1.0 Purpose

The purpose of this procedure is to provide suppliers with details of mandatory documentation and process requirements when supplying parts to Siemens Laboratory Diagnostics (LD) Swords and Flanders sites.

1.1 Supplier Partnership Model

Suppliers are selected based on strategic fit, technical competencies, technology roadmap, cost competitiveness, and quality capability, with the aim of forming a collaborative long-term partnership with feelings of mutual trust. Quality is defined as not just conforming to print, but actual fit for intended use in Siemens end product. What it means to be a Siemens supplier is described in more detail in Appendix III.

1.2 Exception and Waiver

Any waiver to this document shall be documented in writing and approved through deviation by Siemens.

2.0 Scope

The requirements in this document apply to all products provided to Siemens LD Swords and Flanders from the initial design stage (when requested) all the way through to production release. A summary of these product development stages is presented in Appendix I – Project Phases.
The requirements in this document are supplemental to the Purchase Order Conditions of Purchase (POCP). In the event of any inconsistency between this document and the POCP, the terms in the POCP shall have priority.

3.0 Roles, Responsibilities and Functional Group(s)

Roles (Who is responsible to carry out the tasks)	**Responsibilities** (Major tasks to be carried out)	**Functional Group(s) / Teams that typically perform this role** *(Note: This list is not exhaustive.)*
Supplier	a. Adhering to all of the requirements specified in this document. b. Meeting all drawing requirements on all batches of all parts and implementing the necessary process controls to achieve this. c. Ensuring that they have reviewed and understood all of the requirements from Siemens. d. Addressing and resolving any incomplete, ambiguous, or conflicting requirements received from Siemens, prior to commencing manufacturing. Any content clarifications should be directed to the relevant Siemens Quality and/or Procurement contact.	• Supplier • Quality • Procurement

4.0 Process / Procedure Description

All deliveries into Siemens of purchased parts, as defined in Appendix II – Definitions - Product Type, must be accompanied by:

4.1 Quality Documentation

All required Quality documentation, as outlined in section 4.4 of this document, shall be provided to Siemens in the following manner:

Hard Copy Documents

a. Place quality documents in a clearly labeled envelope and include the envelope inside Box #1 for each lot of parts included in the shipment, with a label on the box stating “Quality Documents Enclosed”, or similar, to ensure that documents are easily found. The envelope should be placed so that it is easily retrievable without the need to unpack the parts.

- **DO NOT MIX QUALITY DOCUMENTATION IN THE ENVELOPE CONTAINING THE PACKING SLIP.**

- If there are multiple containers for each lot of parts sent with the shipment, clearly mark which container holds the quality documentation.

Electronic Documents

a. Upload quality documents to the Quality Document Submission application provided by Siemens. Ensure documents are uploaded to the Quality Document Submission application prior to the delivery of parts to Siemens.

4.2 Packaging and Shipping Labeling

Packaging and Labeling shall be provided to Siemens in the following manner:

a. Product must be sufficiently packaged to prevent damage throughout the shipping process. To the extent that the parties do not have any other agreement relating thereto, the products shall be packaged and transported in a defined and reproducible manner at the supplier’s responsibility.
b. For shipments with multiple boxes, the boxes must be marked to indicate box number and total number of boxes in the shipment (e.g. Box 2 of 5).
c. Labeling: Must remain in place and be legible during customary storage and use.

Cable harnesses (HARN) shall be individually packaged in clear bags. Bags should have labels that identify contents with their respective part numbers and revisions.

Printed Circuit Assemblies (PCA’s) shall be individually packaged using anti-static material and the label placed on packaging with part number and revision.

4.3 Packing Slip

A packing slip must be sent with all shipments and must contain the following:

a. Siemens Part Number and Part Version/Revision.
b. Siemens Purchase Order and Purchase Order Line Item #.
c. Quantity Shipped.

The envelope containing the packing slip must be attached to the outside of the skid/pallet, carton or box, visible and easily accessible.

4.4 Quality Documentation Requirements

Table 2 identifies the quality documentation that is required for Siemens Swords and Flanders sites. This is presented based on product type and supplier shipment number.

FAIR Quality Documents Requirements

The following documents must be submitted in order for a FAIR to be processed and approved. Note: all documents must be submitted to Siemens in English.

