

REVISION HISTORY


REV	DATE	ORIGIN	REASON FOR CHANGE(S)
A	06/04/10	Paul Gettins	New
B	01/25/11	Paul Gettins	Added Date code/Lot Code
C	12/22/11	Paul Gettins	Added Approval & Q17 added
D	03/26/13	Adriana Cimpan/ Yee-Wen Khoo	1. Replace EN13980/IECEX OD005 with ISO/IEC 80079-34. 2. Clarifying the access of supplier facility. 3. Add material certificate per ISO/IEC 80079-34 requirement.
E	29Aug2014	Adriana Cimpan	Add requirement for formal signature from supplier's quality representative on the CoC
F	05Apr2018	Daniel Crouse	Added PCN language
G	28Jan2020	Scott Ubl	Update format, match language in Q38A

Q-CODE Q31 QUALITY REQUIREMENTS
For ISO/IEC 80079-34 Safety Critical Custom Components

With acceptance of or shipment of product against a purchase order with this requirement, the supplier agrees to allow Plexus, their customer and regulatory authorities the right of access to their facility and all applicable records including verifying any aspect of their operation that affects the type of protection. The following are the quality requirements for product purchased under Q-code Q31. Unless a written waiver is received from Plexus, the supplier agrees to abide by the quality requirements listed below.

FIRST PRODUCTION RUN/PRE 1ST SHIPMENT/CHANGE TO PRODUCT OR PROCESS

Before a product can be released for production the supplier will be required to meet the documentation and quality requirements. The following actions must be applied to any non-conformances:

ATEX/IECEX Safety critical characteristic impact marked (e.g. )- Plexus will notify and obtain approval from the customer authorized person and the Certified Body before approval is given to the Supplier to ship the product.

Non ATEX/IECEX Safety critical characteristic - Plexus will notify and obtain approval from the customer authorized person before approval is given to the Supplier to ship the product.

A. First Article Inspection Report -

All dimensions must be within print tolerance. Any dimension which is not within print specification must be notified to Plexus in writing. The following requirements must be met when the FAIR is executed:

- A bubble diagram must be submitted indicating all applicable features, characteristics and notes as part of the FAIR submission.
- Only one part or assembly will be selected and inspected as part of the First Article Inspection.
- Only one part or assembly should accompany the FAIR unless otherwise requested.
- Raw materials must have direct traceability with the chemical and physical properties submitted to Plexus.
- All date formats must be Day/Month/Year (DD/MMM/YYYY)
- All Signatures must have a Printed Name (or Unique Identification) and Signature of the person approving the specific section of the FAIR.
- Special processes utilized by the supplier will require a certificate of compliance at a minimum.

B. Process Capability

- a. Manufacturing Process Flow - The supplier must submit a process routing or flow chart which describes the manufacturing process.
- b. 30 piece Pre-production Run - The supplier will manufacture and submit a minimum of 30 pieces off of production tooling and processes representative of a repeatable process. During the manufacture of the parts the supplier will employ the use of X-bar and R Charts to monitor the process, sampling 10 subgroups of 3. All Safety Critical Characteristics will be included.
- c. X-bar and R Charts - The supplier will monitor in-process control parameters via X-bar and R Charts. All Safety Critical Characteristics will be included. 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 product can be shipped.
- d. Capability Study - The supplier will sample 30 pieces prior to shipment from which the supplier will measure all customer designated CTQ and Safety Critical characteristics. All associated data will be submitted to the customer, the supplier will calculate X-bar, Sigma, Cp and Cpk values. Any dimension/characteristic which is not within print specification must be approved in writing before product can be shipped.

- C. Material Certificate - at a minimum the material certification must include a statement declaring that the items are manufactured from the material specified. This may be included with the certificate of compliance. This is only required if the purchased product relates to the material (metals, alloys, non metallic parts, resin and similar)

All Shipments-The documentation and quality requirements for each shipment of parts are as follows:

A. ATEX/ IECEx Declaration of Conformity –

- The declaration must meet all the following requirements
- Annex A of ISO/IEC 80079-34 requirements
- Compliant to ISO17050-1 and ISO17050-2
- State the items conform to their specification
- List the factors to demonstrate product conformity

Note: A Certificate of Conformance, declaring compliance to all specifications, including the component's revision level and signed by supplier's quality function representative that meets the bulleted requirements above can be substituted for the Declaration of Conformity.

- B. X-bar and R Charts - The supplier will monitor in-process control parameters via X-bar and R Charts. All Safety Critical Characteristics will be included. 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 product can be shipped.
- C. Material Certificate - same requirements as C above.
- D. All cartons, packing slips, certificates, and ATEX/ IECEx Declaration of Conformity must match the PO exactly and include the following information:

- Part number
- EC level or Revision level as specified on the PO for the Plexus part number ordered
- Name of Supplier (if different than the actual OEM)
- Name of Manufacturer
- Manufacturers' part number supplied
- 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.¹
- Bar coding this information in 39 or 128 format is optional.

¹ The minimum-required date code format shall identify the 2-digit workweek, 2-digit year (WWYY). If the component marking contains a lot and/or date code, then those markings must be traceable to the COC. Shipments of multiple lot and/or date codes must be identified separately on the COC with the actual quantity shipped for each. Each lot and/or date code shall be independently packaged (i.e., no mixed lot/date codes within a package: reels, trays, tubes, bags, etc.).

Material received without the completion and proper execution of the Quality Requirement allows Plexus the right to return the material as defective. For material that has been previously provided to Plexus, the requirements under subsequent shipments will be followed.

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.