



analogic

Supply Chain Supplier Quality Manual

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1 Introduction

1.0 There shall be no change in the product design or material content without written approval from Analogic Engineering.

1.1 There shall be no change in the manufacturing process with respect to equipment, location, method, tooling or outsourcing without prior written approval of Analogic Purchasing and Quality.

1.2 Approval of these changes can be obtained through the submittal of the Analogic "Supplier Request for Engineering Approval" (SREA) form or PPAP package, as determined by Analogic. Suppliers shall not make changes based on verbal inputs from Analogic Engineering.

1.3 All suppliers shall perform in-process and final inspection or testing at established interval to assure conformance to Analogic specifications.

1.4 Evidence of established inspection or test shall be made available to Analogic upon request through the use of STATISTICAL PROCESS CONTROL methods. Suppliers may be requested to supply evidence of process control data or testing by sending CRITICAL TO QUALITY (CTQ) data sheets with each shipment or as requested by Analogic. Analogic may also request other documentation such as but not limited to X&R Charts, P Charts and C Charts.

1.5 All products manufactured for Analogic shall be in accordance with this document and subject to Analogic Purchase Order Terms and Conditions.

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2 Purchasing and Supplier Quality Assurance Strategy

Analogic does not require its suppliers to have third party certification to ISO9001 but strongly recommends as a minimum that they comply with the ISO9001 standard.

The Analogic "Supplier Quality Manual" is a contractual obligation between Analogic and you, the supplier. Receipt of this manual and acceptance of our purchase order to provide goods and or services constitutes the supplier's commitment to comply with these requirements.

2.1 Suppliers Quality Management System development

The basic objective of Analogic Purchasing and Quality strategy is as follows:

1. To have product available when and where needed.
2. To have product quality consistent with specifications.
3. To provide good long-term supplier relations and source development.
4. To buy competitively and wisely, and keep abreast of the forces of supply and demand that regulate processes, prices and availability.
5. To develop reliable new sources of supply and apply the single source concept where appropriate.
6. To achieve maximum integration with our departments at Analogic.

3 Quality Operating Systems

3.1 General

The supplier must establish and document systems to encompass all elements of their business to ensure the product to be manufactured and delivered meets all customer specifications and expectations. Analogic, a medical industry supplier, has developed its quality operating system to meet the requirements of the ISO13485 standard.

3.2 Analogic Supplier Selection Process

New suppliers must be approved by Analogic prior to any purchase order business awards, and may be evaluated for financial stability, manufacturing capabilities and quality systems effectiveness.

3.2.1 Purchasing Responsibilities

Analogic purchasing may evaluate the potential supplier for financial stability. They may also perform a reference check of key customers accounts and evaluate the supplier's ability to grow with Analogic based on up front structure of the technical support functions for product development. Analogic will also consider the supplier's ability to add capacity.

3.2.2 Product Development Team Responsibilities

Product development teams may perform a manufacturing feasibility and design capability study of the potential new supplier; this will be dependent upon the criticality of the component. This evaluation may include a review of manufacturing, engineering and tooling facilities, to include the organizational structure for new product development and manufacturing systems.

3.2.3 Supplier Quality or Quality Engineering

The Analogic QE or SQE may perform a quality systems audit to verify existence, adequacy and compliance to Analogic Purchasing / SQA system requirements. During the launch of a new component, Analogic may perform a process audit, or run at rate audit. Analogic utilizes the ISO9001 standard as the fundamental requirements for its supplier's quality systems. Analogic may use on-site auditing to evaluate supplier compliance. If discrepancies are discovered during the audits, Analogic may still conduct business with the supplier contingent upon a corrective action plan with measurable milestones, provided the supplier is willing to implement the corrective actions.