1. FAIR (Dimensional report including balloon diagram), see section 4.4.1
2. Certificate of Conformance, see section 4.4.2
3. BOM check, see section 4.4.3
4. RoHS/REACH, see section 4.4.4
5. Process Control Inspection Report / i-Diamond report (if applicable), see section 4.4.5

4.4.1 First Article Inspection Report (FAIR) including balloon diagram

1. **FAIR Definition:** A FAIR is a report generated following a process of measuring and evaluating all the properties and geometry of an initial sample from a lot/batch to verify that it conforms to the all the specifications of the drawing. A FAIR shall be carried out on a Top Level SMN and any subsequent lower level SMN's associated with that part.
2. **Criteria for when a FAIR report is required by Siemens:** The supplier must send a FAIR in the following cases:
   a. First shipment of a new Siemens Material Number (SMN).
   b. New revisions, covering at a minimum, verification of the changed features identified on the drawing.
   c. Where Form, Fit or Function of a part has been altered through engineering change or process change.
   d. Where the manufacturing location has changed.
   e. Where the supplier intends to use a new supplier of sub-assembly parts.
   f. If a previously submitted FAIR is rejected, a new FAIR must be provided.
   g. A FAIR is requested by Siemens.

3. **FAIR Template:** At a minimum the FAIR template must contain the following information:
   a. Supplier Name (supplier logo is acceptable)
   b. Actual Results - Dimensional
   c. Authorized and traceable Signature
   d. Clear designation that report is a FAIR/Siemens template or supplier equivalent
   e. Date of Signature
   f. Dimension Upper and Lower limits
   g. Drawing Dimensions/ Specifications including balloon diagram of released drawing (preliminary drawings not acceptable)
   h. Equipment Description
   i. Equipment ID
   j. Manufacturing Lot/Job/Batch number
   k. Manufacturing Lot/Job/Batch quantity
   l. Pass or Fail designation (for each feature)
   m. Sample Number
   n. SMN & Revision
   o. Siemens Production Purchase Order (PO) Number
   p. Test Results (where applicable)
   q. Comments column

4. Unless the equipment used can generate multiple parts at once (refer to detail #10 below), the FAIR shall be performed on a sample size of one (1) taken from the Production Lot of parts being sent to Siemens.
5. Supplier's FAIR must document 100% of the features that describe the part / assembly as defined by the Siemens drawing. These include:
   - Dimensions and tolerances
   - Material and Finish confirmation
   - Drawing notes
6. All information provided by the supplier must be consistent with the units of measure as dictated by the drawings/ specifications.
7. If the FAIR does not meet the requirements stated on the drawing, the product will not be accepted until a FAIR fulfilling the requirements is supplied.
8. The FAIR and all other relevant information should be sent with the shipment. In the event the documents are missing, Siemens will request them. If the documents are not provided in a timely manner, a quality notification (QN) may be issued and the supplier's monthly and annual evaluation results may be negatively impacted.
9. Data should be traceable to the actual part inspected for the FAIR. The sample used for the FAIR should be clearly designated when shipped to Siemens.
10. For equipment that can generate multiple parts at once (e.g., multi-cavity moulds or multiple dies), data will need to be submitted from each individual cavity or die, and the samples used for the FAIR must be marked accordingly.

11. Supplier is responsible for providing FAIRs for sub-components fabricated to a Siemens drawing.
    a) For common fabricated sub-components that go into multiple buy level assemblies, the supplier may send the original sub-component FAIR for the subsequent assemblies.
    b) If these sub-components are fabricated/ inspected by a secondary supplier, the FAIR requirement still applies.

12. If a dimension or feature was not measured, record "Not Measured" in the Actual Result field of the FAIR template. The pass/ fail and tolerance requirements can be listed as NM. A reason must be provided in the comments section of the FAIR as to why the dimension was not evaluated. The measurement of reference dimensions is optional.

13. The FAIR Template, LQSP-00087-LD-T1, should be used to record First Article (FA) data. The template may be customized by the supplier but must retain all the required fields. Any template that the supplier uses must be internally controlled by the supplier's Quality System and must contain all the fields/sections of LQSP-00087-LD-T1.

