SIEMENS

EBQR

Energy Business Quality Requirements

Revision 2

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1 PURPOSE

The purpose of the Energy Business Quality Requirements is to formally communicate the requirements and expectations in addition to requirements of ISO9001. This specification and any other associated supplier used documents are available to view and download from Supplier Portal.

https://new.siemens.com/global/en/products/energy/supplier-information.html#SiemensCanadaLtd

2 CONTENT, SCOPE and APPLICABILITY

This specification applies to the suppliers and their subcontractors, who manufacture, furnish or process product against the purchase order/ schedule agreement demand of Siemens Energy Canada Ltd (SECL). This specification is the main flow- down document and shall be invoked as the mandatory requirements for the supply into Siemens Energy Canada Ltd (SECL). reserves the right to flow down additional requirements to satisfy customer and / or business requirements.

This specification comprises of two (2) chapters.

Chapter A: - Applicable to all suppliers or partners who supply product against SECL contracts / purchase orders.

Chapter B (or specific sections within): Applicable unless communicated by the Siemens Energy Canada Ltd (SECL). Quality representative. Unless otherwise agreed by the Siemens Energy Canada Ltd (SECL). Quality representative, all sections within Chapter B are applicable to all suppliers. Enables a supplier to obtain Product and Process Qualification (PPQ) approval from SECL.

3 FORMS

Forms to be used are included within the guidelines specific to each process and are available to view and download from the Guidelines section of Supplier Portal. (see also 1)

4 ORDER OF PRECEDENCE

Order of precedence for flow down requirements shall be:

a) Purchase Order
b) This Document
c) Long Term Agreement

5 ABBREVIATIONS AND DEFINITIONS

SECL	Siemens Energy Canada Ltd
BOM	Bill of Materials
CAGE	Commercial and Government Entity
COC	Certificate of Conformance
DOM	Date of Manufacture
FAI	First Article Inspection
FOD	Foreign Objects and Damage / Debris Prevention
QN	Quality Notification
PP	Production Permit
QMS	Quality Management System
RCA	Root Cause Analysis
KIT	A configuration of parts in accordance with a manufacturing bill of materials
NCR	Non Conformance Report
DAR	Drawing Alteration Request
NDT	Non Destructive Testing
SMC	Source and Method Change
SC	Source Change
PPQ	Product Process and Qualification
MDR	Manufacturer Defect Report
FM/FR	Fault Report
PDS	Product Disclosure Statement
FDR	Fault Discovery Report
NDE	Non-Destructive Evaluation
CR	Change Request
SCAR	Supplier Corrective Actions Report/Request

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Chapter A

A1 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

A1.1 Quality management systems certification and approvals

The Supplier Shall:

A) Establish a documented quality management system (QMS) that is independently assessed and certified by a certification body. The certification body must be accredited by a recognized national Accreditation Body to provide audit and certification of Quality management systems.

B) Ensure they work within the scope of their QMS certification and the scope of SECL. as communicated by business contact.

C) Ensure SECL. is notified should the approval be suspended or revoked or when major Non-Conformities (NCRs) are raised by the certifying Body.

D) Maintain a third party / other party approval for the following (as applicable):

a. Design, production - ISO9001[1]
b. Raw material manufacturers - ISO9001[1]
c. Testing and calibration laboratories - ISO/IEC17025

Note 1: T16949 is an acceptable alternative to ISO9001
Note 2: NADCAP accreditation is not SECL. requirement for special processes.

A1.2 Supplier Code of conduct

The Supplier Shall:

Demonstrate compliance with the minimum standard of business behaviors, health, safety and environmental practices applicable laws and regulations and act in a way that is ethical and corporately responsible as specified in Siemens supplier code of conduct.
www.siemens.com/procurement/cr/code-of-conduct

A1.3 Control of documents

The Supplier Shall:

Ensure correction to work Instruction or documents are recorded and traceable to the originator (e.g.
signature, stamp, etc) in ink or other permanent marking method with the original data being legible after the change.

A1.4 Control of Records

The Supplier Shall:

Control records related to SECL. product in a manner that will allow the recovery of a readable version of any records (including electronic records) by ensuring that:

- Records are retrievable on request within 24 hours.
- Data requiring authorization by SECL. are written in the English language or dual language i.e. the supplier's national language plus an accurate English translation made from the original document / record (see also A1.3)
- Records created by and / or retained by subcontractors / sub-tier suppliers are appropriately controlled in accordance with these requirements.