3.2.4 Qualified Supplier List / Approved Manufacturer List

When the supplier has been evaluated and Analogic has determined they have the proper business systems and production capability, the supplier is added to the Qualified Supplier List (QSL). Approval for the QSL allows Analogic to start developing business with the supplier, and allows the supplier to begin accumulating quality and delivery performance history. Analogic also utilize an Approved Manufacturer List (AML). This is used to approve the original product manufacturer if the purchase of parts is through a QSL qualified distributor.

3.3 Component Design and Development

From the earliest moments that the supplier becomes involved with developing products for Analogic they should endeavor to gain as much knowledge as they can about the role of their component in the final assembly and how it will get there. The knowledge of the function of the supplier's component, how it will be during shipping and how it will be assembled into the Analogic product are essential to proper develop the components design.

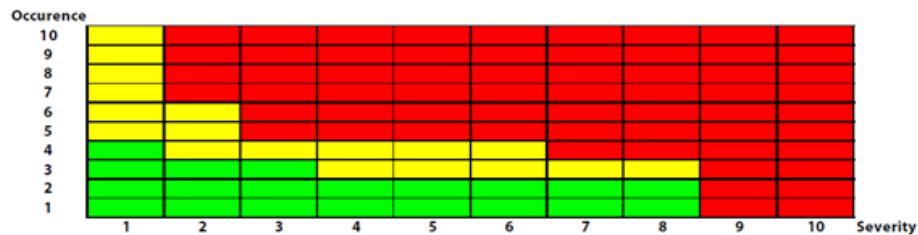
To properly document this Analogic recommends suppliers use the Failure Modes and Effects Analysis for both the Design (DFMEA) and Manufacturing Process (PFMEA).

3.3.1 Failure Modes and Effect Analysis (FMEA)

This is a cross functional team approach to examine all potential causes of failure in the component due to design or manufacturing process. Process FMEAs (PFMEAs) and Design FMEAs (DFMEAs) may be required depending upon the criticality and nature of the product being supplied. When developing the PFMEA, the supplier should begin with a process flow diagram and evaluate each major process step for potential failure modes. Upon completion of the PFMEA, the supplier should attempt to reduce the highest RPNs through redesigns, mistake-proofing or inspections. All controls should be documented in the Control plan.

Analogic may request that the PFMEA and DFMEA are submitted as part of PPAP approval for the component being supplied.

When completing the FMEA an action plan must be established in line with the risk analysis table shown below:



Green area – No actions required

Yellow area – No mandatory actions required, but corrective and preventative actions should be defined and communicated to Analogic to reduce risk to both parties.

Red area – Mandatory corrective and preventative actions are required and shall be communicated to Analogic to reduce risk to both parties.

3.3.2 The Quality Control Plan

The Control Plan is a summary of all quality checks and controls of the parts and process used to manufacture any component for Analogic. It should align with the process flow diagram and the PFMEA. The control plan must start with receipt of any materials used to manufacture the components and follow the process until the components leave the supplier..

4 Sustaining Quality Systems

4.1 General

It is the supplier's responsibility to develop and document systems committed to meeting the expectations of their customers. The supplier should assign adequate resources, to include trained personnel, for the management, performance and verification activities.

4.2 Manufacturing Quality Control

The supplier shall ensure that all manufacturing processes are controlled through documented work instructions for operators, use of statistical techniques for CTQs and corrective actions if nonconformance's occur.

A controlled process is defined as an operation with an established machine or process capability of a minimum 130 capability index (Cp and Cpk) of a minimum 1.33

Analogic and the supplier will determine the frequency for submittal of capability data should it be deemed required. CTQs must be listed in the supplier's process control plan along with the sample size and frequency taken.

4.3 Critical to Quality Characteristics (CTQs)

Critical to Quality Characteristics are used by Analogic to designate dimensions or specifications that significantly affect the form, fit and function of the component. The CTQs are determined by Analogic Engineering.

Analogic expect suppliers to use statistical techniques to control the defined CTQs as stated in "6.2 Manufacturing Quality Control" within this document. Analogic and the supplier will determine the frequency for submittal of capability data.

