Amphenol Alden

Quality Procedure

Title:	Supplier Quality Manual	QP 3.06.01-2

Originated/ Revised By:	Mike Virusso
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Revision:	ı

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1. Purpose

- 1.1. The purpose of this manual is to inform Suppliers of Amphenol Alden Products of the expectations we have regarding quality systems, manufacturing process controls, product compliance, regulatory, and design requirements.
- 1.2. This manual describes what Amphenol Alden Products expects its Suppliers to do to ensure that purchased materials meet and continuously improve against our requirements.
- 1.3. Amphenol Alden Products (AAP) requires Suppliers to control the quality of material shipped to our corporation.

2. Application

2.1. The information in this manual applies to all Suppliers of production components or materials who are doing business with Amphenol Alden Products

3. Definitions

- 3.1. Control Plan: A detailed description of the supplier's proposed processing steps required to produce the part, and the controls that are put into place to control the quality at each step throughout the process.
- 3.2. Lot: Product of one-part number and revision that are made at the same time, under the same processing conditions, from the same lot of raw materials.
- 3.3. Qualification Samples: A supplier-produced production runs of material used for part qualification.
- 3.4. Process Capability (Cpk, Ppk): A comparison of the inherent variability of a process output to specification limits under statistically stable conditions.
- 3.5. SDS: Safety Data Sheets
- 3.6. SQE: Supplier Quality Engineer
- 3.7. Gage R&R: Gage Repeatability and Reproducibility
- 3.8. OSHA: Occupational Safety and Health Administration

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- 3.9. SPCR: Supplier Process Change Requests
- 3.10. SCAR: Supplier Corrective Action Request
- 3.11. RoHS2: Restriction of Hazardous Substances, the 2nd edition that went into effect on 02JAN2013 in the European Union (EU).
- 3.12. REACH: Registration, Evaluation and Authorization of Chemicals, or Regulation (EC) 1907/2006, which established European Chemicals Agency and restrictions on the source of raw materials used for products that are intended to be sold in the EU.
- 3.13. AAP: Amphenol Alden Products
- 3.14. EOL: End of Life
- 3.15. LTB: Last Time Buy
- 3.16. CoC: Certificate of Compliance
- 3.17. CoA: Certificate of Analysis
- 3.18. CTF: Critical to Function
- 3.19. EICC: Electronic Industry Citizenship Coalition
- 3.20. ECR/ECN: Engineering Change Request/ Engineering Change Notification
- 3.21. PO: Purchase Order
- 3.22. Cpk: Process Capability Index. Adjustment of Cp for the effect of non-centered distribution.
- 3.23. Ppk: Process Performance Index. Adjustment of Pp for the effect of non-centered distribution.
- 3.24. FAI: First Article Inspection
- 3.25. PFD: Process Flow Diagram
- 3.26. GDP: Good Documentation Practices
- 4. References
 - 4.1. QF2.06.01-1 Supplier Assessment Survey



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- 4.2. QF2.06.01-3 Supplier Corrective Action Request
- 4.3. QF2.06.01-9 Supplier First Article Inspection Check List
- 4.4. EF2.04.04-4 Product Qualification Report
- 4.5. EF2.04.04-3 First Piece Sample Evaluation
- 4.6. QF2.06.01-7 Supplier Process Control Plan
- 4.7. QF2.13.01-3 Request for Deviation/Waiver
- 4.8. QF2.20.01-1 C=0 Sampling Plan
- 4.9. QF2.06.01-6 Supplier Quality, Documentation and Package Marking Requirements

4.10. QF 2.06.01-16 Supplier Performance Scorecard

- 4.11. QF2.06.01-8 Supplier Process Change Request
- 4.12. QP2.06.01 Supplier Quality Management
- 4.13. QP 2.05.02 Good Documentation Practices

5. Responsibility

- 5.1. Supplier Quality Engineer or (Quality designee) is responsible for disseminating this document to AAP suppliers in accordance with QP2.06.01 Supplier Quality Management.
- 5.2. Suppliers are responsible for reviewing and adhering to the requirements set forth in this document.

6. General

6.1. In today's lean, just-in-time manufacturing environment, product found to be nonconforming at receiving or during production causes serious schedule disruptions. The result; high production costs. Since even the best receiving inspection programs do not detect all defective material, Amphenol Alden Products and its divisions (hereinafter Amphenol Alden Products) requires suppliers to control the quality of material shipped to our corporation.

7. Procedure

7.1. Quality System Requirements

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7.1.1. Quality System

- 7.1.1.1. Amphenol Alden Products requires that each Supplier for materials used in product maintains an effective Quality Management System. ISO 9001:2015 and/or ISO13485:2016 Certification by an accredited certification body is recommended for Class 1 and Class 2 suppliers. In addition, the Supplier should meet all other requirements of this manual.
- 7.1.1.2. Quality Manual & Procedure
 - 7.1.1.2.1. Upon request, the Supplier must furnish Amphenol Alden Products with a controlled copy of the Supplier's Quality Manual and supporting procedures (Class 1 and 2 ranking). The Supplier must notify Amphenol Alden Products of any changes to the Supplier's quality system, top-level management, and/or quality management.
- 7.1.1.3. Control of Sub-tier Suppliers
 - 7.1.1.3.1. The Supplier is responsible for the quality of materials and components provided by their Sub-tier Suppliers and Subcontractors. This responsibility may not be limited to the value of the specific purchase agreement. This does not include Amphenol Alden Products-provided material. Suppliers should impose controls on Sub-tier Suppliers and provide upon request, any quality results and or documentation comparable to the controls applied to Suppliers by Amphenol Alden Products.
- 7.1.1.4. Amphenol Alden Products Involvement
 - 7.1.1.4.1. Where appropriate (typically, this occurs when the sub-tier Supplier is an essential component of the supply-chain process) Amphenol Alden Products performs the following:
 - 7.1.1.4.1.1. Specifies the sub-tier suppliers that may be used.
 - 7.1.1.4.1.2. Evaluates and certifies the sub-tier Supplier's facilities.
 - 7.1.1.4.1.3. Assists the Supplier in controlling the sub-tier Supplier.
- 7.1.1.5. Amphenol Alden Products Evaluation of Sub-Tier Suppliers



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7.1.1.5.1. Amphenol Alden Products reserves the right to evaluate the quality system and records of such sub-tier Suppliers, as necessary. In the event of any Amphenol Alden Products involvement, it does not absolve the Suppliers of the ultimate responsibility of its sub-tier Suppliers and Sub-Contractors quality performance.

