



Supplier Quality Manual

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Revision History

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INTRODUCTION

Air Techniques is the US manufacturer of choice of products for the dental professional to be “equipped for life”. We leverage our market leadership position in core practice equipment to become a leading producer of digital diagnostic systems, hygiene solutions, and other relevant product categories. We believe that continually improving our equipment, products and processes is the key to increasing our competitive market position worldwide and ensuring our continued success. To meet our customers’ world-class expectations, a total commitment to customer satisfaction and continuous quality improvement must be shared by the Air Techniques and all its suppliers. As a part of the supply chain, together we must maintain effective criteria to help assure conformance with the specifications, adequate control of manufacturing process and continuous improvement of those processes.

PURPOSE

The purpose of the manual is to communicate Air Techniques’ Supplier Quality requirements and expectations to suppliers. It is the intent of the Air Techniques to do business with suppliers who can provide parts, materials, processes, and services consistently to specifications at a competitive price, and an accordance with defined delivery schedule. The manual is intended to assist suppliers in their understanding of requirements regarding specific supplier quality management, communication, and reporting processes.

SCOPE

The requirements of this manual apply to all suppliers of finished goods, production materials (raw parts), as well as outside processes and services, where applicable. The manual is the quality standard for every Air Techniques supplier. This common manual allows Air Techniques to evaluate all suppliers across all product groups based on common expectations and performance standards. This information applies to all suppliers who have interest in doing business with Air Techniques. Any questions regarding applicability of the requirements contained in this manual should be directed to your Air Techniques contact(s) for resolution.

This manual supersedes all other prior versions, and this version is the only officially recognized release of this document.

RESPONSIBILITY

It is responsibility of the supplier to review, understand and satisfy the requirements of this manual and any other applicable requirements as part of the acceptance of purchase orders from Air Techniques. The supplier should obtain any referenced documents to ensure full compliance with all applicable requirements.

Air Techniques will maintain and document changes in the general supplier quality requirements included in this manual. Revisions to the Air Techniques’ Supplier Quality Manual will be available on Air Techniques website, URL could be found on the boilerplate of purchase order.

Table of Contents

INTRODUCTION	1
PURPOSE	1
SCOPE	1
Table of Contents	2
1.0 GENERAL SUPPLIER QUALITY REQUIREMENTS	3
1.1 ...Quality System	3
1.2 ...Quality Planning	3
1.3 ...Engineering Prints and Specifications	4
1.4 ...Drawing and Change Control	4
1.5 ...Supplier Material Compliance	4
1.6 ...Control of Subcontracted Materials/Parts/Services/Labor at Sub-Suppliers	5
1.7 ...Control of Air Techniques Supplied (consigned) Materials/Parts	6
2.0 SUPPLIER QUALIFICATION/ASSESEMENT PROCESS	6
2.1 ...Supplier Regular Information	6
2.2 ...New Supplier Self-Assessment	7
2.3 ...On-site Assessment	7
2.4 ...Periodic reevaluation	7
2.5 ...Specific Process Audit	7
3.0 Part Qualification	7
3.1 ...Receipt & Review of Purchase Order	7
3.2 ...FAI Part Requirements	8
3.3 ...Prototypes, First Shot, Pre-production Samples Requirements	11
3.4 ...Production Parts – Lot documentation	12
3.5 ...Manufacturing Control	12
4.0 Supplier Change Management	13
5.0 Packaging	14
6.0 Non-conforming Product	15
7.0 Corrective and Preventative Action Requirements	16
7.1 ...Supplier Initial Response to a SCAR	16
7.2 ...Root Cause(s) and Solution Identification	16
7.3 ...Permanent Solution Implementation	16
7.4 ...Permanent Solution Effectiveness and System Changes	17
7.5 ...Final resolution of the Non-conformance	17
7.6 ...Responsibility Assignment for Corrective Actions	17
7.7 ... Supplier Liability, Chargeback Process and Cost Recovery (Cost of Quality)	18
8.0 Supplier Monitoring	19
Appendix 1 – Supplier Self Questionnaire F-9905-027	
Appendix 2 – FAI Requirements checklist	
Appendix 3 – FAI Inspection Report Form	
Appendix 4 - Supplier Deviation Request Form	
Appendix 5 – Correct example of the CoC and CoA	