If the CTQ data is not submitted at the determined frequency it will be considered a nonconformance and may result in the rejection of supplied product.

4.4 Special Processes

Analogic requires suppliers to have documented controls for any process that cannot be verified by subsequent testing or inspection without affecting fit, form or function of the part.

Special Processes are considered to be but not limited to the following:

- Chemical Processing
- Coatings
- Composite Manufacture
- Elastomer Seals
- Heat Treatment
- NDT
- Non-Conventional Machining (ECM, ECM, EDM, LBM)
- Sealants
- Welding
- Soldering
- ESD

Documented evidence of process control and results must be available for review at Analogic's discretion.

4.5 Document and Data Control

The supplier shall establish and document systems of document control to assure only current drawings supplied by Analogic are in use. The supplier will assure that all obsolete drawings are removed from service and destroyed.

4.6 Records Retention

Records shall be maintained for the life of the program plus five years or as specified by Analogic. Records should be maintained for, but not limited to the following:

- FMEAs
- Control Plans
- Gauge R&R studies
- Functional (ES Test) Test Data
- Raw Material Specifications (Customer specific to latest revision)
- Nonconformance's
- Rework Traceability
- Calibration

4.7 Measurement and Test Equipment Control

The supplier shall identify all inspection, measuring and test equipment, either privately or supplier owned, that can affect product quality. These instruments must be calibrated at prescribed intervals prior to use against certified equipment having a known valid relationship to internationally or nationally recognized standards, (National Institute of Standards Technology). Records of calibration are to be maintained by the supplier.

4.7.1 Gauge Repeatability and Reproducibility (GR&R)

The ability to take accurate measurements is essential. Analogic may require a Measurement Systems Analysis (MSA) / GR&R study to be conducted on all measurement equipment used to accept or fail the product being supplied.

Analogic requires the following acceptance levels to be used:

$GR\&R_{TOL}\% < 10$	Pass - Gage System is Useable
$10 \leq GR\&R_{TOL}\% \leq 30$	Gage System is useable but marginal
$GR\&R_{TOL}\% > 30$	Fail - Gage System is Unstable

- 1) % R&R should be 10% or less for all CTQs
- 2) Marginal gauges (between 10% and 30%) should have an action plan to address and improve the method of measurement.
- 3) Gauges with R&R at 30% or more must not be used.

For more information on GR&R documentation the AIAG manual "Measurement Systems Analysis" is a good reference guide.

4.8 Internal Quality Audits

Internal audits should be performed to confirm the effectiveness of the supplier's quality systems. Results of the audits should be recorded and communicated to those employees having responsibility for the audited area. Any nonconformity should be investigated for the proper corrective actions.

5 Non-Conforming Material

Analogic reserves the right to make a claim on any products with deviation from agreed specifications, reference Analogic Terms and Conditions of Purchase.

5.1 General

The supplier shall establish and document systems to prevent any nonconforming material from being received by Analogic.

5.2 Nonconforming Material at the Supplier

Nonconforming material discovered at the suppliers should be dispositioned in one of the three following ways:

- Scrap
- Rework / Screen
- Use as Is

All product that is not made according to the Analogic drawing specifications is the responsibility of the supplier as well as all actions pertaining to the disposition and handling of that material.

5.2.1 Scrap Material at Supplier

Scrap material and scrapped material will be handled by the supplier according to their systems.

5.2.2 Use as Is / Repair

A Supplier Request for Engineering Approval (SREA) is a tool for use when nonconforming material is thought to be useable "as is" or after repair by the supplier. If repair is carried out, records must be retained and are to be fully traceable to the product batch. However, the supplier should always have an alternative plan in place if the SREA is rejected.

The SREA should be considered a last alternative when the supplier is trying to correct a nonconformance.

5.2.3 Product Change Notification Approval (PCN)

A Product Change Notification Approval (PCN) is a tool for use when nonconforming material is thought to be useable "as is" or after repair by the supplier.

