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Plant/Local : Reference Document

Document #:	DOC-10815	Revision:	3
Document Owners:	Dean Clark	Effective Date:	Oct 29, 2020
<b>Title:</b>	<b>NEU Quality Commitment</b>		

Location(s)	North Haven, CT
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*As a valued customer (“Customer”) of NEU Specialty Materials, LLC (“NEU”), NEU is communicating this Quality Commitment to communicate the quality parameters, expectations and risk surrounding quality matters for the products NEU supplies. In the event of a conflict between this Quality Commitment and any mutually agreed specifications or quality agreement that is executed by NEU, the mutually agreed specifications or signed quality document shall control.*

## 1.0 PRODUCT DESCRIPTION

Thermoplastic material in pellet form.

## 2.0 TEST METHODS

NEU test methods are modeled after ASTM testing standards, where applicable.

## 3.0 OPERATIONAL DEFINITIONS

- 3.1 **Lot (Batch):** Material manufactured at one time.
- 3.2 **Blend:** No more than three lots of a specific raw material, combined together to form a homogeneous mixture.
  - 3.2.1 Full lot tractability of non-proprietary formulations will be reflected on the COC
- 3.3 **Certification:** “Certificate of Conformance” or “Certificate of Analysis” based material requirements
- 3.4 **Certificate of Analysis:** Document containing information that the product conforms to the established Product Specifications.
- 3.5 **Certificate of Conformance:** Document containing confirmation that the product conforms to the defined formulation.
- 3.6 **Finished Product Form:** Finished product shape (Cylindrical, Spherical)
- 3.7 **Product Specification:** the product specifications that are contained in a written document signed by NEU, or if such document does not exist, the Certificate of Analysis or Certificate of Conformance issued by NEU.

## 4.0 PACKAGING

- 4.1 Standard product packaging options include:
  - 4.1.1 Drum
  - 4.1.2 Gaylord
  - 4.1.3 Pail
  - 4.1.4 Individual bag in box



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- 4.1.5 Packaging may include a liner or pallet based on the configuration. Packaging designed to offer adequate protection against damage during normal shipping, handling and storage conditions.
- 4.2 Each container label will show:
  - 4.2.1 Customer Part No. (as applicable)
  - 4.2.2 Customer Description
  - 4.2.3 Manufacturer's Product Code
  - 4.2.4 Manufacturer's Lot Number
  - 4.2.5 Quantity and Units (Example 25 lbs.)
  - 4.2.6 Company Name
  - 4.2.7 Date of Manufacture
  - 4.2.8 Expiration Date (as applicable)

## 5.0 SUPPORTING DOCUMENTATION

- 5.1 **Certification:** Each shipment of product will be accompanied by a Certification that, at the time of shipment, the material conforms to the Product Specifications.
  - 5.1.1 Certification document will include:
    - 5.1.1.1 Customer Part Number
    - 5.1.1.2 Customer Purchase Order Number
    - 5.1.1.3 Customer Material Description
    - 5.1.1.4 Manufacturer's Lot Number
    - 5.1.1.5 Total quantity shipped (with units)
    - 5.1.1.6 Test values (as applicable)
  - 5.1.2 Certification will be sent with each product shipment, addressed to the Customer's shipping location and/or electronically sent to appropriate Customer contact.
  - 5.1.3 The Certification document may contain test values conducted by NEU on the product for those characteristics listed under certification.
- 5.2 **Safety Data Sheets:** A Safety Data Sheet will be made available upon request or may be available on NEU's website. SDS revisions will be issued when a new order is shipped for products where the revision is applied. The SDS is supplied to the shipping location from where the product is ordered.
- 5.3 **Technical Data Sheets:** A Technical Data Sheet will be made available on NEU proprietary technologies upon request.
- 5.4 **Sales Order Confirmation:** A documented response confirming acceptance of a Customer purchase order.

