Supplier Quality Controls Procedure

# Document Control

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| --- | --- |
| Process Owner: | Document Number: 2.PQA.020 |
| Quality Assurance | Revision: N |

# Purpose

## The purpose of this procedure is to document the system of quality controls utilized by General Atomics Aeronautical Systems, Inc. (GA-ASI) in order to ensure externally provided processes, products, and services conform to requirements.

# Scope

## This procedure applies to the processes used at General Atomics, Aeronautical Systems Inc. to ensure conformity of externally provided processes, products and services.

## The procedure applies to production as well as prototype processes.

## This procedure includes identification of quality risks associated with externally provided processes, products, and services.

## This procedure defines and employs appropriate controls for both direct and sub-tier external providers.

## This process begins when a new supplier is requested, a change to an existing supplier is requested, or action is required for an existing supplier. The process ends when GA-ASI ends its relationship with the supplier.

# Roles & Responsibilities

|  |  |  |
| --- | --- | --- |
| Role Name | Disciplines | Key Responsibilities |
| Quality Engineering Director | Program Quality Engineer,  | Flows source inspection requirements to Supplier Quality Engineer (SQE) when requested by the customer. |
| Supplier Quality Manager | Supplier Quality  | Responsible for ensuring that the supplier contracts procedure is implemented. Assigns a SQE or Inspector to source inspection activity. |
| Supplier Quality Engineer (Software Quality for Software Suppliers) | Supplier Quality  | Participates in Supplier Management Teams (SMTs). Works with Procurement to identify suppliers that require an audit. Schedules, conducts and records results of supplier audits. Participates in Capability Reviews, Requirement Reviews or Surveillance Visits. Establishes and maintains quality clauses, Audit activities, Supplier Corrective Actions, Non-conforming material management. |
| Quality Engineer | Program Quality Engineer, RATWorks Quality  | As required, participates in SMTs, supports audits, Capability Reviews, Requirements Reviews, and Surveillance visits. RATWorks QE assigns Standard Purchase Request (SPR) Q-Clauses for RATWorks projects as defined in 2.TS.029 Standard Purchase Requisition (SPR) for Engineering Parts Procedure. |
| Buyer | Purchasing,Subcontracts Management,  | Participates in SMTs. Conducts procurement activities per GA-ASI Procurement Procedures. Works with Supplier Quality and Strategic Supplier Management to identify suppliers that require improvement. Participates in Requirements Reviews. |
| Supplier Management | Strategic Supplier Management (SSM) | Participates in SMT, Defines and manages strategic suppliers per 2.SAM.023 Supplier Management Program Procedure. |
| Engineer | Electrical Engineering; Mechanical Engineering; MS Support Engineering; Project Engineering | As required, participates in SMTs, Capability and Technical Reviews, Requirement Reviews or Surveillance Visits, support Non-conforming material evaluation. |
| Manufacturing Engineer | Manufacturing Engineering; FOF Manufacturing Engineering | As required, participates in SMTs, Capability and Technical Reviews, Requirement Reviews or Surveillance Visits, support Non-conforming material evaluation, and ensures production control procedures are followed when non-conformances are observed. |
| Receiving Inspection | Quality Control – Receiving Inspection | Verifies compliance to Purchase Order (PO) requirements. |

