

Nortech Systems, Incorporated

Supplier Quality Requirements Manual



World-Class Solutions for Electro-Mechanical Applications



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TABLE OF CONTENTS

1.0 Introduction	3
1.1 Mission Statement	3
1.2 Values	3
1.3 Quality Policy	4
1.4 Supplier Quality Culture	4
2.0 Supplier Manual Introduction	4
2.1 Purpose	4
2.2 Scope	4
2.3 Supplier Manual Revision	5
3.0 Obtaining and Maintaining Approved Supplier Quality Status	5
3.1 Supplier Approval Process	5
3.2 Approved Supplier List	5
3.3 Supplier Quality System Requirements	6
3.4 Non-Disclosure Agreement	6
3.5 Supplier Survey and Assessments	6
3.6 Supplier Status	6
3.7 Supplier Continuous Performance Rating	7
3.8 Audits	7
3.9 Corrective Actions	7
3.10 Acceptable Date Codes for Electrical Components	7
3.11 Acceptable Shelf Life for Shipped Components	8
3.12 Business Continuity and Disaster Recovery	8
3.13 Lot Traceability	8
3.14 Record Retention	8
3.15 Qualification of Supplier Personnel	8
3.16 Calibration Providers	8
3.17 Environmental Regulations / Trade Agreements / Certificates of Origin	9
4.0 Change Management Requirements	9
4.1 First Article Inspection	9
4.2 Change Notification Requirements	9
4.3 Conflict Minerals	10
4.4 Management of Sub-suppliers	11
4.5 Drawing and Change Control	11
5.0 Packaging, Shipping Requirements	11
5.1 Packaging	11
5.2 Shipping, Shipping Documents	12
5.3 Delivery	12
6.0 Manufacturing Process Management Requirements	12
6.1 Capability Study	12
6.2 Control Plan	12
6.3 Qualification & Validation Study	13
6.4 Statistical Process Control	13
6.5 Inspection Data	13
6.6 Control of Inspection, Measurement and Test Equipment	13
6.7 Nonconforming Product	13
6.8 Reworking Nonconforming Product	14
7.0 Nortech Systems Tooling	14
8.0 Supplier/Subcontractor Continuous Improvement	14
9.0 Acknowledgement of Manual Acceptance	15

1.0 Introduction

Nortech Systems is a leading provider of design and manufacturing solutions for complex electromechanical systems, assemblies, and components. Nortech Systems serves the medical, aerospace & defense, and industrial markets. Its product development services span from early conceptualization to full scale development, verification, and validation. This includes software, electrical, mechanical, and biomedical engineering with a strong emphasis on compliance for regulated industries. Its manufacturing and supply chain capabilities are vertically integrated around electromechanical systems, devices, and components including printed circuit boards, wire and cable harnesses, and interconnect solutions. Headquartered in Maple Grove, Minnesota, NSI has seven manufacturing locations and design centers across the U.S., Latin America, and Asia.

As part of our contractual agreement with our customers, NSI is required to demonstrate change control with traceability through our suppliers and that our suppliers are able to provide the equivalent control with their suppliers. This is especially critical with our aerospace and medical device customers.

The requirements herein are defined for each supplier. Suppliers accept the requirements listed herein when accepting a purchase order from Nortech Systems, Inc.

Parts may also be identified as military grade or have a military spec listed on the print. For procurement of military grade products, a manufacturer's certification to a specified military or aerospace specification or standard is required. This documentation will contain at a minimum the manufacturer, distributor, distributor purchase order number, part number, quantity, and date code of each quantity supplied.

Suppliers shall provide parts in accordance with the Purchase Order. Exceptions or additions to the requirements listed in this manual will be listed on the purchase order. Whereas there are sections that the supplier may be unable to meet, the supplier shall notify the Nortech Systems Purchasing Contact.

Suppliers may be required to provide information regarding "Materials Hazardous to Health and Environment" (i.e. SDS, RoHS, REACH, etc).

