

# Annex 1:

## PPQ Elements Definition and Supplier Information

### Scope / Target Group

This annex supports the internal SE-Document No 001901 “Product and Process Qualification@SE”. Selected contents of this document should be applied to quality-relevant Suppliers of Siemens Energy during the product and process qualification process.

This annex therefore is both an internal document for SE employees and an external document to be shared with suppliers.

### Purpose

The Product and Process Qualification (PPQ) is an element of qualifying a supplier to deliver according to SE required specifications. This annex serves to define the contents of ‘Product and Process Qualification’ (PPQ) elements used for the PPQ process. Based on an initial risk assessment, SE determines necessity, content and magnitude of a PPQ. The required PPQ elements and the communication method are defined by the PPQ-Team of Siemens Energy.

**General** Siemens Energy purchases products and services.

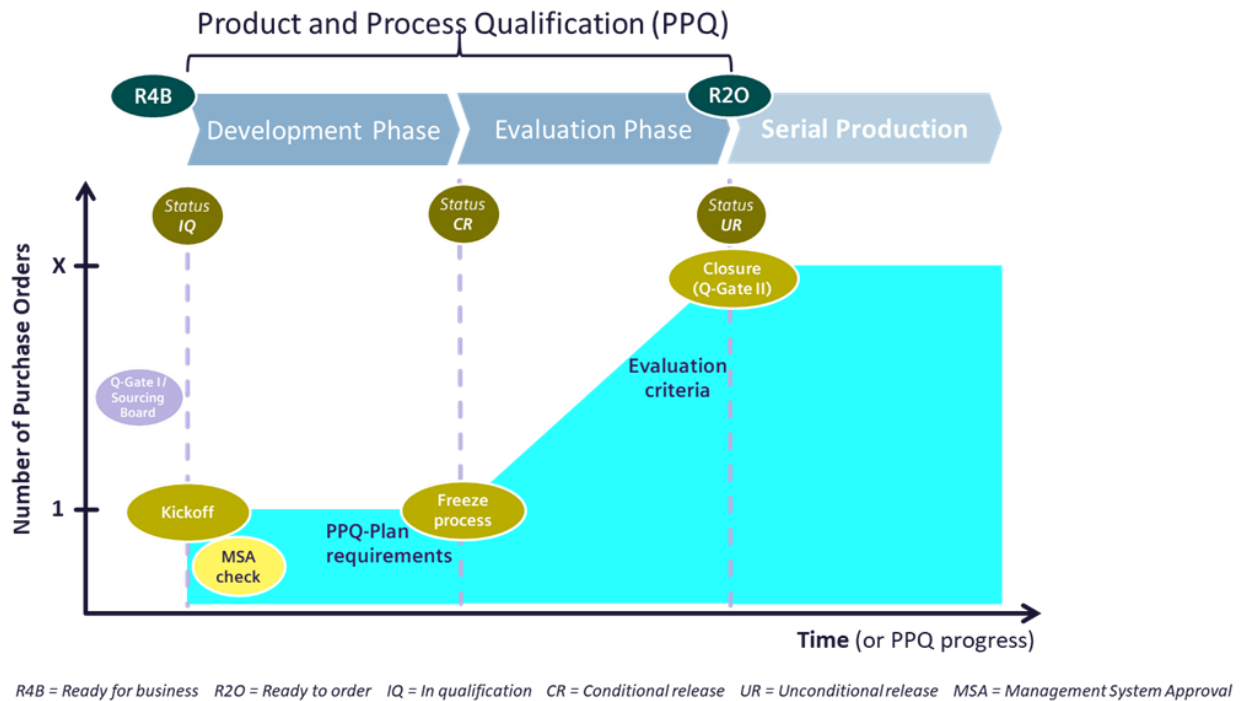
A product is a tangible or digital item (e.g., raw material, component, assembly, equipment, or software package) that is delivered to Siemens Energy with ownership transfer and defined technical specifications, and for which conformity is demonstrated through product focused evidence (drawings/specs, material certificates, inspections/tests, markings).

A service is an activity performed by a contractor that delivers an outcome (e.g., installation, maintenance, inspection, engineering, logistics, training), typically evidenced by reports or records rather than a physical good; ownership transfer of a good is not the primary value.

Whenever the term “product” is used in this document it also applies to “services”. When applied to service orders, the PPQ Plan needs to be adopted accordingly.