4.4.2 Certificate of Conformance (CoC)

1. A CoC is a document declaring that the material meets design and/ or purchase order requirements, see LQSP-00087-LD-T3 Certificate of Conformance template. A general quality statement of product conformance shall be contained within this type of certification.

2. Certificate of Conformance requirements:
    a) Authorized Signature & Date
    b) List of applicable Siemens deviation numbers (QN/TMD/XCR)
    c) Manufacturer's Lot/Job/Batch number
    d) Manufacturer's Lot/Job/Batch quantity
    e) Quantity Shipped
    f) Siemens Part Number & Revision
    g) Siemens PO Number
    h) Statement of Conformance to the Siemens Specifications
    i) Supplier Name
    j) As applicable, code compliance statement per section 4.6
    k) As applicable, statement of rework per section 4.19
    Note: For additional Commodity specific CoC requirements, refer to section 4.6.

3. CoC requirements are defined in Table 2. CoC's may be required before shipments are made.

4.4.3 BOM Verification

1. The supplier must verify item numbers, part numbers, and versions for each of the BOM levels of the supplied part (excluding COT's parts and subparts). Item numbers, part numbers and versions of items verified shall be listed on the FAIR.

2. A FAIR is required for higher level and subsequent lower level part numbers (excluding COT's parts and subparts).

4.4.4 Restricted Material - RoHS/REACH compliance statements

1. RoHS and REACH declarations are required for each part number supplied to Siemens.
2. The supplier is required to inform Siemens, via the BOMCheck portal (or in the EN62474 format), whether products delivered to Siemens contain any declarable substances. It is the responsibility of the supplier to maintain their records in the BOMCheck portal.
3. Siemens will contact supplier directly with this request, in advance of receipt of first delivery. This will form part of the RFQ and FAIR process.

4.4.5 Process Control Inspection Report / i-Diamond Report

1. There are two specific types of inspection features that can be identified on a Siemens drawing.
   a. i-Diamond 

designates a feature of the part for the purposes of manufacturing and assembly.
   b. Critical Quality Attribute(s) or CQA(s) 

designates critical to the function of the final product

   These markers identify part parameters that ***must*** be included on the Process Control Inspection Report with each delivery, unless an LQSP-00087-LD-F1 Part Specific Inspection Plan has been assigned and agreed upon by Siemens with supplier feedback. In this case, the LQSP-00087-LD-F1 will supersede the I-Diamond requirements.

   CQA features shall always be evaluated. There will always be a LQSP-00087-LD-F1 for individual parts with CQA designations.

2. A Process Control or Inspection/ i-Diamond Report is required for assemblies and components in the following situations:
   a. Where i-Diamond dimensions or features have been identified on the Siemens drawing (unless the supplier has received a Siemens part specific inspection plan).
   b. "CQAs" require a Process Control Inspection report (as per Table 2).

   Where i-Diamond or CQA's are not identified on the drawing a process control inspection report is not required.

3. If the any of the supplied parts are fabricated or inspected by a secondary supplier, the Process Control Inspection Report requirements still apply.
4. At a minimum the supplier Process Control Inspection Report must also contain the following information:
   a) Actual Results (for each sample)
   b) Authorized & Traceable Signature and Date of Signature
   c) Clear designation that the report is a Process Control inspection/ i-Diamond Report'
   d) Equipment Description
   e) Equipment ID
   f) Inspection Characteristics and Tolerances
   g) Manufacturing Lot/Job/Batch number
   h) Manufacturing Lot/Job/Batch quantity

i) Pass or Fail designation (for each feature)
j) Sample Quantity
k) Siemens Part Number & Revision
l) Siemens PO Number for top level assembly (not required for sub-components)
m) Test results (where applicable)

5. Sampling plans for incoming, in process, and final inspection must be adequate to establish confidence of acceptable material quality equivalent to or better than Squeglia C=0, AQL 1.0. The number of samples listed on the process control inspection report must reflect respective sampling plan used, refer to Appendix IV for an example of Siemens Sampling Plan
6. Inspection and test data generated shall be traceable by the manufacturer's production Lot / Job / Batch ID.
7. If multiple shipments to Siemens occur from a single production lot, the same Process Inspection Report can be submitted for all shipments if samples were randomly selected from the entire production Lot / Job / Batch.
8. Where test requirements are listed on the drawing the test results shall be included on the Process Control Inspection Report.
9. Where Statistical Process Control (SPC) can be used to show conformity to Siemens Inspection Requirements, a process capability report may be submitted in the place of measurements. If the supplier wishes to use SPC to show conformity, the supplier must work with Siemens to define requirements prior to implementing this process.
10. The Inspection Report, LQSP-00087-LD-T2, should be used to generate the process control inspection reports. If an alternate template is used, all information listed above must be to be included on that template. Any template that the supplier uses must be internally controlled by the supplier's Quality System.

