

## PPQ Requirements – training pack for suppliers

### 1 Purpose

This appendix serves to define the concept of PPQ elements used within the PPQ process, and replace for Montreal a portion of Section B of EBQR.

The required elements and the communication road (ex: PPQ database, etc) will be defined in the PPQ kick off meeting between supplier and Siemens PPQ team.

### 2 Terms and definitions

The PPQ process consists of following generic process steps, as shown in diagram 1.

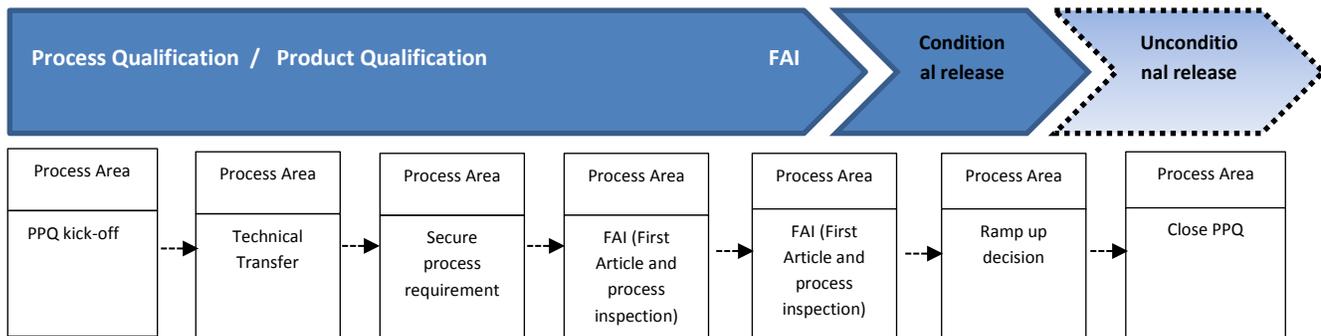


Diagram 1: PPQ process with process steps

MDR = Manufacturer Defect Report

NCR = Non Conformity Report

FM/FR = Fault Report

PDS = Product Disclosure Statement

FDR = Fault Discovery Report

NDE = Non-Destructive Evaluation

CR = Change Request

SCAR = Supplier Corrective Action Report/Request

## 3 PPQ Elements

Element 1: Product Release

Element 2: Supplier Drawings and Specifications

Element 3: Critical to Quality (CTQ) Characteristics

Element 4: Manufacturing Quality Control Plan (MQCP)

Element 5: Inspection Records and Data Sheets

Element 6: Material Data

Element 7: Destructive & Non-Destructive Testing Records

Element 8: Metals Joining Documents

Element 9: Failure Modes and Effects Analysis (FMEA)

Element 10: Process Capability

Element 11: Gage Repeatability & Reproducibility (Gage R&R)

Element 12: Tooling & Gages

Element 13: Discrepancy Reports (NCR/MDR) and Engineering Changes (CR/ECMI)

Element 14: Packaging Instructions & Photos

Element 15: Special Process Documentation

Element 16: Correspondence and Miscellaneous Documents

Element 17: Personnel & Suppliers

Element 18: First Article Inspection (FAI)

Element 19: Fixed Process Control

Element C#: Custom Elements (Added as Required, Numbering Starts with a C)

**The element requirements are explained in the following paragraphs. All elements may not be a requirement for the specific product. This specification covers all elements for explanatory purposes.**

**Suppliers needs to agree with the PPQ**

## B4.1 Product Release

Included in this element must be all Siemens specific documents that the purchase order or product specific documents refer to.

Unpriced copy of the purchase order, including;

- identification of the applicable purchase order item and amendment number
- applicable Drawing
- PDS and revision number
- applicable ASTM or ASME number, DIN, etc.
- if applicable, the Siemens assigned serial numbers.

