Supplier Requirements Manual

Last Revised: August 2020

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GENERAL INFORMATION

Purpose and Scope

The purpose of the Supplier Requirements Manual is to define the requirements and expectations that have been established for any supplier providing goods or services to Norwood Medical (Norwood). It is the responsibility of the supplier to understand and ensure compliance with these requirements throughout their organization.

This document further defines requirements and expectations that may or may not be covered by other procurement documentation, such as purchase order terms and conditions, design specifications, or drawings.

It is our desire to form long-term, mutually beneficial relationships with our suppliers with a common goal of continuous improvement.

General Requirements

Norwood expects suppliers to conduct business with integrity and ethics consistent with Norwood's Code of Business Conduct and Ethics, found on our web page at www.norwoodmedical.com/about-us/policies. Suppliers should operate in full compliance of all laws, including national, state, local, labor, environmental, anti-corruption, anti-trust, and fair competition, amongst others. Suppliers should avoid any transactions, relationships, or other acts that appear to be conflicts of interest.

Suppliers should be socially responsible and show concern for the environment through methods consistent with Norwood's Sustainable Procurement Policy, found on our web page at www.norwoodmedical.com/about-us/policies. Suppliers should uphold the human rights of their workers and ensure a safe and healthy work environment. All suppliers must be conflict-mineral free, sourcing none of the 3TG conflict minerals referenced in the Dodd-Frank Act from prohibited regions. Suppliers must be RoHS and REACH compliant to the current revision and maintain compliance as standards are updated.

Norwood promotes diversity by giving equal opportunities to suppliers owned by diverse groups (such as woman, veteran, minority, small business, and hub zone). A Supplier Diversity Form will be sent to each supplier requesting the supplier's diverse-ownership status. Norwood encourages suppliers to promote procurement within their organizations from diverse suppliers as well.

Suppliers should notify Norwood in writing on Company letterhead of any pending ownership and/or company name changes (including any changes to ownership by diverse groups) as soon as possible once they are known.

Suppliers must be capable of sending and receiving data such as purchase orders, invoices, drawings, and specifications electronically. Suppliers must be capable of accessing and reading CAD data and be able to supply data in support of tolerance requirements.

Confidentiality Agreement

All suppliers reviewing any Norwood data or visiting the Norwood campus will be required to sign a confidentiality agreement (QP07-WI01-F0X). All of the supplier's employees, associates, and sub-tier suppliers must adhere to the terms of the agreement. The supplier agrees to have a documented process with strong internal controls for protecting confidential information, detecting improper disclosures, and reporting improper or unapproved disclosure or use of such information.

Supplier Qualification Process

Norwood's supplier qualification process is used to qualify new suppliers and to periodically evaluate existing suppliers to ensure they are capable of manufacturing and delivering quality product on time. A supplier survey (QP07-WI01-F01) will be sent to the potential supplier. All potential new suppliers will be requested to provide standard information depending on the product or service being provided.

Business Continuity Plan

Norwood strongly recommends all suppliers have a Business Continuity Plan (BCP) and Disaster Recovery (DR) Plan implemented, regularly reviewed, and tested. Certain high-risk suppliers will be **required** to have validated plans. The BCP and DR plans should be available for Norwood to review upon request. Norwood needs to ensure suppliers are able to mitigate supply risk, survive potential disruptions, and recover in a timely manner in the event of a business interruption.

Customer Service/Contacts

Suppliers are expected to provide a primary and secondary contact, who understand our requirements, as well as quality and engineering contacts. Norwood expects the supplier to promptly respond to any quality, delivery or other issue that may arise. Any changes to the contact personnel should be communicated at the time of change.

Scorecard

Norwood expects its suppliers to achieve 100% on-time delivery and quality performance. Norwood monitors supplier performance and certain suppliers will receive an annual Supplier Performance Evaluation (QP07-WI04-F01). This evaluation rates the supplier on quality and delivery. Those suppliers who do not pass the scorecard requirements will need to take corrective actions and a SQCAR will be issued with initial responses expected back within 2 weeks or sooner as requested.

Business Review Meeting

Norwood will conduct a business review meeting with specific suppliers to discuss current and future business, quality, cost, service, delivery and action items specific to the supplier. Norwood will provide the agenda to those suppliers selected for a business review in a given year. The agenda will be used by Norwood and the supplier to create a combined presentation to be used during the review. Supplier

content for the presentation should be provided to Norwood no later than one week prior to the business review.