7.2. Supplier Approval Process

7.2.1. Approval requirement

- 7.2.1.1. All suppliers of raw materials and components used in the manufacture of products or processes and services which impact the quality of products released to production intended for sale to AAP's customers must be Approved Suppliers. Approved Suppliers are selected in their ability to provide products or services that meet AAP requirements. The supplier approval process consists of the following three approval elements:
 - 7.2.1.1.1. QF2.06.01-1 Supplier Assessment Survey completed by the Supplier.
 - 7.2.1.1.2. Acceptance of terms in QF 2.06.01-6 Supplier Quality Agreement Form. QF 2.06.01-6 Supplier Quality Agreement Form includes an agreement requesting suppliers to notify AAP about any changes impacting the availability, quality, materials, performance, reliability, manufacturing location, manufacturability, process or any other component characteristic deemed critical to use in AAP's products.
 - 7.2.1.1.3. A documented audit of the Supplier's quality system procedures, if required.
 - 7.2.1.1.4. An on-site assessment, if required.

7.2.1.2. Process Initiation

- 7.2.1.2.1. The criteria for the selection and evaluation of suppliers is proportionate to the risk associated with the purchased product. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.
- 7.2.1.2.2. If it is determined that a Supplier potentially fits within Amphenol Alden Products supply chain needs, the Purchasing group or SQE requests that the Supplier complete a QF2.06.01-1 Supplier Assessment Survey and

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acceptance of terms in **QF 2.06.01-6 Supplier Quality Agreement Form**. When the Supplier returns the questionnaire, a Purchasing designate reviews the questionnaire with the SQE (or Quality designee) to determine whether to proceed with approval of the Supplier and which approval elements are required.

- 7.2.1.2.3. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product in accordance with QP2.06.01 Supplier Quality Management.
- 7.2.1.2.4. A risk based approach is used during the evaluation of new or existing suppliers, critical control points for the purchase of products are evaluated during the Supplier Assessment Survey (QF2.06.01-1) and also during the Supplier Audit.
- 7.2.2. Document Audit (If Required)
 - 7.2.2.1. A SQE (or Quality designee) is assigned to review the Supplier's Quality Manual and supporting procedures to determine if the documented quality system meets Amphenol Alden Products requirements in accordance with Amphenol's Supplier Quality requirements set forth in QP3.06.01-6 Supplier Quality Manual.
- 7.2.3. On Site Assesment
 - 7.2.3.1. AAP may perform an on-site assessment of the supplier's facility. The supplier will be given a minimum of 15 days notice of such assessments. Every effort will be made to schedule this activity at a mutually convenient time to both AAP and the supplier. These on-site assessments include one or more of the following components:
 - 7.2.3.1.1. Quality System Audit:
 - 7.2.3.1.1.1. A quality system audit helps AAP to understand the Supplier's quality system and its effectiveness.
 - 7.2.3.1.2. Business Assessment:
 - 7.2.3.1.2.1. A Business Assessment helps AAP to understand whether the supplier has the needed financial resources, production capacity, and other business resources needed to fulfill Amphenol Alden Products business, delivery and production needs and continuity of supply. This action may be performed

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and approved by purchasing prior to or in conjunction with a quality system audit

- 7.2.3.1.3. Continuous Improvement Assessment:
 - 7.2.3.1.3.1. A Continuous Improvement Assessment determines whether there are proactive quality programs such as team-based problem-solving activities, use of metrics and objectives, strong culture of quality, etc.
- 7.2.3.1.4. Technology Assessment:
 - 7.2.3.1.4.1. A Technology Assessment determines whether the supplier has the needed technical resources, including production and inspection equipment, facilities, engineering resources, electronic commerce capability, etc.

7.2.4. Approval

7.2.4.1. If the assessment team determines that the supplier meets all of the Amphenol Alden Products requirements, the supplier is awarded with approved status and classification ranking and added to the approved supplier list. The Classification ranking assigned to suppliers is proportional to the risk associated with the purchased product or services. Approved suppliers are eligible to bid on new business and supply production materials.

7.3. Part Qualification

- 7.3.1. In order for a component or assembly to be evaluated for production, a supplier may be required to supply the following elements and submit the appropriate documentation. If there are any additional requirements or any exception, a written approval by SQE/Quality designee may be needed.
 - 7.3.1.1. List of Documentation that might be required for Component Approval
 - 7.3.1.1.1 Engineering Evaluation Samples
 - 7.3.1.1.2. PFMEA (Process Failure Mode and Effects Analysis)
 - 7.3.1.1.3. GAGE R&R Study
 - 7.3.1.1.4. CTF, Process Capability Study
 - 7.3.1.1.5. First Article Inspection report
 - 7.3.1.1.6. Process Control Plan, Material Certification CoC or CoA
 - 7.3.1.1.7. Assembly Bill of Materials

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7.3.1.1.8. SDS

7.3.1.1.9. Process Validation

7.3.1.1.10. ROHS/ Reach /Conflict Metals

7.3.2. Approved Supplier List

7.3.2.1. Qualification

- 7.3.2.1.1. Amphenol Alden Products maintains a list of the approved suppliers. Approved Suppliers are suppliers of raw materials and components used in the manufacture of products or processes and services which impact the quality of products released to production intended for sale to AAP's customers. Suppliers must successfully complete the general supplier approval process described in Section 2 and pass the part qualification requirements listed below to a specific production part or material (part number).
- 7.3.2.1.2. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

7.3.3. First Article Checklist

7.3.3.1. For each new or changed material, part, assembly, or new manufacturer, the supplier is required to prepare a first article inspection report. The report is prepared in accordance with QF2.06.01-9 Supplier First Article Inspection Check List. The checklist identifies the requirements that must be completed for qualification of the material, part, or assembly for volume production. Further qualification elements may be also requested as per Section 7.3.1.1 List of Documentation that might be required for Component Approval.

7.3.4. Failure Mode & Effects Analyses

7.3.4.1. Process Flow Diagram \The supplier is encouraged to provide a process flow diagram of the processes used to produce supplier's parts.