Note: Electronically scanned files are permissible In lieu of storing hardcopies. All electronic records must be controlled, retained and retrievable per the same requirements identified for hard copy records. For electronic records that are transferred from computer files, the storage media must be capable of maintaining the data integrity for the full retention period.

A1.5 Retention of Records

The Supplier Shall:

Retain the records for a minimum periods per category specified below:

A) **Category A:** Permanently. Retained permanently or until SECL has instructed the supplier to dispose of the records.

B) **Category B:** 6 years. Retained for (6) years minimum commencing from the date product was delivered to SECL. The supplier can dispose of these records at the end of specified period.

A2 RESOURCE MANAGEMENT

A2.1 Training, Competences and Awareness:

The supplier shall:

Establish a documented procedure for identifying training needs, achievement and review of competence of all personnel performing work directly or indirectly affecting conformity to product or production process requirements.

A2.2 Eye Examination

The supplier shall:

A) Establish a documented procedure to ensure that eye examinations, including visual acuity and color vision, as applicable are administered by a medically qualified or trained person, to all individuals
performing visual inspection and/or other product acceptance activities that require visual acuity.

- Intervals shall not exceed two year.
- Individuals shall be tested in at least one eye, either corrected or uncorrected.
- Color Perception testing is required one time only. Individuals shall be capable of adequately distinguishing and differentiating colors used in the method for which certification is required, the process being performed or inspection activity.

B) Documentation shall be retained for each individual performing

- Visual inspection (i.e. calibration, non-weld, in- process and final, layout, dimensional)
- Visual Inspections on Welds
- Nondestructive Testing (NDT)

A3.1 Critical items and assurance of product Integrity

The supplier shall:

A) Ensure personnel are aware of critical items incorporated into the SECL. product and the potential
consequences of delivering product that does not conform to requirements.[1]

B) Specify, as applicable, any critical items, during purchasing / subcontracting, product design and development and production design and development, including any key characteristics, and specific actions to be taken for these items.[1]

Note 1: Only applicable to drawings that specify critical control features/items.

A3.2 Control of work transfers (source change)

Control of work transfers (Source Change) is applicable to suppliers planning the temporary or permanent transfer of work and is used to control and verify that the product conforms to requirements during and after the following types of transfers:

- From the supplier's facility to another facility
- From the supplier's facility to a subcontractor / sub-tier supplier
- From a subcontractor / sub-tier supplier to the supplier's facility
- From one subcontractor / sub-tier supplier to another subcontractor / sub-tier supplier
- Any transfer of work within the supplier's facility that could have an effect upon the continuity of supply of product

Control of work transfers (source change) is NOT applicable to:

- Purchased standard catalogue hardware or deliverable software
- A proposed source that holds a current valid First Article Inspection Report (FAIR) or PPQ for the product
- Raw material purchased from a stockist / distributor
- SECL Global Indirect contracts

The supplier shall:

A) Establish a documented procedure for the control of work transfers (source change) to plan, control and verify the conformity to specified requirements during the temporary or permanent transfer of work. The procedure shall contain (but not be limited to):

- Formal notification to all stakeholders and customers before any change commences
- Risk assessment and mitigation
- Transfer plan
- Demonstration of capacity at the in-loading area to protect customer delivery
- Demonstration that generation of buffer stocks are built into load and capacity plans to protect customer delivery

B) Complete and submit the form(s) associated with this activity to their SECL purchasing contact (see forms below)
C) Proceed with the work transfer (source change) when a response has been received from their SECL purchasing contact and comply with requirements specified in the response.
D) Ensure that work transfer (source change) documentation / information is communicated along the purchase order cascade.
E) Ensure delivery performance is protected prior to any work transfer (source change).
F) Maintain records of work transfers (source change) as category 'B' (see A1.5).