1.1 Mission Statement

Nortech uses intelligence, innovation, speed and global expertise to provide manufacturing and engineering solutions in partnership with our medical, industrial and defense customers, enabling them to be leaders in digital connectivity and data management to achieve their business goals. Nortech strives to be a premier workplace that fosters valued relationships internally and in our communities.

1.2 Values

Nimble & Innovative: Thrive on responsiveness, creativity, ingenuity, on-going education & a sense of urgency.

Outreach: Appreciate the diversity of our communities & strive to build strong community partnerships.

Results-oriented: Guided by quality decision making, accountability & winning with integrity.

Teamwork: *Treat each other with respect, trust one another & value diverse perspectives.*

Excellence: We are committed to timely execution, continuous improvement & a strong commitment to quality.

Communication: *Committed to timely execution, continuous improvement & a strong commitment to quality.*

High Performance: *Strive to be proactive as we design & manufacture quality products & deliver on-time.*

1.3 Quality Policy

Nortech Systems is advancing our rich history to be the most trusted and nimble engineering and manufacturing services and solutions company in our chosen markets. We produce quality products, services, and value-added solutions that meet or exceed customer, statutory, and regulatory requirements. We provide all employees a working environment that fosters products designed and built defect free and on time while keeping focus on customer needs. We are committed to developing and maintaining an effective Quality Management system that leads to continuous improvement.

1.4 Supplier Quality Culture

Nortech Systems requires that its suppliers foster a culture where its employees are made aware of and understand their responsibilities with respect to:

- Their contribution to product or service conformity. This includes reporting and not passing on defects or non-conformities internally or to NSI and informing NSI of products or services delivered with known or suspected quality or regulatory problems.
- Their contribution to product safety. Materials, parts and services procured by NSI may be incorporated into products that have serious implications for the safety of personnel or the environment.
- The importance of ethical behavior. This includes respecting the laws, regulations, and internal policies and procedures regarding conflicts of interest; intellectual property; export compliance regulations; engaging in criminal activity; acceptance or proposals of gifts; or invitations or favors with customers or suppliers.

2.0 Supplier Manual Introduction

2.1 Purpose

The purpose of this manual is to communicate NSI's quality requirements and expectations to suppliers as well as outline NSI's commitment to awarding suppliers business through evaluations of ongoing performance ratings.

2.2 Scope

The contents of this manual apply to all NSI's current and potential suppliers of production

related material and/or services that have a direct impact on product and/or service quality.

2.3 Supplier Manual Revision

Nortech will provide all suppliers access to the current revision of the Supplier Quality Requirements Manual if revisions occur.

3.0 Obtaining & Maintaining Approved Supplier Quality Status

3.1 Supplier Approval Process

Below describes the basic process through which a supplier is approved for doing business with NSI. Although the path may vary by supplier and by circumstance, suppliers are not on the Approved Supplier List (ASL) until they have passed the evaluation step.

Supplier agrees to allow ON-SITE audits by NSI, its agent, or customer, at NSI's discretion, and in support of any mandated audit to be performed by a relevant NSI customer or regulatory body. NSI also reserves the right to audit the manufacturing process as well as the quality management system of the supplier. NSI will work with the supplier to minimize the frequency of audits and the disruption of business.

Supplier Approval Process:

Complete the following:

- Non-Disclosure Agreement
- Supplier Qualification Survey
- On-site or Desk Audit (per NSI's discretion)
- Acknowledge Acceptance of "Supplier Quality Requirements Manual"

With satisfactory results and completion of the above, the supplier will be added to Approved Supplier List.

On-going Performance:

- Monitored by Supplier Scorecard

3.2 Approved Supplier List

Materials and/or services that have a direct impact on product and/or service quality shall only be purchased from suppliers on the current NSI Approved Supplier List. NSI evaluates and selects suppliers based on their ability to supply quality products in accordance with specified production and delivery requirements.