7.3.4.2. Process FMEA

7.3.4.2.1. All suppliers are encouraged to perform a Process Failure Mode and Effects Analysis (Process FMEA). AAP's requirements are set forth in section 7.3.1.1 List of Documentation that might be required for Component Approval.

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7.3.4.2.2. The process FMEA considers all reasonably foreseeable potential failure modes of each process. Based on the potential seriousness and likelihood of the problem, the supplier develops manufacturing controls. It is recommended that the process FMEA should be a living document, and that it is updated when one of the following occurs:

7.3.4.2.2.1. Process is changed

7.3.4.2.2.2. Defective material is produced.

7.3.4.3. Design FMEA

7.3.4.3.1. For materials, parts, and assemblies that are designed by the supplier, it is recommended to perform a Design Failure Modes and Effects Analysis (Design FMEA). Amphenol Alden Products designee can be made available to aid in FMEA projects.

7.3.5. Control Plan

7.3.5.1. The control plan is a detailed description of the supplier's proposed processing steps required to produce the part, and the controls that are put into place to control the quality at each step. The supplier may be required to complete QF2.06.01-7 Supplier Process Control Plan or equivalent and submit it to Amphenol Alden Products for approval. Refer to Section 7.3.1.1 List of documentation that might be required for component approval.

7.3.5.2. Format

7.3.5.2.1. Suppliers may use their own format, but the Control Plan must include all items contained in the Amphenol Alden Products Control Plan.

7.3.5.3. Components:

- 7.3.5.3.1. The control plan should include the following information:
 - 7.3.5.3.1.1. All in-house processing, external processing, inspection, packaging, and shipping.
 - 7.3.5.3.1.2. Measurement devices and fixtures used to verify Amphenol Alden Products Parts. These devices/fixtures must be identified with a gauge number and drawing.
 - 7.3.5.3.1.3. Gage R&R reports for all measuring devices and fixtures used to check Amphenol Alden Products parts. Refer to section 7.3.11 for requirements.
 - 7.3.5.3.1.4. All critical product and process characteristics.
 - 7.3.5.3.1.5. Where detailed instructions are required, the supplier details those instructions in an inspection method, or equivalent, which must be listed in the Control Plan. Inspection methods, sample sizes, and sampling frequencies should be based on

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the process capabilities, seriousness and likelihood of potential non-conformances, process stability and overall risk.

7.3.5.4. Critical characteristics that do not meet Amphenol Alden Products process capability requirements must be inspected 100%, unless otherwise approved in writing by Amphenol Alden Products SQE (or Quality designee).

7.3.6. Assembly Bill of Materials

- 7.3.6.1. Where needed and when designated by the SQE (Or Quality Designee), the supplier is required to submit an Assembly Bill of Materials (BOM).
- 7.3.6.2. The BOM should include a list of all suppliers for each part.

7.3.7. Qualification Samples

7.3.7.1. The Qualification Samples are selected from a supplier-produced production run of material for material qualification. The required quantity defined by AAP and outlined in the Purchase Order. Refer to Section 7.3.1.1 List of documentation that might be required for component approval.

7.3.7.2. Production Environment

7.3.7.2.1. The material must be produced under volume-production conditions, including material, machines, tooling, processing parameters, cycle times, operations staff, etc.

7.3.7.3. Exceptions

7.3.7.3.1. Any exceptions to the volume-production conditions must be approved in writing by the supplier quality engineer and recorded in the data package submitted to Amphenol Alden Products.

7.3.7.4. Qualification Sample Submissions

- 7.3.7.4.1. Sample Submissions and/or on-site inspections may be required when any of the below conditions apply:
 - 7.3.7.4.1.1. Initial Submission
 - 7.3.7.4.1.2. Engineering Change
 - 7.3.7.4.1.3. Correction of Discrepancy
 - 7.3.7.4.1.4. Process Change
 - 7.3.7.4.1.5. Production Location Change

7.3.8. Process Validation

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- 7.3.8.1. Process Validation Means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.
- 7.3.8.2. When is required:
 - 7.3.8.2.1. For class 1 and class 2 components, where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The supplier is encouraged to conduct process validations where appropriate or when required by Amphenol Alden Products Supplier Quality Assurance.
- 7.3.8.3. Report
 - 7.3.8.3.1. AAP reserves the right to approve the supplier's protocol and report for any validation documentation.
- 7.3.8.4. Sub-Supplier Certifications & Tests
 - 7.3.8.4.1. For material and other specified requirements for which the supplier does not have the equipment to test, the supplier must obtain material certifications (or test reports) from their sub-supplier(s) or other test agency. Refer to Section 7.3.1.1 List of documentation that might be required for component approval.
- 7.3.8.5. Components:
 - 7.3.8.5.1. The Material Certification Reports Must Include The Following Information:
 - 7.3.8.5.1.1. Specification/Drawing number/Revision/PO# (as applicable)
 - 7.3.8.5.1.2. Specified material/dimensional/physical requirements
 - 7.3.8.5.1.3. Inspection/test results (certificate of analysis with actual measurements) when so required.
 - 7.3.8.5.1.4. Signature of the organization that performed the testing.
 - 7.3.8.5.1.5. Other information as requested by AAP.
 - 7.3.8.5.1.6. A simple statement that the material meets the requirements is not sufficient without the above required information
 - 7.3.8.5.2. Traceability:
 - 7.3.8.5.2.1. The reports must be traceable to the Supplier's material lots and production processes.
- 7.3.9. Safety And Environmental Compliance

7.3.9.1. Safety Data Sheets

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7.3.9.1.1. The supplier must furnish Safety Data Sheets (SDS) for all materials shipped to AAP facilities. Refer to Section 7.3.1.1 List of documentation that might be required for component approval.

7.3.9.2. RoHS/ REACH

- 7.3.9.2.1. Any product purchased for production parts under a Purchase Order requiring RoHS, REACH, or any other Regulatory Compliance related restriction must meet or exceed the restricted levels or have a valid and documented exemption in effect at the time of purchase.
- 7.3.9.2.2. A RoHS and/or REACH or other Regulatory Compliance related certification shall be included on the Certificate of Conformance or as a separate attachment when requested on the Purchase Order or Drawing. Suppliers shall pass this requirement on to all of their vendors supplying any articles used to manufacture articles delivered under the Purchase Order. In other words, Suppliers shall certify entire assembly as well as components and raw materials.