The type of documentation required to accompany each batch/lot of material supplied to Siemens will depend on the product type. The product types are defined in Appendix II.

Table 2: Quality Documentation Requirements for parts supplied to Siemens LD

		Siemens LD Swords & Flanders Quality Documentation Requirements						
Product Type	**Supplier Shipment Number**	**FAIR**	**Sub Component FAIR**	**Process Control Inspection / i-Diamond Report**	**Sub-component Process Control Inspection / i-Diamond Report**	**CoC**	**BOM Verification**	**Code Compliance Data**
COTS	All	NA						Refer to section 4.6
Fab-P	1	**Yes**	No	**Yes**	**NA**	**Yes**	**Yes**	Refer to section 4.6
	Subsequent	NA	NA	**Yes**	NA	**Yes**	NA	
Fab-A	1	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	Refer to section 4.6
	Subsequent	NA	NA	**Yes**	Yes	**Yes**	NA	
Harn	1	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	Refer to section 4.6
	Subsequent	NA	NA	**Yes**	**Yes**	**Yes**	NA	
PCA	1	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	Refer to section 4.6
	Subsequent	NA	NA	**Yes**	**Yes**	**Yes**	NA	
Labeling	1	**Yes**	NA	**Yes**	NA	**Yes**	NA	Refer to section 4.6
	Subsequent	NA	NA	**Yes**	NA	**Yes**	NA	

Legend:
1 = First receipt of a new part or for a new revision of an existing part
Subsequent = All subsequent shipments of a part under the same revision.
NA = Not Applicable

4.5 Commodity Specific Requirements

Cable Harnesses **(HARN)** will also require the following information;

a. Agency (UL, CSA, etc.) File number (if applicable).
   - Mark can be visually seen on the part
   - C-of-C declaring safety listing and adherence to the requirement
b. Statement on C-of-C: “Harness was electrically tested to ensure all point to point connections are as defined per the drawing and there are no un-intended electrical short circuits per IPC standard identified on the drawing”.

Printed Circuit Assemblies **(PCA)** will also require the following information;

a. PCB Manufacturer
b. Testing if applicable (i.e. specified in Testing Specification)
c. Flame Rating of PCB (Bare Board)

4.6 Code Compliance Parts Requirements

Parts identified as code compliant parts must also include the following:

Additional **HARN, PCA, Fab-P, Fab-A and COTS** Part Requirements.

a. Work Order Number or Lot Number or Date Manufactured
b. Agency (UL, CSA, etc.) File number (if applicable)
   - Mark can be visually seen on the part
   - C-of-C declaring safety listing and adherence to the requirement

Additional **PCAs** requirements.

a. Fuse(s), Fuse Holder(s) & Relay(s) - Identify Manufacturer, Type, and Electrical Ratings. All Fuses, Fuse Holders & Relays used must be UL or CSA listed.
b. Comparative Tracking Index (CTI) Rating

Plastic Parts: **HARN PCA Fab-P Fab-A COTS**
Parts identified as CODE COMPLIANCE, must also include:

- Flame Rating of Plastics
- Completer List of Material(s) including the Complete Material Name(s)

Plastic Parts: **Fab-P Fab-A**
Additional requirements for assemblies with fabricated PLASTIC components

- Unique Batch Identifier (e.g. Work Order, Job, or Lot)
- Percent of re-ground material used (when regrind limits are identified on drawing)

4.7 Part Marking

For all commodities, please ensure that revision of part matches Siemens Purchase Order requirements. This must be reflected through part marking identification and supplier shipment documentation.