1.0 GENERAL SUPPLIER QUALITY REQUIREMENTS

1.1 Quality System

As a medical device manufacturer, Air Techniques Quality System must comply with one of the following International Quality Standards and regulations:

- ISO 13485:2016
- ISO 9001:2015
- ISO 14971:2007
- FDA 21CFR Part 820
- AS 9100:2016

As well as:

- SOR/98-282 – Medical device regulations (Canada)
- TG(MD)R Sch3 – QMS Requirement for Australia
- RDC ANVISA 16/2013 – Brazilian GMP
- MHLW MO 169 – Japanese QMS Ordinance
- MDD – Medical Directive (93/42/EEC)
- MDR – Medical Device Regulations (2017/745)

Air Techniques expects that Quality System of our supply base shall follow one of the above listed or equivalent International Quality Standards or regulations as well.

Suppliers that do not have any International Quality Standard Certificates must have their Quality System developed in reference to the ISO 9001 or AS 9100 specifications or equivalent and will be evaluated on their individual merit.

1.2 Quality Planning

“Defect prevention is preferred to defect detection.” Quality Planning is a systematic process for establishing measurable objectives and requirements, and lays down sequence of steps for realizing them within a specific timeframe. Suppliers are required to document a plan for quality that addresses the following:

- Verification of Air Techniques' requirements.
- Having the necessary resources to provide desired parts (people, equipment, time, finance).
- Processing and specification verification procedures.
- Delivering the product or service according to established requirements and timing.

1.3 Engineering Print and Specifications

Suppliers are required to ensure they have received and fully understand the requirements of all Engineering Prints and Specifications related to the product(s) that they furnish to Air Techniques.

- Any missing and/or questions related to the understanding of the intent of Air Techniques' Engineering Prints and Specifications shall be communicated to Procurement prior to initiating supply to Air Techniques.
- Any revisions to the Engineering Prints and Specifications will be communicated through the Air Techniques procurement, or through revision level called on the Purchase Orders.

1.4 Drawing and Change Control

Suppliers must have documented systems in place to control changes to prints, specifications, processes, or produced parts. System should be capable of handling changes being requested by the customer, and changes requested by the supplier.

The supplier's quality system pertaining to Prints and Specifications must contain:

- Documented procedure that describes the method used for the receipt, review, distribution, and implementation of all changes to drawings and specifications.
- Control of obsolete drawings and specifications.
- Method used to contain new or modified parts until approved by the customer.

1.5 Supplier Material Compliance

Air Techniques requires understanding and verification of the composition of their raw materials. At any time, Air Techniques reserves the right to request raw material confirmation on any supplier purchased product.

- Supplier should be able to provide a Certificate of Compliance (CoC) or Certificate of Analysis (CoA) report when required.
- A material composition report may be required to verify that the raw material contained within the purchased product meets known or specific industry standards.
- Air Techniques can require ongoing material certification be provided on routine basis for any purchased product at the supplier's expense during the life of the product.

CoC demonstrates product compliance to the minimum production, technical and/or safety standards. It is required to state and declare that a product and company's manufacturing processes meet all the product requirements depending on the product type.

CoC or CoA must include the following but not limited elements:

- Manufacturer / importer's identification such as the legal name, address and contact number.
- Customer legal name and address.
- Product Identification with the product description covered in the CoC (PO#, Part Number and Revision Level, Part Description, Quantity, Batch/Lot Number, Date of Shipment).
- List of certificates awarded to the manufacturer that the product has been tested and is compliant.
- The date and place where the products were manufactured.
- Date and Place where product was tested for compliance with the product safety rule cited.
- Identification of any 3rd party laboratory / certification agency with an indication who did the test or issued the certificates.
- Authorized person signature and date.