The PCN must include a detailed description of the non-conformance and submitted to Analogic for approval. Please note that Analogic may request samples to accompany the PCN submission.

The supplier cannot ship any nonconforming product until the PCN has been approved by the appropriate Analogic Engineer. To do so will result in an immediate rejection of the shipment.

5.3 Nonconforming Material Communication

The supplier shall have a process in place to communicate in a timely, efficient manner all nonconformities that may affect Analogic or its customers.

5.4 Nonconforming Material Discovered at Analogic

If nonconforming material is discovered at Analogic it will be immediately rejected from its location and moved to the appropriate MRB area. If Analogic has immediate production needs for the material, Analogic may require the supplier to arrange sorting or rework at Analogic. If Analogic's need is not immediate the nonconforming material may be returned or swapped with good material shipped by the supplier. In all instances Analogic production must be unaffected.

All actions and associated costs related to the nonconforming material is the responsibility of the supplier.

5.4.1 Containment at Analogic

If the supplier is unable to immediately perform the necessary action to fulfill Analogic's production needs, Analogic may begin sorting and/or rework operations.

The supplier should note that Analogic is not in the business of sorting and reworking material. Such incidents that require Analogic to perform these actions on the suppliers material will be looked upon very unfavorably.

6 Corrective Action

If the supplier is notified that product it has shipped to Analogic does not conform to drawing or other specifications the supplier must have a system to efficiently and effectively determine the root cause of the non-conformance and implement permanent corrective actions.

6.1 Corrective Action Requests

Analogic will notify suppliers of each shipment that does not conform to Analogic specifications via a Supplier Corrective Action Request (SCAR).. Notification will be sent to the supplier with information about the non-conformance. Analogic's preferred response methodology is the 8D, however if a supplier has a format that covers all of the information below, that is acceptable.

- Containment Response: Within 48 hours of receipt of SCAR notification.
- Root Cause Analysis
- Interim and Permanent Corrective Actions
- Final SCAR submission

Analogic requires a full SCAR response within 25 business days, however this may be extended if specifically requested by the supplier to the Analogic Quality representative.

6.2 Corrective Action Request Levels

Analogic will issue SCARs in three categories when supplier non-conformances are found.

6.2.1 SCAR Level One

This is assigned to non-conformances that have the possibility of getting through Analogic's systems and getting to the customer. Level one SCARs are the most serious of SCARs and may be accompanied by a flat rate chargeback when the supplier is found to be at fault for the nonconformity.

6.2.2 SCAR Level Two

This is assigned to non-conformances that will cause Analogic to assign additional handling of the material, such as sorting, rework or returning to the supplier. The supplier maybe charged a flat rate chargeback for level two SCARs.

6.2.3 SCAR Level Three

This is assigned to non-conformances that can be used with no additional actions by Analogic. This level is for components that are found to have a characteristic out of specification, but the situation will not affect the form, fit or function of the assembly. Though the out of specification characteristic may not affect the assembly, the concern must be corrected before it escalates.

6.3 Critical Problem Resolution Meetings

Critical Problem Resolution Meetings are designed to afford positive corrective actions due to major problems, line shutdowns or repetitive problem occurrence. The supplier may be requested to visit Analogic to present the "Eight Discipline Corrective Action" (8D) report. This must include a full response and also demonstrate the use of root cause analysis tools such as 5WHY, Fishbone diagram, Hypothesis Testing, etc.

The 8D presentation should be made by the suppliers Quality representative and other senior staff members as deemed necessary.

The time and date of the Critical Problem Resolution Meeting will be arranged between Analogic and the Supplier.

6.4 Audits for Critical Problem Resolution Meetings

Analogic may visit the supplier's location when problems become systemic from the supplier or a major quality concern has been discovered. The audit will be conducted by Analogic and will assess what part of

the supplier Quality Operating System has failed. The audit will also be based on determining if the supplier's systems are in compliance with ISO9001. Results of this audit will be used to help develop corrective actions to bring suppliers systems back into effective compliance and prevent the situation from reoccurring.

