NEWT Supplier Quality Manual

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Amendments:

	Issue 1	New Issue
11/22/2010	Issue 2	Added Section 8, Environmental; Amended Section 6 regarding certification lapse or probation; Added Supplier Acknowledgement; Added Section 9, SCAR; Added to Section 1 90-day perspective; Renamed Purchasing Requirements to Supplier Quality Manual Distribution and added acceptance in principle.
02/09/2013	Issue 2	Reviewed
01/09/2015	Issue 3	Changed contact information.
02/18/2016	Issue 4	Move signature information to last page, minor corrections
01/31/2023	Issue 4	Updated supplier Quality Manual Distribution section. (There are no ASL incidental supplier.) No training necessary.
07/08/2024	Issue 5	Changed originator, added section 10 regarding counterfeit part prevention.
12/12/2024	Issue 6	Added title page, table of contents page and added agreed upon, updated section 5.

Scope

This manual defines quality requirements and preferences for Suppliers doing business with New England Wire Technologies, NEWT.

This procedure affects Purchasing, Quality, and Suppliers.

Introduction

Most of NEWT's customers place quality requirements on us as reflected in this Supplier Quality Manual. This includes companies registered as medical device manufacturers and manufacturers supplying product for federal acquisition involving FAR (Federal Acquisition Regulations) and DFAR (Defense Federal Acquisition Regulations).

NEWT requests the support of our suppliers in fulfilling these quality requirements for our mutual customers in the chain of supply. We request that if you have questions or concerns regarding the clauses of the Supplier Quality Manual that you notify NEWT's Buyer in the Purchasing Department so that an explanation can be provided or a resolution can be achieved.

NEWT pledges to remain respectful of our supplier's needs and we are thankful for their ongoing support

Supplier Quality Manual Distribution

Purchasing will distribute a Supplier Quality Manual to all suppliers for production orders on the Approved Supplier's Log. Any ASL supplier who accepts a purchase order from NEWT is considered to have accepted the Supplier Quality Manual in principle even if they have yet to return a signed-off copy.

Supplier Quality Requirements and Preferences

1. **Changes that impact product and changes that can potentially impact product, supply, or quality**

   NEWT needs notification of changes to mitigate consequences, including unintended consequences, through planning. Many of our customers require notification from NEWT about changes at the sub-tier level so they too can mitigate consequences.

   - NEWT requests notification as early as possible regarding a pending change or an implemented change. (As a perspective: 90 days' notice is often not enough time to evaluate the change and build samples for our customer to do their evaluations.) Please notify about changes as soon as possible.)
   - In all cases, NEWT shall be notified of any change made to a part at the time a reorder is placed.
   - NEWT may want to place an order before changes are incorporated. We appreciate the chance to do so.

- Post order or delivery notifications of change should be avoided by preorder notification, but if circumstances are such that a change affects material on order or delivered material, we still want to know.
- NEWT wants suppliers to understand and consider that, we and many of our customers, especially medical device customers, will incur substantial costs to validate materials that have changed. Medical device customers often have to submit validation data or resubmit their device to the FDA or other governmental regulators.

a) Changes to the product
- change in specifications
- change in materials (In formulation or components)
- change in process
- change in significant tooling or equipment
- changes in sub-tier suppliers
- changes in testing

b) Indirect changes to the product
- significant change in production location, especially to another facility
- major overhaul of equipment

c) Changes that may affect supply or quality
- material obsolescence
- going out of business
- change in management or owners
- shut downs
- strikes
- disasters that impact production such as fires, floods, or wind damage

2. Access to Quality Records

NEWT needs to have access to quality records associated with material sold to us. This access is for the purpose of validation/qualification or verification efforts, investigations into problems and audits. Access to quality records would take the form of requests for copies or viewing at the time of a scheduled visit.

3. Right of Access

NEWT may inquire about access to facilities producing material sold to us. This access is for the purpose of validation/qualification or verification efforts, investigations into problems and audits. In some instances, we may bring a customer or governmental representative. The purpose for access is to view processes, quality records, or audit quality systems.

4. Traceability

The supplier shall establish a traceability system for the identification, control of materials, parts, and assemblies from acquisition through fabrication, assembly, test and delivery. Traceability should include part numbers, lot numbers, and serial numbers (when applicable) tied to quality records and the NEWT purchase order number they were delivered against.

5. Certificate of Conformance / Analysis

NEWT requires either a Certificate of Conformance (CoC), Certificate of Analysis, or a Test Report for all shipments. This certification documentation should tie the product shipped to the system for traceability at your facility, preferably by lot numbers.