Agreed suppliers demands of specifications or other clarifying documentations stated in the purchase order as;

- Drawings (Siemens)
- Product specifications (Siemens)
- Procedures (product or project specific procedures from Siemens)
- Packing instructions (Siemens)
- Photos (when referenced to from Siemens)
- Final Check List (if applicable) Siemens.
- Quality Record Package (QRP) distribution list (if applicable). List who gets a copy of QRP every shipment, who gets SSR in receiving plant including telephone & fax numbers (Siemens).
- Documentation Plan (for large scope projects – what is due when and by whom) from Siemens
- Hold/Witness Plan with verification forms (if applicable) from Siemens
- Manufacturing schedule (detailed plan vs. actual) from Siemens

Examples: Copy of Purchase Order (un-priced), Copy of PO Confirmation (un-priced), Technical Transfer Check-list, i.e. list of all drawings and specifications etc.

## B4.2 Supplier Drawings and Specifications

All customer, supplier and sub tier supplier issued drawings, procedures and specifications. A document list that states issue no and status.

Balloon drawings and non-Siemens issued drawings

This element is used to store

- all supplier created drawings and specifications that describe the final product or interim production steps,
- the reference between the drawing and the inspection records & data sheets, for instance by a balloon/ bubble drawing,
- In case no supplier drawings or specs are created this PPQ element is to be filled with a supplier statement confirming that no supplier specific drawings/ spec's will be utilized throughout the production process.

Examples: List of all supplier and sub-tier supplier issued drawings and specifications including released product definition provided by supplier's engineering (in case of 3rd party design of purchased catalogue items (pipes, helicoils, etc.), balloon/ bubble drawing as reference between drawing and the inspection records & data sheets.

## B4.3 Critical to Quality (CTQ) Characteristics

A CTQ is a dimension or characteristic 'critical' to the final customers. These dimensions or characteristics require continuous monitoring and reporting to Siemens, as well as continuous improvement and process control programs throughout the life of the product to assure conformance to requirements

The dimensions not specified as CTQs may still be important, but do not require the statistical study and continuous process improvement that a goes along with marking a dimension or characteristic as a CTQ.

Statistical data is required for these dimensions or features. Additional part specific CTQs may be added during the PPQ process.

ALL dimensions and tolerances for the part must be met, CTQs or not.

Dimensions other than those indicated as CTQs may require measurement, for capability.

CTQs may start out requiring statistics for 100% but can later on be reduced.

In the event of a discovery NCR/FR, record traceability back to the shipment and production batch is required by the supplier.

CTQs are crucial features. The outlined CTQ points listed and references points drawings need to be referred to in the MQCP and FMEA documents.

These dimensions or characteristics require continuous 'real time' monitoring and reporting, as well as continuous improvement and process control programs throughout the life of the product to assure conformance to requirements.

Three sources need to define CTQs:

1. **Engineering** - which are the important dimensions, characteristics or material properties for the part/ set of parts in qualification,
2. **SQM/Supplier** - which process steps at the supplier need to be closely monitored and recorded to ensure the final part has the expected quality,
3. **Siemens Manufacturing** - which dimensions, surface shapes, etc. are important to ensure smooth final machining of the part/ set of parts.

The CTQs should be defined in a commodity-specific specification or can be provided in other controlled documents like drawings or part related specifications. In case no CTQs have been identified before the PPQ kick-off, the PPQ Team has to identify the needed CTQs for the upcoming PPQ.

The dimensions/ characteristics not specified as CTQs may still be important in their own way, but do not require the statistical study and continuous process improvement that goes along with marking a dimension or characteristic a CTQ.

Statistical data is required for each of these dimensions or features. The data needs to be continuous, that is, each part/ set of parts should be tracked in the sequence it enters a process with other parts. Additional part specific CTQs may be added at the start of the product process qualification (PPQ) process, during the qualification process, during re-qualification or at the request of a supplier process improvement team.

It is important to recognize that ALL dimensions and tolerances for the part must be met, whether they are marked as CTQs or not. Also, dimensions other than those indicated as CTQs may require measurement either for a time to prove capability, or because the vendor has decided they are important for internal control, or to help insure that CTQ dimensions are held.