Cost Reductions

Suppliers shall work with Norwood to develop cost reduction ideas each year. Cost reduction efforts shall not compromise quality or reliability, and suppliers must comply with Norwood quality requirements in regards to change control. Any cost reduction proposal which is the result of a change in design, manufacturing process, or specification must be approved in writing by Norwood prior to implementation.

Service Provider Safety Agreement

Any service provider, contractor, vendor or outside service personnel will be required to follow the Norwood safety agreement. The agreement will be sent to the service personnel prior to the start of work. This agreement must be signed prior to work being performed on Norwood premises. This agreement is to help prevent accidents and personal injuries and is not intended to be all-inclusive but rather a guide. It is the responsibility of the service provider's management to enforce the agreement and all other safety rules and good safety practices. All safety rules must be obeyed, and personal protective equipment (PPE) must be worn while working on Norwood premises.

QUOTES & ORDERS

Quotation Process

All quotes must be detailed to include Norwood part number, revision level, manufacturer's part number, piece price, quantity breaks, inventory levels, tooling cost (if applicable), packaging cost, lead time, country of origin and any relevant information detailing the item quoted. It is Norwood's policy to avoid transactions in foreign currencies; therefore, all quotations must be in US dollars. All quotes are to be submitted electronically to the purchasing department within 24 hours after request, if possible. Exceptions to any quote must be clearly stated. Any non-confidential suggestions regarding changes in specification that may help reduce cost or improve quality should be submitted separately. **NO** work is to be started without a purchase order. If the supplier chooses to begin work prior to receiving a purchase order and/or without proper written authorization from the Norwood purchasing department, the supplier will be responsible for the order and will be no charge to Norwood.

All tooling should be quoted as a separate line item and not added into the piece price. All pricing for tooling should include the cost for samples needed to qualify the tool(s).

Purchase Orders and Order Confirmations

Purchase Orders (POs) will be submitted by Norwood to the supplier for any work that is to be performed. POs contain key terms and conditions regarding the relationship. PO terms and conditions will take precedence over any conflict between PO terms and conditions and anything in the Supplier

Requirements Manual or order acknowledgement. Order confirmations and invoices must match the PO details to ensure on-time delivery and timely invoice payment.

All Purchase Orders must be processed with proper specifications and/or according to work instructions supplied by Norwood.

Subcontracting of the Purchase Order

Subcontracting of the purchase order is prohibited without prior written authorization from the Norwood Buyer and the Norwood Quality Department.

Engineering Changes Affecting Orders

Suppliers must ensure that engineering changes are incorporated without jeopardizing cost or timing to programs unless authorized by Norwood. All changes or samples run without proper written authorization from Norwood will be the responsibility of the supplier and will be no charge to Norwood.

Invoicing & Payment Terms

All invoices must be detailed to include Norwood purchase order number, Norwood part number, unit price, extended price, unit of measure, packing slip number and payment terms. **All invoices are to be sent electronically to accounts.payable@norwoodmedical.com.** Please provide accounts receivable information on all invoices.

Payment terms are 2% 10, net 30. All invoices will be paid electronically via ACH. An ACH form (QP07-WI01-F08) will be sent requesting the supplier's bank name, routing number and account number. It is the supplier's responsibility to inform Norwood of any changes to the ACH information.

QUALITY

Norwood requires that all suppliers have a documented and implemented Quality Management System through which they are able to ensure quality that conforms to customer drawings and specifications. All suppliers are highly encouraged to achieve ISO certification, and preference will be given to suppliers certified to ISO 13485. It is the supplier's responsibility to provide ISO certificates, including renewals, to Norwood. Each supplier should actively monitor the effectiveness and efficiency of its manufacturing processes and continually improve its performance in regards to quality, cost, delivery, and service.

Workmanship

All items ordered shall be fabricated, processed, protected and finished in such a manner as to be uniform in quality and appearance and be free of defects that will affect form, fit, function, life, safety or serviceability. The physical appearance of a product is very important in the medical industry. External parts must have a consistent finish and be free of blemishes. Products submitted to Norwood for acceptance must be provided clean and free of burrs, dirt, and manufacturing fluids.

Nonconformances

If a product is found to be defective and/or not meet the specified requirements, the product should be rejected, separated from conforming product, labeled as non-conforming, and a dialogue should be started as soon as possible between Norwood and the supplier. If the non-conforming product was already received by Norwood, the supplier will be notified, and an RMA number will be requested. The supplier and Norwood personnel will agree on whether the product should be returned, reworked, or scrapped. The supplier covers the transportation cost incurred for returning the defective product.