A3.3 Purchasing / Subcontracting

Note: Only applicable to:

- Classified Components (Critical and Sensitive)
- Procurement of Castings and Forgings

The supplier shall:

A) Only purchase from a source holding appropriate certification (see A1.1) unless agreed with SECL Supplier Quality.
B) Unless otherwise noted from SECL, only purchase from a SECL approved source (see A1.1) unless the supplier (purchaser) is:

Approved / authorized by SECL to 'control subcontractors / sub-tier suppliers'

-------- OR --------

Purchasing the following:

- Conventional rough machining on castings or forgings to produce the 'condition of supply' shape / configuration

- SECL / RR. material specifications from a material stockist / distributor[1]
- Non-SECL/ RR material specifications from a material stockist / distributor[2]
- Non-SECL/ RR material specifications from a raw material manufacturer
- Industry standard parts (only qualified manufacturers shall be used when specified in a related
- technical specification)

-------- OR --------

Sub-contract/sub-tier approval is waived by SECL Supplier Quality Contact.

C) Ensure that the purchasing information / documentation:

- Communicates (flows down) the supplier's (purchaser's) requirements and SECL requirements
  (including applicable SECL Supplier Requirements) to subcontractors / sub-tier suppliers
- Specify the supporting documentation to be provided with the purchased product on receipt that
  states that the product meets specified purchase requirements.

D) Maintain records of purchasing / subcontracting as category 'B' (see A1.5)

Note 1: Traceability to the raw material manufacturer is required.
Note 2: Test to specification by a certified inspection and testing laboratory is required.

A3.4 Preventative Maintenance [1]

The supplier shall:

Identify key process equipment and provide resources for machine / equipment maintenance and develop an effective planned total preventive maintenance system that includes the following:

- Planned maintenance activities (including the identification of critical spares)
- Packaging, protection and preservation of equipment, tooling and gauging
- Availability of replacement parts for key production equipment
- Documenting, evaluating and improving maintenance objectives
- Identification and control of all safety-critical plant and equipment
- Loss to available capacity related to planned maintenance activities

Note1: Only applicable to the equipment and Processes utilized to fulfil SECL demand

A3.5 Customer Property

The supplier shall:

A) The Supplier shall exercise care with SECL property while it is under the Supplier's control or being used by the Supplier. The Supplier shall identify, verify, protect and maintain SECL property provided for use or incorporation into the product. SECL property that is lost, damaged or otherwise found to be unsuitable for use shall be recorded and reported to the SECL immediately to prevent delays in process or delivery.

B) Return all documents, records, gauging, tooling, stamps, or other customer supplied product upon written notification from Customer or when business with the Supplier has ceased.

A3.6 Foreign Object Debris (FOD) Prevention

The supplier shall:

Carry out a program for prevention, detection and removal of foreign objects from its products with minimum requirements as follows:

- A FOD training program shall be in place to increase employee awareness on causes and effects of FOD. The training is required for all employees and contractors (internal and

external) as applicable and shall be on going, (i.e., initial and periodic) to maintain employee awareness

- Establish a process to detect and prevent Foreign Object Debris. The process should contain the
following elements as a minimum:

  i. Physical entry control into FOD critical areas (where applicable)
  ii. Inspection for foreign objects prior to closing apertures and compartments during assembly. Ensure that all incidents of actual or potential FOD is reported and investigated (see A5.4)

A3.7 Storage and inventory

The supplier shall:

A. Provide secure storage facilities for product, equipment, tools and material
B. Ensure the conditions of storage prevent deterioration and damage of stored items
C. Assess the condition of product in stock at appropriate planned intervals in order to detect deterioration
D. Use an inventory management system to optimize inventory turns over time and assure stock rotation, such as “first-in-first-out” (FIFO)
E. Establish an inventory management procedure that includes (but is not limited to) the following:

   - Rule for determining safety stock levels
   - Method to guarantee inventory accuracy
   - Key performance indicators to monitor inventory
   - Method to monitor, review and action slow-moving work in progress
   - Control of shelf life product [1] [2]

F. Ensure segregation of serviceable product, equipment, tools and material from unserviceable product,
G. equipment, tools and material
H. Ensure that access to storage facilities is restricted to authorized personnel.
I. of their shelf life period remaining from the date of manufacture unless specifically agreed with SECL Supplier Quality representative.

Note 2: Products supplied to SECL spares division and subject to shelf life restrictions shall be supplied with a minimum of 75% of their shelf life period remaining from the date of manufacture unless specifically agreed with SECL Supplier Quality representative.