7.3.10. Supplier Gauges & Standards

- 7.3.10.1. The supplier should develop or obtain gauges and/or standards to:
 - 7.3.10.1.1. Control the supplier's processes.
 - 7.3.10.1.2. Inspect the product.

7.3.10.2. Acceptable

7.3.10.2.1. Gauges or standards used to inspect material may be attribute (go/no-go) gauges, color/texture standards, or variable gauges designed to inspect the aesthetics and functionality of the material.

7.3.10.3. Duplicates:

7.3.10.3.1. Duplicate gauges or standards may be used at Amphenol Alden Products to verify the Supplier's First Article inspections including adherence to all color and texture standards.

7.3.10.4. Approval:

7.3.10.4.1. AAP reserves the right to approve the supplier's protocol and report for any validation documentation.

7.3.11. Gauge Repeatability & Reproducibility Studies

7.3.11.1. For those characteristics specified by the SQE (or Quality designee), the supplier must:

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7.3.11.1.1 Perform a gauge repeatability & reproducibility (R&R) study
7.3.11.1.1. Analyze the study results using an Amphenol Alden Products approved statistical method.

7.3.11.2. Approval:

7.3.11.2.1. AAP reserves the right to approve the supplier's protocol and report for any validation documentation. If the gage system fails, the supplier shall take corrective action to make the gage measurements repeatable and reproducible. A gage shall be proven repeatable and reproducible before it can be used in a capability study or to be used to accept or reject products.

7.3.11.3. Frequency:

7.3.11.3.1. The supplier shall outline the revalidation requirements in the Gage R&R protocol.

7.3.12. Gauge/standard correlation studies

- 7.3.12.1. AAP may request the supplier to perform a correlation study.
- 7.3.12.2. The correlation study may include but is not limited to the following steps:
 - 7.3.12.2.1. The supplier identifies, measures, and records a specified amount of production material.
 - 7.3.12.2.2. The supplier sends the sample material to Amphenol Alden Products for measurement confirmation.
 - 7.3.12.2.3. The SQE (or Quality designee) compares Amphenol Alden Products measurements with the supplier's measurements to determine the correlation between the gauges or standards.

7.3.13. Process Capability

7.3.13.1. Process Capability (Cpk) is a comparison of the inherent variability of a process output to specification limits under statistically stable conditions. Most methods for estimating capability require that the characteristic being evaluated is approximately normally distributed, and in statistical control. The distribution should be determined prior to estimating capability. If the process is not in statistical control, all assignable causes must be identified and removed. Special techniques are available for calculating capability when inherent assignable causes, such as tool wear, are present. AAP requires a Process Capability study for CTF characteristics as deemed by the AAP print. Refer to Section 7.3.1.1 List of documentation that might be required for component approval.

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- 7.3.13.2. Where applicable, the following Process Capability requirements apply:
 - 7.3.13.2.1. A Cpk of at least 1.33 is required for Critical Dimension & Features.
 - 7.3.13.2.2. For 1.0<Cpk<1.33, the process may be acceptable to start production and meets Amphenol Alden Products requirements on a limited time basis.

 Requires SQE (or Quality designee) written approval.
 - 7.3.13.2.3. After part approval, begin production following the approved Control Plan with additional attention to the process until an ongoing Cpk>1.33 is achieved.

7.3.14. First Article Inspection

- 7.3.14.1. The supplier must select representative material, parts, or assemblies from the qualification sample run for first article inspection. The SQE (or Quality designee) notifies the supplier of the quantity to be inspected.
- 7.3.14.2. The inspection process is as follows:
 - 7.3.14.2.1. The supplier inspects or tests each sample for all dimensions, drawing notes, material requirements, and specification requirements listed on the current revision of the Amphenol Alden Products drawing. Unless otherwise specified or agreed to, a minimum 3-piece sample is required for each tool, die, mold cavity or set-up as appropriate.
 - 7.3.14.2.2. The supplier numbers a copy of the Amphenol Alden Products drawing and specification to correspond with the supplier's results.
 - 7.3.14.2.3. The supplier itemizes each requirement on form QF2.04.04-3 First Piece Sample Evaluation or equivalent and records the results.
- 7.3.14.3. For all nonconforming characteristics, the following must occur:
 - 7.3.14.3.1. The Supplier investigates and corrects the tooling, process, etc., and produces new product.
 - 7.3.14.3.2. Nonconforming samples are sent to Amphenol Alden Products only after the Supplier has done all that can be done to correct the parts, and after obtaining approval from the SQE (or Quality designee).
 - 7.3.14.3.3. Supplier should update FMEA if necessary
 - 7.3.14.3.4. Non-conforming material may not be sent to any Amphenol Alden Products facility or customer without a written Deviation Approval approved by AAP in writing.

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- 7.3.15.1. The part qualification process is as follows:
- 7.3.15.2. The SQE (or quality designee) notifies the supplier of the data required in the data package, the number of samples, and the shipping instructions.
- 7.3.15.3. The supplier submits a data package. Including, but not limited to: FAI checklist, PFD, PFMEA, GR&R, Control Plan, Process Capability, etc., and part samples to Amphenol Alden Products for approval.
- 7.3.15.4. All documents sent to Amphenol Alden Products must contain the Amphenol Alden Products part number, revision, and name of the actual manufacturer. Refer to section 7.3.1.1 list of documentation that might be required for component approval.

7.3.16. Documentation and Records

- 7.3.16.1. Suppliers are expected to follow Good Documentation Practices for both paper records and electronic records to assure data integrity. These principles require that documentation have the characteristics of being accurate, legible, contemporaneously recorded, original and attributable.
- 7.3.16.2. Good documentation practices (GDP) should be followed when supplier submits documents or records to AAP. Documents should follow minimum the following requirements:
 - 7.3.16.2.1. Document approval: Approved, signed, and dated by appropriate authorized personnel
 - 7.3.16.2.2. Document modification: Handwritten modifications are signed and dated.
 - 7.3.16.2.3. No spaces are left blank if unused, they are crossed out or "N/A" (or similar text) entered.