A dimension or characteristic that is marked as a CTQ will require a continuous improvement program to try and make the distribution of parts/ set of parts closer and closer to nominal throughout the life of the program. Dimensions or characteristics not listed as CTQs may only require programs to bring the distribution of parts/ set of parts into tolerance and held there. These dimensions, that are not listed as CTQs, are also possible candidates for further engineering analysis to check, if tolerance relief is possible and cost reduction opportunities exist.

Final CTQs to be monitored during serial production will be agreed to at the end of the PPQ process (unconditional process approval) by the PPQ Team.

These are very crucial features for the parts/ set of parts hence more care and attention needs to be given to these points. These need to be referenced in the MQCP and FMEA documents.

## B4.4 Manufacturing Quality Control Plan (MQCP)

Manufacturing Quality Control Plan (MQCP) -Supplier must prepare a MQCP using the Siemens template or using a supplier provided template if approved by the PPQ team. The MQCP need to identify the production process the supplier will use to manufacture the product and should describe the key work elements and process controls that affect the quality characteristics. These include all, process control charts, process checks, process inspections, sampling inspection, quality audits, and outgoing inspection.

The MQCP must incorporate controls for the production process including Siemens identified CTQs and identifying which control in the MQCP that determines the conformity to which CTQ.

Sampling plans – Sampling plans must be approved by Siemens and the acceptance criteria must be a c=0 sampling plan. Sampling should be used to control a process, not used for acceptance of product. 100% inspection shall be used if process cpk is below 1.33.

The MQCP must include the following as indicated in the template:

- Identify the supplier's name, part and process name, drawing- and sub number.
- Indicate the MQCP's issue date and last revision date
- Indicate PPQ number, prepared by and person responsible
- List all process steps used (The process steps of the MQCP should be the same as the process steps of the FMEA).
- Identify name of the machines, jigs, fixtures, tools to be used for the product
- Identify name of the tools and inspection tools/gages used in the process.
- Identify each characteristic how it is controlled and documented. (I.e. 100% inspection, go/no-go, X -R charts, etc.) If sampling is utilized, also indicate sample size, frequency and acceptance criteria.
- Identify where in the process each CTQ are controlled with a reference number to each CTQ.
- Indicate inspection methods, frequencies and how it is documented for each controlled characteristic.
- Indicate action to take when a process or characteristic is out of control.
- Standard process procedures for blasting, painting, preservation, prep for shipment, etc, as applicable.

SPC is required as a method for controlling CTQs during production. If it is agreed by Siemens PPQ team that SPC is not possible or applicable in any instance, the supplier must show how to prove a stable and controlled process.

The MQCP must be reviewed and updated as appropriate whenever:

- The product has changed.
- The process is changed.
- The process becomes unstable.
- The process becomes not capable.

This element is used to store

- The Manufacturing and Quality Control Plan (MQCP) filled out by the supplier to document the detailed production process the supplier will use to manufacture the approved. This document describes also the needed checks and inspection specs to control the manufacturing process.
- Manufacturing checklists like job router (if any).

Examples: MQCP/MIP/ITP/QTP, copy of job router document

## **B4.5 Inspection Records and Data Sheets**

This element is used to store

- Result of the inspection documented by the filled out inspection records and data sheets.

Examples: Dimensional Inspection record template, completed dimensional inspection record data sheet, the filled out inspection records & data sheets, visual inspection results, witness reports.

A full dimensional layout inspection is to be provided for at least one part for all drawing requirements including drawing notes. The format of this layout inspection will include:

- A copy of the drawing, which is marked up with "bubble number", references to the inspection report.
- An inspection report presented that lists all features, dimensions, drawing notes and boilerplate notes. For each of these items, a location reference listed to show the drawing page and grid location on the print from which the print characteristic was taken. These should match up one-for-one with the "bubble number" on the marked up drawing

Inspection is to be performed using the production gages identified for use in the MQCP, unless otherwise approved by Siemens.