A4.1 Certificates of Conformance and Release documentation

The supplier shall:

A) Provide separate release documentation with each delivery to SECL. [3]
B) Ensure that the release documentation:

- Is written in English or in a language specified by the customer
- Refers to a single purchase order / schedule
- Refers to a single part number
- Is legible and protected from damage / deterioration
- Is attached to the outside of the secondary packaging and one copy included with the batch

C) Contains the following information as a minimum:

- Unique traceable document reference number
- Supplier's name, address and telephone number
- Country of origin
- Delivery address
- SECL purchase order number (including purchase order item number)
- SECL plant and storage location (when specified)
- Description of the product (as referenced on the SECL purchase order)
- Part number (as referenced on the SECL purchase order)
- Kit number (when applicable) – plus a list of part numbers, quantities, serial numbers
- Traceable reference (serial, batch, lot, heat, cast numbers - as applicable)
- Quantity
- Any applicable Concession/production permit references
- Quality plan number (if applicable)
- Date of dispatch
- Conformance / compliance statement[1]
- Signature of person authorized to release the product to the customer

D) Provide additional information (when applicable):

- Approved PPQ/First Article Inspection Report (FAIR) front sheet.
- Modification, repair scheme, or service bulletins
- Hazardous substances / safety data sheet (safety data sheet to be provided)
- Shelf life (cure date, batch, group) – no mixed cure dates / batches
- Virus-free declaration (computer software)
- Cross reference to the original raw material manufacturer's name (stockists / distributors)
- Cross reference to customer name and purchase order (material processors)

E) Provide a certificate of analysis or raw material manufacturer's certificate with the shipment of raw material that contains the following:

- Traceable reference to batch, lot, heat, cast numbers
- Chemical analysis including constituent elements and percentages
- Physical analysis, i.e., stress strain data, and temper

F) Maintain records [2] of release documentation as category 'A' when the product definition specifies. Fixed Process Control" (see B4.7). All other records will be maintained as category 'B' (see A1.5).

NOTE 1: Typical compliance statement: "Certified that the whole of supplies hereon has been inspected / tested and unless otherwise stated, conform in all respects to specification, drawing and purchase order requirements".

NOTE 2: Records of release documentation held electronically shall contain all of the information shown on the Original document and a traceable reference to the person authorized to release the product to customer.

NOTE 3: Electronically generated release documentation is acceptable without the physical signatures provided controls are in place at the supplier of un-intended use of authorized person credentials.

A4.2 Control of non-conforming product

The supplier shall:

A) Establish a method of detection and feedback of product nonconformities or process noncompliance.

B) Take necessary actions to contain [1] the effect of the nonconformity on other processes or products i.e. work in progress, stores stock, shipping area, in transit, sub-tier / subcontract activities, similar products, dispatched / delivered to customer (within 48 hours).

C) Stop shipment of product when notified of non-conformance by SECL. until appropriate corrective action has been established.

D) Parts deemed scrap must be clearly identified and rendered unusable within 30 days of final disposition unless otherwise instructed, in writing, by SECL.

E) Verbal agreements or instructions shall under no circumstances be construed as approval or authorization to deliver such parts.

F) Maintain records related to the control of nonconforming product as category 'A' (see A1.5).

NOTE 1: To assist SECL. Investigation related to the impact of any delivered nonconforming product, the supplier shall segregate any undelivered nonconforming product and hold until a response related to the disposal of the product has been received from SECL.

A4.3 Production Permit / Concessions

The supplier shall:

A) Complete and submit the form(s) associated with this activity to their SECL. contact.
B) Take appropriate corrective action.
C) If required, mark the product as indicated on the deviation permit / concession, including (but not limited to) the relevant concession category and concession number allocated

by SECL. in accordance with the applicable identification marking method (and location) specified in the product definition.

D) Ensure Concession is approved prior to the shipment of a product which does not conform to specified requirements. [1]

E) Maintain records of deviation permits / concessions as category 'A' (see A1.5).

NOTE 1: Cost of Non-Quality Claims

Following amounts are claimed as a standard charge (US dollars) by SECL for Quality Notifications in declared and un- declared categories.

- Concessions submissions (New, Revised and Rejects): $600
- Rejects at receipt: $850
- Rejects as a result of assembly/test complaints: $1100
- Rejects as a result of customer/operator complaints: $1800

This information could be found in the Supplier Portal, section Notice to suppliers: NTS SC 005 Quality cost:

https://assets.new.siemens.com/siemens/assets/api/uuid:30ffa9f3-6b21-4e85-9631-0ad0aa46d0df/version:1560775696/nts-sc005-dec-2015-suppliers-quality-cost-en-.pdf

A4.4 Quality and delivery performance

The supplier shall:

A) Monitor quality and delivery performance using key performance indicators [1]

B) Ensure 100% quality performance and 100% on-time and in-full delivery performance is achieved

C) Take appropriate corrective action when quality or delivery performance is not, or will not be, achieved

D) Inform their SECL purchasing contact immediately when delivery schedules are not, or will not be, achieved and submit a recovery plan (within 24 hours) to their SECL purchasing contact.