See example of the CoC and CoA in the Appendix 4

1.6 Control of Subcontracted Materials/Parts/Services/Labor at Sub-Suppliers

The Primary Supplier is responsible for the quality of parts, materials, and outside processing provided by their sub-suppliers and sub-contractors. The extent of the controls may vary, depending on the nature and complexity of the product and processes, but should normally include:

- Evaluation and qualification of the sub-supplier facilities.
- Control to ensure that the raw materials used meet Air Techniques' requirements.
- Controls to ensure that the sub-suppliers of parts used are those approved by Air Techniques, where applicable.
- Part qualification, including first article inspection.
- Control of drawing/revisions.
- Control of nonconforming material.
- Corrective and Preventative Action programs.
- A continuous quality improvement program.

Where appropriate, Air Techniques may specify the sub-suppliers used, however, it does not absolve the Primary Supplier of the ultimate

responsibility for the quality performance of their sub-suppliers.

1.7 Control of the Air Techniques Supplied (consigned) Material/Parts

Whenever Air Techniques' supplier (consigned) materials/parts to supplier, the Supplier is responsible for properly handling, storing, and maintaining those materials/parts. Air Techniques can request inventory verification at any time and the supplier will be responsible to provide per request.

If consigned materials/parts will be shipped to the sub-contractors for subsequent production, supplier is responsible for entire process from the start to the finish (Drop ship, inspection, and finish)

Any material/parts that are lost, damaged, or deemed unsuitable must be reported to Air Techniques immediately for disposition.

2.0 SUPPLIER QUALIFICATION/ASSESEMENT PROCESS

All Suppliers of production materials to Air Techniques must be qualified suppliers. The objective of the Air Techniques' Supplier Qualification/Assessment Process is to identify potential suppliers who have operational systems and controls which are compatible and complimentary to Air Techniques and to periodically evaluate current suppliers to ensure those systems and controls are being sustained.

The extent of the qualification process is dependent upon the critically of product purchased, services provided, and other factors determined by Air Techniques. The qualification process consists of four parts:

2.1 Supplier Regular Information

- Location by factory qualifying for production.
- DUNS number by factory qualifying for production.
- **Primary Supplier Contact** by qualifying factory location – For all issues regarding the supply chain and procurement activity contact Air Techniques buyer.
- **Secondary Supplier Contact** by qualifying location for Product/Part Quality – For all issues regarding product quality, contact Supplier Quality Engineer (SQE) at the using Air Techniques site.
- A Copy of their 3rd party Quality System Certificate.
- Quality Manual.
- Table of Contents or Listing of Quality System Documents

2.2 New Supplier Self-Assessment

A QMS self-assessment shall be completed by the Supplier, using Air Techniques' supplier assessment survey Form F-9905-027. The criteria generally, follow ISO 9001 adding specific requirement to ensure effective process control and quality result. Suppliers completing self-assessments shall submit action plans to improve any section not meeting minimum requirements. Air Techniques reserved the right to perform On-site Supplier QMS audit based on the results of the self-assessment.

2.3 On-site Assessment

Audit conducted at the manufacturing location, if determined, by Air Techniques personnel or their authorized agent. This On-site assessment consists of various quality system and process control categories and is intended to provide a fair appraisal of the supplier's quality system, process controls, and commitment to quality at the time of the audit.

2.4 Periodic Re-evaluation of Existing Supplier

Periodic re-evaluation / re-assessment of the supplier to determine status in Air Techniques' supply base. Approved Supplier must notify Air Techniques immediately if their 3rd party regulation expires or is revoked. Air Techniques reserves the right disqualify, suspend and/or terminate suppliers based on substandard performance. In such case full requalification will be required prior to resuming the business.

2.5 Specific Process Audit

Air Techniques reserved the right to conduct audit focusing on the specific process and process quality control that Supplier has in place for the products being manufactured for Air Techniques, as well as part/commodity specific process requirements. Air Techniques reserved the right visit supplier without advance notice.

3.0 PART QUALIFICATION

3.1 Receipt and Review of Purchase Order

Your purchasing agent will send Purchase Orders (PO) for Air Techniques material needed. Purchase Orders (PO) are to include at minimum part number, revision, price, delivery date and quantity. All Engineering

specification, criteria and/or order details shall already be agreed upon before purchasing agent has released PO for each part number that we will receive from you. The Engineering specification is the common source of understanding between Air Techniques and its suppliers regarding what requirements must be satisfied with each part's manufacture and delivery.