4.8 Controls

4.8.1 Process Controls

1. The supplier shall establish and maintain procedures and processes for the identification and lot traceability of parts with i-Diamond or Critical Quality Attribute(s) during all stages of production, as well as for delivery to Siemens. Identification must be traceable through to the finished product by serial numbers or Lot / Job / Batch ID. Both forward and backward traceability shall be available.
2. Inspection data generated by supplier shall at a minimum provide evidence of conformity to all Siemens identified inspection requirements, per section 4.10, and Critical Quality Attributes (CQAs) characteristics.
3. CQA parameters shall always be evaluated and the results recorded.

4.9 Inspection Measuring and Test Equipment (IMTE)

4.9.1 General Requirements

Suppliers shall ensure that all IMTE, including mechanical, automatic, or electronic inspection and test equipment, are suitable for their intended use. This applies to all IMTE used for in-coming, in-process, and final inspection as well as equipment used during validation/ verification activities.

a) Controls shall be in place to ensure that IMTE functions as intended; while in-use, in transit, or in storage
b) Supplier is responsible for maintaining records to provide objective evidence that IMTE is being maintained and calibrated

4.9.2 Calibration Requirements

The process for calibrating IMTE shall be defined and documented by the supplier. As part of the calibration requirements, the supplier shall maintain records of the IMTE calibration, equipment labeling, calibration processes used, and the frequency of calibration

a) IMTE are to be more accurate than the feature specified
b) The system must provide for regular routine calibration of IMTE
c) Calibration reference standards are to be traceable to a National/ International Standards

4.9.3 Preventive Maintenance (PM) Requirements

Suppliers shall document the process used for equipment maintenance, including preventive maintenance records, scheduling, identification, storage and shall perform maintenance in accordance with such plans.

4.10 Configuration Control / Deviation

1. Product/ Process Deviation – The supplier is not permitted to ship non-conforming product to Siemens. Noted discrepancies or requests for deviation shall be identified and communicated via the Temporary Manufacturing Deviation (TMD) process. The supplier is not permitted to ship such product until prior receipt of an approved copy of the TMD from Siemens.
2. If the deviation request is rejected, the supplier is NOT permitted to ship the non-conforming product to Siemens.
3. Supplier is not permitted to change any part of a process that may impact on the Form, Fit & Function of the product without obtaining prior agreement from Siemens.
4. If the supplier intends to change location, this must be communicated to Siemens in advance, allowing sufficient time to plan inventory cover and new site / process approvals as required.
5. Supplier cannot substitute any component or change the design of any component without receiving prior written approval from Siemens.
6. Under no circumstances is a supplier permitted to change their suppliers (i.e. Siemens sub suppliers) without first informing Siemens in advance.

NB – all parts produced post event as outlined in points 4.5 & 4.6 above, must be submitted to and approved via the suppliers own first article process and submitted to and approved via Siemens FAIR process.

4.11 Supplier Self Control

Suppliers have primary responsibility for managing their sub-suppliers and the resolution of technical issues. Suppliers shall develop a system for controlling the quality of the product they provide. Their system shall include verification that the manufactured item(s) agree with all the requirements stated in the Siemens drawing, function as required and that areas not specified but are of concern to Siemens are addressed and resolved. The supplier must notify Siemens before shipment if they are unable to comply with any requirements and must not ship unless approved by Siemens.

4.12 Quality Record Retention

1. Supplier shall establish and maintain procedures for identification, collection, indexing, filing, storage, protection, maintenance, retention, and disposal of all quality records in line with current good manufacturing processes.
2. The supplier shall maintain records that adequately provide evidence of adherence to the requirements specified in this document.
3. A copy of a record(s) shall be made available to Siemens within 2 business days of the request.
4. Prior to disposal of records pertinent to the product provided to Siemens, supplier shall contact Siemens for disposition.

4.13 Return of Non-Conforming Product to Supplier

1. It is Siemens expectation that all parts supplied meet specification. In circumstances where material is identified as non-conforming at either Incoming Inspection or within the production process, this material will be dispositioned through the Material Review Board (MRB).
2. Non-conforming material may be determined as either supplier liability or Siemens liability. This material will be returned to the supplier for repair with costs determined appropriately per the disposition.
3. Parts will be returned to suppliers on a discreet repair Purchase Order (P/O). Each P/O placed should be fulfilled within 3 months of placement, after this time Siemens will take the following action:

   For parts returned at supplier liability, the P/O will be closed and the parts will not be accepted after this time. The supplier has responsibility to dispose of the parts in such a way as to ensure the parts are not returned to Siemens under any other P/O, under any circumstance.

