

Standard Operating Procedure

Title: Rework Procedure

- 1.13. Goods will be transferred to process area (WIP/PS1/PS2/IP) as requested in the form. One copy of 'Goods Return For Rework form' will be kept in the warehouse. The original will be sent with the goods. Finished goods are to be transferred in the way separated from the other Raw materials and Components.
- 1.14. When the goods are transferred production operator should check the pallet for correct product code and batch number. Label the pallets with 'Product to be Reworked Form' (**Form-510**).
- 1.15. If additional components are required a request will be sent from production by issuing 'Material Transfer Order Form' (**Form-055**). See SOP **WAR-015** for issuing of components.
- 1.16. The Rework proceeds. The Rework Protocol must be followed and signed off.
- 1.17. On completion of the Rework the Rework Protocol and samples are forwarded to the QA. The form 'Batch Documentation Checklist **Form-555** must be included with the Rework documents. Page 1 of this form must be completed by Production. See **SOP QMS-085**.
- 1.18. All activities, relating to the Rework **MUST** be documented. All documentation, relating to the Rework **MUST** be included with the batch documents. Information can be included in the DR or in the specific Rework Protocol
- 1.19. After rework and before the pallets are sent to the Warehouse, remove the signs and clean them using IPA.

2. Procedure for Reworking Product at Contract Manufacturer

The procedure for Reworking product at a contract manufacturer is covered in **SOP QMS-110**.

3. Rework Protocols

All Reworks must be carried out with an approved Protocol. A Rework cannot be started until approved by QA.

The following templates are to be used:

- **TEM-115 / TEM-125.**

The Protocol must replicate the usual production process as closely as possible. Checks and tests performed in the usual production process **MUST** be included in the Protocol. For example, if check-weighing of packed cartons is part of the usual production process, then it must be included in the Rework Protocol.

The Rework Protocol can be prepared by an Operations team member or a QA Staff. Usually the Protocol generated as a response to DR.

The Protocol is to be checked and approved as follows prior to execution:

Prepared by:	QA Team member or Operations Team member
Checked by:	Production Manager (or delegate)
Approved by:	Quality Assurance Manager (or delegate)

3.1. Protocol for Manufactured Finished Goods Rework, TEM- 115.

TEM-115 is to be used when a Finished Good is being repacked from one BPN to another RBPN

The following information is to be provided in the request for Rework Protocol for Manufactured Finished Good:

- Why the Rework is being done.
- The related DR number
- Initial BPN and Expiry
- Quantity (excluding original sample qty)
- Final RBPN and Expiry