Air Techniques expects that each supplier review and approve a PO for fitness against previously agreed Engineering specification(s) prior to making and shipping the contents of any given order.

If you receive a Purchase Order from Air Techniques that contains a part number/revision combination for which you currently do not have the corresponding Engineering specification(s) to review and ensure that you can satisfy the expectations that come with it – then contact your assigned Purchasing Agent and they will gather appropriate parties needed to facilitate request.

Supplier shall acknowledge the receipt and acceptance of the Purchase Order within 3 (three) days.

If the PO received is the first one for a given part number, or if a PO is new revision of specification that your site has never fulfilled previously, the PO may have a note "FAI (First Article Inspection) is Required"

3.2 FAI Part Requirements

Complex custom components, or assemblies whose failure will result in the device not functioning and exposed to the patient/user to harm, or custom components that can affect the manufacturability of the device, or finished devices which are directly distributed – FAI (First Article Inspection) is required.

First Article inspection (FAI) – Part(s) Approval Process is required, but not limited to the following:

- An initial purchase (New part being ordered for the first time).
- An initial purchase following a design change.
- An initial purchase following a supplier change.
- Existing part from same supplier at new location.
- An initial purchase of "or equal" material.
- An initial purchase following a supplier manufacturing method, tooling, or mold change/repair.

Based on Air Techniques' Part(s) Approval Process, First Article Inspection is

performed by the Supplier, for production parts, materials, processes, and services qualification in accordance with the Air Techniques drawings or Supplier drawings specified in the Air Techniques Purchase Order.

If applicable, FAI Requirements/Planning checklist will be provided to the Supplier, listing the steps and information that shall be submitted for qualification of the components or assembly for production. The checklist Items selected are based on the Air Techniques requirements and type of the part or assembly to be supplied.

The content of the FAI submittal package consists of the following:

- FAI Requirements checklist.
- Copy of the Purchase Order (without cost itemized) – **Attachment 1**
- Deviations, Waivers & Status (if applicable) – **Attachment 2**
- Part Number (List of Part Numbers) – **Attachment 3**
- List of Drawing(s) (Including lower-level drawing Revision & Status) – **Attachment 4**
- Software Configuration & Status (if applicable) – **Attachment 5**
- List of Qualification and Routine Inspection and Test Procedures, Work instructions & Status - **Attachment 6**
- List of Unit(s) Qualification Test Reports (if applicable) – **Attachment 7**
When required, the supplier must provide the specified Performance/Qualification/Durability test report(s). This report(s) must include the type of the testing to be conducted, Equipment used for testing, specified material and/or physical requirements, and the inspection/test result. A simple statement that the Performance/Qualification/Durability of the part meets the requirements is not acceptable. Each report must be traceable to the supplier's part and must be signed by the organization that performed the testing.
- Routine & Test Inspection Reports (including bubble drawings) - **Attachment 8**
- List of Assembly/Special Processes (Welding, soldering, painting, lamination others... - Title, Control document number & Status) – **Attachment 9**
- List of material Qualification Test Reports Results & Status (Material certificates, MSDS, MDS, Material Catalog page) – **Attachment 10**
- Manufacturing Plan, Including Workflow Diagram – **Attachment 11**
- Other Requirements (e.g., AWS weld qualifications, color verifications, packaging, acceptance criteria, serialization, list of samples with their approval status) - **Attachment 12**

FAI package should be submitted to the Procurement and Quality

representatives in electronic format (preferable Adobe Acrobat or Microsoft Office).

Air Techniques Quality will review FAI package (e.g., report, ballooned drawing, CoC or CoA) for completeness and verify conformance to specified requirements according to the material print.