7.3.17. Anti-Counterfeit Policy

7.3.17.1. The Supplier shall maintain a material authenticity program that has, as its goal, the avoidance, detection, mitigation, and disposition of counterfeit parts in accordance with the requirements set forth by Amphenol Alden Products. The supplier shall maintain objective evidence that the chain of custody has been maintained from original manufacturing of the part to the delivery of the part to the Buyer's receiving dock. The supplier shall provide the buyer will all required certificates of conformance and acquisition traceability. Upon Amphenol Alden request, the supplier shall also provide objective evidence, including chemical evaluation test results from an independent third party testing laboratory, that the material supplied to the buyer's receiving dock meets all stated requirements and has not sustained any chemical contamination or chemical substitution.

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7.4. Manufacturing Control

7.4.1. Process Control

7.4.1.1. Amphenol Alden Products suppliers are required to control all manufacturing processes in accordance with the control plan, which is approved during product qualification.

7.4.2. Statistical Process Control

- 7.4.2.1. Where specified in the control plan, the supplier is required to apply effective statistical process controls. Effective controls may include, but are not limited to:
 - 7.4.2.1.1. A Process Control Chart that displays correctly calculated statistical process control limits.
 - 7.4.2.1.2. A Process Control Chart that is at the process area, visible to the operator, or persons who are responsible for controlling the process.
 - 7.4.2.1.3. Documentation of actions to be taken to bring the process back into control (for each out-of-control condition).
 - 7.4.2.1.4. Documentation of the sorting, scrapping, reworking, or disposition of all products produced during any out-of-control condition.

7.4.3. Process Improvement

7.4.3.1. Recommended Correction

7.4.3.1.1. Out-of-control or unstable processes (which have assignable causes) and processes that do not meet the minimum Cpk/Ppk, or similar AAP's approved requirements should be identified and corrected. The supplier should also improve processes with low yield rates.

7.4.4. Lot Control

- 7.4.4.1. A lot consists of product of one-part number and revision that are made at the same time, under the same processing conditions, from the same lot of raw materials.
- 7.4.4.2. Each container of material shipped to Amphenol Alden Products must be identified with the supplier's lot number. Inspection records must be traceable to lot numbers. The primary purpose for identifying lots is to determine the scope of actions that must be taken when problems arise during further manufacturing or with customers.
- 7.4.4.3. Lot Number Changes (Examples)

7.4.4.3.1. The following are typical conditions that result in a change of lot numbers: 7.4.4.3.1.1. Change of part number or revision.

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- 7.4.4.3.1.2. Change of part number or revision of components.
- 7.4.4.3.1.3. Interruption of continuous production (typically for more than a few hours).
- 7.4.4.3.1.4. Repairs or modification to the tooling or equipment.
- 7.4.4.3.1.5. Tooling changes (other than minor adjustment, or replacement of consumable tooling).
- 7.4.4.3.1.6. Change to a different lot of raw materials.
- 7.4.4.3.1.7. Change in shift.
- 7.4.4.3.1.8. Significant process changes

7.4.5. Traceability

7.4.5.1. Traceability ties finished product back to the components used in the product.

Traceability should be effective down to the individual component (lot code, batch, or serial should be identifiable through records).

7.4.6. Workmanship

7.4.6.1. When workmanship standards are not referenced on Amphenol Alden products drawings or specifications, the supplier is expected to follow industry-accepted standards for molds, plastics, or metal-forming applications. When in doubt, refer to the SQE (or quality designee) for clarification.

7.4.7. Safety & Environmental

7.4.7.1. AAP seeks its suppliers to establish appropriate controls to minimize risks to exposure to hazardous materials or conditions in the manufacture of the parts it purchases.

7.4.7.2. Inherent Hazards

7.4.7.2.1. For items with inherent hazards, safety notices must be clearly observable. As applicable, SDS may be required during the first article process.

7.4.7.3. Standards

- 7.4.7.3.1. Suppliers may consider ISO 14001 Certification to enhance their control hazards risks. Residues, films, out-gassing products, and packaging materials should comply with all Occupational Safety and Health Administration (OSHA) Standards or local Government Standards. Amphenol Alden Products subscribes to the current industry standards of environmental awareness and requires the same from its suppliers. Third party certification to the ISO14001 standard is recommended.
- 7.4.7.4. Supplier Product or Process Compliance Requirements.
 - 7.4.7.4.1. The supplier shall comply with all AAP requests pertaining to environmental or sustainability compliance regulations. This shall

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include, but is not limited to RoHS, REACH, EICC Sustainability, Conflict Metals, etc.

7.4.7.5. Requirements

7.4.7.5.1. AAP requests may include but are not limited to: full materials disclosure reports on all products supplied to AAP, certificates of compliance to REACH or Conflict Metals, ROHS regulatory requirements, and support for external and/or AAP EICC sustainability site audits.

7.4.8. Maintenance

- 7.4.8.1. Maintenance and Calibration Level. The supplier must maintain all facilities, manufacturing machines, tools, measuring devices, and other equipment in such a manner that the supplier can support Amphenol Alden products production requirements, and the quality of material, parts, or assemblies manufactured for Amphenol Alden Products are not degraded in any way. Preventative maintenance and calibration of equipment should be in line with manufacturers instructions and recommendations and shall be documented by the supplier
- 7.4.8.2. Amphenol Alden Products-Supplied Equipment and Tooling.
 - 7.4.8.2.1. All of the above maintenance requirements apply equally to any and all Amphenol Alden Products-supplied equipment and tooling. This customer-supplied equipment and tooling must be maintained in such a manner as to maintain quality product throughout the expected life of the equipment or tooling. The supplier also is required to notify Amphenol Alden Products if any Amphenol Alden Products-supplied equipment or tooling is expected to exceed its usable life within the following 12 months. All such equipment and tools must be clearly identified and properly stored when not in use.

7.5. Internal & External Change Control

- 7.5.1. External Drawing Change Control
 - 7.5.1.1. The supplier must have a documented system for assuring that the latest Amphenol Alden Products drawings (which have first articles approved by Amphenol Alden Products) are in effect at their facility.
- 7.5.2. The supplier's quality manual should contain a written procedure that includes a description of the following:
 - 7.5.2.1. The method used for receipt, review, distribution, and implementation of all changes to drawings and specifications.
 - 7.5.2.2. The method used to contain new or modified parts until approved by the customer. In addition, there should be a procedure for addressing and eliminating obsolete

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drawings and specifications, coupled with defining which current drawings must be in place at each location in the supplier's process.