For a Siemens Energy supplier, the benefit of a PPQ process is to obtain approval that the process is ready and capable of meeting all Siemens Energy requirements consistently throughout future production runs, not just the first run.

A PPQ consists of two phases, Development Phase and Evaluation Phase, as shown in the picture below.



Picture 1: PPQ Overview

The following chapters describe the possible content and documentation required as prerequisites for unconditional release. Element 1 is mandatory, additional elements are chosen by the PPQ Team based on the use case and risk mitigation. All applicable elements must be defined in the individual PPQ plan or by already existing commodity specific PPQ-Plan templates.

Applicable PPQ elements must be communicated to the supplier in a PPQ Kick Off meeting or by other means.

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## 1. Element 1: Product definition and release

PPQ Element 1 is used to provide Siemens Energy product specifications. If this element is chosen, the supplier has to confirm that he received and understood all necessary Siemens Energy product specifications and that those comprehensively define the product to be delivered. It may include :

- all information that defines the product to be delivered by the supplier
- confirmation by the supplier
- potential technical deviations from the Siemens Energy product definition
- documentation from the PPQ Kick-off Meeting with the supplier
- product release information
- special release/rejection criteria for the PPQ
- un-priced copy of the purchase order
- agreed suppliers demands of specifications or other clarifying documentations stated in the purchase order, e.g:
  - drawings (Siemens Energy and/or customer)
  - product specifications (Siemens Energy)
  - standards or norms to be applied
  - procedures (product or project specific procedures from Siemens Energy)
  - packing instructions (Siemens Energy)
  - photos (reference by Siemens Energy)
  - final Check List (if applicable) Siemens Energy
  - quality Record Package (QRP) distribution list (if applicable)

## 2. Element 2: Supplier Drawings and Specifications

All supplier and sub tier supplier issued drawings, procedures and specifications are covered by Element 2. A document list that states issue number and status is usually to be provided.

This element is used to provide information and store

- all supplier-created drawings and specifications that describe the final product or interim production steps
- all destructive or non-destructive test procedures issued by the supplier
- the reference between the drawing and the inspection records & data sheets, for instance by a ballooned / bubble drawing

## 3. Element 3: Critical to Quality (CTQ) Characteristics

The purpose of this element is to define all relevant CTQs. A CTQ is an attribute of a part, assembly, sub-assembly, product, or process that is literally critical to quality or more precisely, has a direct and significant impact on its actual or perceived quality. These dimensions or characteristics require continuous monitoring and reporting to Siemens Energy, as well as continuous improvement and process control programs throughout the life of the product to assure conformance to requirements.

Three sources should provide CTQs:

1. **Engineering** - which are the important dimensions, characteristics or material properties for the product in qualification? Are there any special requirements coming from our end customer?
2. **Supplier Quality (with supplier)** - which process steps at the supplier need to be closely monitored and recorded to ensure the final product has the expected quality?
3. **Siemens Energy Manufacturing** - which dimensions, surface shapes, etc. are important to ensure smooth final machining and assembly of the product?

The CTQs should be defined in a commodity-specific specification or can be provided in other controlled documents like drawings or product related specifications. In case no CTQs have been identified before the PPQ kick-off, the PPQ-Team shall receive confirmation that there is no need of CTQs for the upcoming PPQ. Additional product specific CTQs may be added at the start of the qualification process, during the qualification process, during re-qualification or at the request of a supplier development program.

Final CTQs to be monitored during serial production by the supplier will be agreed to at the end of the PPQ process (unconditional release) by the PPQ-Team. A dimension or characteristic that is marked as a CTQ will require a continuous improvement program to try and make the distribution of product closer and closer to nominal throughout the life of the program.

Statistical Process Control (SPC) is the standard method for controlling CTQs during serial production. If it is agreed by Siemens Energy PPQ-Team that SPC is not possible or applicable in any instance, the supplier must show how to prove a stable and controlled process by other means that are accepted by the PPQ-Team.

CTQ's need to be referenced in various supplier process documentation, such as the MQCP, ITP and FMEA documents.

Note: It is important to emphasize that all dimensions and tolerances for the product shall 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 supplier has decided they are important for internal control or to help ensure that CTQ dimensions are observed.

