Procedure: Final Acceptance Inspection

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| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
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| Authorised by: | Job title: | Signature: | Date: |

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Final acceptance inspections vary from product to product so this procedure will need to be modified to reflect the procedures of the company. Describe what paper or electronic records are used to record final inspection and release of product.

As with other procedures, this procedure assumes the use of a work order (refer QP708 Production Work Order and History Record).

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for performing the final acceptance inspection and release of the finished product.

# Scope

The scope of this procedure includes all finished products manufactured at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Control (QC) Inspectors |  |
| Quality Assurance (QA) Inspectors |  |
| Quality Manager |  |

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

In this procedure, the final inspection is mainly a review of production paperwork (i.e. the work order(s)) to ensure that all procedures were followed and all specifications met. Expand this procedure to describe final product inspection and testing, as appropriate.

## General

The focus of [Company] is on defect prevention rather than defect detection. Verification procedures are therefore focused on control of starting materials, processes and in-process inspections rather than on end-product testing.

Final inspection includes a review of in-process inspections and tests and functional tests of the final product.

## Final inspection

All finished products are subjected to final acceptance inspection and formal release before release for sale.

Product may be an individual item or a batch, usually what has been manufactured on one work order. Edit as applicable.

QA is responsible for final inspection and release of product. QC inspectors perform the final inspections or tests.

Any suitably qualified/trained person may be authorised to make product release decisions.

The final acceptance inspection is carried out in two stages:

* First: acceptance of product and release for packaging and labelling
* Second: inspection of the packaging and labelling and release for sale of the complete packed product.

Edit as appropriate – it may not be necessary to release product in two steps.

The first stage of final acceptance inspection includes a review of:

* work order(s) to confirm all specified operations, processes and in-process inspections are complete, satisfactory and signed off
* traceability records and inspection data
* other inspection reports, control charts and production records referenced in or attached to the work order(s)
* the product itself for completeness and any visible quality problems
* measurements/tests performed as evidence of product conformity
* records of actual measurements and test results

Products that pass all first stage reviews, inspections and tests are labelled with an ACCEPTED sticker or tag and are signed off by the inspector. Passed products are then moved to the packaging and labelling area.

The second stage of the final acceptance inspection includes:

* inspection of product packaging and labelling
* release of product for shipping or to the finished product store

Products that pass second stage packaging and labelling inspection are released in accordance with Section 3.3 of this procedure.

Complex products, where functional testing may be involved, are inspected according to approved checklists or procedures and results are recorded in inspection reports.

Describe the final inspection checklists and instructions used at [Company].

## Release of product

Only authorised QC inspectors have the authority to release product.

Products are released following the final packaging and labelling inspection. Released products are labelled with a RELEASED sticker or tag and are moved to the shipping area or to the finished product warehouse.

“Movement” of product to the “warehouse” may be achieved electronically.

Product release is documented on the work order. The record includes the date of the release and the name and signature of the QC inspector.

Released products (only) may be stored in the finished product warehouse or packaged and dispatched.

## Non-conforming product

When non-conforming product is identified or there are issues with the Device History Record (DHR), the product is labelled as REJECTED.

An NCR (*Form FM805-1: Product Non-Conformity Report*) is raised, the number marked on the REJECTED label and the product moved into a quarantine area.

The NCR is processed as per Procedure *QP805: Control of Non-Conforming Product*.

## Inspection record

The final inspection record contains the inspection results and the signed and dated work order(s). Additional checklists or reports prepared during the inspection are attached to the work order(s).

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 |
| 01 |  |  |  |
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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 |
| QP805 | Control of Non-Conforming Product |
| FM805-1 | Product Non-Conformity Report |

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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