7 Handling, Storage and Delivery

The supplier shall have documented systems for the handling, preservation and delivery of product to Analogic. These systems shall describe the proper methods to package, handle, store and prepare for the shipment of product to prevent damage or deterioration to the quality of the product.

7.1 Handling and Storage

The supplier shall have controls to prevent the mixing of visually similar components. The mixing of components constitutes non-conforming material and is grounds for rejection and return to the supplier at the suppliers expense.

The supplier shall package parts to ensure the product being supplied is adequately protected from damage, deterioration and tarnishing. In a case where material has a shelf life, making it subject to deterioration from aging, the packaging must indicate the latest date to which material may be used. The supplier shall also have adequate ESD protection where required using the specified guidelines in ANSI/ESD: S20.20. Suppliers of Lithium batteries must comply with the latest revision of IATA Dangerous Goods Regulations for of packaging, labelling, and shipping.

7.2 Delivery

The supplier shall establish systems to support 100% on time shipments to meet Analogic production and service requirements. If 100% on time shipments are not maintained the supplier should implement corrective actions to improve delivery performance, including communication of delivery problems to Analogic.

7.3 Labeling of Shipping Containers

All shipping containers should be labelled with the Analogic part number, revision, quantity, purchase order number, supplier name, supplier vendor code and manufacturing date. There may also be a requirement to attach labels showing product compliance such as RoHS. Shipments not properly labelled may be considered as nonconforming and subject to rejection and return to supplier.

7.4 Certificate of Compliance (C of C)

Suppliers are to submit certificates of compliance when requested by Analogic. Analogic may require a C of C to accompany each delivery of product and require any compliance requirements to be included such as RoHS, REACH, etc.

7.5 Material Safety Data Sheets

Materials such as lubricants, sealants, solvents and preservatives must also have Material Safety Data Sheets (MSDS) sent with product at least once every 12 months.

8 Analogic Ship to Stock Program

Analogic's ship to stock program is a measure of the consistent quality and delivery of the supplier. Components that qualify for this program are eliminated from incoming inspection due to their proven history of dimensional capability and quality. The Ship-to-Stock program is an important tool that allows Analogic to reduce the cost of manufacturing products.

8.1 Part Qualification – Ship to Stock

Before a part can be placed on the Ship-to-Stock list it must meet all the following requirements:

- Be shipped from an Analogic Approved Supplier
- Have an First Article package if applicable
- Have a history of at least 3 shipments of lot acceptance

8.2 Part Disqualification and Requalification

Parts will be removed from the Ship-to-Stock list if a Level One or repetitive Level Two SCARs are issued against the part. Once removed, the part can re-qualify only after a permanent corrective action plan has been approved and verified. The part must go a minimum of three lots with accepted shipments before it will be placed back onto Ship-to-Stock status.

9 Supplier Performance Measurables

Analogic will monitor data on a number of performance categories for use in rating its supplier base. Analogic expects its suppliers to maintain self-directed performance measurables and present to Analogic upon request. Analogic and its suppliers should use this information to determine their performance and verify the effectiveness of continuous improvement programs.

9.1 Performance Measurables

Analogic will monitor the following metrics,

- Parts Per Million (PPM) or Rejection Rate %
- On-Time Delivery
- Number of SCARs
- Ship to Stock %

Other metrics may also be added at Analogic's discretion. Suppliers are also expected to track these and similar performance metrics.

9.2 Supplier Cost Reduction Program

It is expected that suppliers have a formal internal cost reduction program with measurable performance goals. These goals should be shared with Analogic as Analogic may be prepared to "invest" in cost reductions where the payback is acceptable and is applicable to Analogic business.

Suppliers should focus their efforts to reduce costs on those factors that affect their manufacturing processes. Key factors to this would include Labour overhead, Inventory carrying costs, Scrap, Setting / Start Up waste, Rework costs, First time yield, Excess shipping costs, Cycle times, etc.