- 7.5.3. Internal Process & Engineering Change Control
 - 7.5.3.1. Suppliers should have systems in place to control changes to drawings, specifications, processes, or produced product. Systems should be capable of handling changes being requested by the customer, and also changes requested by the supplier. The approval process is directed at a given part number for a specified revision level produced in a specific area of the manufacturer's facility. Suppliers may not make any changes in their process, location, material, or to the product without written approval from the Amphenol Alden Products SQE (or Quality designee). The supplier must obtain an approved SPCR QF2.06.01-8 Supplier Process Change Request for all Amphenol Alden Products materials, parts, or assemblies.
 - 7.5.3.2. A change shall be considered anything impacting the availability, quality, materials, performance, reliability, manufacturing location, manufacturability, or any other component characteristic deemed critical to use in AAP's products.
 - 7.5.3.3. Supplier is required to apply for a Product/Process Change Request, using SPCR QF2.06.01-8 Supplier Process Change Request Form, including, but not limited to, the following situations:
 - Design Change.
 - Change in Production Equipment, workshop, or production lines.
 - Process Change.
 - Molds or tooling Change.
 - Change in Sub- Suppliers.
 - Manufacturing Site Location Change.
 - · End of Life.
 - Ability to meet regulatory requirements such as RoHS, REACH or Conflict Minerals.
 - Material(s) Change.
 - 7.5.3.4. Supplier Change Notification.

Supplier should notify AAP about these changes without requesting a written approval:

- Supplier Name/Company Ownership Change.
- Product Name or Identification Change.
- Change in certification or accreditation status.
- 7.5.4. Supplier Process Change Request Form

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- 7.5.4.1. The supplier must request changes to a released part, process, drawing, or specification using QF2.06.01-8 Supplier Process Change Request Form.
- 7.5.4.2. Amphenol Alden Products encourages supplier-initiated SPCRs (Supplier Process Change Requests) with the stipulation that prior to submission to the SQE (or Quality designee), the supplier thoroughly reviews their FMEA and Control Plan to ensure that all process-related issues have been addressed and resolved
- 7.5.4.3. AAP may require the Supplier to submit an updated FMEA and Control Plan prior to approval of such permanent changes. AAP may also require other portions, or all, of the related qualification process to be repeated.
- 7.5.4.4. Supplier Product/Process Change Requests shall be submitted to AAP minimum 90 days prior to implementation unless contractually agreed upon. A Process Change Request involving an End of Life (EOL) part shall be submitted at least 1 year prior to the planned LTB (last time buy) date or as soon as possible to provide an opportunity to find a replacement.

7.5.4.5. Components

- 7.5.4.5.1. The originator of a supplier process change request should provide the following information at a minimum:
- 7.5.4.5.2. Drawing or part number
- 7.5.4.5.3. Drawing or part title
- 7.5.4.5.4. Description of problem or recommended change
- 7.5.4.5.5. Reason for change or "rationale"
- 7.5.4.5.6. Proposed effective date
- 7.5.4.5.7. Signature of originator

7.5.4.6. SPCR Approval Process:

- 7.5.4.6.1. The supplier submits Supplier Process Change Request with the revised FMEA (if applicable) and Control Plan to the responsible Amphenol Alden Products SQE (or Quality designee) for evaluation of the following:
 - 7.5.4.6.1.1. Supplier-demonstrated process capability and stability
 - 7.5.4.6.1.2. Comparison to first article data
 - 7.5.4.6.1.3. Industry standards
 - 7.5.4.6.1.4. Supplier process engineering capabilities
 - 7.5.4.6.1.5. Supplier's adherence to supplier control plans
- 7.5.4.6.2. After the SQE (or Quality designee) has completed the review, and concurs with the supplier, the SQE (or Quality designee) documents the request on the appropriate AAP engineering change, first article, etc.).

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- 7.5.4.6.3. The request is processed through the appropriate Amphenol Alden Products purchasing personnel for approval.
- 7.5.4.6.4. The SQE (or Quality designee) notifies the supplier as to the final disposition of the Supplier Process Change Request and part submittal requirements and dates.
- 7.5.4.6.5. Suppliers must obtain an approved a SPCR QF2.06.01-8 Supplier Process Change Request in order to implement change.
- 7.5.4.6.6. Submission of a QF2.06.01-8 Supplier Process Change Request Form to AAP does not indicate approval of a proposed product change. AAP reserves the right to reject any proposed change, require additional information or data to be supplied or seek Customer(s) concurrence prior to granting approval.
- 7.5.4.7. Approval Identification
 - 7.5.4.7.1. Any parts sent to Amphenol Alden Products that have been approved on form QF2.06.01-8 Supplier Process Change Request must be clearly identified on the box, container, or other packaging method with the appropriate Supplier Process Change Request number.
- 7.5.5. Supplier Request for Deviation
 - 7.5.5.1. Authorization
 - 7.5.5.1.1. A supplier is <u>never</u> permitted to ship product that deviates from the print, specification limits, or design intent without prior written authorization from the Amphenol Alden Products SQE (or Quality designee). If such a condition exists, the supplier may petition the Amphenol Alden Products SQE (or Quality designee) responsible for the item in question to allow shipment of the product under a signed written deviation from Amphenol Alden Products.
 - 7.5.5.2. Testing
 - 7.5.5.2.1. If directed by the Amphenol Alden Products SQE (or Quality designee), the supplier must send samples of all non-conforming items to Amphenol Alden Products for evaluation. The cost of any testing required in determining the acceptability of the product will be charged to the supplier.
 - 7.5.5.3. Deviation Acceptance

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7.5.5.3.1. Representatives from the applicable Amphenol Alden Products organizations will determine the item's acceptability and what actions (if any) are required beyond the deviation. The responsible Amphenol Alden Products SQE (or Quality designee) will communicate these requirements to the supplier. The deviation is only intended to be an interim action and is <u>not</u> to be construed as an engineering change. The supplier should begin work immediately to correct the condition in question within the time frame stated on the deviation. Failure to comply with the mutually agreed upon closure date for the deviation may result in the supplier's rating being affected, as well the chargeback of fees and other related costs. Any SDR (Supplier Deviation Request) should be submitted with a description of the supplier's root cause analysis of the deviation.