The acceptance criteria for FAI parts and materials shall be provided by the Design Engineer, and should include but is not limited to design specification, drawings, test procedures and final appearance requirements. Applicable requirements must be listed in the Purchase Order and provided to the supplier by the Purchasing Department. Purchase Order must have indication as "First Article". Copy of the Purchase Order must be included into the FAI package (**Attachment 1**)

Purchase Order's for the "First Article" materials shall include the following Requirements per item:

- Quantity of the FAI parts.
- If more than one FAI part will be ordered, FAI package must contain reports demonstrating conformance with the print(s) specifications for every ordered FAI item.
- Packaging requirements for FAI material. Label must indicate "First Article" with the PO#, Part# and Revision level, that are listed in the Purchase Order
- Every FAI item, inside package must be identified individually as "First Article" with attached tag matching with the corresponding FAI Inspection Reports. Every Tag must have Identification mark or number matching with the identification mark or number on the corresponded FAI Inspection Reports

FAI package must be resubmitted when the previous FAI package submission was rejected. In this case, material will be kept in quarantine or put on hold and concurrently not inspected until FAI package will be corrected.

FAI parts must be produced under production condition, including materials, machines, tooling, processing parameters, cycle times etc. Any exceptions to the production conditions must be approved in writing by the Air Techniques and included in the FAI package (**Attachment 2**) submitted to the Air Techniques. Form to submit Supplier Deviation Change Request (SDCR) is in the Appendix 3.

The supplier inspects or tests each FAI part for all dimensions, drawing notes, and specification requirements listed on the current revision drawings and/or specification. Using engineering drawing, supplier must create "ballooned" drawing with numbered "balloons" that are points to corresponding individual dimensional and geometrical features and/or other specifications notes. The supplier must record the results of the inspection into FAI Inspection Report Form or equivalent form. Item numbers with recorded values of the measurements or results of verifications Pass/Fail on the FAI Inspection Reports must correlates to the numbered "balloons" on the "ballooned" drawing. A copy of the "ballooned" drawing and FAI Inspection Report must be signed by the Supplier quality and must be submitted as a part of the FAI package (**Attachment 8**).

All FAI samples must be visually inspected to ensure that they are free of flaws, or discontinuities that might adversely affects the form, fit, function or durability of the part or that might injure a person handling the material. Such flaws may include burrs, nicks, chatter marks, scratches, or contamination. The FAI part may be rejected for substandard workmanship, even if such characteristics are not specifically identified on the engineering drawing or related specifications. Air Techniques Cosmetic Inspection Specifications for the Molded Parts, and Cosmetic Inspection of the Coated Surfaces, shall be provided to the supplier with the Purchase Order (if applicable).

After FAI material evaluation, Air Techniques Purchasing Department shall submit FAI report to the supplier for review. If Air Techniques accepts a FAI parts using the supplier supplied data, and if found out later those parts do not meet the Air Techniques specification, our acceptance of the FAI parts does not alleviate the supplier from future responsibility. If material was rejected by the Air Techniques' Engineering and Quality, Nonconforming FAI report (DMR) will be provided to the supplier so the corrections can be made. Purchasing may request the supplier to provide new FAI material for inspection and review.

3.3 Prototypes, First Shot, Pre-production Samples Requirements

Package with samples shall be labelled accordingly with the requirements listed on the Purchase Order provided to the supplier by Purchasing Department. Samples intended to be used as prototypes, do not need Air Techniques' part number assigned to them on the Purchase Order. The Purchase Order line is entered as "others", and the Part Number is entered as "Requestor name". Every Sample must be packed and tagged individually. Tag must contain reference to the corresponding requirements defined in the

Purchase Order (i.e., drawings, material certificates, testing requirements). Dimensional inspection reports and/or test reports must contain reference to the corresponding sample/tag. Dimensional Inspection and/or test reports and material certificates must be included into the shipping package.

3.4 Production parts – Lot Documentation

Air Techniques may require the supplier to furnish inspection, test, process performance, Material certification, or other quality data with each shipment to ensure, that product meets Air Techniques' requirements. Requested quality data must accompany each shipment, or be emailed to Air Techniques at the same time the lot is shipped. All documentation must be clearly identified with Air Techniques Purchase Order number, part number, Lot number.