   Open P/O's for parts returned at Siemens liability, will be reviewed after 3 months have elapsed. Unless rationale has been received from the supplier for the delay in returning the parts, the P/O will be closed and the cost of parts debited against the supplier account.
4. The above control of P/O's is required to ensure that non-conforming material returned to suppliers is actioned in a timely manner, so that relevant data analysis is completed and process change implemented if required. Such timely action will help in maintaining overall process control.

4.14 Rework of Non-Conforming Material

1. Non-conforming material may be reworked by the supplier provided these operations are carried out according to written procedures and are carried out by personnel having the necessary knowledge and skill sets to perform the rework. Reworked material must be re-inspected and re-tested, and pass all originally specified requirements and quality attributes. The rework operations, including the re-inspection and re-tests, are to be recorded.
2. Documentation to be submitted by the supplier with reworked material must include but is not limited to:
   a) Certificate of Conformance,
      i) Statement of rework must be added. This is used by Siemens QC to determine inspection results needed. This statement is required even if the assemblies or components were replaced. This statement is required whether the rework is under a supplier cost or Siemens cost Purchase Order.
   b) Process Control Inspection Report when the rework affects CQA's or other specified Siemens inspection features (per section 4.10).
   c) Re-test data verifying conformity to specification.
   d) Remove any existing labels that identify the product as non-conforming, i.e. QN labels.

5.0 Terms

The definitions for these words can be found in the Diagnostics Glossary of Terms App or in DQSP 00021 A2 Diagnostics Glossary of Terms and Glossary Guidance.

- None.

6.0 Attachments

- Appendix I Project Phases
- Appendix II Definitions – Product Type
- Appendix III Supplier Partnership Model
- Appendix IV Sampling Plan

7.0 Required Documents (includes forms and templates)

- LQSP-00087-F1 Part Specific Inspection Plan
- LQSP-00087-LD-T1 FAIR Template
- LQSP-00087-LD-T2 Inspection Report
- LQSP-00087-LD-T3 Certificate of Conformance Template

8.0 References/Support Documents

(includes guidance and other documents needed to support the process in this procedure)

- DQSP-00001 Siemens Healthcare Diagnostics Quality Manual and references therein

APPENDIX I Project Phases

Phase 1: Design Phase:
Siemens develops using a set-based concurrent engineering model which can involve low volume prototype tooling, frequent small prototype trials and component/ formulation revisions. It is anticipated that the supplier will contribute to the specifications identifying key fit, form and functional criteria, to assure that the design meets the needs of both parties.

Phase 2: Pre-Production Phase:
Early Supplier Interaction (ESI) is entered into at this stage. Siemens will run pre-production trials concluding in a validation to assure the manufacturing processes and products. As Siemens partners, suppliers will become fully involved with design revisions and the Quality Plan evolution to address issues such as component tolerances.

Phase 3: Design Review and Product Verification
Design review and analysis of a product are scheduled at various stages as defined by the Product Development Process (PDP). This is the authorized process used by Siemens for new product development.

Phase 4: Production Release Phase
Once the design is complete and the process for the product is statistically stable and robust to specifications, Siemens will review the quality data and jointly decide the types of controls necessary for normal production. Simply stated, the more robust the supplier's product is relative to its specifications, the less the need for ongoing statistical and manual inspection techniques. Frequently, capable processes receive no special control requirements over the supplier's normal internal quality system.

APPENDIX II Definitions – Product Type

The type of documentation required to accompany each batch/lot of material supplied to Siemens will depend on the product type, the main product types are defined here:

Catalog Off-The-Shelf Parts – COTS

a) Defined by supplier created drawings or specifications.
b) Specified by the supplier or supplier's part number.
c) In some cases, a supplier supplied drawing is stored in the Siemens design control system and may be provided.
d) Examples include (but are not limited to): Unterminated Sensors, Valves & Motors, Hardware selected from supplier catalog, Ball Bearings, Hinges, Tubing Rolls, Communication Cables and Power Supplies.