7.5.5.4. Containment

7.5.5.4.1. In all cases, the supplier must fully contain all product suspected of being non-conforming at the supplier location. In addition, the supplier may be required to sort any suspect product at Amphenol Alden Products or be charged for any and all costs for this sorting.

7.6. Packaging & Labeling

7.6.1. Required packaging each supplier is expected to adequately plan for packaging designed to eliminate shipping damage. Suppliers are expected to provide expendable packaging, where appropriate, that provides for maximum density and protection from any damage that may occur. Packaging, labeling, and shipping materials must comply with, as a minimum, the requirements of common carriers, in a manner to secure the lowest transportation costs. If packaging requirements are specifically defined as part of the product specification, the supplier shall comply with these requirements. Amphenol Alden Products requests that any supplier-initiated packaging improvements be validated by industry standard shipping tests (drop, vibration, crush...) and be approved by Amphenol Alden Products SQE (or quality designee) prior to implementation.

7.6.2. Legality/ Safety

7.6.2.1. Expendable materials and packaging must be legal and safe for standard, industry disposal and/or recycling. It is expected that suppliers adhere to legal safety, disposal and environmental requirements as applicable.

7.6.2.1.1. Contamination

7.6.2.1.1.1. Contamination is a serious concern to Amphenol Alden Products. Packaging is expected to protect the components

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from contamination, including fibers from the packaging materials.

7.6.3. Shipping Containers & Pallets

7.6.3.1. Pallets

7.6.3.1.1. All material is expected to be palletized on four-way pallets to permit handling with lift trucks when sufficient parts are shipped. One full layer of cartons on a pallet is sufficient volume to require that parts be palletized. Pallet overhang is not allowed.

7.6.3.2. Securing Pallets

7.6.3.2.1. All shipping containers are expected to be secured to pallets. Amphenol Alden Products requests that pallets be strapped by at least two bands lengthwise and two bands widthwise and by stretch or shrink film where applicable. Polyester and nylon strapping are recommended.

7.6.3.3. Container Contents

7.6.3.3.1. Only one-part number, one color, and one supplier lot is to be packaged in a container. Whenever possible, only one-part number, one color, and one supplier lot will be contained on a pallet.

7.6.4. International Shipment Requirements

7.6.4.1. Handling special requirements for international shipments may exist. Any applicable requirements will be forwarded by Amphenol Alden Products purchasing when purchase orders are placed. Supplier should contact Amphenol Alden Products purchasing agent if any additional information is required.

7.6.5. Labeling

7.6.5.1. Information

7.6.5.1.1. Each package must contain the following information:

7.6.5.1.1.1. Amphenol Alden Products part number

7.6.5.1.1.2. Amphenol Alden Products purchase order number

7.6.5.1.1.3. Quantity

7.6.5.1.1.4. Supplier's name

7.6.5.1.1.5. Manufacturing facility (if supplier has more than one facility)

7.6.5.1.1.6. Lot Identification: Lot must be identified as first lot produced when change has occurred

7.6.5.1.1.7. Certificates where required

7.6.5.1.2. Bar Code



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7.6.5.1.2.1. Bar Code requirements are not being used but are being reviewed for future potential development. The supplier is encouraged to also explore this initiative.

7.7. Corrective Action

- 7.7.1. Amphenol Alden Products expects suppliers to use a documented closed-loop corrective action system whenever a processing problem is encountered in their manufacturing facility, or after the product has been shipped to Amphenol Alden Products.
- 7.7.2. Corrective Action Process

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7.7.2.1. The supplier's corrective action system used is expected to have at a minimum the following:

	Element D	escription
1	Use team approach and immediately contain any suspect product	Immediate containment of any suspect product and suspension of production, if warranted. Action plan for team formation.
2	Describe the problem	Process flow diagram to define the process. Control charts to indicate special causes. Check sheets to define "what, when, where, who, how, and how much". Action plan to coordinate problem definition actions.
3	Implement and verify interim (containment) actions	Check sheets to evaluate effectiveness of actions. Control charts and histograms with intensive sampling for process monitoring. Action plan to coordinate interim fixes.
4	Define and verify root cause(s)	5 Why Root Cause Analysis Failure to detect Systematic Failure
5	Implement Permanent Corrective Actions and Preventive Actions	Control charts and check sheets to monitor process performance. Control plan, process documentation update, or ECR/ECN as appropriate.
6	Verify effectiveness of permanent corrective action	Control charts and histograms to evaluate process stability and capability. Check sheets to collect product or process evaluation information.
7	Prevent recurrence	Action plan to coordinate required changes. Evaluate other areas where the problem could also occur. FMEA update.

7.7.3. External Corrective Action

7.7.3.1. The Amphenol Alden Products SQE (or quality designee) issues a Supplier Corrective Action Report (SCAR) via e-mail, or other means, to the supplier when nonconforming material, parts, or assemblies are found at any of the following:

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7.7.3.1.1. Receiving inspection

7.7.3.1.2. In production

7.7.3.1.3. In test

7.7.3.1.4. In audit

7.7.3.1.5. By an Amphenol Alden Products customer.

7.7.3.2. Response

7.7.3.2.1. Within 72 hours from initial notification, the supplier is expected to respond by e-mailing an initial observation based from the SCAR, back to the SQE (or Quality designee). The supplier's initial observation is an acknowledgement that the supplier has been informed of the problem and has begun to gather information about the problem.

7.7.3.2.2. Table 2- Supplier Response to Non-Conforming Product

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Required Action

Supplier must take immediate containment action upon notification of the nonconformance.

Supplier must submit the SCAR back to the Amphenol Alden Products SQE reporting the Supplier's initial observation and defining the interim containment plan.

The Containment Plan must clearly define the containment actions at the Supplier's facility, to assure that no nonconforming product is shipped to Amphenol Alden Products. The Supplier must:

- Address all suspect stock in transit, and any stock at any Amphenol Alden Products facilities.
- Specify what actions are to be taken.
- Must bound the problem by identifying all suspect lot numbers and associated quantities involved.
- Supplier must cover all sorting and additional transportation costs (Sort on site or return to Supplier)

Supplier must report the results of the Supplier's investigation into the cause of the problem.

Supplier must submit the Permanent Corrective Action to be taken to prevent recurrence of the problem, and the effective date (the date the Corrective Action will be implemented.).

Supplier should keep Amphenol Alden Products informed of progress towards implementing the Corrective Action.