# Process Inputs

## Approved Supplier List (ASL) Requests

### New Supplier Request

### Supplier Change Requests

## Quality Information Record (QIR) Request to add either a new part or a revised part to supplier’s portfolio.

## Customer requests source inspection or determined necessary by SQE.

## Non-conformances are observed.

### At receiving inspection Systems, Applications & Products Quality Notification (SAP QN)

### In production (SAP QN)

### In the field Failure Reporting, Analysis & Corrective Action System (FRACAS)

### Corrective and Preventive Action (CAPA)

## Supplier performance review results in poor performance

## Supplier visits/audits/Critical Safety Item (CSI) Audit Schedule

# Process Outputs

## Updated ASL Supplier Status in SAP

## Supplier audit/visit results

### Trip / Audit reports – 2.PQA.020-002 Supplier Trip Report Template

### Supplier Quality System Survey Checklist (2.SAM.023-004)

### GA-ASI Software Supplier Quality Assessment Survey (2.PQA.020-005)

### Meeting the CSI Audit Schedule

## Supplier Rating

## Completed Quality Information Record (QIR) in SAP

## Supplier CSI parts meet requirements per 2A.TS.013

## Completed Supplier Survey Checklist Counterfeit Part Mitigation (2.PQA.020-003)

# Entry Criteria

## A supplier exists on the ASL

## A new supplier is requested

# Exit Criteria

## GA-ASI has ended its relationship with the supplier.

# Process Procedure

## Note: This procedure addresses Suppliers of processes, products and services, either of which may include software. For suppliers of software services or products that contain software, SQE shall enlist Software Quality to determine and execute controls requirements.

## New processes, products, and services

### Supplier Quality Engineer (SQE) is notified through the material master validation process of new product to be purchased or a product that requires a new process.

### SQE, along with Quality Engineer as required, and RATWorks Quality if for a RATWorks project, review the requirements for the process, product, or service being acquired.

### Based on requirements, SQE, determines the Quality Clauses (Q-Clauses) appropriate for parts or services procured on a PO/SPR. SQE or RATWorks QE (as defined by 2.TS.029 determines quality clauses for parts or services procured through SPRs). Q-Clauses may be imposed on any PO/SPR to communicate requirements to suppliers and are defined in form 2.PQA.020-001 Q-Clauses. Refer to Appendix A, Q-Clause Assignment Guidance for assigning Q-Clauses.

#### Requests for Q-clause assignments and approval are routed to SQE using SAP Workflows for parts managed in SAP. For SAP released parts, Q-Clauses are maintained in the material master in the Enterprise Resource Planning (ERP) system.

#### SAP workflows to assign Q-Clauses are also used for Non-SAP parts. However, Q-Clauses for non-SAP managed parts are maintained in the SPR/PO line item.

#### Quality clauses for parts not managed in SAP may be added if specified by the requestor, SQE or RATWorks QE.

#### In unique cases, separate quality clause documents may be created and tailored for specific suppliers. For example, 2.PQA.020-004 Quality Clauses – L3Harris-CSW Modifications. Such documents should be created in collaboration with SSM and Procurement.

### For some customers, procedures for CSI may be contractually imposed and CSI parts are identified per 2A.TS.013 CSI Procedure. If the part is a CSI, SQE will ensure procedural requirements are met.

## Requests to add or make changes to ASL suppliers

### Additions and Changes to the ASL are conducted in accordance with (IAW) 2.SAM.004 Approved Supplier List Procedure, using form 2.SAM.004-001 ASL Request additions and changes to the ASL are conducted in accordance with 2.SAM.004 Approved Supplier List Procedure, using form 2.SAM.004-001 ASL Request Form – Add Supplier and 2.SAM.004-004 ASL Request Form – Supplier Change. The ASL Approval status in SAP is used to control which suppliers may be issued POs for production processes, products, or services. Supplier ASL Approval status is initiated, maintained, and controlled in SAP by SQE. Supplier ASL Statuses are detailed in Appendix B.

## Supplier to Supplier Part/Product/Process/Service Moves

### Driven by business need, Procurement may request to move a process, product, or service from one approved supplier to another approved supplier or from a part that is produced at GA-ASI to a supplier. For parts that require a First Article Inspection, the Buyer will request a Quality Information Record (QIR) update for the supplier in SAP. The receiving supplier shall be reviewed, at minimum, by SQE. If necessary, SQE will consult with Engineering and Quality to ensure technical and quality capabilities are adequate to meet requirements.

#### Review drawing to evaluated changes, if any, to requirements

#### Review supplier to ensure capabilities are approved

#### Update Quality Information Record (QIR) in SAP

#### If the part is a contractually imposed CSI by the customer, SQE will ensure procedural requirements are met per 2A.TS.013.