Fabricated Parts (Fab-P)

a) Defined by Siemens created drawings or specifications.
b) Such parts DO NOT have a BOM as everything required to form the part is fully defined by the single drawing set.
c) Examples include (but not limited to): Machined Part (no pressed-in pins), Sheet Metal Part (no clinch nuts), Molded/Cast Parts (no inserts), and Hazard Labels.

Fabricated Assemblies (Fab-A)

a) Fabricated Assemblies are anything that specifies the joining of a defined set of parts on a Bill of Material (BOM), where the joining is defined by a Siemens created drawing.
b) The BOM components may be anything from machined, molded, or formed material parts, to purchased Electrical or Hardware items.
c) Examples include (but not limited to): Motors with Gear, Connector & Encoder, Valves with Connectors, Terminated Sensors, molded Parts with molded-in Hardware, Sheet Metal with Clinch Nuts and Machined Parts with Pressed in Pins. In all cases, these parts have a BOM.

Cable Harness Assemblies (HARN)

a) Cable Harness Assemblies are fabricated from standard harness materials (connectors, wires, etc.) where the components are defined by Supplier created drawings or specification. Only wire cut lengths and selection are defined by Siemens specification.

Printed Circuit-board Assemblies (PCAs)

a) PCAs can be either populated circuit boards or a collection of boards in a fabricated enclosure. This type of assembly collects COTS components (ICs, resistors, etc.) with custom Circuit Boards and Enclosures.
b) Test Specifications may be required to verify functionality of the Board Assemblies.
c) Boards & Enclosures will require documentation proving they meet requirements.

Labeling

a) Package labels
b) User Manuals
c) IFUs (Instructions for Use)
d) Product labels
   - Containing Content Identification, Revision, Part Numbers, Batch or Lot number or Serial Number

Table 3 below illustrates the information that will be provided to the supplier by Siemens for each product type.

Table 3. Siemens Material Specification by Product Type

Product Type	Assembly or Inspection Drawings	CAD Files	Bill Of Material	Supplier ID and Supplier P/N	Schematics	Fab File, Artwork, Schematic, Gerber File	PCA Test File
COTS	-	-	-	Yes	-	-	-
Fab-P	Yes	Yes	-	-	-	-	-
Fab-A	Yes	Yes	Yes	Yes	-	-	-
HARN	Yes	-	Yes	-	Yes	-	-
PCA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Labeling	Yes	-	-	-	-	Yes	-

APPENDIX III Supplier Partnership Model

What does it mean to be a Siemens Supplier?

1. Suppliers are selected based on strategic fit, technical competencies, technology roadmap, cost competitiveness, and quality capability, with the aim of forming a collaborative long term partnership with feelings of mutual trust.

2. Supplier is expected to pro-actively enable the quality of material supplied to Siemens, and develop a system to control the quality and verification of material, the target is approved FAIR with no re-spins. Quality is defined as not just conforming to print, but actual fit for intended use in Siemens end product.

3. Supplier is expected to proactively innovate to assure achievement of cost target as design evolves to meet function.

4. Siemens intent is to integrate suppliers as early as early possible into the design process (ESI), with expectation that supplier will provide insight to mature the design from their expertise and technology, and also provide cost estimates and prototypes at fast turnaround to support project schedules.

5. In maturing designs and solving any non-conformities it expected that a proactive technical problem solving model be applied by supplier.

6. The supplier and Siemens continue to interface and share relevant expertise regarding end use, new innovations, new technology, to influence the product for mutual benefit (continuous improvement in cost, robustness and lead-time).