E) Use a cross-function team to develop continual improvement policy and plans to meet customer performance expectations.

F) Monitor the implementation of improvement plans and evaluate the effectiveness of the results.

NOTE 1: Where SECL has provided the supplier with a scorecard the supplier will use the score card as a Key Performance Indicator (KPI).

A5 ADDITIONAL REQUIREMENTS AND CLARIFICATIONS

5.1 Definition Alteration Request (DAR)

DAR is applicable to:

- Changes that DO NOT affect fit, form or function
- Changes that impact upon SECL requirements
- Changes that require a decision by SECL Engineering

The supplier shall:

A) Complete and submit the form(s) associated with this activity to their Quality Contact.[1]
B) Maintain records of definition alteration requests as category 'A' (see A1.3).

Note 1: Evidence of repeated Concessions/ Production Permit's acceptance on same feature and same deviation shall result in a DAR submission requesting updates to the drawings.
Note 2: Cost of Non-Quality Claims (see A4.3) is not applicable for Concessions applications if DAR is submitted to SECL.

A5.2 Reduced Inspection

The Reduced Inspection process is NOT applicable to purchased standard catalogue hardware.

The supplier shall:

A) Only apply reduced inspection of variables as a means of product acceptance when:

- Process stability and capability can be demonstrated during product verification activities
- Process capability data has met the requirements specified by SECL
- The proposed sample size and verification method of the product characteristic taken from every
- product within the batch has been documented in a control plan (see B1.4)
- The control plan (see B4.4) has been submitted to and authorized by the SECL.
- Or when otherwise approved by the Energy Business Engineering Design Authority

B) Only apply reduced inspection of formed characteristics [1] as a means of product acceptance when:

- Appropriate control methods such as control of process settings, tooling, standard processes and / or error –proofing have been introduced.
- Measurable evidence demonstrates that the control methods are effective and continually produce a product that conforms to requirements.
- The method by which the formed characteristic is produced plus the verification method and the
  verification intervals are documented in a control plan (see B1.4)
- The control plan (see B1.4) and measurable evidence of product conformance have been submitted to, and authorized by the SECL (on request)

C) Ensure that reduced inspection activities related to fixed process-controlled product (see B1.7) are appropriately controlled and authorized by their SECL prior to being introduced.

D) Ensure that reduced inspection is NOT applied to the following:

- Product used for First Article Inspection (see B1.18)
- Non-destructive testing inspection operations (unless specified in a controlling specification)
- Functional testing

E) Maintain records of reduced inspection as specified for product verification

NOTE 1: Reduced inspection of formed characteristics may apply to a group or family of products that are produced by the same process at the same source.

A5.3 Sample Inspection

The Sample inspection process is NOT applicable to purchased standard catalogue hardware.

The supplier shall:

A) Only introduce sample inspection as a means of product acceptance when:

- Process stability and capability can be demonstrated using variation management (see B 1.10, B1.11)
- The sample size and the verification method for each product characteristic under consideration has been documented in a control plan (see B1.4)

The control plan (see B1.4) and statistical data (see B 1.10, B1.11) have been submitted to, and authorized by the SECL. Ensure that sample inspection activities related to fixed process-controlled product (see B1.3) are appropriately controlled and authorized by SECL Quality, prior to being introduced.

B) Ensure that sample inspection is NOT applied to the following:

- Product used for First Article Inspection (see B1.18)
- Non-destructive testing inspection operations (unless specified in a controlling specification)
- Functional testing
- Product classified as critical (see RRES90002)

C) Maintain records of sample inspection as specified for product verification (see B1.3, B1.4, B1.5).

A5.4 Packaging and labelling

The supplier shall:

A) Ensure that products are packaged to a standard that provides adequate protection against damage, deterioration and tampering during shipment, storage and distribution.
B) Ensure that the product packaging is labelled to a standard that provides adequate identification and traceability of the product.
C) Establish work instructions (see B1.14) to ensure that the packaging and labelling of the

product is performed in a consistent and acceptable manner.