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5.5 **Regulatory Documents:** A document referencing the then-current regulatory status of the applicable product(s) at the time of shipment. Such documents are provided on request, and as applicable.

## 6.0 CUSTOMER AUDIT

6.1 Customer may request to visit and inspect NEU's facility relating in the manufacture of product. Inspection may include applicable internal systems, calibration programs, laboratory practices, and equipment pertaining to the Customer-specific product.

6.1.1 Adequate prior notice (30 days) must be given, with a proposed agenda.

6.1.2 The scope of the inspection is at the discretion of NEU.

6.1.3 Non-Disclosure Agreement and/or Visitor Confidentiality Agreement is required of Customer.

## 7.0 SUPPLIER CONTROL and REGULATORY RESPONSIBILITY

7.1 The control of suppliers and regulatory responsibility of the vendors and product supplied by NEU to the Customer are dependent on the specification and ownership of the components used to manufacture the product, as further outlined below.

7.1.1 Raw materials, components and suppliers developed or specified by NEU are controlled and monitored by NEU.

7.1.2 Raw materials, components and suppliers developed or specified by Customer are controlled and monitored by Customer.

7.1.2.1 NEU may survey suppliers specified by Customer on behalf of Customer to satisfy a Customer request for information. Such inquiries by NEU do not transfer supplier control responsibilities to NEU.

## 8.0 CHANGE NOTIFICATION

### 8.1 General Notification

8.1.1 NEU will notify the Customer of the following changes to all NEU compounded materials:

8.1.1.1 Product nomenclature

8.1.1.2 Product Specifications

8.1.1.3 Manufacturing site

8.1.2 All notifications will be given to the purchasing contact at the purchasing locations of the products supplied. It will be the responsibility of Customer to order sufficient quantities of materials to allow for any required qualification prior to the implementation of the change. Notification of changes will be given with as much advance notice as possible, but a specific advance notice timeline cannot be guaranteed.



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## 8.2 Proprietary Technology

8.2.1 NEU will notify the Customer of its intent to substitute a chemical (limited to CAS# change only) used in the manufacture of the compound(s), as well as changes affecting the Product Specifications agreed to by NEU.

## 8.3 Customer Specified Formulations

8.3.1 NEU will notify Customer of a vendor-notified change to the specified material or source. Upon notification from the NEU supplier, NEU will notify the Customer of the effect on the manufacture of the compound(s) (such as raw material availability, vendor name changes, vendor manufacturing location, and vendor nomenclature).

## 9.0 CUSTOMER FEEDBACK

9.1 NEU will use commercially reasonable efforts to (i) acknowledge receipt of Customer complaints within one business day; (ii) conduct an investigation and communicate a resolution to Customer within 30 days after receipt of the complaint. In the event that the NEU determines that it is the root cause of the Customer complaint, a corrective action will be issued, and preventive actions will be developed to address the root cause.

## 10.0 MANAGEMENT OF SUPPLIERS

10.1 NEU will maintain and ensure oversight and monitoring of applicable suppliers in accordance with the requirements of ISO 13485 Quality Management System.

## 11.0 TRACABILITY, RECORDS & RETENTION

- 11.1 NEU is responsible for establishing and maintaining controlled documentation of product and raw material component traceability during all stages of production and shipment.
- 11.2 An electronic record of the manufacturing conditions and raw materials (vendor ID and lot number) used to manufacture each batch is retained and preserved for a period of at least 7 years from the manufacture date or as specified by applicable Regulatory Requirements.
- 11.3 An electronic record of the Customer purchase order and NEU sales order confirmation will be retained and for a period of at least 7 years from order acceptance date.
- 11.4 A representative sample of the product manufactured will be retained for a period of at least 1 year from manufacture date.

## 12.0 EXPIRATION

12.1 NEU's obligations contained in this Quality Commitment will automatically expire if the Customer does not purchase product from NEU for a period of one year.