Procedure: Verification of Purchased Product

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This procedure provides an overview of how to verify purchased products, including the receiving process, handling of products requiring QC inspection and conducting on-site inspections. Modify this as required to reflect the company’s practices.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for receiving and inspecting incoming products at [Company].

# Scope

The scope of this procedure includes the verification of purchased components including raw materials, parts, software, firmware, labelling, packaging, etc, that are intended to be part of the finished device.

This definition is modified from CFR 820.3(c).

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Control (QC) analyst |  |
| Stores staff |  |
| Quality Manager |  |

Amend roles and responsibilities according to your company processes and structure.

# Procedure

## Verification methods

Modify this section to describe the methods used by the company. Review the criteria with regard to QC inspection and edit appropriately. The regulations and standard are not specific in this area.

Received products are subjected to an incoming inspection. This includes verification of the identity and quantity of the delivery, visual inspection to ensure the packaging and contents are not damaged and identification of any documents delivered with it. Section 4.2 of this procedure describes this in more detail.

Acceptance of components can be based on this initial receiving inspection only, if all the following apply:

* the component is not critical to device safety
* defects in the component are likely to be apparent during production or assembly or during in-process or final inspections
* there is a high level of confidence in the supplier's quality system and product verification program. (This may be based on the supplier's quality certification, supplier audits and satisfactory history)

If the components do not meet all the above criteria, the following additional evidence of conformity must be sought:

* the supplier must provide evidence of product conformity such as inspection, testing, process control records or certificate of analysis, or
* the component is subjected to in-house QC inspection and testing

Incoming components that require additional in-house QC inspection or that are supplied with quality records that must be evaluated and approved by QC, are quarantined until the QC inspections are complete.

Edit to describe how the company handles and quarantines components awaiting inspection, approval and release by QC.

## Receiving inspection

Modify this section to reflect the company’s procedures but ensure that:

a) the original purchase order information is available at the inwards goods receipt

b) the identity, quantity and condition of incoming goods is inspected and verified

c) items requiring further QC inspection are identified and quarantined

d) identification, inspection status and traceability are maintained through the receiving process.

Incoming deliveries are unloaded and the stores staff checks:

* the number of packages delivered
* the marking/identification of each package
* for evidence of contamination or damage

If the incoming inspection is satisfactory, the delivery receipt is signed. Any shortage or damage identified is noted on all copies of the delivery receipt.

In the event of any external damage to shipping packages, it may also be appropriate to notify the original shipper and the transport company.

Inspected packages are moved to the stores receiving area. The stores copy of the relevant purchase order is retrieved and the packing slips (delivery dockets) are removed from packages. The purchase order copy and packing slip are compared and any differences noted.

Packages are opened and the contents inspected and, where practical, counted. Part numbers or other identifications are verified against the purchase order and packing slip. The incoming material is examined visually for sign of damage or contamination.

The stores staff verifies that all the required documents (quality records) are enclosed or have been received independently.

When all incoming inspections are completed, the stores copy of the purchase order is stamped.

| Purchase Order Inspection Stamps | Description |
| --- | --- |
| Approved | Delivery matches the order, the goods pass the visual inspection and no further testing is required |
| Hold for QC inspection | When further QC testing or review of documents is required |
| Rejected | Delivered goods are not what was ordered, are damaged or do not meet specifications. |

The stamped stores copy of the purchase order must be signed and dated by the stores staff.

Only CFR 820 specifies that acceptance/inspection records to be signed. This is not required by ISO 13485.

Using a stores copy of the purchase order is effective but may require modification to allow for partial shipments. Alternatively, copy the purchase order for each shipment and record on it details of the quantity received, etc.

If a non-conforming delivery is identified during the initial inspection, the stores staff initiates a Non-Conformance Report (NCR) in accordance with Procedure *QP805: Control of Non-conforming Product*. The “REJECTED” label is marked with the NCR number and copies of the NCR are forwarded to purchasing and QA for review.

On completion of incoming inspections, the received goods are labelled and stored.

|  |  |
| --- | --- |
| Received Goods Inspection Stamps | Description |
| Approved | Goods labelled as approved and moved to the released goods area of the store |
| Hold for QC testing | Goods labelled as requiring additional QC testing. They are sampled and moved into the secure quarantine area of the store; the samples are clearly labelled and transferred to QC for testing, along with any associated quality records |
| Rejected | Goods labelled as rejected are moved into the secure reject area of the store. |

Alternative systems for identifying and segregating incoming materials are acceptable and include labelling, secure physical segregation or electronic segregation. Whatever system is used, it must ensure that untested and approved materials are not mixed and that unsatisfactory components are not used unintentionally.

When the initial inspection is satisfactory but the required quality records have not been received, the received goods are also labelled “HOLD FOR QC INSPECTION” and are moved to the designated quarantine area.

## QC inspection

Modify this section to describe how QC inspections are performed. It should include:

a) scope of testing

b) method of inspection

c) acceptance criteria

d) calibration of measuring equipment

e) inspection records

f) inspection status identification.

It is essential that this matches procedures for identification and processing of Non-conforming product.

QC is responsible for assembling the relevant technical documentation including material specifications, test procedures, drawings, standards and regulations. The test procedure describes how to perform the inspection or test and contains the approved acceptance criteria.

QC receiving inspections include:

* review of material certificates, on-site inspection records, compliance certificates and other documentation specified in the purchase order
* random sampling based on a documented statistical sampling plan
* visual inspection to detect any gross damage or other visible problems
* taking measurements and performing tests as specified in protocols
* appropriate statistical analysis of results
* recording the inspection and test results

On completion of QC testing, the test protocol is stamped:

* “PASSED BY QC” – if the tested material passes the QC inspection
* “REJECTED BY QC” – if the material does not comply with specifications.

The analyst must sign and date the test protocol.

Only CFR 820 specifically requires that acceptance/inspection records to be signed.

A copy of the result is forwarded to the store where the stores staff is responsible for appropriate labelling and storing of the associated goods:

* materials passed by QC are labelled “APPROVED” and moved to the designated storage area in the warehouse
* materials rejected by QC are labelled “REJECTED” and moved into the secure reject store

If the incoming material fails to meet specifications, the QC inspector initiates an NCR in accordance with Procedure *QP805: Control of Non-conforming Product*. Copies of the NCR are forwarded to Purchasing and QA for review.

## On-site inspection

Provide more detail of why, when and how on-site inspections are performed. If on-site inspections are not performed, delete this section.

Where an on-site verification of purchased materials is required, the arrangements and method of product acceptance are specified in the purchase order.

The on-site inspection may be performed by the company, by a third party on behalf of the company or performed or witnessed by a customer.

## Acceptance and inspection records

Acceptance of products is recorded on the stores copy of the purchase order:

* products inspected by the stores staff - the stores copy of the purchase order is stamped “APPROVED”, “HOLD FOR QC INSPECTION” or “REJECTED”, as appropriate, then signed and dated by the stores staff
* products inspected by QC - the test protocol is stamped either “PASSED BY QC” or “REJECTED BY QC” , as appropriate, then signed and dated by the analyst

Signing of acceptance and inspection records is only required by CFR 820.

On completion of all specified inspection and testing, the stores copy of the purchase order is stamped and signed by the stores staff.

Stamped and signed stores copies of the purchase order are filed in the inwards goods warehouse by the stores staff. Copies of associated inspection reports and quality records are filed with the copy.

Stamped and signed purchase order copies may be returned to purchasing or be forwarded to accounts payable or to QC. Modify the above two clauses to reflect the company’s procedure.

Acceptance and inspection records must at least include the following:

* identification of the product
* identification of the manufacturer or supplier
* the acceptance activities performed (i.e. procedures, work instructions or specifications)
* acceptance criteria
* the results and quantities accepted and rejected
* identification of measuring and testing equipment
* signature and date of the person conducting the acceptance activities

When a copy of the purchase order is used to establish the record, most information needed is already on the order. Record the quantities accepted and rejected and then sign and date the record.

Acceptance and receiving inspection records are a part of the Device History Record. However, they are not maintained in the same file with other production history records unless full traceability is required.

This reflects an established interpretation of CFR 820.80(e) for receiving inspection records.

When traceability of incoming materials is required, the acceptance and receiving inspection records are linked to the devices in which the component is used. The system and methods for establishing and maintaining traceability are defined in Procedure *QP712: Product Identification and Traceability*.

Delete the above clause if it does not apply.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP712 | Product Identification and Traceability |
| QP805 | Control of Non-conforming Product |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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