Right of Access

Work under this Supplier Agreement is subject to surveillance by Norwood, Norwood customers, and/or any regulatory agencies at the supplier's facility. A QA Representative may elect to conduct Inspection on a surveillance basis, or perform 100% on any or all materials included in our orders. Supplier will be notified if inspection or surveillance is to be performed on specific shipments. Source inspections or release of product prior to shipment is not required, unless written notification is received. No shipments are to be held for inspection, unless written notification is received prior to the scheduled ship date.

Source Inspection

When source inspection is required at the supplier's facility, this inspection may be performed by Norwood, Norwood Customers, and/or any Regulatory Agencies. Supplier is responsible for notifying the appropriate personnel at least five days prior to processing or manufacturing so that planning for source inspection can be accomplished. In the event a QA Representative from either Norwood or a regulatory agency cannot be located, the Norwood buyer shall be notified immediately. All drawings and specifications necessary for inspection shall be readily available for the QA Representative at the time of inspection. Evidence of such inspection shall be recorded on the appropriate documentation.

Audits

Since Norwood is obligated to follow specific regulations and standards relating to quality, it is necessary for Norwood to ensure all suppliers conform to the same standards. Norwood reserves the right to conduct on-site quality audits at all supplier facilities. Arrangements will be made in advance with the appropriate supplier personnel. These audits are used to confirm that procedures are applied in a manner that assures the quality of products. These audits will generally be limited to not more than one audit in a calendar year, unless a specific quality issue warrants additional audits.

Regulatory Inspections

Supplier must notify Norwood of any regulatory inspections or actions related to our product or the facility in which product is manufactured. Upon completion of the inspection, the supplier should inform Norwood of any findings or observations that may impact the production of our product.

Process Documentation Requirements

Norwood may require supplier to provide certain process documentation such as process flow, control plans, PFMEAs, contact agents, material declarations, and Safety Data Sheets. Product qualification data such as process validations, first article inspections, capability assessments, and measurement system analysis may be requested as well.

Corrective Actions

Upon request, supplier shall provide statements of corrective action for failures of supplier's product. These statements must be made using forms supplied by Norwood or on Supplier forms containing the same elements as Norwood's. Corrective action statements, at Norwood's option, may require approval signatures by Norwood quality representatives. All rejected articles resubmitted by supplier to Norwood shall bear adequate identification including reference to Norwood's rejection document.

Change Control

The supplier and its subcontractors must not make any changes to designs, manufacturing processes, specifications, programming, materials, machines, or tooling (new or modified) without prior written approval from Norwood. Norwood must be notified of the proposed change so we can determine the impact on finished product as well as get approval for the change from our customer, if necessary, prior to implementation. The supplier is responsible for ensuring its subcontractors comply with the above requirements.

Approval and Monitoring of Sub-tier Suppliers

Primary suppliers of Norwood are expected to manage their sub-tier suppliers, subcontractors, and service providers to ensure conforming quality of delivered products and services. Approvals of sub-tier suppliers, subcontractors, and service providers should comply with established criteria and control requirements for quality as appropriate.

Norwood suppliers should establish and maintain an approved supplier list to ensure purchases are only made from approved suppliers with the appropriate controls. Norwood suppliers should also have monitoring systems in place to ensure that their sub-tier suppliers, subcontractors, and service providers continue to conform to quality and delivery expectations and are qualified to remain on their approved supplier list.

Certificate of Conformance/Certificate of Analysis

The supplier shall furnish a Certificate of Conformance/Certificate of Analysis (Certificate), signed by an official representative for the supplier. Materials, processes, services and/or furnished items, in accordance with the instructions, drawings, and specifications furnished with the purchase order shall have a signed certification included with the packing slip in the form of a Certificate. Each Certificate shall identify the purchase order number, part number, revision, serial number (if applicable), specification, drawing, and lot/batch number as applicable to the content of the purchase order.

Inspection and test data shall be maintained for at least twenty (20) years, unless otherwise specified, and is subject to Norwood and/or regulatory examination.