The certification documentation (CoC, CoA or Test report) must:

- Include supplier part number
- Include supplier lot number(s) and quantity shipped for each lot
- list all applicable standards and specifications
- include a statement of conformance

NEWT desires that the certification documentation (CoC, CoA or Test report) contain the following, but is not required unless specified on the PO:

- Include the NEWT PO Number
- Include the NEWT Part Number
- Include an authorizing signature

6. Quality Systems

NEWT believes that an established and proven quality system is an important asset for our suppliers. We prefer suppliers with a quality system registered to the ISO 9001 standard or one of the industry specific standards based on ISO9001. While having a registered quality system is not the only consideration, suppliers who have valid registrations are given preference over suppliers who do not have registered quality systems.

NEWT requires our suppliers with registered quality systems to notify us if they discontinue registration, are put on probation, or have their registration rescinded. Upon such notification NEWT will work with the supplier to initiate an action plan to ensure that their quality management system will be adequate to support quality products on time and with the proper documentation.

7. Intellectual Property

When a NEWT request for quote contains proprietary intellectual property, we will identify it as such, and give instruction on how the information is to be treated.

When your offer contains proprietary intellectual property, it must be identified as such. Seller must have the legal right to make intellectual property part of their offer. Seller will be responsible for all costs associated with the use of the intellectual property. These costs could be licensing fees, royalties, or court costs for defending NEWT from suits regarding intellectual property or claims of intellectual property used in product from the supplier.

8. Environmental Stewardship / Regulatory Compliance

New England Wire Technologies is dedicated maximizing the performance benefits of our products while minimizing environmental impact. We are further dedicated to helping our customers achieve their environmental goals. NEWT will need disclosure on compliance of your products to various environmental regulations. This disclosure will be in regard to the regulated chemicals in your products. It is essential that suppliers can identify and report on the level of compliance their products have with RoHS, REACH, and other regulations as requested by NEWT.

Suppliers should also keep up with evolving regulations and be able to address specific substances of concern before regulations go into effect.

Some of our customers are asking for “full disclosure” of chemicals present in products for the purpose of creating a data base to use in evaluating the impact of evolving regulations. NEWT asks for your support in developing methods to do a “full disclosure” without compromising your proprietary information.

9. Supplier Corrective Action Request

Where a product is deemed nonconforming to the specification, NEWT may request a Supplier Corrective Action to track and document the supplier’s corrective and preventive actions. The supplier shall cooperate with NEWT in working to closure of corrective and preventive actions in a timely manner.

10. Counterfeit Part Prevention

Supplier shall comply with applicable standard such as SAE AS5553 (Counterfeit Electronic Parts; Avoidance, Detection, Mitigation, and Disposition) and not supply to New England Wire Technologies any items or materials that are or contain counterfeit goods. Supplier shall maintain a system to adequately prevent the delivery of counterfeit materials and/or parts. Supplier shall bear the responsibility of procuring authentic items from its suppliers and subcontractors and shall flow down the requirements of this section to its suppliers and subcontractors.

"Counterfeit Goods" shall mean items, including any material, part, component, module, or assembly of such items, whose description, origin, material, source of manufacture, performance or characteristics are misrepresented. This term includes but is not limited to (i) items that are an unauthorized copy or substitute of an Original Equipment Manufacturer or Original Component Manufacturer (collectively, OEM/OCM);
(ii) items that are not traceable to an OEM/OCM to ensure sufficient authenticity; (iii) items that are not constructed in accordance with the OEM/OCM design; (iv) items which have been (re)marked to disguise them or falsely represent the identity of the manufacturer; (v) previously used parts pulled or reclaimed and provided as "new"; and (vi) items that have not passed successful OEM/OCM required testing, verification, screening, and quality control processes.

Suppliers Acknowledgement of the Supplier Quality Manual, QA1329 Issue 6

NEWT requires that suppliers acknowledge receipt and acceptance of the Supplier Quality Manual. If there are exceptions or clarifications, they must be noted on this document or an attachment.

I have read and understand the Supplier Quality Manual regarding the expectations and requirements for suppliers. I agree to comply with the expectations and requirements as defined in the Supplier Quality Manual except as noted.

Please note all clarifications or exceptions that you may have with this document:

_____

_____

_____

_____

Company name: _____

Name: _____

Signature: _____ Date: _____

Title: _____

Please return this acknowledgement page to NEWT Purchasing Department by E-Mail, or Mail

For Internal Use:
If exceptions are taken document to be reviewed by Quality Representative:

Name: _____

Signature: _____ Date: _____

Title: _____