Quality Control Inspection (QCI) records may be supplied as an alternate to a dimensional layout inspection if approved by Siemens.

## **B4.6 Material Data**

List all materials used in the scope of this product.

For material purchased, include copies of CofCs, final material test reports, Metallurgical analysis reports, functional test reports, etc.

Include metallurgical samples and pictures.

This element is used to store all necessary material information for the related product to ensure appropriate, useful and approved material including:

- list all materials grades used in the scope of this product,
- list all material suppliers with their approval status relative to required supplier qualification noted within the material spec,
- copy of material substitution requests and approvals,

- results from Siemens internal and external material testing, such as mechanical and metallurgical properties including microscopic and macroscopic pictures,
- function test reports,
- material test reports including mechanical, chemical, residual stress, heat stability test results, ...
- for material purchased, include copies of CofCs, final material test reports, metallurgical analysis reports, functional test reports, etc.

Examples: Used material list, mechanical test results, chemical test results, metallurgical pictures and samples (both: internal and external)

#### **B4.7 Destructive & Non-Destructive Testing Records**

Destructive: If applicable, will include test reports for destructive testing such as corrosion tests, vibration test, etc.

When destructive testing is required, it may be allowable to use a scrapped part, when the scrapped part is representative of a production part using the same parameters and in the same manufacturing condition. (e.g. heat-treat, machining)

This element shall include test reports for NDT methods as Penetrant Inspection (PT), Radiographic Inspection (RT or "X-ray"), Ultrasonic testing (UT), Magnetic Particle testing (MT) and others as applicable.

This element is used to store:

- Non-Destructive Examination/Testing (NDE or NDT) results including test reports for NDT methods such as Penetrant Inspection (PT), Radiographic Inspection (RT or "X-ray"), Ultrasonic testing (UT), Magnetic Particle testing (MT) and others as applicable,
- Destructive testing, if applicable. This element will include test reports for destructive testing such as corrosion tests, vibration test, etc.

Examples: NDE Reports, Other test reports

#### **B4.8 Metals Joining Documents**

This element is used to store all relevant documents defining and documenting the joining of metals including:

- Welding Performance Qualification (WPQ),
- Welding Procedure Spec (WPS),
- Procedure Qualification Record (PQR),
- Weld Map,
- Weld Joint Records (WJR),
- Weld Joint cards (WJC),
- Brazing information, drawings etc. (if any).

Examples: Weld Maps, Weld Joint Records (WJR), Weld Joint Cards (WJC), Welding Procedure Specifications (WPS), Welding Procedure Qualification Record (WPQR), Welding Performance Qualification (WPQ)

## **B4.9 Failure Modes & Effects Analysis (FMEA)**

FMEA is used to identify process and design weaknesses. Siemens provided excel template can be used to create the FMEA at the supplier.

Supplier shall include all steps of the production process as well as additional consideration of possible failure related handling, packaging and storage.

FMEA shall include all production steps/operations and utilize a cross-functional team from the supplier to ensure that potential failure modes and possible effects are analyzed.

The FMEA is to be a living document (i.e. not frozen at PPQ). It is to be updated throughout the lifecycle of the product/process when:

- Any process and design changes are made.
- New understanding of the process and design is gained.
- Non-conformance data becomes available (Suppliers internal data, NCR, FR, MDRs, FDRs, SCARs, etc.) which cover failures not already identified in the suppliers FMEA or if non-conformance rates are different than predicted in the FMEA.

The supplier is to provide Siemens with updates to the FMEA at every revision, until full process approval is given.

The supplier shall use the RPN feature of the FMEA to determine when corrective action is required. The supplier should correct the process for RPNs of 100 or higher.

This element is used to document Failure Modes & Effects Analysis carried out by the supplier. FMEA is to be utilized as a tool to identify possible process and design weaknesses and to aid the supplier in creating a more robust production process.

Examples: Siemens provided standardized Excel spreadsheet or equivalent

## B4.10 Process Capability

Supplier is responsible for performing statistical analysis of all Siemens and supplier identified CTQ characteristics.