3.5 Manufacturing Control

Manufacturing Control Plan must include but not limited to the following:

- Process Control - Air Techniques suppliers are required to control all manufacturing process in accordance with the manufacturing control plan, which is established during the part(s) qualifications.
- Statistical Process Control – to control effectiveness of the process including:
 1. Charts for product displays control characteristics and limits charts in the process area, visible to the operator, or person responsible for controlling the process
 2. Charts for all out-of-control condition, actions are taken to bring the process back into control. Actions taken must be recorded.
 3. Product produced during any out-of-control condition is sorted, scrapped, reworked, or dispositioned through the supplier material review process.
- Process performance – compare actual process variation to the specification critical characteristics
- Process improvement – Out-of-control or unstable processes and processes that do not meet the minimum requirements must be identified and corrected.
- Lot Control – A lot consists of products 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. Each shipment of the material to the Air Techniques must be identified with the Supplier's lot number. Inspection records must be traceable to lot numbers.
- Traceability – Ties finished product back to the components used in the final product.

- Workmanship – When workmanship standards are not references on the Air Techniques drawings and specifications, the supplier is expected to follow Industry-accepted standards (e.g., ANSI, IPC).
- Safety – At no time should any customer, or person at Air Techniques facility, be exposed to hazardous material or situation that are not inherent in the component's structure. Residues, films, out-gassing products, and packaging material should comply with OSHA standards. For items with inherent hazards, safety notices must be clearly observable. As applicable, MSDS sheets must be provided during the First Article process.
- Maintenance – Suppliers must maintain all facilities, manufacturing machines, tools, measuring devices, and other equipment in such manner that the supplier can support Air Techniques production requirements and quality of parts manufactured for Air Techniques.
- Electrostatic Discharge (ESD) Control – For ESD-sensitive material, supplier must maintain effective ESD program that meets all requirements for the material produced.
- Limited Shelf-life materials Control – For the materials with the limited shelf life, supplier must maintain effective Shelf-Life Management Program.

4.0 SUPPLIER CHANGE MANAGEMENT

All product design, process, source, location, and material changes and/or deviation request to the current part approved level is required to be submitted for formal approval through Supplier Process Deviation and Change Request (SDCR form in the Appendix 3), this includes all sub-tier supplier changes and/or deviations. This requirement also applies to any change resulting from any form of process or product improvement or cost reduction activity or any previous product nonconformance. Supplier must obtain written approval from Air Techniques prior to implementation of any requested changes or shipment of any product containing deviation to Air Techniques specification.

A (SDCR) Form is used to request a temporary deviation or permanent change to a released part, process, drawing, specification, or material. The supplier shall complete the form for either deviation or change request and submit it to the Purchasing Department and await approval prior acting.

The originator of an SDCR shall fill up the following:

Tab - SDCR Form:

- Section 1 – Supplier Information including Supplier DCR internal number
- Section 2 – Part Information (leave ATI Change Control # cell blank)
- Section 3 – Deviation/Change Details

- Section 4 – Supplier Approval
- Section 5 – Corrective Action Plan

Tab – In Pictures (optional):

- Tab can be used to provide picture, snapshot from the drawing to better describe deviation and/or change request.

Supplier must submit SDCR with completed FMEA and/or Corrective Action Plan, revised Control Plan (if applicable) to Air Techniques for evaluation the following:

- Supplier demonstrated process capability
- Comparison to the FAI part/data
- Industry Standards
- Supplier process engineering capabilities
- Supplier's adherence to control plan

After Air Techniques has completed the review, and concurs with the supplier, Air Techniques will notify the supplier as to the final disposition of the SDCR and part requirements and dates. If SDCR is approved, the new deviation form must be submitted for EACH shipment containing deviated parts. Any parts sent to Air Techniques that have been approved on a deviation must be clearly identified on the box, container, or other packaging method with the appropriate markings decided jointly by Air Techniques and supplier.

5.0 PACKAGING PLAN

The supplier must adequately plan for packaging of material shipped to Air Techniques. The supplier shall provide a documented packaging plan including container size, number of parts per container, packaging configuration, etc. Packaging shall be designed to provide protection from any damage that may occur (including environmental damage). Packaging labeling, and shipping materials must comply with the requirements of common carriers to secure the least transportation costs. The Packaging Plan should be discussed during the quotation process and agreed upon from both parties. The Packaging Plan shall be submitted prior the first production shipment, as a part of the FAI Package submittal.