3.3 Supplier Quality System Requirements

NSI's suppliers for custom parts and services are not required to be ISO certified or FDA registered; however, it is preferred that the suppliers have and maintain a fundamental quality system that provides for continuous improvement opportunities and emphasizes defect prevention while reducing product variation and waste. It is preferred that the supplier's quality systems consist of the following:

- Documentation Control
- Product Traceability
- Controlled Calibration System
- Corrective Action System to Address Customer and
- Internal Complaints
- Documented Training System
- Supplier Monitoring System
- Control of Nonconforming Product

3.4 Non-Disclosure Agreement (NDA)

Suppliers may be required to complete a Confidentiality and Non-Disclosure Agreement.

It is the responsibility of NSI direct suppliers to obtain a signed copy of NSI's Non-Disclosure Agreement from the subcontractor and to provide a copy to NSI upon request.

3.5 Supplier Surveys and Assessments

Potential suppliers are required to complete a "Supplier Qualification Survey".

Along with the initial Supplier Qualification Survey, an on-site audit (see Section 3.1) may be conducted to assess Production Capability. This assessment shall only be conducted for the potential production items that NSI is looking to purchase. Any subsequent changes to the product NSI wishes to purchase may also require an assessment. NSI reserves the right to determine if an on-site audit is required.

3.6 Supplier Status

NSI shall determine the supplier's status. Status levels are defined below.

Approved Supplier: A supplier that has been selected based on evaluation results indicating that they can provide product meeting specified requirements.

Approved Supplier with a Performance Plan: A supplier may be identified as Approved with a Performance Plan if the supplier fails to continue to meet requirements to remain Approved or if the supplier's performance remains below an acceptable level.

Disqualified Supplier: A supplier that may no longer be purchased from due to continuing unsatisfactory quality or delivery performance, unresolved corrective actions, pricing, changes to its risk profile, or other adverse reasons.

NSI's Quality and Purchasing shall determine the status of the supplier. If the supplier is selected to supply to NSI, the supplier shall be notified. If the supplier is not selected to supply to NSI, the supplier shall be notified in writing of their status in order to make improvements and possibly become a future supplier for NSI.

3.7 Supplier Continuous Performance Expectations

NSI has set a number of supplier performance expectations listed below. These expectations should be met by the supplier unless an approved Supply Agreement exists that states otherwise. See note below.

- Defective Parts Per Million (DPPM) – Receiving Inspection rejection rate: 1,000 DPPM
- On-time Delivery: 98% on time (On time: zero days late, no more than 3 days early)
- Service Responsiveness:
 - Supplier Corrective Action Requests (SCARs): Complete containment within 3 business days, complete root cause analysis and action plan within 30 days, and implemented systemic corrective action within 60 calendar days
 - Returned Material Authorizations (RMAs): Issued within 5 business days of initial request and parts replaced or returned within 60 calendar days
 - General inquiries responded to within one business day

Note: this may not be an all-inclusive list. For a complete list and details, please reference scorecard.

NSI Supply Chain may generate scorecards periodically to monitor supplier performance.

3.8 Audits

NSI reserves the right to perform periodic audits of the supplier's entire quality system. The audits may be performed at the supplier's location or remotely as a desk audit.

3.9 Corrective Actions

When a deficiency occurs with regard to product quality, on-time delivery, or failure to meet a requirement, NSI may require a written corrective action response.

The supplier's quality program must provide a plan for timely containment and corrective action on all conditions detrimental to product quality, including product deficiencies encountered during processing, fabrication, assembly or test, or those occurring at a sub-tiered supplier.

The written corrective action report must be supplied to the supplier quality contact at NSI in the timeframe listed below:

Containment: Typical response time within 3 business days unless otherwise dictated by business needs.

Corrective Action Completion: Complete containment within 3 business days, complete root cause analysis and action plan within 30 days, and implemented systemic corrective action within 60 calendar days. Nortech's business needs may require more immediate completion of any and/or all of the corrective action stages which will be communicated to the supplier. If more time is required, an extension must be requested at least 2 business days prior to the due date.