The intent of capability studies is to prove the supplier's process is capable of producing future parts within tolerance. The supplier will incorporate SPC into the MQCP to ensure that process capability is maintained/improved.

The recommended software to perform process capability is MINITAB.

Initial approval will be withheld if the process cpk for a specific number of lots or parts is not  $\geq 1.33$  and process is determined to be statistically unstable. Process cpk may be calculated by industry accepted methods/software, but the basic formula for cpk is:

$$cpk = \frac{\bar{x} - LSL}{3s} \text{ - or - } cpk = \frac{USL - \bar{x}}{3s} \text{ (Whichever gives the lowest cpk)}$$

$\bar{x}$  = process average  
 USL = Upper Specification Limit  
 $\sigma$  = process standard deviation  
 LSL = Lower Specification Limit

NOTE: Process capability studies are not always suitable as method. The method is mainly recommended for products produced in sets or larger series.

For parts produced in sets:

- Preliminary capability studies shall be provided at First Article Inspection "FAI" for whatever quantity was produced for FAI (e.g. 6 pieces).
- Full process capability studies measuring 100% of the parts shall be made available with each production set during the "conditional approval" state of process qualification.
- Trend data showing mean and standard deviation from set to set shall be provided as pilot run parts are produced during "conditional approval" production.
- PPQ team will specify number of parts required to prove process capability.

For parts not produced in sets:

It may not be able to perform process capability on FAI parts that are not produced in sets, due to insufficient data points for CTQ's. Then the PPQ team/lead defines number of components to be produced to establish process capability.

Ongoing process control

This element is used to store necessary information regarding all identified CTQ characteristics. The supplier is responsible for performing statistical analysis of all Siemens and supplier identified CTQ characteristics. These will be identified via the print, specifications, or correspondence with Siemens Energy. Only Siemens Energy provided excel template should be used to document the analysis. The recommended software to perform process capability is MINITAB.

Examples: Minitab reports, Siemens provided standardized Excel spreadsheet.

## B4.11 Gage Repeatability & Reproducibility (Gage R&R)

The intent of Gage R&R is to provide evidence that the inspection measurement system being utilized is appropriate. Wrong measurement system used, may result in a high Gage R&R result and add additional variations to the process.

Gage R&R studies shall be performed by accepted methods. The Gage R&R is to be stated in terms of percent of tolerance.

$$\frac{P}{T} = \frac{5,15 \times \frac{R}{d_2}}{\text{Tolerance}}$$

T=total tolerance i.e. ± 0.2 = 0.4

Recommended software is MINITAB. In MINITAB, use the “crossed” method for non-destructive inspection and the “nested” method for destructive inspection.

When possible samples for a Gage R&R are not to be randomly selected. They are to be selected so that the samples span the tolerance range. In MINITAB, for a Gage R&R to be statistically valid, it should have at least 5 “distinct categories”. Select the proper combination of samples, operators and repetitions to achieve this. A rule of thumb would be to have (# of samples) x (# of operators) x (# of repetitions) ≥ 40.

For gauging methods that involve computer controlled inspection, i.e. CMM, a Gage R&R will still be performed to ensure that the programming is correct and that fixturing and re-fixturing do not add excessive sources of variation.

Acceptance criteria for Gage R&R is stated in terms of % Gage R&R.

- A Gage %R&R below 10% is considered acceptable.
- A Gage %R&R between 10% and 30% is questionable and must be approved by the Siemens PPQ team. Acceptance in this range should only be considered when no cost effective method of improving the R&R is available.
- A Gage %R&R >30% is unacceptable and the inspection measurement system must be improved to reduce the %R&R to an acceptable level.
- The %R&R is calculated two ways and both methods are valuable. The two methods for %R&R are “percent of variation” and “percent of tolerance”. The percentage of variation is the preferred method, however, if process capability is low (below 1.0 cpk) and 100% inspection is being utilized to contain defects, then a high %R&R of tolerance means the Gage is likely not adequate for 100% inspection even if %R&R of variation is acceptable.
- If an inspection process with a high gage R&R will be used in production, the supplier must add additional controls to the process. They must indicate how they will avoid false acceptance of parts near the edge of the tolerance caused by Gage inaccuracy. E.g. will they have a tightened tolerance as control limits and an additional method of verification will verify parts beyond the control limits by multiple inspectors.