Samples and Pre-production parts, service parts, and special-order parts shall be packed according to the approved proposal unless otherwise approved by the Air Techniques Purchasing Department. Suppliers may not deviate from shipping the quoted and approved packaging without prior authorization.

Non-compliance with these requirements will influence the delivery scoring on the Supplier Scorecard Report. The supplier may be charged for additional cost incurred for shipments that do not comply with requirements.

6.0 NON-CONFORMING PRODUCT

Nonconformity is defined as the non-conformance of Production approved parts to one of the following documented requirements:

- Print dimensions
- Material Specification
- Engineering Specification
- Packaging Specification
- Mixed/wrong parts within the shipment
- Improper identification of parts
- Failure of part to perform during the functional test at Air Techniques
- Failure of part to perform during the warranty period Air Techniques due to supplier created discrepancy
- Non-conformance in the C of C

Material identified as nonconforming from the following sources:

- Incoming Inspection
- In-Process (Product Line rejection)
- Returns (RMA material)

and automatically generates Discrepant Material Report (DMR). Nonconforming product will be identified with an appropriate tag and moved to a HOLD location.

When a supplier non-conformance has been identified, a Supplier Discrepant Material Report (SDMR) will be issued to communicate the nonconformance to the supplier. SDMR should contain the following: Supplier Name, SDMR Number, Part number, Part Revision, Part Description, Discrepant quantity, Purchase Order Number, Non-conforming report date, SDMR issued date, Nonconformance Code, and Nonconformance Details.

Based on the criticality of the material, severity of the nonconformance, and prior supplier performance, Air Techniques Quality Management and/or Material Review Board (MRB), may determine further information is required and issue a Supplier Corrective Action Request (SCAR).

7.0 CORRECTIVE AND PREVENTATIVE ACTION REQUIREMENTS

7.1 Supplier Initial response to a SCAR

The supplier initial response is an acknowledgement that the Supplier has been informed of the problem and is taking appropriate action.

The initial response must define their problem statement utilizing the customer information, supplier part and process knowledge.

If containment plan is applicable, it must clearly define the containment action at the supplier's facility to assure that no nonconforming product is shipped to Air Techniques. If suspected product has already been shipped, the supplier must address all suspect stock in transit and any stock at Air Techniques. The supplier will assist Air Techniques in identifying customer risk by identifying all suspect lot numbers and associated quantities involved. SCAR or any other document additionally attached to the SCAR must include (but not limited to): SDMR Number, Part Number, Serial Number (if part or assemblies is serialized)

7.2 Root Cause(s) and Solution Identification

It is a supplier's responsibility to confirm the root cause(s) of the discrepancy identified and identify effective solutions to eliminate the true root cause(s). A written preliminary Corrective and Preventative Actions (CAPA) must be sent to Air Techniques within ten (10) working days identifying the root cause(s). There are many potential tools to assist supplier with this including (but not limited to): 5 why analysis, 8D, control chart, decision matrix, design/process failure mode effect analysis, and so on. Air Techniques does not prescribe a specific root cause analysis method. The supplier shall demonstrate root cause validation on the SCAR response. Air Techniques will review the submitted root cause validation. Where, in Air Techniques opinion, the measurement and analysis plan does not clearly validate the potential root cause(s), Air Techniques may reject the supplier's response to the SCAR. If proposed plan is rejected, supplier is responsible for providing alternative plan to provide conforming material.

7.3 Permanent Solution Implementation

Once approved, the supplier is responsible for implementing the proposal.

The SCAR shall be updated by the supplier to indicate progress.

Air Techniques will monitor the progress based on effectivity dates of the planned activities and milestones. Where assistance is required to achieve the plan, the plan cannot be implemented as defined or will not solve the original problem, the supplier shall notify Air Techniques before due dates are compromised.

