

NON-CONFORMITY REVIEW, DISPOSITION AND REWORK

1.0 GENERAL

1.1 It is the policy of the Company to establish and maintain documented procedures for the review and disposition of non-conforming product.

2.0 RESPONSIBILITY

2.1 The responsibility for the review and disposition of non-conforming material shall ultimately lie with the General Manager, but on matters of internal release of product, this may be delegated to members of QA/QC staff.

3.0 REQUIREMENTS

3.1 Documented procedures shall be prepared for the review and disposition of non-conforming product, which may be

- reworked
- accepted with or without repair by concession
- re-graded for alternative applications
- scrapped

3.2 Documented procedures shall be established for the rework of non-conforming products, that shall include the means of re-inspection. Reworked product shall be subject to release upon the authority of the Quality Assurance Deputy.

3.3 A procedure shall be established and maintained for the use of concessions and/or process variation permits these are defined as:

- a) Production permits shall be used when an alteration in manufacturing method is required that does not directly affect the quality of the finished product. These may be granted upon authorisation of the Quality Assurance Deputy.
- b) Concession applications shall be used when product does not conform to specified requirements. These must be authorised by the customer. Such concessions may only be granted providing that regulatory requirements are met.

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- 3.4 Where a product is supplied to a customer under concession, the actual condition of the product as supplied shall be recorded by means of retention of the original non-conformance report and concession as part of the batch manufacturing record.
- 3.5 Where products are reworked or repaired, this shall be carried out in accordance with documented instructions.

4.0 RELATED PROCEDURE

- 4.1 Non-conformity Review, Disposition and Rework

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