3.10 Acceptable Date Codes for Electrical Components

Where a supplier is supplying NSI with electrical components, on an individual basis, these codes must be within 2 years of the date of manufacture. Where date codes are greater than 2 years the supplier shall not ship without prior NSI approval.

For assemblies which may contain components with date codes of greater than 2 years NSI assumes that the suppliers have completed their due diligence prior to using these components.

3.11 Acceptable Shelf Life for Shipped Components

Supplier shall not ship a product to NSI where less than 75% of the total shelf life remains without prior notification and NSI approval. Where supplier inventory is maintained at an NSI location, shelf life shall be managed by supplier to ensure inventory is free of expired material.

3.12 Business Continuity and Disaster Recovery

NSI expects suppliers to make reasonable efforts to assess the potential impact of risks that could result in a disruption to their normal business operations. Suppliers shall take actions to mitigate risks where practical. NSI recommends having a documented Business Continuity and Disaster Recovery Plan. Supplier shall notify NSI if a Business Continuity and Disaster Recovery Plan does not exist.

3.13 Lot Traceability

Suppliers may be required to maintain lot traceability to the original raw material or part manufacturer in the form of serial numbers, date codes, lot codes or any other process mutually agreed upon with NSI.

3.14 Record Retention

Quality records supporting the design, manufacturing, acceptance and distribution of materials and parts designed by NSI must be maintained for at least 10 years unless otherwise specified. The supplier may not discard or destroy any such records without first obtaining written NSI permission. NSI may decide to arrange transfer of the records to NSI.

3.15 Qualification of Supplier Personnel

Nortech expects suppliers to qualify and evaluate the competence of personnel whose job responsibilities have an impact on product quality.

3.16 Calibration Providers

Suppliers providing calibration services shall establish, implement, and maintain a quality management system (QMS) that:

- Complies with the requirements of the current version of ISO 9001, ISO 13485 or ISO/IEC 17025 and
- Covers calibration services within its scope.

Original Equipment Manufacturers that are providing calibration services for their own equipment shall be capable of performing the required service to the satisfaction of ISO/IEC 17025, ISO 10012:2003 or ANSI/NCSL Z540.3.

Supplier may only outsource calibration to a sub-contractor that has been approved by the supplier through its QMS and meets requirements outlined above.

3.17 Environmental Regulations / Trade Agreements / Certificates of Origin

Suppliers are to ensure that all materials and products being supplied to Nortech satisfy current government and safety constraints on Restricted, Toxic, Environmental, and Hazardous Materials. Suppliers are required to identify all restricted, hazardous, and otherwise regulated materials and warrant that the supplied materials comply with applicable regulations and must provide (SDS) Safety Data Sheets on any and all materials supplied when applicable or required by Nortech Systems or its Customers. Suppliers are required to supply on an annual basis an updated Certificate of Origin (COO), North America Free Trade Agreement (NAFTA), United States-Mexico-Canada Agreement (USMCA), Conflict Minerals Survey (CMRT), RoHS3 certificate, REACH declaration, and Prop65, when applicable and requested, by Nortech Systems or its Customers.

4.0 Change Management Requirements

4.1 First Article Inspection

When required by NSI, the supplier shall conduct First Article Inspection (FAI) to confirm that supplied components meet all NSI supplied drawing and specification requirements using normal manufacturing conditions by inspecting 1 part to match the print in full on a new part or the changes made for a revision change. A copy of the FAI paperwork shall be provided to NSI with the first shipment. When a supplier deviates from the established process and the last approved FAI, NSI must be notified. First Article Inspection may be required to be documented on an AS9102 report depending on the component supplied. An FAI is required, at a minimum, when a part is a first time build for NSI or when a part changes revision level, but it may also be required at other times per the purchase order.

4.2 Change Notification Requirements

Written notification by the supplier within five (5) business days of any significant changes to the organization or quality management system is required with written approval by NSI. Examples include changes in location, ownership, and loss or withdrawal of its ISO 9001, ISO 13485, AS9100D, or ISO/TS16949 certification or ISO/IEC 17025 accreditation.

