REVISION HISTORY

REV	DATE	ORIGIN	REASON FOR CHANGE(S)
A	08Jan16	Scott Ubl	New
B	29Sep16	Eric Steif	Added clarification language to COC requirements
C	09Dec16	Scott Ubl	Adding 100% inspection option
D	5/04/18	Daniel Crouse	Added PCN language

Q-CODE QV3 QUALITY REQUIREMENTS

Supplier's Manufacturing Process Qualification (SMPQ)

The following are the quality requirements for product purchased under the Q-code QV3. For the Pre-production run/ 1st Qualification Run/Lot all requirements must be submitted for the Part, Process and Tooling approval prior to delivery of product. 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 shall 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.

Qualification – Consists of 2, OQ runs lots and 1, PQ run lot using a statistical methodology to establish and understand the process variations, determine and define how to control it and demonstrate capability. If the 100% ongoing inspection strategy is used in place of the statistical methodology for CTQ (circled/annotated) features, no capability study will be required and the PQ inspection data will be based off of 1 lot. Before a product will be released for production the supplier will be required to demonstrate the product meets specification and has control of variation in order to reliably produce good product. The following steps and deliverables are required of the supplier:

A. 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, customer designated, process control, 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.
B. Measurement System Analysis (MSA) – All measuring strategies for CTQ variable control characteristics must be studied with a MSA. Studies for variable measurements must use a minimum 3 operators, 3 trials and 10 pieces in a MSA/Gage R and R report.
C. Capability Study - During the qualification run, the supplier will sample from an appropriate number of pieces that represent the distribution of the process. From these pieces the supplier will perform a capability study on all CTQ (Critical to Quality) characteristics and supplier chosen process control characteristic; calculating X-bar, Sigma, evaluate/show the data distribution and the Pp and Ppk values. All of the associated data will be included. This is not required if CTQ characteristic is 100% ongoing inspected.
D. 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. This will be documented and submitted on a report for a minimum of 5 pieces. When using 100 % ongoing inspection, the 5 piece FAIR will be used for the PQ data report and no OQ characterization will be required unless specified by Plexus.
E. 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.
F. 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 that are not able to be verified or measured. All

protocols require Plexus approval prior to execution. The execution of the validation shall result in an approved result with appropriate ongoing process controls. Documentation of such must be represented in the Quality Control Plan. Please see the Appendix A for additional definition of process validation.

G. 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 A for additional definition of process validation.

H. 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.

2nd and 3rd Qualification run/Lot (not required for 100% ongoing inspected CTQ characteristics)

A. Control Charts - 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 the use of SPC charts (X-bar and R Charts are preferred) for variable and to monitor the process, as well as the control characteristics, CTQs and validation characteristics specified.

B. Capability Study – When using statistical methodology and during the 2nd and 3rd qualification run, the supplier will sample from an appropriate number of pieces that represent the distribution of the process. From these pieces the supplier will perform a capability study on all CTQ characteristics and supplier chosen process control characteristic; calculating X-bar, Sigma, evaluate/show the data distribution and the Pp and Ppk values. All of the associated data will be included. This is not required if the CTQ characteristic is 100% ongoing inspected.

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

- Prior to execution, the protocols for the Validation of Special Processes shall be reviewed and signed 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 Pp value of 1.333 and Ppk value greater than 1.333 with a minimum of a 30 piece sample unless otherwise agreed. When performing 100% ongoing part inspection the 5 piece FAIR will be used for the PQ data report and no process capability analysis or process comparison will be required
- Plexus designated variable characteristics have Pp values greater than 1.333 and Ppk values greater than 1.333 with a minimum of a 30 pieces sample.
- When using the 100% ongoing inspection method a minimum of a 5 piece FAI is required.
- First Article Inspection Reports show all dimensions within the print tolerance
- All variable measurement systems must pass with a Gage R and R value less than 25%

Table 1: Summary of Sample Size Requirements

Qualification Strategy for CTQ features	1st lot – CTQ Features	1st Lot – non CTQ features	2nd lot CTQ Features	3rd Lot CTQ Features	Ongoing Lots
Capability 1.33 Ppk	30 pieces	5	30	30	Per QCP
100% Inspection	5 piece lot minimum	5	Same as Ongoing Lots	Same as Ongoing Lots	100% inspected

*Processes are not always double sided or normally distributed. In these cases a comparative measure and representation of Process Capability shall be recommended by the supplier and approved by Plexus.

The documentation for the 3 qualification runs (or 1 lot with 100% ongoing inspection) must be submitted and approved

prior to shipping the 1st shipment. The 2nd and 3rd qualification lots will require the Capability Studies, Material certificate and PQ Validations to be repeated and submitted for approval prior to shipment of the lot. Any shipment received without the documentation and approval will be considered defective.

If the qualification criteria is met, and capability is proven for a total of 3 qualification runs (or 1 lot, 100% ongoing inspected), utilizing the defined processes, the supplier will be granted a SMPQ approval from Plexus and the product will be released for production builds. 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 before concessions to this plan can be made. Any concessions made will require an alternative strategy with approval by the supplier and Plexus with an updated QCP. This most commonly will include a 100% sampling of the measurement or use of a Poke Yoke device.

All Shipments - The following are the quality requirements for the shipment of all shipment of purchased parts qualified per Q-code QV3. 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 must use the approved process (as defined in the qualification runs above) to manufacture and supply the part.

B. Critical to Quality (CTQ) Verification and Report
As agreed and defined in the QCP, at a minimum the following CTQ inspections and deliverables will be required:
   - SPC control charts - The supplier will monitor CTQs (variable and attribute) as well as in-process control parameters via SPC control charts. Measurements must be completed with an approved gage per the MSA study and QCP. 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.

   and/or

   - 100% inspection on any CTQ characteristics (required if using 100% inspection strategy instead of capability)

C. 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). The certification will 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
   - Location of manufacturing facility
   - Manufacturer's Part Number
   - The Lot # and/or Date Code (both preferred, but date code at a minimum) for each shipment - the COC and packing slip must contain a quantity for each lot and/or date code in the shipment
   - If the product has a shelf life, the shelf life and expiration date must be included (note: the remaining shelf life must be greater than 50% of the stated shelf life)
   - 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

D. All cartons, packing slips, reports and certificates must have part number, EC level or revision, quantity and P.O. number listed on them.

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 an updated control plan, IQ, OQ, PQ, FAI and the effected elements used to qualify the process due to the change.

The above "All Shipments" documentation must be submitted with every shipment. Any shipment received without this documentation will be considered defective.

Appendix A

1 VALIDATION DOCUMENTATION FOR THE IQ, OQ AND PQ METHODOLOGY

A specific format of the validation documents is not required, 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.
- 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

Refer to Table 1 for sampling plans. When using 100 % ongoing inspection the 5 piece sample plan will be used for the FAIR and this data will be acceptable to use for the PQ data and no OQ characterization data will be required unless specified by Plexus.

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.