D) Compile a 'Packaging and Labelling Data Sheet' to define the packaging and labelling applied to the product and submit to SECL Quality (on request) (B 1.14)
E) Comply with the 'Protection Packaging and Labelling Guidelines [1].

NOTE 1: Protection Packaging and Labelling Guidelines is available to view and download from the Supplier Portal.

A5.5 Unclassified and Sensitive components

The supplier shall:

A) Use following exceptions for the drawings that flows down the following specifications [1]

• Drawing callout RRP50000- Technical Control of Manufacturing Processes: Special process approvals no longer require initial approval as mandated in RRP50000. The First tier is responsible for selecting and controlling sub tiers for special processes. The first tier does not require specific approval to select the Subtler, however; approval of the selected supplier must be in written agreement with the Siemens Technical Authority. Siemens will not maintain approval records nor issue approval certs for Special processes.

Siemens component specific validation and approval for the special process will be mandated and granted in the PPQ process. All component quality acceptance requirements are still applicable, RQSP, CME etc. Siemens Energy Canada Ltd reserves the right to audit the first tier and associated sub tiers if deemed necessary. If required, specific to part work instructions (data cards) will be requested, reviewed & approved in the PPQ process.

• Drawing callout RRP58000, RRP58003, RRP58004, RRP58006, RRP58007 & RRP58009 NDT inspection requirements: The specification RRP58012 category B applies. The intent is to allow the use of industrial specifications for the NDT inspection of the said parts.

In all the above both cases A and B, the approval to use selected supplier and alternative industry specifications must be in agreement with the Siemens technical authority using SMC and PPQ process.

- RRP58000 - Technical Control of Non-Destructive Testing.
- RRP58003 - Fluorescent Penetrant Inspection

- RRP58004 - Magnetic Particle Inspection
- RRP58006 - Radiographic Inspection
- RRP58007 - Visual Inspection
- RRP58009- Digital Radiographic Inspection
- RRP50000 – Technical Control of Manufacturing Processes.

Note 1: - The content of this NTS does not apply to Critical Parts.

A5.5 Parts with Fly Sheets

This section applies to those parts where Siemens drawing references Aero Common part number.

A) Concessions

The supplier shall:

Submit concessions directly to Siemens if Aero common part number is marked as per Siemens drawing " fly sheet". Disposition will be given to Fly sheet mentioned part number. Supplier assumes full
responsibility and shall not use Siemens disposition to accept similar nonconformities that may potentially end up on a RR product.[1]

B) Production Permits

The supplier shall:

Submit Production Permit directly to Siemens if Aero common part number is marked as per Siemens
drawing " fly sheet". Disposition will be given to Fly sheet mentioned part number. Supplier assumes full responsibility and shall ensure product is segregated during manufacturing; Inspection, certification and dispatch process, ensuring parts are only released against Siemens Purchase Order. [1]

C) Source and Method Change

The supplier shall:

Submit all documentation to Siemens for approvals under the Siemens part number. PPQ process will require all data cards, inspection reports, Certificate of conformity etc. Referencing the LW or Siemens part number. Siemens shall not approve any document with reference to Aero common part number. [2]

Note 1: - If supplier cannot ensure segregation of parts from RR, PP/ Concession shall be submitted to RR for approvals.

Note 2: - Alternate option: - Supplier shall submit application to RR under the Aero-Common part numbers. RR Approvals shall be included in the PPQ package for Siemens fly sheets part numbers in addition to other documents requested by PPQ lead (read across of RR approvals will be applied within PPQ).

CHAPTER B

1 Content, Scope and applicability

This section applies to those suppliers and their subcontractors, who will be participating in the Product and Process Qualification (PPQ) process. PPQ has replaced FAIR process and all new product introduced are subject to PPQ requirements.

- **PPQ is NOT applicable for the following (unless specified by the customer):**

- Purchased standard catalogue hardware or deliverable software
- Development product
- Product provided by the SECL to the organization

- **PPQ approval demonstrates that:**

- All customer design record and specification requirements are properly understood, accounted for, verified and recorded by the product supplier.
- The manufacturing process / tool / facility have the potential to produce product consistently meeting these requirements during an actual production process run at a quoted production rate.