#### If the supplier is new, 2.SAM.004 will be followed.

## Quality Controls for Existing Suppliers

### For Suppliers listed on the ASL, performance is monitored and ASL change requests are reviewed, to determine if the Supplier’s performance and capabilities meets the GA-ASI goals and metrics.

### Quality performance evaluations for suppliers on the ASL are conducted in a number of ways. These tools and methods are used to determine if further action is required by GA-ASI and/or the supplier in order to provide compliant product to the Customer.

#### Performance Ratings are determined quarterly through the Performance Rating Process and Supplier Review Board (SRB) per 2.SAM.023 Supplier Management Program Procedure.

#### Receiving Inspection verifies Supplier compliance to requirements per 2.PQA.013 Receiving Inspection Procedure and adhering to inspection plans created per 2.PQA.021.

#### Notifications to SQE from Suppliers for potential escapes are evaluated and processed per 2.PQA.003 Control of Nonconforming Material Procedure and 2.PQA.025 Suppler Disposition Request.

#### Quality Notifications (QNs) are issued per 2.PQA.003 Control of Nonconforming Material Procedure.

##### Each item of each QN coded with a supplier related cause code will also be assigned a Defect Class in SAP by SQE.

##### Defect Classes are assigned “Supplier responsible High”, “Supplier responsible Med”, “Supplier responsible Low”, or “No Impact on Rating” as defined in SAP.

##### Defect Classes are used to calculate the quality rating portion of supplier performance ratings.

#### FRACAS monthly reports are reviewed and analyzed.

#### Supplier surveillance visits are conducted and/ or Audits are executed per schedule or Customer Request. Refer to Appendix C, Types of Supplier Site Visits/Audits. Refer to Appendix D, Site Visit Matrix based on Supplier Significance. Refer to the “Supplier Audits” section in this document for further details on conducting audits.

### Per 2.SAM.023, results of these processes and tools are reviewed in quarterly Supplier Review Boards, led by Strategic Supplier Management. Participation in the SRBs is by SSMs, SQE, and Buyers. Adequacy of performance is evaluated. Action Items generated during the SRB are documented and tracked to closure at subsequent meetings.

### SQE, Quality, and/or Procurement determine if further action is required based on performance. The performance period can be based on a single QN or per Quarterly reviews.

#### Corrective and Preventive Action (CAPAs) per 2.PQA.009, Corrective and Preventive Action (CAPA) Management Procedure may be issued by the SQE. SQE may also issue CAPAs for a non-conformance discovered in Receiving, during Manufacturing, or as a result of a FRACAS report without waiting for the quarterly performance report.

#### When necessary, improvement plans, sometimes referred to as “Return to Green (R2G) plans”, are developed by Procurement, in conjunction with Quality, Supplier Quality, and Engineering SMEs as required, and executed with the supplier.

#### Unscheduled audits may be conducted by the SQE, Procurement, Manufacturing Engineering, and Engineering as required (see “Supplier Audits” section in this document).

#### Surveillance visits may be scheduled by the functions indicated in Appendix C.

#### Source inspection may be implemented, including customer mandated source inspection (see section 8.6 of this document).

#### Per 2.SAM.004, suppliers may be removed from the ASL if supplier efforts to improve performance do not result in meeting the expectations. Removal from the ASL may also occur if the supplier’s process, product, or service is no longer required.

## Supplier Audits

### Supplier audits are used to evaluate a supplier’s quality system. SQE and SSM identify the suppliers that require an audit, which typically include suppliers of production items.

### SQEs may conduct supplier quality management system audits prior to contract award, for periodic surveillance as determined by SQE, as a result of performance degradation, or per customer requirements. Approval from a recognized customer or a third party registrar/accreditation body may be utilized in lieu of an initial audit if determined sufficient by SQE and SSM. Supplier audits are performed on-site at the supplier’s facility.

### Audits may be conducted for GA-ASI direct suppliers or for sub-tier suppliers. When conducting an audit at a Sub-Tier supplier with which GA-ASI does not have a direct relationship, the SQE will coordinate the audit through the direct supplier.