Supplier and Amphenol Alden Products SQE (or Quality designee) verify that the Corrective Action is effective in correcting the problem. The Amphenol Alden Products SQE (or Quality designee) then closes out the SCAR.

7.8. Supplier Monitoring

- 7.8.1. Amphenol Alden Products continually monitors its suppliers to ensure they continue to meet Amphenol Alden Products requirements, and to ensure that the supplier continues to ship acceptable material, parts, or assemblies. This monitoring may consist of:
 - 7.8.1.1. A quality system surveillance audit at the supplier's facility.
 - 7.8.1.2. An audit of the supplier's control plan.
 - 7.8.1.3. A normal material quality verification of a lot.
 - 7.8.1.4. Source inspection of product at the supplier's facility.
 - 7.8.1.5. Review Of supplier-furnished data packages.
 - 7.8.1.6. Supplier performance evaluation.



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7.8.2. Supplier Audits

7.8.2.1. Availability: It is expected that the supplier must make their facility available for onsite process verification by the Amphenol Alden Products SQE (or Quality designee). AAP will make every effort to conduct Audits at a mutually agreeable time.

7.8.3. QA & Production Inventory Control

- 7.8.3.1. Amphenol Alden Products expects its suppliers to furnish material that conforms to all requirements, and that does not need to be inspected when Amphenol Alden Products receives it.
- 7.8.4. Source Inspection at The Supplier's Facility
 - 7.8.4.1. Amphenol Alden Products may inspect product at the supplier's facility, to detect potential problems prior to shipment to Amphenol Alden Products. Amphenol Alden Products may also inspect product at the supplier's sub-suppliers.
- 7.8.5. Supplier-Furnished Lot Documentation
 - 7.8.5.1. Required Data
 - 7.8.5.1.1. Amphenol Alden Products may request the supplier to furnish inspection, test, process performance, or other quality data with each shipment to ensure that the product meets Amphenol Alden Products requirements. A CoC must accompany all shipments unless otherwise specified.
 - 7.8.5.2. Timina
 - 7.8.5.2.1. When data submission is required, the data must be shipped with product and/or e-mailed to the Amphenol Alden Products receiving inspection department (or other specified location) at the same time the lot is shipped.
 - 7.8.5.3. Identification
 - 7.8.5.3.1. All documentation must be clearly identified with the Amphenol Alden Products part number, and the supplier's lot number.
 - 7.8.5.4. Data Packages

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7.8.5.4.1. AAP may require the supplier to submit via email monthly data packages to the SQE and/or designee. Data packages may consist of copies of control charts and Cpk & Ppk calculations for specified characteristics. Other data may be requested by the SQE (or Quality designee).

7.8.6. Supplier Performance Evaluation

- 7.8.6.1. This evaluation considers supplier performance in the areas of quality, service, cost management, commitment, and risk management. Supplier performance evaluations are documented using QF 2.06.01-16 Supplier Performance Scorecard.
- 7.8.6.2. Suppliers whose performance is deemed to need improvement in one or more categories are required to improve their performance. Additional verification of activities and actions are taken when requirements are not met. The activities related to the improvement of Supplier's Performance shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements
- 7.8.6.3. Suppliers may be requested to perform one or more of the following activities:
 - 7.8.6.3.1. Prepare and submit a corrective action plan to address any category that is identified as needing improvement.
 - 7.8.6.3.2. Support and participate in joint supplier development initiative(s).
- 7.8.6.4. If the supplier is determined to be unacceptable then other suppliers with a proven track record of meeting these expectations will be considered.

7.8.7. Supplier Agreement

7.8.7.1. Amphenol Alden Products expects its suppliers to sign a yearly supplier agreement containing the statement of adherence to this quality manual including clauses for responsibility and indemnification for non-compliance; this is indemnity may be limited to product value and will include, at least, all related costs associated with the non-compliance.

7.8.8. Proprietary Data

7.8.8.1. Amphenol Alden Products suppliers are required to sign a proprietary information agreement prior to the transfer of proprietary data. The intent of the agreement is to establish the rules regarding confidential information which may be transferred to a supplier. Proprietary information includes, but is not limited to, drawings, specifications, graphics, statistics, correspondence, and all information which is identified as confidential.

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DOCUMENT CHANGE RECORD					
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REVISION		SECTION /			
NO	DATE	BY	PARAGRAPH REFERENCE	CHANGE SUMMARY	
н	04 March 2019	Mary Horgan	Section 4.3 Section 7.1.1.1 Section 7.3.17 Section 7.3.17.1	Removed QP3.06.03 Approved Supplier List Updated "ISO 9001" to "ISO 9001:2015 and/or ISO13485:2016" Added "Anti-Counterfeit Policy" Added "The Supplier shall maintain a material authenticity program that has, as its goal, the avoidance, detection, mitigation, and disposition of counterfeit parts in accordance with the requirements set forth by Amphenol Alden Products. The supplier shall maintain objective evidence that the chain of custody has been maintained from original manufacturing of the part to the delivery of the part to the Buyer's receiving dock. The supplier shall provide the buyer will all necessary certificates of conformance and acquisition traceability. Upon Amphenol Alden request, the supplier shall also provide objective evidence, including chemical evaluation test results from an independent third party testing laboratory, that the material supplied to the buyer's receiving dock meets all stated requirements and has not sustained any chemical contamination or chemical substitution."	
			Section 7.5.4.6	Combined 7.5.4.6 & 7.5.4.7	
	17 July 2020	M. Virusso	Section 4.10	Removed QP3.06.01-4 SUPPLIER PERFORMANCE EVALUATION Renumbered remainder of section	
I			Section 4.10	Was: QF3.06.01-4 Supplier Performance Scorecard Is: QF 2.06.01-16 Supplier Performance Scorecard	
			Section 7.2.1.1.2	Was: QF 2.06.01-6 Supplier Quality, Documentation and Package Marking Requirements Form Is: QF 2.06.01-6 Supplier Quality Agreement Form	
			Section 7.2.1.2.2	Was: QF 2.06.01-6 Supplier Quality, Documentation and Package Marking Requirements Form	
			Section 7.8.6.1	Is: QF 2.06.01-6 Supplier Quality Agreement Form Was: QF3.06.01-4 Supplier Performance Scorecard Is: QF 2.06.01-16 Supplier Performance Scorecard	

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