

VOP			
Operating sub Process			
Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection			
Created:	27/03/06	VOP 05	Issue 1
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<u>QC</u>			

SCOPE

This procedure is established to describe the system used within the company for the control of purchasing of product and evaluation / assessment of suppliers and sub-contractors. It is used in conjunction with the individual sub procedures, which show the relevant information necessary.

RESPONSIBILITIES

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures, are adhered to. It is the responsibility of the relative supervisors to ensure that their requirements are made clear. The Warehouse Controller is responsible for the ongoing evaluation of suppliers / sub-contractors.

OBJECTIVES

It is the Objective of this VOP to demonstrate the handling of Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection. To detail how Suppliers are dealt with in the companies and how we control products and returns with suppliers. How we deal with suppliers and products that do not conform or are rejected.

PURCHASING

A warehouse request is submitted by a member of staff. This is picked up by the Warehouse controller, they then generate a Purchase order PVM for Viamed, PAN for Vandagraph, PST for Vandagraph Sensor Technology, in Intrastats. To cover the supply of products for warehouse stock, or immediate customer delivery.

The purchase order is raised for goods or materials as required, and the details entered into the correct supplier on Intrastats. The purchasing documents should clearly describe requirements, i.e. quantity, price, description. Purchase orders not processed by a director are forwarded to a director for approval. Once it has been approved it can then be sent to the supplier. Purchase order must contain a supplier code, the field should not be blank.

Warehouse request for orders may be initiated by:

Engineers – stock needed for production or repairs.

Office staff – when they check stock for customers order and it shows we will not have sufficient stock.

Warehouse controller – to bring stock items up to minimum level or against goods not already in stock or already ordered, to supply customer orders in hand.

All Purchase orders are approved by a director.

Purchase orders are processed by the following means;

- Addressee abroad – By Email

- Non urgent orders – By Email
- Urgent orders – By Email
- Extremely urgent orders – By Telephone/Email

Purchase Order Number is generated automatically. Purchase Orders contain all relevant data to the supplier, part numbers or product codes, description and quantity.

The purchase order is stored in the Intrastats system. These are printed, when goods are received and then filed with the supplier paperwork by the goods in department, in the Purchase Order file, in purchase order number order. So that when the goods come in, they can be checked against our original paperwork. When the goods are received this is stamped as such. Then Intrastats is checked and barcodes produced booking into stock.

Also see VM3COP27.51 Incoming / Goods in Contamination Control.

The Purchase Order must specify any requirements for inspection and tests, and any certification required, include special instructions for packaging, labelling or delivery. Special goods receiving information is also displayed on the booking in system. Additional information where appropriate is advised e.g.

- Quoted price when applicable.
- “Urgent Please” if supply is required urgently.
- “Partial shipment acceptable/not acceptable”.
- Preferred method of shipment.
- If supplier needs to know for traceability of specified instruments or service. We can give the customer or instrument details.
- Requirement on Purchase Order for serial numbers / LOT numbers / batch numbers for traceability.
- Conformity Certification needs to be requested from the supplier when required.

Purchase Orders will be reviewed and authorised by the Managing Director, Director or Warehouse Controller.

It is the responsibility of the individual raising the purchase order to ensure that all the relevant and correct information is entered onto the purchase order. It is the responsibility of the person receiving the goods to ensure the purchase orders are filed accordingly.

ASSESSMENT OF SUPPLIERS / SUB-CONTRACTORS

All products provided to us under ISO 9001 or 13485, the most up to date version, must be procured from a quality assured source, or is internally QA / Verified. When a customer orders products, in accordance with the companies Approved Supplier List, then a quality assured source will be:-

- Companies assessed by certification bodies within the UK.
- Companies assessed by certification bodies outside the UK to equivalent systems.
- A Company specifically nominated by a customer in his order will also be considered a Quality Assured Source for that particular customer, or where the customer has specified the product by brand or specific part number.

APPROVAL OF SUPPLIERS

New products will be considered by the Managing Director, by assessment of supplier capability to meet the required quality standards.

Have an acceptable delivery date and to make sure the firm maintains batch segregation, inspection and test records. A Internal Supplier Review questionnaire, is carried out for ISO registered companies. A Supplier/Sub contractor questionnaire (Form QC06) will be used to approve non ISO companies suppliers.

An Approved Supplier List of approved Suppliers/Sub contractors will be maintained by Managing Director or his chosen representative in Intrastats, which will distinguish between Quality Assured and non-Quality Assured Sources.

At least once per year all suppliers will be re validated or re-assessed.

An Approved Supplier List of current suppliers is available and maintained in Intrastats. This list is monitored and evaluated on a regular basis, and formally reviewed annually for the management review. The determination of supplier suitability is made on the basis of third party approval, historical acceptable performances, pricing, delivery or other such factors as may be deemed appropriate.

Information received from all departments, on an annual basis, will be taken into consideration for review of this Approved Supplier List.

SUPPLIER QUALITY CONTROL

The Managing Director will be responsible for ascertaining whether Suppliers / Subcontractors performance is satisfactory or unsatisfactory. They can use details based on the following feedback from Issues:

Rejects as a result of non-conformance to purchase order.

Rejects as a result of damage in transit.

Incorrect or lack of correct documentation.

Incorrect quantities delivered.

Risk assessments.

Customer complaints.

Length of time taken in correcting situation

Corrective action will be taken by the Managing Director

REJECTED GOODS

Where goods fail incoming Inspection as per VOP 06. Also see VM3COP27.51 Incoming / Goods in Contamination Control. They will then be quarantined and put on hold awaiting return to the supplier or agreed action.

If a product is rejected due to, damage in transit, failure to meet relevant specification, it is placed in the return to supplier ducket, specific to each supplier.

The supplier will be contacted and an RMA requested. The supplier will be asked for confirmation and once we receive conformation, the goods scanned to the returns

shelf. The goods to be returned to the supplier will be done through Intrastats Supplier Returns.

PRODUCTS OUTSIDE THE REGISTRATION

Any product which is not included in the Registration will be clearly identified in the covering documentation so that there can be no misunderstanding on the part of the customer.

Similarly if a supplier has not been approved as specified Approval of Suppliers, their products must not be sold without them being clearly identified and confirmed in the covering documentation, as follows - "This item procured from a non ISO 13485 or ISO 9001 source".