9.3 Supplier Strategic Reviews

Periodically Analogic may meet with its top suppliers to review their current capabilities, recent performance and future developments. The goal of these meetings is to evaluate the partnership between Analogic and its key suppliers and chart the future course of relationships to meet our ultimate customers developing needs and expectations. Issues which may be covered at the meeting include but are not limited to:

- Supplier current and future production capabilities
- Supplier quality performance with emphasis on SCAR trends, parts with repeat SCARs, PPM rates and problems that have interrupted Analogic's production.
- Supplier delivery performance with emphasis on late delivery trends and delivery situations that have interrupted Analogic's production schedule.
- Supplier cost performance with emphasis on cost reduction projects that effect Analogic.
- Current status of new component programs or transferred programs.

10 Supplier Control of Subcontracted Products or Services

The supplier is responsible for verifying that all materials purchased from subcontractors for use in products for Analogic meet all Analogic specifications and requirements. The supplier shall document data for the inspection and or test to ensure the material meets specifications and requirements.

The supplier shall also have a process to monitor and address the performance of all its sub-suppliers.

10.1 Subcontracting Material

In the event the supplier decides to subcontract a product that it was previously manufacturing, the supplier must contact Analogic to authorize the transfer of product. The supplier may be requested to submit a PPAP for the product it intends to transfer, and cannot begin shipments of subcontracted product until the PPAP or Analogic approval is given. If timing becomes critical the supplier may submit an SREA to cover the time period needed to process the PPAP or gain approval of transfer from Analogic, while shipments are being made from the additional location.

10.2 Emergency Subcontracting

In the event of an emergency due to capacity problems, natural disasters, etc the supplier must notify Analogic of the reason for the transfer and submit an SREA for approval to cover the emergency time period until formal approval can be given by Analogic.

10.3 Non Counterfeit Parts

The supplier must have a process established to eliminate any potential for counterfeit parts to be entered into the supply chain. This includes controls at subcontractors. Analogic may request evidence of non-counterfeit parts that are being supplied.

10.4 Disaster Recovery / Contingency Planning

The supplier shall have a process to ensure the continuation of supply to Analogic in the event of a catastrophic failure, either man made or act of nature.

10.5 Analogic Owned Tooling

The supplier will be responsible for keeping all Analogic owned tooling in accordance with terms and conditions called out in the original supply agreement. This may also include assigning an Analogic asset tag to the tool showing ownership. It is also expected that the tooling be captured on a Preventative Maintenance (PM) schedule to ensure it is maintained to avoid unplanned stoppages.

10.6 Training and Resource Management

The supplier will have sufficient resources to ensure product realization to meet Analogic's drawing, specification and PO requirements.

11 Regulatory Requirements

All suppliers are required to comply with the most current regulatory requirements of the EU RoHS and REACH Directives, as well as the WEEE Directive, Battery Directive, Packaging Directive, Machinery Directive and the Conflict Minerals requirements of the Dodd-Frank act, and to provide information regarding the status of their compliance as requested by Analogic.

Analogic reserves the right to ask for updates of this information on a periodic basis particularly during any change to regulatory requirements that may affect the product.

12 Revision History

Document Details

Detail	
Title	Supplier Quality Manual (AQM005)
Owner	Alan Eckford
Change Authority / Approver	Alan Eckford / Pete Trainor

Change Record

Date	Author	Version	Change Reference
9/19/2012	Alan Eckford	00	Initial release
8/01/2013	A.C. Cefalo	01	Update Regulatory Section 13 change "expected" to "required"
9/25/2013	A.C. Cefalo	02	Updated Regulatory section to make clarifications of requirements.
2/16/2016	Pete Trainor	03	PFMEA clarification, Lithium Battery compliance, Run at Rate Audits
7/9/2018	Greg Ames	04	Correct grammar. Remove references to PPAP and AIAG. Removal of specific dollar amounts regarding supplier chargeback. Removal of special labelling requirements.