For attribute Gages, e.g. Go/No-Go Gages, Gage R&R studies should be performed if attribute gages are used for final product acceptance. Gage R&R for in process measurement may be waived at the discretion of the Siemens PPQ team.

Supplier's calibration procedures should include a provision for repeating Gage R&Rs on a regular frequency to ensure that tooling/Gage wear is not affecting the ongoing gage R&R.

All practical sources of variation are to be considered. For example:

- If inspection fixtures are involved, parts must be completely removed from fixture and the fixture reset between readings during the Gage R&R study.
- If it is typical to calibrate the particular Gage before use, then the Gage must be recalibrated between every reading during the Gage R&R study.
- If parts will be inspected on multiple shifts during production, then the study must include readings taken during all such shifts during the study. This is to help take into account changes in ambient temperatures and humidity as well as off-shift personnel that may affect R&R.

This element is used to store Gage R&R results. The intent of Gage R&R is to provide evidence that the inspection measurement system being utilized on the CTQ is appropriate. If the wrong inspection measurement system is used, a high Gage R&R may result, which may add additional and preventable variation to the process.

Examples: Minitab reports, Appropriate Excel spreadsheets

## **B4.12 Tooling & Gages**

Product specific jig/fixture inspection tooling reports for tooling that is needed to assure process control (with list of tool ID#s and calibration traceability information.)

List of thread Go/No-Go Gages applicable to the product (Product specific tools)

List of Siemens owned tooling/Gages

- If Siemens has paid for tooling, gages or equipment a list shall be included in the PPQ of those Siemens owned items.
- If Siemens drawings were used to produce the property, then the drawing number and revision will also be listed. If non- Siemens drawings were used, then copies of the drawings must be uploaded to the database.
- Identity no, localization, photo and maintenance routines of the equipment/tools needs to be documented in the PPQ.

This element is used to store all relevant information regarding used tools and gages for the material or product including:

- list of all supplier owned and Siemens owned tools, gages, jigs, fixtures that will be used on the parts / set of parts,
- serial number, tool id and picture of the tools and gages,

- calibration schedule for gages and procedure for calibration process (in-house or outsourced),
- jig/ fixture/ machine inspection reports,
- list of thread gauges size / Go No-Go gauges that will be used,
- list of functional gauges or sweep gauges that will be used.

Examples: List of tools and gages including serial number, tool id and picture, calibration schedule and procedure, related inspection records.

#### **B4.13 Discrepancy Reports (NCR/FM/MDR) and Engineering Changes (CR/ECMI)**

MDRs (Material Disposition Reports)

MDR's are used in the North American region for reporting material discrepancies.

List of NCRs (hereinafter also meaning FM/MDRs) All NCRs must be closed before unconditional approval is granted. NCRs are to be included in this list whether initiated by supplier or Siemens (even if the disposition is "accept as is").

This element is used to store all discrepancy records for this product or material and its manufacturing process including:

- engineering change requests (ECR) that affect the PPQ parts in qualification,
- list of manufacturing deviations (MDRs/NCRs, VEDAS Event, SAP Q-notification) with closure dates (all manufacturing deviations must be closed before unconditional approval is granted).

Examples: List of all ECRs (Engineering Change Request) with rev #., copy of all closed MDRs/NCRs, VEDAS Events, NachtragsAEL, Change or Revised Engineering Release(ER), Re-Issueing (OneP), SAP Q-notifications for this product including pictures and datasheets that describe deviations as well, highlight all issues in a spreadsheet and what can be done to prevent them next time.