APPENDIX IV Sampling Plan

	Index Values (Associated AQLs)															
	0.010	0.015	0.025	0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10.0
Lot Size	Sample Size															
2 to 8	*	*	*	*	*	*	*	*	*	*	*	*	5	3	2	2
9 to 15	*	*	*	*	*	*	*	*	*	*	13	8	5	3	2	2
16 to 25	*	*	*	*	*	*	*	*	*	20	13	8	5	3	2	2
26 to 50	*	*	*	*	*	*	*	*	32	20	13	8	5	3	2	2
51 to 90	*	*	*	*	*	*	80	50	32	20	13	8	7	6	5	4
91 to 150	*	*	*	*	*	125	80	50	32	20	13	12	11	7	6	5
151 to 280	*	*	*	*	200	125	80	50	32	20	20	19	13	10	7	6
281 to 500	*	*	*	315	200	125	80	50	48	47	29	21	16	11	9	7
501 to 1200	*	800	500	315	200	125	80	75	73	47	34	27	19	15	11	8
1201 to 3200	1250	800	500	315	200	125	120	116	73	53	42	35	23	18	13	9
3201 to 10,000	1250	800	500	315	200	192	189	116	86	68	50	38	29	22	15	9
10,001 to 35,000	1250	800	500	315	300	294	189	135	108	77	60	46	35	29	15	9
35,001 to 150,000	1250	800	500	490	476	294	218	170	123	96	74	56	40	29	15	9
150,001 to 500,000	1250	800	750	715	476	345	270	200	156	119	90	64	40	29	15	9
500,001 and over	1250	1200	1112	715	556	435	303	244	189	143	102	64	40	29	15	9

Source: Squeglia, N.L., *Zero Acceptance Number Sampling Plans*, 4th ed., ASQ Quality Press, Milwaukee, WI, 1994.

For example, for a batch size of 200, a sample quantity of 20 parts are required to have i-Diamonds/CQA parameters measured.

(Supplier Name)

SIEMENS Healthineers

Classification:

- ◉ **First Article Inspection Report**
  - ☐ Initial Shipment of a New Part
  - ☐ Supplier Manufacturing Process Changed
  - ☐ Other (explain): _____
- ○ **Inspection Report**

Part Information:

Siemens Part Number: _____ Siemens Part Rev: _____

Siemens PO Number: _____ MFG Lot/Job Number: _____

Sample Quantity: _____ MFG Lot/Job Quantity: _____

Name	Function	Signature and Date YYYY-MM-DD

Feature #	Sample #	Model or Drawing Dimension Value	High Limit	Low Limit	Actual Dimension	Pass /Fail	Equipment Description	Equipment ID	Comments/ Siemens Audit Results (List applicable QN number(s) below)

Feature #	Sample #	Model or Drawing Dimension Value	High Limit	Low Limit	Actual Dimension	Pass /Fail	Equipment Description	Equipment ID	Comments/ Siemens Audit Results (List applicable QN number(s) below)

SIEMENS Healthineers

Process Control Inspection / i-Diamond Report

(Supplier Name)

7

Siemens PO Number:	
Siemens Part Number:	
Siemens Part Revision:	**Sample Size:**
MFG Lot Number:	**MFG Lot Qty:**

Authorized Signature:	**Name:**	
	Signature:	**Date (yyyy/mm/dd):**

Page ___ of ___

	Inspection Characteristic and Tolerances	Sample: ___	Sample: ___	Sample: ___	Sample: ___	Sample: ___	Sample: ___	Sample: ___	Equipment Description	Equipment ID	Pass/Fail	Comments (List applicable QN/TMD
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												
18												
19												
20												

Supplier name

Address etc

Date

Certificate of Conformance

Suppliers name certify that etc…….conform to the Siemens Specifications.

Siemens PO number:

Siemens SMN:

Revision:

Manufacturer's Lot/Job/Batch number:

Manufacturer's Lot/Job/Batch quantity:

Quantity shipped:

Applicable Deviations: If no deviations type N/A

Statement of rework (per section 4.19): If no rework type N/A

Code compliance statement (as per section 4.6) :

Authorized Signature & Date

_____

Part Specific Inspection Plan

Version

SMN		Siemens Sites Effected:	
Vendor code(s)		Vendor Name :	

Approvals (Requires approval from affected sites for shared SMN's)

Vendor Approver Name	Dept	Signature	Date
SIEMENS Approver Name and Site	**Dept**	**Signature**	**Date**
SIEMENS Approver Name and Site	**Dept**	**Signature**	**Date**
SIEMENS Approver Name and Site	**Dept**	**Signature**	**Date**

Inspection Plan

ID reference # or SMN #	Zone (If Needed)	Inspection Attribute:	AQL / Sample Size	Comments

Additional Comments: