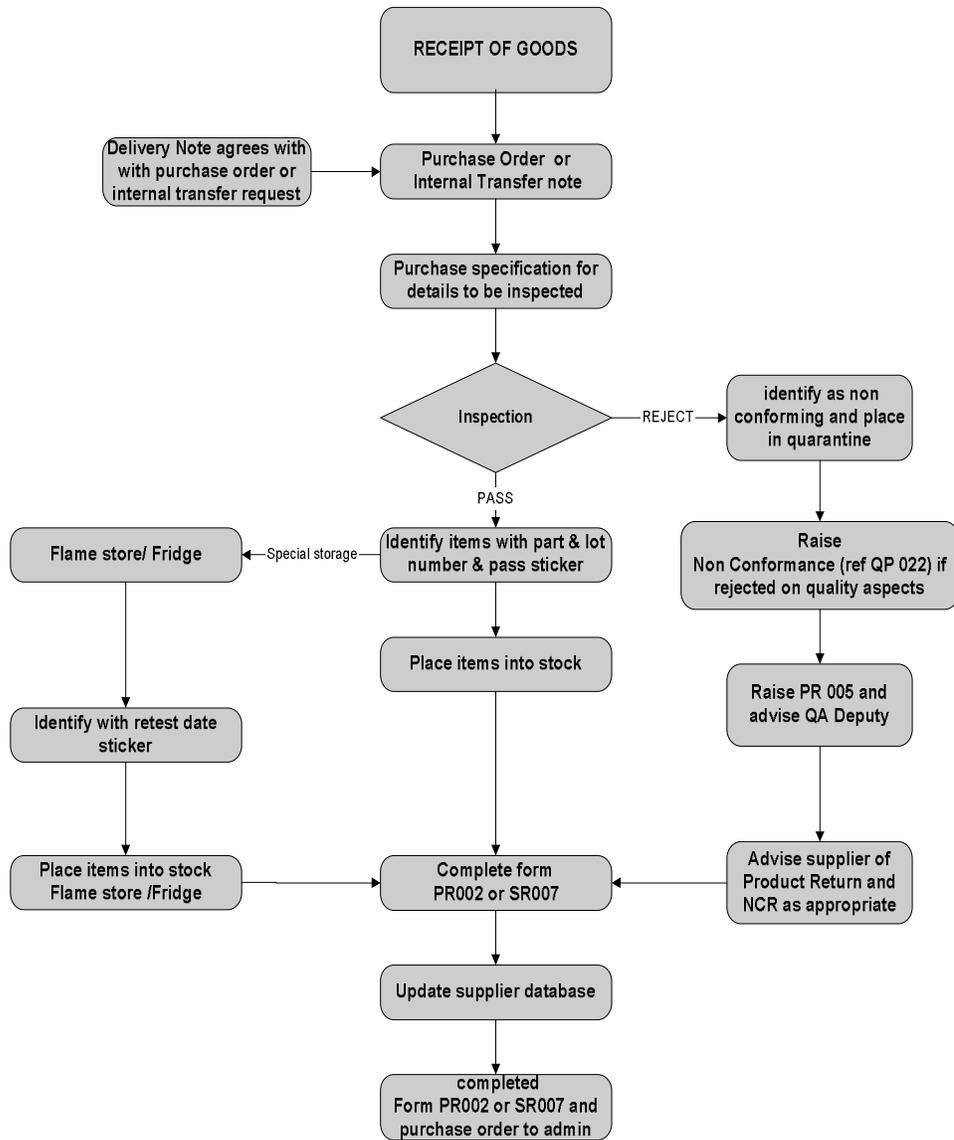


CONTROL OF INCOMING GOODS

**PROCEDURE QP 017
GOODS INWARD**



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AUTHORISED BY: QA Manager	TITLE: CONTROL OF INCOMING GOODS		DR001 No: 9597
PREPARED BY: L Kane	REVIEWED BY: QA		

1.0 SCOPE

To establish procedures for the control and acceptance or rejection of incoming deliveries in accordance with the requirements of 21 CFR Part 820.80 (b), ISO 13485, and Council Directive 93/42/EEC Annex II Sect.3.2d/e.

2.0 DOCUMENTS RELATING

- QP 006 Purchasing and Order Processing
- QP 007 Supplier Approval Procedure
- QP 008 Preparation of Purchase Material and Service Specifications
- QP 027 Packaging and Delivery
- QP 033 Statistical Methodologies
- TM007-06 Statistical Sampling Plans.

3.0 RECORDS UTILISED

Ref	Title	Custodian
PR 002	Purchase Order + Attachment	Administration Dept.
PR 005	Returns Note	QC Inspector
QR 003	Sampling Inspection Record	QC Inspector
QR 132	Certificate of Conformity	QA Dept
SR 007	Shipping Note	QC Inspector

4.0 RESPONSIBILITIES

The QC Inspector shall be responsible for the following:

- a) To carry out goods inward inspections in accordance with the Purchase Specifications.
- b) to raise PR005 – Returns Note in the event of non-conforming goods
- c) to enter all receipt details onto the Supplier History database

The Administration Department shall be responsible for the inputting of data into the computerised accounts system.

5.0 GOODS RECEIPT & INSPECTION

5.1 Where goods are received and require a signature that the goods received are in good order then the goods must be fully examined before signing the carriage documents OR the carriage documents must be endorsed "UNEXAMINED".

Note: Failure to comply with this requirement will remove the carriers liability for damage sustained in transit and the Company will be unable to claim compensation for any loss.

5.2 A "Hold" sticker shall be affixed to each container of the consignment pending inspection and the goods shall be held in one of the following areas:

- a) Flammable Materials Store – (Solvents e.g. Isopropyl alcohol, Xylene, Dispersions)
- b) Goods Inward Quarantine Area.

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Note: For bulky items e.g. boxes it is permissible to place these directly into storage pending receipt procedures.

In the case of Internal Transfers a Biosil Pass sticker may be attached to the goods, the appropriate purchase specification shall document the incoming goods acceptance requirements i.e.

- a) Items may be accepted on receipt of a certificate of conformity, as documented as required on Purchase Specification, in which case no change is required to the pass sticker.
- b) Items may be accepted on receipt without a certificate of conformity, as documented as not required on Purchase Specification, in which case no change is required to the pass sticker.
- c) Goods may require to be held pending further testing as documented as required on the Purchase Specification, in which case affix a 'Hold' Sticker over the original pass label until test status is determined.

5.3 The Delivery Note or SR 007 (Shipping Note for Internal Transfers) shall be held by the QC Inspector pending inspection of the goods.

5.4 Incoming goods shall be inspected and/or tested in accordance with the requirements of the appropriate Purchase Specification to the stated criteria.

The following details must comply with the Purchase specification:

- a) Product Description
- b) Supplier Name
- c) Supplier Part Number
- d) Certificate of Analysis/Conformity required

5.5 If the specification requires a Certificate of Analysis/Conformity this shall be checked for compliance with specified requirements. Each Certificate shall be annotated with a sequential number which shall be noted on the Purchase Order to aid retrieval.

5.6 Where required, -sampling inspection shall be carried out in accordance with the requirements of TM007-06 – Statistical Sampling Plans.

5.7 Components supplied inter-company must be accompanied by a "**Certificate of Conformity**". This will enable the receiving officer to ensure that the components have met the internal quality standards.

5.8 When all delivery inspection/testing activities have taken place, details of the delivery (excepting internal transfer) shall be entered onto the Supplier History Database before transfer of documentation to the Administration department for entry into the computerized accounts system.

6.0 GOODS REQUIRING SAMPLING INSPECTION / TESTING (not including Internal Transfers)

Where goods are received which require sampling inspection/testing which will cause a delay in the receipt process then the following is to be actioned:

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QC Inspector will complete sections 1 to 5 inclusive on Purchase Order Attachment together with the relevant Purchase Order No. This attachment is then to be passed to administration department who will enter the goods into relevant quarantine warehouse on the computerised accounts system, this being demonstrated by signing section 6 of attachment. The attachment shall then be passed back to the QC Inspector to await completion of sample inspection/testing.

This is to enable these goods to be viewed as present on Biosil premises for accounts and insurance purposes.

7.0 CONFORMING GOODS WHICH DO NOT REQUIRE SAMPLING INSPECTION / TESTING (not including Internal Transfers)

- 7.1 Upon acceptance of incoming goods which can be processed within a timely manner due to not having to be sample inspected/tested all relevant information shall be entered onto the attachment to the Purchase Order by the QC Inspector. The completion of the attachment will exclude section 6.
- 7.2 The Biosil part number, description, supplier, quantity and Lot number shall be entered onto the "Hold" label together with a "PASS" sticker. The goods shall then be transferred to the appropriate storage area.
- 7.3 The 'order complete' section of the purchase order shall be signed, affixed to the delivery note together with the purchase order attachment and details of the delivery entered into the Supplier History Database before transfer of documentation to the Administration Department. For part complete orders, a photocopy of the annotated purchase order shall be passed to the Administrator, the original being retained until items outstanding are received.
- 7.4 The administration department will then complete section 13 of the Purchase Order attachment.

8.0 CONFORMING GOODS FOLLOWING SAMPLING INSPECTION / TESTING (not including Internal Transfers)

- 8.1 Upon acceptance of goods following sampling inspection / testing all remaining relevant information shall be entered onto the attachment to the Purchase Order by the QC Inspector.
- 8.2 The Biosil part number, description, supplier, quantity and Lot number shall be entered onto the "Hold" label together with a "PASS" sticker. The goods shall then be transferred to the appropriate storage area.
- 8.3 The 'order complete' section of the purchase order shall be signed, affixed to the delivery note together with the purchase order attachment and details of the delivery entered into the Supplier History Database before transfer of documentation to the Administration Department. For part complete orders, a photocopy of the annotated purchase order shall be passed to the Administrator, the original being retained until items outstanding are received.
- 8.4 The administration department will then complete section 13 of the Purchase Order attachment.

9.0 NON-CONFORMING GOODS (not including Internal Transfers)

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9.1 Non-conforming goods shall be held in quarantine pending return to supplier or acceptance under concession.

9.2 Where goods are to be returned to the supplier:

- 1) The QC Inspector shall generate a PR 005 - Returns Note, stating the quantity to be returned and the reason for rejection. Copies of this note shall be distributed to the following:

Copy 1: To be returned with the goods to the supplier.

Copy 2: To the Administration Department

Copy 3: To be retained by the QC Inspector if replacement / rectification of goods is required.

The supplier database shall be updated with the goods returns note number.

- 2) Where goods are to be returned to category 1 or 2 suppliers due to quality issues, e.g. failure to meet specification, an NCR shall be raised documenting the failure. A copy of the NCR shall be returned with the goods to the supplier. The supplier shall be advised that an investigation into the failure is required by Biosil and that an inadequate response will result in a review of their supplier status.

The supplier database shall be updated with the goods returns note number and NCR number

9.3 Where goods have been accepted under concession, a copy of the concession shall be retained with the delivery documentation and the Supplier History shall be annotated accordingly.

9.4 To enable review of supplier performance receipt details of conforming and non-conforming goods shall be entered onto the Supplier History section of the QA database.

10.0 CONFORMING GOODS (Internal Transfers only)

10.1 Upon acceptance of incoming goods, the following information shall be entered onto the SR 007 – Shipping Note:

- a) Items received by & Date
- b) Items checked by & Date

10.2 Either remove 'Hold' label if original, ensure that 'Pass' Label is in good condition or replace whole of label ensuring that all relevant information has been entered. The goods shall then be transferred to the appropriate storage area. Traceability of Original Lot No's must be maintained following Transfer between sites.

10.3 The completed Shipping Note should then be passed to Administration.

11.0 NON-CONFORMING GOODS (Internal Transfers only)

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- 11.1 Goods not recoverable – Pass to Administration for transfer onto 'Write-Off Stock'
- 11.2 Goods recoverable – Pass to administration for transfer to site of origination for rework/regrading to take place.

12.0 DATABASE ENTRY (Not including Internal Transfers)

12.1 **Go to "W:\Databases\Supplier History Ash.mdb" or "Supplier History Cum.mdb"**

- 12.2 Select "New (blank) record, and from the Purchase Specification and Purchase Order:
 - a. Type in the Purchase Number (PO Number)
 - b. Type in the Stock Code
 - c. Type in the Due Date
 - d. Type in the Date Received (Rec Date)
 - e. Type in the Supplier ID
 - f. Select the order status
 - g. Select the lot sentence Pass or Fail. Note if Fail type in the Returns Note number and the NCR Number* (if applicable)
 - h. Type in the Certificate of Conformity / Analysis No (if applicable)
 - i. Select the 'entered by' name from the drop down menu.
 - j. Select 'Save'

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