Prior written notification by the supplier and written approval by NSI are required for changes that are made that affect form, fit or function of parts for which NSI owns the design. NSI shall provide feedback regarding specific requirements for testing or approval of the planned change. For parts that are designed by the supplier, NSI will be notified of such changes.

Examples of changes that require prior notification are (this is not an exhaustive list):

- Use of different manufacturing equipment than those qualified, including the use of different presses, lines and items with different serial numbers that may be identical make and model
- Transfer from one facility/location to another facility/location
- Movement of equipment within a facility
- Reduced frequency of preventive maintenance or calibration
- Significant equipment or tooling malfunction or repair
- Changes in sterilization method or process parameters
- Changes of direct materials contents or specifications
- Changes in manufacturing process parameters
- Changes in software or programs used to make or check product
- Changes in suppliers used for raw materials or components
- Inspection requirement changes - reduction in sampling frequency or features inspected
- Manufacturing materials (lubricants, releases, cleaners) that contact the product

- Rework not qualified initially as part of the process
- Design changes to components
- Transfer of a qualified process to/from an outside vendor/supplier
- Transfer of a qualified process from one outside vendor/supplier to another outside vendor/supplier
- Changes in RoHS status or REACH declaration for part supplied as compared to most current regulation
- Lapse of third party certificate for quality system

Any questions regarding the applicability of a change should be directed to the Supply Chain contact at NSI. If the intent is to utilize various locations or pieces of equipment, multiple suppliers, rework processes, ranges of process parameters, then all should be qualified initially as part of the Item Qualification Request.

****Absolutely no changes** can be made to material or product specifications without written approval from the NSI Supply Chain contact. This includes material substitutions and/or tolerance changes. If written authorization is received, the certificate of compliance (C of C) must indicate the “authorized” changes. (Please include a copy of the written authorization statement with the C of C). If an updated drawing is provided prior to shipment, parts must be identified with the new revision and inspected and approved accordingly. Prior approval from the NSI Supply Chain contact is required to ship parts to the previous revision.

NSI expects at least 60 days’ advance notice of any scheduled extended plant shutdowns, where extended is taken to mean greater than 5 days excluding government-approved national holidays.

4.3 Conflict Minerals

Certain regions where some minerals, commonly used in the electronics industry, originate have been identified as “conflict” regions. The Democratic Republic of the Congo and adjoining countries are identified as conflict regions due to reported human rights abuses, environmental concerns and actions against citizens. Certain minerals that originate (are mined) from this region have been identified as “conflict minerals” and include gold (Au), tantalum (Ta), tungsten (W) and tin (Sn).

Suppliers are required to undertake due diligence in reviewing/assessing their supply chain to assure that these minerals, if they are contained within the product supplied, are not sourced from mines that are in this conflict region which are controlled by non-government military groups or unlawful military factions.

Additionally, suppliers are expected to:

- Have in place (and provide information about upon request) a conflict free sourcing policy and controls for assuring only conflict free minerals are procured
- Monitor their supply chain as reasonably necessary to help avoid procuring “Conflict Minerals”
- Provide, upon request, supporting data/information confirming status and compliance
- Support the Responsible Business Alliance activities/initiatives in this area

4.4 Management of Sub-Suppliers

Where suppliers to NSI choose to outsource any process that affects product conformity with requirements, it is the supplier's responsibility to maintain control over those processes. These controls must address those requirements listed in Sections 4.2 and 4.3. NSI expects our suppliers to flow down the other applicable requirements of this manual to their supply chain and sub-tier suppliers. In addition, we expect suppliers to follow due diligence when selecting sub-tier suppliers. This includes performing assessments and monitoring their performance on an on-going basis with the use of scorecards or defined criteria. This data shall be available for review at any audit, and sub-tier performance issues shall be proactively communicated to NSI.

