier is required to evaluate, define, document the specifications and submit the specifications for approval to Plexus. The specifications shall be adequately defined to assure consistency in packaging methods and protection during the shipping and handling.

The following criteria must be met for acceptance of the Supplier Manufacturing Process Qualification

- Prior to execution, supplier validation protocols shall be reviewed by Plexus.
- All IQ, OQ and PQ qualifications must be executed, documented and reports need to be signed by Plexus.
- Supplier's process control dimensions must have a minimum Ppk value greater than 1.33* unless otherwise agreed to
- Plexus designated characteristics have Ppk values greater than 1.33*
- Print outs of 100% inspection will be supplied on request.
- Both supplier's and Plexus generated first article inspection reports show all dimensions to be within print tolerance (100% controlled dimensions)
- All variable measurement systems must pass with a Gage R and R value less than 10%.

* Note all processes are not double sided or normally distributed. In these cases the comparative measure and representation of Capability shall be recommended by the supplier and approved by Plexus.

If the above criteria are met, the supplier will be granted an approval from Plexus and the product will be released for production builds from the defined process. If any of the above criteria are not met during the SMPQ approval builds the supplier must notify Plexus and use the data to make the appropriate tool, sampling, measurement system and/or process corrections in order to re-execute the qualification successfully.

All Shipments - The following are the quality requirements for the shipment of all shipment of purchased parts qualified per Q-code QV1A. Unless a written waiver is received from Plexus, the supplier agrees to abide by the quality requirements listed below. The following steps and deliverables are required of the supplier:

A. Approved for Production – the supplier when use the approved process to manufacture and supply the part.

B. Change Control – No changes will be made to the part, materials or manufacturing process unless the manufacturing process, validation and part has be re-qualified and approved by Plexus.

C. Critical to Quality (CTQ) Verification and Report

As defined in the QCP the following CTQ inspections and deliverables are required:

- 100% Inspection - The supplier will inspect and record the measurements of all Critical CTQ callouts before shipment. Inspection must be completed and recorded with a approved gage per the MSA study above. A report will be provided with first 200 and available upon request.
- SPC control charts - The supplier will monitor all Critical, Major and Minor callouts for CTQ's as well as and in-process control parameters via an SPC control charts for subassemblies. Measurements must be completed with an approved gage per the MSA study and Quality Control Plan. Out of control points should have process corrections indicated on the chart. Any chart that has had process corrections and does not show control regained must be approved by Plexus in writing before the product can be shipped. The charts will be provided with each shipment.

D. Certificate of Compliance - required with all shipments of product. The certification must define the product and the process as qualified that was used (approved via the QCP). Must include a statement of overall compliance to all the applicable specifications (statement is not required to list, but shall cover all the applicable specifications such as; drawing, PO, customer specifications, Plexus G9000-3, IPC specification, etc). It also must include the following information for traceability

- Name of Supplier (if different than the actual OEM)
- Name of Manufacturer
- Manufacturer's Part Number
- The Lot # and/or Date Code (both preferred, but date code at a minimum) for each shipment – COC and packing slip must contain each lot and/or date code
- Plexus part number ordered on the PO
- EC level or Revision level as specified on the PO for the Plexus part number ordered
- Plexus PO number
- Bar coding this information, using a 39 or 128 format is optional

For production shipments the supplier will be required to abide by the Q-code listed on the PO unless otherwise assigned or approved by Plexus. ONCE COMPLETED, NO CHANGES TO ANY PART OF THE PROCESS, MATERIALS, EQUIPMENT, MATERIAL or PART DEFINED AND COMPLETED BY THIS PART QUALIFICATION CAN BE MADE BY THE SUPPLIER WITHOUT PLEXUS APPROVAL. Change Control approval will at a minimum include a resubmission of the Risk Analysis list, control plan, IQ, OQ, PQ, FAI and the effected elements used to qualify the process due to the change.

The above listed documentation must be submitted before the first shipment. Any shipment received without this documentation will be considered defective.

Appendix 1

1 VALIDATION DOCUMENTATION FOR THE IQ, OQ AND PQ METHODOLOGY Any recommendations for format of validation documents are not mandatory, but consistency, completeness and accuracy in the documentation are required.

2 VALIDATION PROTOCOLS

A protocol is a written plan that describes how to conduct qualification/validation activities, the set process or methods, and define acceptance criteria. All protocols must be reviewed and approved for technical content and regulatory compliance by the supplier and Plexus prior to execution.

All protocols shall be controlled and contain the following information:

- Title Page.
- History and Document Revision Control.
- Table of Contents.
- Approval Record: An approval sheet with name, signature, and date of each Validation Team member must be part of the Protocol along with the risk analysis sheet and justifications.
- Personnel Identification Form: If anywhere within validation package a person uses initials only to sign a document (such as test records), a table or form that provides initials and signature cross-reference for each person using their initials needs to be included.
- Purpose: Provide a clear, concise statement describing the intent of the Qualification.
- Scope: Identifies the process/system to be Qualified.
- Assumptions/Strategies: State any assumptions or strategies that pertain to the qualification. General Description of Process or System: Description of the process/system, equipment location within the facility and the site location where the validation activities will occur.
- References: List the applicable regulatory standards, equipment manuals and specifications, procedures, software versions, and other documents that are needed to plan the Qualification.
- Definition.
- Personnel/Responsibilities: Record title/function of any internal or external personnel required to complete the Qualification tasks.
- Test and Acceptance Criteria: List the requirements of the items to be verified, including pass/fail criteria, to conclude that the results of the given protocol are acceptable. Test and Acceptance criteria shall be traceable to a customer, industry requirements or manufacturer specifications as applicable. Otherwise engineering characterization or DOE studies should be conducted to make the determination
- Procedure: Details qualification activities based on product/process requirements:
  - Determine what to verify/measure
  - Determine how to verify/measure
  - Determine how many to verify/measure
  - Define acceptance/rejection criteria
  - Define required documentation for collecting and reporting data

Note: *Once the validation team approves the protocol, the protocol can only be revised in a controlled manner.*

3 VALIDATION SAMPLING PLAN

Sampling plans, when used, shall be based on a valid statistical rationale. 30 pieces will be used.

4 VALIDATION REPORT

At the conclusion of executing any formal protocol a validation report is required. The validation report is an overview of the respective protocol and actual validation activities.

A validation report shall contain the following:

- Purpose
- Scope
- General Description of System/Process
- Training and the verification of training records
- References (if required)
- Review of Discrepancies (if required)
- Acceptance Criteria
- Gage R and R or Verification of Measurement System with data
- Capability Statistics and Study with data
- Verification/inspection data
- Conclusions, include validation activities results summary
- Rationale for acceptance and conclusions (if required)
- Statement Authorizing Release of the System/Process
- Approval signatures

Validation reports for each respective validation protocol stage must be reviewed and approved prior to beginning the execution of the next step.

Product change notification

Upon acceptance of conforming product, documentation, and the requirements of this Q-code, the supplier's manufacturing process shall be considered "qualified". All changes require written approval from Plexus prior to implementation. Product or Process change notification requests (PCNs) shall be submitted to pcns@plexus.com.