### On-site supplier audits may be waived for Commercial-off-the-Shelf (COTS), distributors, or non-CSI part providers as directed by SQE supervision.

### Per 2A.TS.013, CSI parts require annual process audits. Notification to the customer prior to the process audit is required. The customer has the option to participate or waive participation in the process audit.

### Results of audits are maintained in the Quality Management System (QMS) database by supplier name and six-digit supplier number, including related records such as:

#### Trip reports

#### Checklists

#### Supplier documents

#### Third party certifications

#### Any other relevant records

### For suppliers of applicable electronic parts (defined as integrated circuits, discrete electronic components including, but not limited to, a transistor, capacitor, resistor, or diode, or a circuit), SQE performs a survey of procedures to address prevention of use of Counterfeit parts using 2.PQA.020-003 Supplier Survey Checklist Counterfeit Part Mitigation. If a survey was previously conducted, a new survey does not need to be conducted unless a result of performance issues.

### If the Audit results in findings, SQE issues a CAPA to the supplier.

## Source Inspection

### SQE may initiate source inspections when: material is to be drop-shipped, material is large, expedited acceptance is required, there is a history of quality problems, critical inspect/test points are not available at final inspection, or mandated by the customer. Source inspections may be performed by GA-ASI, third party services or customer representatives and may be discontinued or waived when deemed appropriate by Quality Engineer or the customer. Waivers must be in writing, and are issued from Quality Engineer to the supplier. The supplier must include the written waiver with each shipment.

### Source Inspection may be requested by Defense Contract Management Agency (DCMA). Mandatory source inspections requested by the customer, per contractual requirements, are flowed to the Quality Engineering Director who notifies the Supplier Quality Manager. SQE applies Quality Clause Q-1, Government Inspection to the product(s) in the ERP material master.

### When source inspection is performed, the method of product release is a stamp or signature by the Buyer’s Quality Representative or DCMA representative on the Seller’s shipping or inspection documents.

## The management of the supply base used in support of product development / prototyping (non-SAP material) is performed in accordance with 3.PQA.020.1 RATWorks Supplier Quality Control process.

## Disposition Requests may be made by the supplier and are executed using 2.PQA.025 Supplier Disposition Request Procedure. The SDR process documents a method for allowing a supplier to report a discrepancy, product escape, suggested design improvements and design changes that requires GA-ASI review, disposition and approval.

# Metrics

## Supplier Quality metric

# Associated Process Documents

## 2.PQA.003 Control of Nonconforming Material Procedure

## 2.PQA.009 Corrective and Preventive Action (CAPA) Management Procedure

## 2.PQA.013 Receiving Inspection Procedure

## 2.PQA.020-001 Quality Clauses

## 2.PQA.020-002 Supplier Trip Report

## 2.PQA.020-003 Supplier Survey Checklist Counterfeit Part Mitigation

## 2.PQA.020-004 Quality Clauses – L3Harris - CSW Modifications

## 2.PQA.020-005 GA-ASI Software Supplier Quality Assessment Survey

## 2.PQA.020-006 Certificate of Volatility (COV) Form

## 2.PQA.021 Inspection and Testing Procedure

## 2.PQA.025 Supplier Disposition Request Procedure

## 2.SAM.004 Approved Supplier List Procedure

## 2.SAM.004-001 ASL Request Form – Add Supplier

## 2.SAM.023 Supplier Management Program Procedure

## 2.SAM.023-004 Supplier Quality System Survey Checklist

## 2.TS.029 Standard Purchase Requisition (SPR) for Engineering Parts Procedure

## 2A.TS.013 Critical Safety Item (CSI) Procedure

## 3.PQA.020.1 RATWorks Supplier Quality Control

# Process Flow

##

# Definitions and Acronyms

## Definitions

|  |  |
| --- | --- |
| Desk Audit | An audit performed without visiting the supplier site. The audit includes review of supplier provided documents and certifications, website verification of information and references, and verification of previously determined capabilities against the required capabilities of a product, process, or service. |
| Production Process | Any manufacturing process used in the creation of products and services with the intent of being sold to customers. |
| Production Product | Any product made or purchased by GA-ASI then sold to GA-ASI customers. |
| Production Services | Any service sold by GA-ASI to enable operation of or support production products. |