Quality Documentation and Record Retention

Supplier shall have a quality system that requires sufficient documentation to be available for the product quality and effective operation of the quality system. All documentation should be legible, dated (including revision dates), clean, readily identifiable, and maintained in an orderly manner. Data forms may be paper or electronic. The supplier shall retain records as a means of objective evidence of the quality of items supplied (manufactured, fabricated, assembly, inspection, test, special processes, etc.) for a minimum of twenty (20) years, or as otherwise indicated on the purchase order. Records shall be subject to examination by Norwood Medical and/or regulatory agencies and copies of these records shall also be available upon request.

Calibration Control

The supplier shall control the calibration of all Measuring and Test Equipment (M & TE) against certified measurement standards, traceable to NIST. The calibration control system shall conform to specification ISO/IEC 17025 "Calibration System Requirements" or equivalent.

Preventative Maintenance, Training, Housekeeping, and Environmental Controls

Norwood suppliers should take the appropriate measures to ensure that their machinery and equipment, employees, and environment are available, suitable, and safe for the manufacture of quality products. This includes having programs and processes in place for regular preventative maintenance of machinery and equipment, training of employees, and housekeeping and environmental controls in the facilities.

SHIPPING

Safety Data Sheet (SDS)

Supplier must email the SDS prior to initial delivery of product to the buyer and to receivinginspection@norwoodmedical.com. The SDS must also accompany the initial shipment and any changes that would affect the SDS.

Packaging and Labeling

Packaging weights cannot exceed 35 pounds per container. All wood packaging materials and skids shipped to Norwood must be heat treated in compliance with the International Standards for Phytosanitary Measures Publication No. 15 (ISPM 15) and appropriately identified as such. ISPM 15 currently provides for the use of methyl bromide as an alternative method of fumigation, but the use of wooden packaging fumigated with methyl bromide is prohibited by Norwood. All products must be packaged in such a manner to protect the parts from damage during transport and unloading at Norwood. Any labeling that is applied shall be designed to ensure it remains in place during customary

conditions or raw material receipt, distribution, storage, and use. Storage conditions must be clear and placed on the label. If a product has an expiration date, the date must be noted on the label.

All paperwork must be supplied at the time of shipment and must be accurate. Packing slips must state the purchase order number, Norwood part number, revision level, manufacturer's part number, supplier's name, quantity, and expiration date (if applicable). The material certs must contain all the mechanical and chemical data, Norwood part number, and part description. Suppliers must supply a Certificate of Conformance stating that all work performed complies with all drawing and purchase order specifications. The Certificate of Conformance must reference the Norwood job number.

Freight and Delivery

Norwood employs lean manufacturing practices and expects deliveries on time and to the quantity specified. Approved freight carriers will be supplied by Norwood. Norwood will provide delivery schedules as required, including part numbers, quantities and due dates. On-time delivery = 0 days late for all suppliers, and no more than 3 days early for raw material or component suppliers based on the purchase order due date.

NORWOOD MEDICAL
2122 Winners Circle, Dayton OH 45404
Phone (937) 228-4101 • Fax (937) 228-1608

SUPPLIER REQUIREMENTS MANUAL ACKNOWLEDGEMENT

SUPPLIER CONTACT INFORMATION	
Supplier Name:	**Phone:**
Address:	
Is the above address the manufacturing/distribution location for items supplied to Norwood Medical? ☐ Yes ☐ No **If NO, or if there is more than one manufacturing/distribution location for items supplied to Norwood Medical, list the address(es) of any other location(s).**	

I agree to refrain from copying this manual and from distributing this manual outside of my company.	☐ Yes ☐ No
I understand that previous Supplier Requirements Manuals are no longer valid. I will destroy, or clearly mark as obsolete, any previous Supplier Requirements Manuals.	☐ Yes ☐ No
I understand that any exceptions to the requirements outlined in this manual must be documented and sent to the Purchasing Department with this acknowledgement.	☐ Yes ☐ No
I understand that failure to return this acknowledgement within 30 days may result in a hold status for business.	☐ Yes ☐ No
I acknowledge that my company has received this manual.	☐ Yes ☐ No
I have read and understand the contents of this manual.	☐ Yes ☐ No
I will meet all applicable requirements of this manual and have attached any exceptions to the requirements, along with explanations and alternative options.	☐ Yes ☐ No

This acknowledgement must be signed by a quality manager and/or an officer of the company.			
Printed Name:		**Title:**	
Signature:		**Date:**	
Printed Name: (optional)		**Title: (optional)**	
Signature: (optional)		**Date: (optional)**	

This acknowledgement page (Page 12 of 12) must be completed, signed, and returned to the Norwood Medical Purchasing Department at purchasing@norwoodmedical.com.