7.4 Permanent Solution Effectiveness and System Changes

The supplier is responsible for providing evidence of the effectiveness of the corrective and preventative actions or control the root cause(s) on the non-conformity. This evidence shall be included in the SCAR response. Where the evidence provided does not clearly indicate the problem has been solved, the supplier will be notified to include additional or more comprehensive Evidence.

7.5 Final resolution of the Non-conformance

Final resolution of the corrective and preventative action will be made within thirty (30) working days of the supplier's submittal. Any request for additional time should be directed to the Air Techniques and shall be in writing. An extension of time may be granted based upon the corrective actions required on the nature of the nonconformance. However, a detailing timing plan shall be provided by the supplier targeting implementation and resolution of the corrective and preventive action(s).

7.6 Responsibility Assignment for Corrective Actions

- **Supplier Responsibility**
Part or material analysis shall be documented using SCAR format. This format is also utilized to monitor the effectiveness of the CA over time by each component. The supplier has the obligation and responsibility for any reasonable and customary cost associated with the non-conforming part or material.
- **No Fault Found (NFF)**
Part or material analysis results in the declaration of NFF after completing the SCAR processes. Supplier must clearly describe document and provided result data on how they arrived at this conclusion. The NFF status in the warranty analysis process must follow systematic elimination of potential root cause factors. NFF typically describes a scenario whereby testing indicates the returned part meet Air Techniques and/or our customer part and performance requirements as defined in purchase order, Purchase specification and warranty terms and agreements. Disposition must be done by the Air Techniques.
- **Not Supplier Responsibility**
When the supplier investigation has determined the defect is not them responsibility, with the potential of Service or Customer issues, the suppliers need to provide all supporting documentation for justification of this type of failure.

In the event, that Air Techniques disagrees with a supplier response, Air Techniques will give timely notice of its objection. If Air Techniques declines a submitted response, the supplier will be asked to amend it.

A rejected supplier response, where the parties do not agree as the content effectiveness, shall not be binding upon Air Techniques. The supplier shall retain the affected parts, until the issue is resolved in a positive and professional manner.

7.7 Supplier Liability, Chargeback Process and Cost Recovery (Cost of Quality)

In the event, that non-conforming parts or material result in a cost liability to Air Techniques, Air Techniques reserves the right to charge the supplier costs associated with the resolution of the non-conformance. It shall be supplier's responsibility to aid Air Techniques in evaluating and correcting the problem. If necessary, Air Techniques will request the Supplier to be on-site to help support nonconforming activities and present corrective action to the Air Techniques' Management team. The supplier has the obligation and responsibility for any reasonable and customary costs associated with the non-conforming part or material including but not limited to:

- First Article rejection
- Sorting of suspected material
- Third party containment
- Premium Freight / shipping
- Warehousing
- Rework / repair
- Production Downtime
- Overtime
- Scrap
- Administrative
- Engineering efforts
- Laboratory Testing
- Customer Charges
- Warranty / Recall
- Travel and associated costs

Costs incurred may be reviewed with Purchasing Department and/or assigned point of use representative and may be debited from the suppliers account at Air Techniques' direction. A supplier shall comply with Air Techniques process to recover costs associated with a supplier's performance liability. Upon notification

of the intent to debit, if there is no response from the supplier, Air Techniques will consider this lack of response as acceptance of the charges.

8.0 SUPPLIER MONITORING

Air Techniques monitors its suppliers to ensure they continue to meet Air Techniques' requirements, and to ensure that the supplier continues to ship acceptable parts. Monitoring methods may consist of:

- Supplier Scorecards & Performance Evaluation
- A QMS surveillance audit at the supplier's facility
- An on-site specific process audit at the supplier facility
- A random incoming inspection of a batch of product
- Review of supplier finished data packages
- A supplier progress review meeting conducted periodically at the supplier's site or Air Techniques' site.

APPENDIX 1

Supplier Self Questionnaire Form

APPENDIX 2

FAI Planning Checklist Form

APPENDIX 3

Supplier FAI Report Form

APPENDIX 4

Supplier Deviation Change Request Form

APPENDIX 5

Example of correct CoC and CoA