## Acronyms

|  |  |
| --- | --- |
| ASL | Approved Supplier List |
| CAPA | Corrective and Preventive Action |
| COTS | Commercial Off-the-Shelf |
| CSI | Critical Safety Item |
| DCMA | Defense Contractor Management Agency |
| ECC | Enterprise Central Component |
| ERP | Enterprise Resource Planning |
| FRACAS | Failure Reporting, Analysis & Corrective Action System |
| GA-ASI | General Atomics Aeronautical Systems, Incorporated |
| IAW | In Accordance With |
| PO | Purchase Order |
| PR | Purchase Requisition |
| QIR | Quality Information Record |
| QMS | Quality Management System |
| QN | Quality Notification |
| RATWorks | Rapid Action Team Works |
| R2G | Return 2 Green |
| SAP | Systems, Applications & Products in Data Processing |
| SMT | Supplier Management Team |
| SPR | Standard Purchase Request |
| SQE | Supplier Quality Engineer |
| SRB | Supplier Review Board |
| SSM | Strategic Supplier Management |
| VOE | Verification of Effectiveness |

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| Revision | Release Date | Author | Description |
| A | 12/07/2016 | Craig Roberts | Initial release of document, replaces QPP 6.1.1 |
| B | 08/16/2017 | Chris Young | Added 2.PQA.020-004 which replaces ASI-13100 (sections 8.3.2 and 10.7) |
| C | 05/02/2018 | Jon Wineski | Updated 2.PQA.020-001 Q-Clauses: Added Q-7, Q-14 (a, b, c), Q-38a, and Q-44; updated Q-17, Q-20, Q-21, Q-24, Q-30, Q-37, and Q-41 |
| D | 07/10/2018 | Teresa Kassen | Significant rewrite |
| E | 08/02/2018 | Teresa Kassen | Added section 8.4.2.3, Q-Clause Q-6 to Appendix A, Q-6 to 2.PQA.020-001, and also updated section 8.7, updated disciplines |
| F | 09/18/2018 | Teresa Kassen | Revised section 8.2.1 to align with revised ASL Procedure, 2.SAM.004. Revised sections 3 and 8.1.3 to align with new Standard Purchase Requisition (SPR) for Engineering Parts Procedure, 2.TS.029. Revised Appendix A to accommodate changes Q-clauses. |
| G | 03/26/2019 | Teresa Kassen | Add sections 8.4.2.4.1-3 to provide definition for defect class assignments for supplier related QNs. |
| H | 06/17/2019 | Teresa Kassen | Updated 2.PQA.020-001: revised Q-37 – removed duplicated paragraph; revised Q-39 |
| J | 01/26/2020 | Teresa Kassen | 8.1.3.4 & 10.8 referenced 2.PQA.020-004 title changed. 2.PQA.020-004 was updated to add Quality Clauses: Q-6, Q-7, Q-38a, Q-45 and Q-46 and title changed Complete re-write of 2.PQA.020-001. Updated Table, Appendix A to reflect 2.PQA.020-001 changes. |
| K | 03/04/2020 | Teresa Kassen | Updated 8.1.3.4 to add clarity and responsibility. Updated 2.PQA.020-004 to reflect New Q-Clause numbers and alternate references. Updated 2.PQA.020-001 to make corrections and add requirements  |
| L | 08/27/2020 | John Wineski | Added reference to 3.PQA.020. |
| M | 09/21/2020 | Teresa Kassen | Update and added Q- Clauses (2.PQA.020-001: Added clarity to items 2 and of QA003, and paragraph 3 of QA006. Added last sentence paragraph 1, QS004A, Added new clause QS007B. Clarified requirement is paragraph 1, QS008A. Added definition reference in QS009C background for material properties. Added Q-clause QS015D, Clarified language in QS022. Added definitions for Chemical, Mechanical and Physical properties. |
| N | See System for Date |  | Updated 2.PQA.020-001 only: Update Table of Contents to correct previously missing clause and to add new clause QT003B, Added new clause QT003B to Section 3 Table, QS008B added requirement to list Serial Numbers on paperwork, QS008C added requirement to list Serial Numbers on paperwork, QT003, Rewrote Clause to add clarity regarding allowed sources to prevent counterfeit and required unbroken chain of custody documents to be retained, Added clause QT003B to be issued if unbroken chain of custody documents are to be provided. Added definitions for Authorized Distributor, Authorized Supplier, Intermediary, Original Component Manufacturer and Original Equipment Manufacturer, made minor administrative edits. |