Suppliers shall use NSI's customer-designated or approved external providers, including process sources (e.g. special processes) where specified.

4.5 Drawing and Change Control

The supplier shall maintain the latest NSI or NSI's Customer supplied drawings and specifications identified on the purchase order or other approved/transmitted documentation. The supplier also shall maintain a record of the change effectivity dates and acknowledge transmitted changes.

5.0 Packaging and Shipping Requirements

5.1 Packaging

NSI expects suppliers to package product in a manner that shall protect it from damage and/or deterioration while in transit to NSI and during transport and storage within the NSI facility. Specific packaging arrangements are made at the time of product launch and should be identified on the Quote-Purchase Order documents.

Any unsuitable, lost or damaged product shall be recorded and reported. The supplier must communicate the NSI packaging requirements to all appropriate personnel, including sub-suppliers.

Partial trays/layers shall be limited to the top layer, with less than full quantity noted.

Where NSI specifies that scrap parts must be returned, the container must clearly identify those as scrap parts. Red or florescent orange paint is preferred but tagging is acceptable. Scrap parts must be kept separate from good parts, packaged in separate containers, and clearly labeled as scrap.

When NSI approves the use of X-out PCB's, the printed circuit board must be packaged separately and clearly marked to avoid mixing with non X-out materials.

Any NSI-supplied packaging shall be used exclusively for NSI product and may not be used for any other purpose.

Any material that is electrostatic discharge (ESD) sensitive and requires ESD handling precautions must be identified on the packaging.

Boxes packed with more than one item must not exceed 50 lbs per box.

5.2 Shipping Documents Requirements

A packing slip must be furnished with all shipments, and include the following:

- NSI purchase order (PO) number
- Part number and revision level
- Quantity of each box and total quantity
- Packing slip must have a reference number for tracking purposes
- Each container shall identify its contents by part number, revision, quantity, and PO number (preferred)

In addition to the packing slip, a Certificate of Conformance (C of C) shall accompany the shipment when any of the following is called out on the print/drawing or NSI purchase order:

- Specific material
- Specific finish/coating/treatment
- Conformance to a standard
- A serial number (S/N) list shall accompany serialized product

Or, the manufacturing process is considered a “special” process and was validated/verified by NSI or the facility has current NADCAP certification and the certificate has been provided to NSI and the C of C signifies that the parts were made to that validated/verified process.

Non-Authorized distributors are required to provide an original manufacturer certification and/or test data from an independent test laboratory.

If a Certificate of Conformance is required, it must be maintained on file by the supplier and will be made available to Nortech upon request.

5.3 Delivery

Suppliers are expected to deliver product on time. Whenever circumstances prevent on time delivery, it is the supplier’s responsibility to communicate and negotiate an alternate plan in advance of the missed delivery. On time deliveries are defined as zero (0) days late and no more than three (3) days early.

6.0 Manufacturing Process Management Requirements

6.1 Capability Study

Upon request of Nortech Quality Engineering, the supplier is required to perform a capability study for agreed upon “critical” dimensions. (Goal to reach 1.33 Cpk or better). If not at that level, the supplier should implement improvement processes to work towards achievement.

6.2 Control Plan

Upon request of Nortech Quality Engineering, suppliers shall develop and maintain control plans which describe the quality planning for a specific part or family of parts. The plans shall be presented to NSI upon request.

6.3 Qualification & Validation Study

Upon request of Nortech, suppliers shall perform qualification of equipment, tools, and fixtures as well as validation and verification for processes, inspections, and test fixtures.

6.4 Statistical Process Control

Upon request of Nortech Quality Engineering, the supplier is required to perform on-going SPC for mutually agreed upon “critical” dimensions.

6.5 Inspection Data

Upon request of Nortech Quality Engineering, the supplier shall maintain records of inspection data per the approved control plan. Inspection data is required to accompany each shipment of parts.