- **It is the responsibility of the supplier to obtain PPQ approval from the customer.**

The supplier shall:

A) Obtain PPQ approval from the SECL technical authority [1] for the following:

- New product
- Product modified by engineering change (see A5.1)
- Correction of a discrepancy on a previous submission / product
- When specified by customer-specific requirements

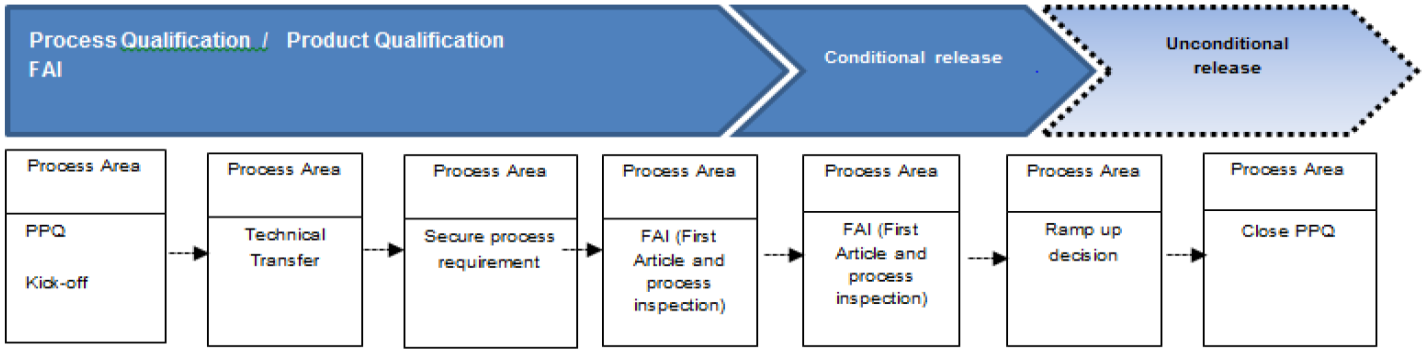
B) Establish a documented procedure to comply with the requirements of this chapter

C) Define the person(s) responsible for PPQ (supplier PPQ coordinator)

NOTE 1: Applicable PPQ elements specific to the component/ project will be communicated to Vendor in PPQ Kick Off meeting and all questions concerning the need for PPQ should be addressed to the SECL technical authority.

2 Process Flow

The PPQ process consists of following generic process steps as shown in diagram below



B 1 PPQ ELEMENTS

B 1.1 Product Release

This Element includes:

A) 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.

B) 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)
- Packaging 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

B 1.2 Supplier Drawings and Specifications

This Element includes:

- 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
- 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.

Note: - 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/ specifications will be utilized throughout the production process.

B 1.3 Critical to Quality (CTQ) Characteristics

This Element includes:

A) A list of CTQ's (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.

B) The CTQ's are defined by three (3) sources:

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

C) The CTQs are defined in a commodity-specific specification or 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.

D) 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.

E) 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.

F) Final CTQs to be monitored during serial production will be agreed at the end of the PPQ process (unconditional process approval) by the PPQ Team and must be referenced in the MQCP and FMEA documents.

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

H) ALL dimensions and tolerances for the part must be met whether they are marked as CTQs or not.

NOTE: - CTQs will start out requiring statistics from 100% inspection but this inspection can later on be reduced.

B 1.4 Manufacturing Quality Control Plan (MQCP)

This Element includes:

A) MQCP prepared by supplier using the Siemens template or own 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.

B) 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.

C) 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.

D) 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.

E) 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.

B 1.5 Inspection Records and Data Sheets

This Element includes:

A) A full dimensional layout inspection for at least one part covering all drawing requirements including drawing notes.

B) 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

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

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

B 1.6 Material Data

This Element includes:

A) 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.
- A 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 Certificate of Conformities, final material test reports, metallurgical analysis reports, functional test reports, etc.
- Metallurgical samples and pictures

B 1.7 Destructive & Non-Destructive Testing Records

This Element includes:

A) Non-Destructive Examination/Testing (NDE or NDT) results including test reports for NDT methods such as Penetrate Inspection (PT), Radiographic Inspection (RT or "X-ray"), Ultrasonic testing (UT), Magnetic Particle testing (MT) and others as applicable.

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

NOTE: - 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)

B 1.8 Metals Joining Documents

This Element includes:

A) 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).