# IMPACTED DISCIPLINES (current revision only)

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| --- | --- |
| Discipline | Scope of Impact |
| None | No impact |
|  |  |

# Appendices

## **Appendix A. Q-Clause Assignment Guidance**

|  |  |
| --- | --- |
| Catalog (i.e.: McMaster Carr, MSC)  | QA001, QA002 (Q-6), QA003 thru QA006, QZ002 (Q-31) |
| Products from Distributors and COTS  | QA001, QA002 (Q-6), QZ001 (Q-8), QT001 (Q-9), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS028 (Q-22), QS008A (Q-24, as appropriate). Add additional Q-clauses where deemed applicable. |
| Complex, critical purchased part (P or vendor number)  | QA001, QA002 (Q-6), QZ001 (Q-8), QT001 (Q-9), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS018A (Q-23), QS008A (Q-24), QS026 (Q-7), QT003 (Q-41). Add additional Q-clauses where deemed applicable.  |
| Raw material and processes  | QA001, QA002 (Q-6), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS018A (Q-23), QS008A (Q-24), QS009B or QS009C, or QS009D (Q-33), as applicable. Add additional Q-clauses where deemed applicable. |
| Shelf Life/Time Sensitive is required per Windchill  | QA001, QA002 (Q-6), QZ001 (Q-8), QT001 (Q-9), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS024 (Q-20), QS008A (Q-24), STOCK (note – MMDG creates the Material Master in SAP using the Windchill requirements. Add additional Q-clauses where deemed applicable. |
| Part number (typically vendor number) has a released Vendor Item Drawing  | QA001, QA002 (Q-6), QZ001 (Q-8), QT001 (Q-9), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS018A (Q-23), QS008A (Q-24) (as appropriate), QT003 (Q-41) (as appropriate). Add any additional Q-clauses where deemed applicable. |
| GA-ASI P/N - part (that could be manufactured outside)  | QA001, QA002 (Q-6), QZ001 (Q-8), QT001 (Q-9), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS008A (Q-24). Add any additional Q-clauses where deemed applicable.  |
| Parts that require testing by Production Test personnel during receiving inspection  | QA001, QA002 (Q-6), QZ001 (Q-8), QT001 (Q-9), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS018A (Q-23), QS008A (Q-24), QT003 (Q-41), (INSP NOTE). Add additional Q-clauses where deemed applicable. |
| All printed wiring boards and assemblies  | QA001, QA002 (Q-6), QZ001 (Q-8), QT001 (Q-9), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS018A (Q-23), QS008A (Q-24), QT003 (Q-41). Add additional Q-clauses where deemed applicable. |
| All inspection, measuring, and test equipment including air speed indicators and altimeters | QA001, QA002 (Q-6), QZ001 (Q-8), QT001 (Q-9), QA004, QA005 (Q-10), QA006, QA003 (Q-11), QS013 (Q-16). Add additional Q-clauses where deemed applicable. |

## **Appendix B. Supplier Approval Categories**

### B.1 Approved

### B.1.1 Supplier is “Approved” for use and QC objective evidence of review is available in the SAP-ECC database, as noted in this procedure.