#### 4. Element 4: Quality Control Plan (MQCP / ITP)

If this element is chosen, the supplier must describe the amount of manufacturing and quality control steps used during production. Commonly used tools are a Manufacturing Quality Control Plan (MQCP) or an Inspection & Test Plan (ITP). The PPQ-Team shall decide what tool is to be used and if 2nd-Tier suppliers are to be included. It is to describe e.g.:

- the production processes the supplier will use to manufacture the product
- the key work elements and process controls that affect the quality characteristics
- milestones and witness points needed to approve semi-finished or final products by SE before continuing production
- process control charts
- process and product checks
- process and product inspections
- sampling inspections
- internal product or process audits
- outgoing inspection
- control the conformity to CTQ

Sampling should be used to control a process. Sampling plans shall be approved by Siemens Energy. If a CpK is required, 100% outgoing inspection must be performed by the supplier if process CpK is below 1.33 and not agreed otherwise with the PPQ-Lead.

The Quality Control Plan may include the following:

- list of all process steps used
- list of related specifications and process descriptions
- name of the machines, jigs, fixtures, tools to be used for the product
- name of the tools and inspection tools/gages used in the process

- 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
- where in the process each CTQ are controlled with a reference number to each CTQ
- indicate inspection methods, frequencies, acceptance criteria and how it is documented for each controlled characteristic / CTQ
- indicate action to take when a process or characteristic is out of control

Generally, a process described in an MQCP is considered "frozen". A frozen process must be thoroughly monitored by supplier to prevent product process variation outside the limits or acceptance criteria. A frozen process cannot be changed without prior acceptance from SE.

The Quality Control Plan must be reviewed and updated as appropriate, but at least when:

- the product has changed
- the process is changed
- the process becomes unstable or not capable
- the manufacturing facility has changed

## 5. Element 5: Inspection Records and Data Sheets

This element is used to determine and to document the completed inspection records and data sheets.

Examples of inspection records are:

- dimensional inspection record
- performance test report / final inspection report / FAT report / completed inspection records & data sheets
- visual inspection results
- witness reports

A full dimensional layout inspection is to be provided for at least one product for all drawing requirements including drawing notes. As per decision of the PPQ-Team, the format of this layout inspection could include:

- a ballooned drawing. The numbers on the ballooned drawing correlate with the numbers found on the Dimensional Data Sheet or 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 "ballooned number" on the marked up drawing or equivalent for model-based product definition

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

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

## 6. Element 6: Material Data

This element is used to determine and to document all necessary material information for the related product to ensure appropriate, useful, and approved material.

Examples are:

- list of all materials grades used in the scope of this product

- list of 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 Energy internal and external material testing, such as mechanical and metallurgical properties including microscopic and macroscopic pictures
- functional test reports
- material test reports including mechanical, chemical, residual stress, heat stability test results, metallurgical pictures etc.
- for materials purchased: copies of Certificates of Conformance (CofC), final material test reports, metallurgical analysis reports, functional test reports, material certificates (e.g. 3.1 certificates), etc.

## 7. Element 7: Destructive & Non-Destructive Testing Records

This element is used to determine and to document test reports for Non-Destructive Examination/Testing (NDE or NDT) results, including test reports for NDT methods such as

- Training records of test personnel in accordance with ISO 9712 (e.g. Penetrant testing (PT), Radiographic testing (RT), Ultrasonic testing (UT), Magnetic testing (MT) )
- and others as applicable

It is also used to determine and to document test reports for destructive testing, if applicable. This element 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 product on condition the scrapped product is representative of a production part using the same parameters and in the same manufacturing condition. (e.g. heat-treat, machining).

## 8. Element 8: Materials Joining Documents

This element is used to determine and to document all relevant documents defining and documenting the joining of materials, e.g. metals.

Examples are:

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

## 9. Element 9: Preventive Risk Assessment (e.g. FMEA)

The purpose of this element is to identify possible process and design weaknesses and to aid the supplier in creating a more robust production process. The supplier needs to demonstrate that the Critical to Quality Characteristics (CTQs) have been addressed. The element is also used to document

Failure Modes & Effects Analysis or other industry accepted methods of addressing preventative risk assessments carried out by the supplier.

Siemens Energy shall ensure FMEAs meet the minimum requirements outlined in Document 001822 "Application of Failure Modes and Effects Analysis". It is highly recommended to utilize the FMEA templates as outlined within Annex 1 through 3 of Document 001822 (or APQP4Wind FMEA template for SE WP) or equivalent recognized format for proper FMEA documentation. Any deviations to the FMEA templates shall be reviewed and approved by SE Supplier Quality and the Supplier prior to execution of the FMEA(s).

A Design-FMEA is to be conducted by design responsible suppliers only.

For the Process-FMEA, the supplier must include all steps of the production process that are deemed relevant by the PPQ-Team as well as additional consideration of possible failure-related handling, packaging and storage.

A cross-functional team from the supplier must ensure that potential failure modes and possible effects are analyzed.

The Risk Assessment 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 and is different than predicted

The supplier shall provide Siemens Energy with updates to the Risk Assessment at every revision, until full process approval is given.

## 10. Element 10: Process Capability

The intent of this element is to prove the supplier's process can produce future products within tolerance and according to specification.

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

For products produced in sets:

- preliminary capability studies must 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 products 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 must be provided as pilot run products produced during "conditional approval" production
- PPQ-Team will specify the characteristics and the number of products required to prove process capability

Statistical methods in process management are described in ISO 22514. Using Statistical Process Control (SPC) as a method, a CpK equal or greater than 1.33 indicates that the process is capable, stable and meets specification limits. Any value less than this may mean variation is too wide compared to the specification or the process average is away from the target. Any deviation to this should be agreed with the PPQ-Team. Some characteristics (e.g. safety related) may require higher CpK values as specified by the PPQ-Team.

Ongoing process control must continue until such point the Supplier and Siemens Energy agree it is no longer a requirement.

## 11. Element 11: Measurement System Analysis (e.g. Gage R&R)

The intent of gage capability study is to provide evidence that the inspection measurement system being utilized is appropriate. When a wrong measurement system is used, it may result in additional variations to the process.

Special characteristics (e.g. CTQ's) require Measurement System Analysis and these studies will include Gage Repeatability & Reproducibility (Gage R&R) studies on measurement equipment used during assembly or quality control checks calibration records for all gages and measurement equipment must be included.

For gaging methods that involve computer-controlled inspection, i.e. CMM, a gage capability may still be performed to ensure that the programming is correct and that fixturing and re-fixturing do not add excessive sources of variation.

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

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

All practical sources of variation are to be considered.

## 12. Element 12: Tooling & Gages

This element is used to record all relevant information regarding tools and gages used for the material or product, which may include:

- list of all supplier owned and Siemens Energy owned tools, gages, jigs, fixtures that will be used on the product
- serial number, tool ID and picture of the tools and gages
- calibration / maintenance schedule for gages and procedure for calibration process (in-house or outsourced)
- jig/ fixture/ machine inspection reports
- list of thread gages size or Go/No-Go gages that will be used
- list of functional gages or sweep gages that will be used
- list of thread Go/No-Go gages applicable to the product (product specific tools)

Siemens Energy owned tooling/gages must be clearly marked as such.

The result should be a list of tools and gages including serial number, tool id and picture, calibration schedule and procedure and related inspection records.

## 13. Element 13: Discrepancy Reports and Engineering Changes

This element is used to store all discrepancy or non-conformance records for the product, material or service and its manufacturing process including:

- engineering change requests/notifications (ECR or ECN) that affect the PPQ products in qualification
- list of manufacturing deviations with closure dates, disposition, responsible for disposition and results after rework, if necessary
- pictures and recommendations to avoid recurrence on next manufacturing

All manufacturing deviations must be closed before unconditional approval is granted.

Examples are:

- list of all Engineering Change Request with rev #.
- change notifications
- copy of all closed Material Disposition Reports / Nonconformance Reports
- changed or revised Engineering Release
- quality-notifications

#### **14. Element 14: Packaging and Marking / Labeling**

This element is used to store instructions that explain how the products will be packaged and marked or labeled to ensure suitable protection during transportation and maintain traceability.

The supplier shall prepare these instructions for Siemens Energy review.

The supplier should include evidence that the packaging standards have been achieved, for example photos of the packaging stages / steps and product marking and labeling. For specific cases, Siemens Energy provides packing instructions for some products and these instructions override any supplier approved packing instructions.

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

#### **15. Element 15: Special Process Documentation**

This element is used when special processes or certifications as well as special lab certifications of the supplier need to be considered.

A special process is 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 of special processes are:

- any process affecting material structures (e.g. hardening, thermal spraying, laser cutting, heat treatment, hiping, coating, diffusion bonding, welding, brazing, etc.)
- any process that can produce remelt layer, micro cracking or IGA (e.g. EDM, ECM, laser removal, chemical processes, etc.)
- casting
- additive manufacturing
- NDT processes

Special processes must be performed under controlled conditions and the parameters that influence quality need to be monitored.

This will likely revolve around 3 key variables:

- control of equipment / machinery
- qualification of personnel
- periodic monitoring of the process

In case of a special process and if no commodity-specific approach with respect to that topic exists, then at least the need for initial and frequent special process assessments must be determined.

The supplier needs to provide evidence that special processes have been identified and the methods necessary to control them have been implemented.

## 16. Element 16: Correspondence and Miscellaneous Documents

This element is used to store any relevant correspondence and misc. documents regarding the PPQ. Only those items that directly apply and have significance to PPQ should be included. This could include but not be limited to:

- minutes of meetings
- copy of important emails related to this product, process or qualification
- other documents or emails needed such as written temporary substitution information etc.
- any formal letters or correspondences received from Siemens Energy

## 17. Element 17: Personnel & Sub-Suppliers

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

- list of certified NDE, welding personnel and all personnel that need certificates of knowledge to be able to perform their work
- list of key supplier's personnel, i.e. a matrix showing the communication team (consisting of personnel from both Siemens Energy and the supplier)
- list of sub-tier suppliers involved with the product, materials etc.

The list of sub-tier suppliers should include what each sub-tier supplier provides to the supplier, their name, contact and location, list of outsourced services, who does it and where they are located, together with their contact information. This includes 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), if applicable.

## 18. Element 18: Product Inspection (FAI)

First Article Inspection is defined as the inspection of the "first" products produced using the proposed production process.

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 e.g.:

- quality specifications
- product specification
- purchase order
- engineering drawings / specifications
- other applicable design documents

This element is used to store:

- the result of the First Article Inspection and the related report
- related Minutes of Meetings
- the result of the Siemens Energy incoming inspection

## 19. Element 999: Confidential Information

This element can be used to store confidential documents and information that shall not be made available / visible to the supplier:

Examples are:

- Q-Gate MoM
- Q-Gate 2 hand-over presentation

- to-be material data
- risk estimates

### Custom Elements

If needed, additional custom elements may be added to the record. Custom elements should be clearly named after they have been communicated and agreed between SE and supplier. If a unique category number is necessary, it may be chosen with an element number starting from 20.

### Change management

Changes can be initiated during or after the PPQ-process, either by SE or by the supplier.

SE initiated changes are handled according to the applicable Change Management process in the responsible business area. It needs to be ensured that the changes are communicated to all affected parties, and they are reflected in the purchase order to the supplier (e.g. new revision of drawing or specification) before they apply.

Supplier initiated changes shall be forwarded to the pre-determined SE representative by submitting a Product Process Change Notification (PCN) or Quality Note (QN) via SAP before implementing the change. Changes might be e.g. design, location and/or changes to the frozen process. Supplier Quality evaluates the risk and the impact of the change with the cross-functional team and defines the change implementation actions. Supplier Quality informs the supplier about the decision and necessary additional activities, e.g., re-qualification.

### Abbreviations and Definitions

Ballooned drawing	A ballooned drawing contains numbered “balloons” that point to individual dimensions and requirements of the product.
CMM	Coordinate Measuring Machine
CofC	Certificate of Conformance
CpK	Process Capability Index
CTQ	Critical to Quality
ECM	Electro-chemical Machining
ECR	Engineering Change Request
EDM	Electrical discharge machining
FAI	First Article Inspection
FMEA	Failure Mode and Effects Analysis
Frozen process	A fixed process including steps needed to provide a product according to SE requirements.
Gage R&R	Gage repeatability and reproducibility
IGA	Intergranular attack
ITP	Inspection and Test Plan
MDR	Material Disposition Reports
MQCP	Manufacturing Quality Control Plan
MT	Magnetic particle testing
NCR	Non-conformance Report
NDE	Nondestructive Evaluation
NDT	Nondestructive Testing
PQR	Procedure Qualification Record
PT	Penetrant Inspection
QCI	Quality Control Inspection

QN	Quality Notification
QRP	Quality Record Package
RT	Radiographic Inspection
SPC	Statistical Process Control
UT	Ultrasonic Testing
WJC	Weld Joint cards
WJR	Weld Joint Records
WPQ	Welder Performance Qualification
WPS	Welding Procedure Specification