B 1.9 Failure Modes & Effects Analysis (FMEA)

This Element includes:

A) Failure Modes & Effects Analysis carried out by the supplier. FMEA is utilized as a tool to identify possible process and design weaknesses and to aid the supplier in creating a more robust production process. Siemens provided excel template can be used to create the FMEA at the supplier.
B) FMEA shall include all production steps/operations (as well as additional consideration of possible failure related handling, packaging and storage) and utilize a cross-functional team from the supplier to ensure that potential failure modes and possible effects are analyzed.
C) The FMEA is a living document (i.e. not frozen at PPQ). It is 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.

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

NOTE: - The supplier shall use the RPN feature of the FMEA, however, to determine when corrective action is required shall be understood by the PPQ team. The use of RPN threshold for corrective action implementation (= 100) is Not recommended.

B 1.10 Process Capability

This Element includes:

A) Statistical analysis performed by supplier on all Siemens and supplier identified CTQ characteristics [1].

- 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 <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:

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

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

B) Process capability studies are not always suitable as method. The method is mainly recommended for products produced in sets or lager 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.

NOTE1: - 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.

B 1.11 Gauge Repeatability & Reproducibility (Gauge R&R)

This Element includes:

A) Evidence of Gauge R&R studies/results performed by the supplier to accepted Siemens methods demonstrating that the inspection measurement system being utilized on the CTQ is appropriate.[1][2]

B) The acceptance criteria for Gauge R&R are to be stated in terms of percent of tolerance.

$$\frac{P}{T} = \frac{5{,}15 \times \frac{\bar{R}}{d_2}}{\text{Tolerance}}$$ T=total tolerance i.e. ± 0.2 = 0.4

- 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 1.33 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.

C) 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.

D) 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 consider changes in ambient temperatures and humidity as well as off-shift personnel that may affect R&R.

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

F) 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.

Note 1: Wrong measurement system used, may result in a high Gage R&R result, which may add additional and preventable variation to the process.
Note 2: 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 Gauge 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 study 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.

B 1.12 Tooling & Gages

This Element includes:

A) 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.
- 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.

B1.13 Discrepancy Reports (NCR/FM/MDR) and Engineering Changes (CR/ECMI/DAR)

This Element includes:

A) 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").

- Engineering change requests (ECR) / Drawing Alteration request that affect the PPQ parts in qualification,
- List of manufacturing deviations (MDRs/NCRs, VEDAS Event, /Concessions/ Production Permits, ATLAS Q-notification) with closure dates (all manufacturing deviations must be closed before unconditional approval is granted).

NOTE: MDR's (Material Disposition reports) are used in the North American region for reporting material discrepancies.

B 1.14 Packaging Instructions and Photos

This Element includes:

A) Work instructions prepared by the supplier that explain how the parts will be packed/ preserved including photos showing the product/parts/set of parts in its packaging ready for shipment including shipping procedures and also parts markings showing what was marked on the part/ set of parts and where it was marked.

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

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

B1.15 Special Process Documentation

This Element includes:

A) Special lab certifications the supplier may have like Thermal spraying, Laser Cutting or other special processes like Post Welding Heat Treatment and Heat treat charts that are not included in the MQCP but provided by the supplier and tables showing ramp up, hold and cooling time and temperature and Hardening.

B) Results of the process that 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.

B1.16 Correspondence and Miscellaneous Documents

This Element includes:

A) All relevant correspondence and misc. regarding the PPQ like 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 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.

B1.17 Personnel & Suppliers

This Element includes:

A) Information on suppliers' key personnel, sub-tier supplier contacts and Siemens employees which are involved in the PPQ process.

- List of key supplier's personnel, (Top management, Manufacturing, QA, welders and all personnel that need certificates of knowledge to be able to perform their work)
- List of certified NDE/NDT and welding personnel including their certificates.

- 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 sub-tier supplier and approved sub-contractors that need certificates of knowledge to be able to perform their work or run production.
- 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.

B) List of suppliers used to buy parts / set of parts, materials etc for our SIEMENS product (e.g. helicoil, pipes,flanges, plates etc).

C) List of what each sub-tier supplier provides to the supplier, their name, contact and location.

D) List of outsourced services (calibration, NDE, Heat Treatment, welding etc), who does it and where they are located together with their contact information.

B1.18 First Article Inspection (FAI)

This Element includes:

A) Inspection of the "first" parts produced. This is performed at the supplier's location and 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.

B1.19 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#.