6.6 Control of Inspection, Measurement and Test Equipment

Suppliers shall, at a minimum, establish a system of calibration, equipment maintenance, and service for all measuring and test equipment used in the manufacturing or acceptance of NSI purchased product.

6.7 Nonconforming Product

NSI expects all products to meet and be in compliance with all product specifications provided to the supplier. Should a nonconformance be discovered at NSI, the supplier shall be contacted and an appropriate response is expected within the timeframe requested. This means that a sense of urgency is taken to ensure that the production schedule of NSI and its customers are not impacted. The supplier shall notify NSI of nonconforming material that has shipped immediately after the issue is identified. The supplier will be responsible for costs to replace, including freight, or credit any nonconforming material provided by the supplier. When an RMA is issued by the Supplier or notice that supplier credit will be given is received, NSI will take a Debit for the parts. A new Purchase Order will be issued for any rework or replacement parts required.

These costs may include but are not limited to:

- Testing, inspection, and sorting as required
- Process changes which become necessary in order to remedy nonconformity
- Recall costs
- Travel incurred
- Cost of Product(s) or additional Material impacted by the nonconformity
- Support costs that are directly related to the resolution of the nonconformity
- Any external analysis
- Any additional services incurred by Nortech to remedy the nonconforming material

Options to correct nonconforming product include but are not limited to:

- The supplier sends personnel on-site to conduct sorting or rework activities.
- The supplier contracts a third party service to provide on-site sorting or rework
- The product is returned to the supplier for sorting or rework.
 - Replacement parts and shipping arrangements must be determined based on the scheduled production requirements of NSI.
- NSI performs sorting or rework on behalf of the supplier at the supplier’s expense.
- Nonconforming product may be scrapped at NSI or returned at the supplier’s expense.

6.8 Reworking Nonconforming Product

Nonconforming product identified at the supplier or returned from NSI to the supplier may be reworked upon NSI's approval if a standard work instruction does not exist provided that doing so does not adversely affect the form, fit, function, quality, performance, safety, or reduce the life expectancy of the part. Returned reworked nonconforming product shall be packaged separately, not mixed with new parts. A packing slip is required indicating RMA/RGA/RA number, along with the other requirements as listed in Section 5.2. If a C of C was required initially, a new C of C is required, identifying that parts were reworked and what was done. The C of C should also list the RMA/RGA/RA number.

7.0 Nortech Systems Tooling

Suppliers are responsible for identifying, verifying, tracking and protecting NSI-owned or NSI customer-owned tooling. Suppliers must notify NSI regarding tooling that has been lost, damaged or becomes otherwise unsuitable for use.

When NSI's customers change a product from current production to "obsolete", NSI expects suppliers to hold non-production tooling for our customers to allow NSI to produce service parts. The amount of time this tooling shall be held shall vary from customer to customer. NSI shall try to relay the requirements to suppliers at the time of the product obsolescence.

NSI requires suppliers to notify the procurement department before scrapping any NSI tooling. NSI requires suppliers to provide tooling maintenance data upon request.

8.0 Supplier/Subcontractor Continuous Improvements

NSI encourages and recognizes suppliers that take an active role in shared continuous improvements.

NSI promotes the use of NSI's FOCUS program (NSI's lean/continuous improvement program), or a similar version, to encourage supplier-initiated improvement suggestions. FOCUS shall help to create an environment that promotes open communication and mutual benefit between NSI, its suppliers and its customers.

Supplier Quality Requirements Manual Acknowledgement of Acceptance

Nortech Systems, Inc. Supplier Quality Requirements Manual is being provided to you with the basic requirements for doing business with Nortech Systems Inc. This Supplier Quality Requirements Manual is applicable to all NSI facilities.

Please complete the acceptance of the receipt block on this page, and return within 30 days of receipt if requested.

Nortech Systems, Inc. Supplier Quality Requirements Manual Acknowledgement of Acceptance	
Received by:	Date:
Print Name:	Signature:
Title:	Company Name/Location:

**Please return a copy of the completed form to:
The Nortech Systems contact who provided it.**