#### **B4.14 Packaging Instructions and Photos**

The supplier must prepare work instructions that explain how the parts will be packed. These instructions along with photos showing the product in its packaging shall be included in this element. Packaging and Labelling instruction to be found on Supplier Portal.

If returnable packaging is used, supplier must explain how packaging material will be controlled.

Siemens provides packing instructions for some parts and these instructions overrides any issues of supplier approved packing instructions.

This element is used to store instructions that explain how the parts/ set of parts will be packaged and photos showing the product in its packaging. The supplier must prepare these work instructions and provide appropriate photos. If returnable packaging is used, supplier must explain how packaging material will be controlled.

Examples: Photos showing how the part / set of parts will be preserved and packaged for shipment, packing and shipping procedure and photo of the part / set of parts markings including what was marked on the part/ set of parts and where it was marked.

#### **B4.15 Special Process Documentation**

This element would include such things as special lab certifications the supplier may have or other special processes or certifications.

A process whose results cannot be fully verified through subsequent nondestructive inspection and testing of the product and where processing deficiencies may become apparent only after the product is in use.

Examples: Thermal spraying, Laser Cutting and other similar special process qualification records. Additional ISO Management system certifications, in case Post Welding Heat Treatment and Heat treat charts are not included in the MQCP but provided by the supplier and tables showing ramp up, hold and cooling time and temperature, Hardening.

#### **B4.16 Correspondence and Miscellaneous Documents**

This element is used to store all relevant correspondence and misc. regarding the PPQ like e-mails, letter, etc. that directly apply to the PPQ. These may be clarifications of PPQ requirements or notices of who will be involved on the PPQ review team or etc. Only those items that directly apply and have significance to the PPQ should be included.

Examples: PPQ Kick-Off Meeting Minutes, Copy of important emails related to this product, process or qualification, any other documents or emails needed such as written temporary substitution information etc., any formal letters or correspondences received from Siemens, main meeting minutes.

#### **B4.17 Personnel & Suppliers**

List of supplier's key personnel (Top management, Manufacturing, QA, welders and all personnel that need certificates of knowledge to be able to perform their work)

NDE personnel and process approval letters shall be included for methods used, and personnel that were used, or are planned to be used if required by Siemens.

List of approved sub-contractors that need certificates of knowledge to be able to perform their work or run production. (Sub-suppliers, see Element 4 and 6)

Communication team, a matrix showing the communication team (consisting of personnel from both Siemens and the supplier)

Stating: Name, function, phone no and e-mail address.

This element is used to store information on suppliers' key personnel, sub-tier supplier contacts and Siemens employees which are involved in the PPQ process.

- List of certified NDE and welding personnel including their certificates,
- List of key supplier's personnel,
- List of sub-tier supplier.

## Examples:

PPQ Communication Matrix,

List of certified NDE and welding personnel including their certificates, list of key supplier's personnel (Top management, Manufacturing, QA, welders, Machinists) involved with the part / set of parts, copy of suppliers' organization chart, list of approved sub-contractors (Sub-suppliers) where the supplier will be buying parts / set of parts, materials etc for our SIEMENS product (e.g. helicoil, pipes, flanges, plates etc) including what each sub-tier supplier provides to the supplier, their name, contact and location, list of outsourced services (calibration, NDE, Heat Treatment, welding etc), who does it and where they are located together with their contact information.

### **B4.18 First Article Inspection (FAI)**

First Article Inspection is defined as the inspection of the "first" parts produced using the proposed production process. This is performed at the supplier's location.

The FAI is a complete, independent, and documented physical and functional inspection process to verify that prescribed production methods have produced an acceptable item as specified by:

- engineering drawings
- quality specifications
- PDS
- planning
- purchase order
- engineering specifications
- other applicable design documents.

### **3.19 Custom Elements**

If needed, additional custom elements may be added to the record. If a unique category is necessary, they may be added starting with element number C#.

## Change History

### Change History

Revision	Date	Description of Change
1	March 2017	This document is an initial issue of Siemens Energy, Inc. Quality Requirements