### B.1.2 Supplier “Process Capability” and “Supplier Type” is indicated.

### B.1.3 ASL Status reads “Approved”

### B.2 Conditional

#### B.2.1 Suppliers approved with exception due to limitations regarding commodity, quantity, process or other factors. The vendor classification categories shall be “Conditional” and indicate one or more of the following in the SAP-ECC characteristic description:

##### B.2.1.1 Reason for conditional status

##### B.2.1.2 Conditional expiration date

##### B.2.1.3 Commodity or process capability category

#### B.2.2 ASL Status reads “Approved” (current approved suppliers) and/or “Conditional” (new addition suppliers)

### B.3 Disapproved

#### B.3.1 Supplier is “Disapproved” for use. Refer to comments entered in SAP-Enterprise Central Component (ECC) Supplier Master to support the “Disapproved” status, as required.

#### B.3.2 If a SAP-ECC Receiver exists, the Inspector is prevented from inspecting and processing the product via a warning message in SAP-ECC.

#### B.3.3 Order cannot be placed.

#### B.3.4 ASL Status reads “Disapproved”

### B.4 Inactive

#### B.4.1 Supplier is “Disapproved” for use due to no procurement activity for 25 months or more. Refer to comments entered in SAP-ECC Database to support “Disapproved” status, as required.

#### B.4.2 Order cannot be placed.

#### B.4.3 ASL Status reads “Inactive”

**Appendix C. Types of Supplier Site Visits/Audits Guideline**

|  |  |  |
| --- | --- | --- |
| **Type** | **Purpose** | **Results Documented On** |
| Capability Review | Evaluate risk and capability to make and inspect part | Checklist and/or Trip Report |
| Supplier Audit | Evaluate QA program | Trip Report  |
| Requirement Review | Review Subcontract and/or Purchase Order requirements | Trip Report  |
| Surveillance Visit | Monitor systems | Trip Report |
| Source Inspection | In-process and/or final inspect of items prior to shipment | Shipping or inspection document |
| CAPA Verification of Effectiveness (VOE) Confirmation | Review and verification of Effectiveness of CAPAs | CAPA form or, if not available, a Trip Report |

## **Appendix D. Site Assessment/Visit Matrix Guideline based on Supplier Significance**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Assessment/ Visit Matrix*** | **ACritical Safety Item Suppliers; Critical Safety Services(Direct)** | **BNon-Critical Safety Item Suppliers, Processes(Direct)** | **CCOTS, Non-Critical Services, Prototype(Direct)** | **DDistributors(Direct)** | **ENon-production related(Indirect)** |
| *Suppliers of parts the Customer or GA-ASI designated as Critical Safety Items (CSI) requiring scheduled surveillance.* | *Suppliers that provide custom or customized products, services and processes that are not defined as safety-critical. Tooling and equipment suppliers.* | *Suppliers of products that can be purchased with no changes to the Manufacturer Part Number. Prototype suppliers. No SCDs unless prototype. Services include Calibration, Inspection Services, etc.* | *Suppliers of hardware, components and other products manufactured by a 3rd party and purchased as catalog items* | *Suppliers that have an indirect effect on production of final product. Examples include building construction, equipment maintenance, engineering services, etc.* |
| **Risk Assessment (Risk, Capabilities, etc.)** |
| Buyer Risk Assessment | Per 2.SAM.023 |
| **Quality Audit** |
| Initial (QMS/Process) | Yes | Yes | As determined by SQE | No | No |
| Annual (QMS/Process) | Yes | As determined by SQE/Buyer | As determined by SQE/Buyer | No | No |
| Periodically (QMS and/or Process) | As determined by SQE | As determined by SQE | As determined by SQE | No | No |
| For Cause/CAPA VOE (Process or QMS) | As required | As required | As required | As determined by SQE | No |
| Desk Audit | No | No | As determined by SQE | At minimum | No |
| **Other Visits** |
| Surveillance Visit | As determined by SQE | As determined by SQE | As determined by SQE | No | No |
| Requirement Reviews | As determined by SQE | As determined by SMT | No | No | No |
| Source Inspection | As determined by Customer or SQE | As determined by Customer or SQE | No | No | No |