1.0 Policy

This procedure is to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

2.0 General

Nonconforming material is defined as parts or materials that do not meet documented specifications, purchasing requirements, or workmanship standards. Nonconforming material must be identified and segregated by means of a reject ticket or Nonconforming Material Form.

3.0 Associated Documents

- 80-1018, two-part reject tag
- 80-1012, Nonconforming Material Form

4.0 Identification and Documentation

QC inspectors and production personnel are responsible for the identification of nonconforming product in the course of their inspection activities, including, but not limited to, those described in 90-2000-7.4.3, Verification of Purchased Product and 90-2000-8.2.4, Monitoring and Measurement of Products.

All nonconforming product is documented in one of two possible ways – the two-part reject tag, Form 80-1018 (typically used by production personnel), or the Nonconforming Material Form, Form 80-1012 (typically used by QC inspectors). In either case, the nonconforming condition is noted on the form. The form remains with the nonconforming product until the nonconforming condition is resolved. The form is finally sent to QA.

5.0 Segregation

Nonconforming product is typically segregated along with its associated tag (80-1018) or form (80-1012). Nonconforming product may, however, remain with the job if it is clearly and individually marked as nonconforming. Segregation areas

include rejected materials quarantine areas and separate, clearly-identified areas on the production floor.

6.0 Evaluation and Disposition

Nonconforming product is evaluated and dispositioned by any member of the Material Review Board. The Purchasing Manager, Manufacturing Manager, members of QA, Production Supervisor, Test Supervisor, and Engineering Manager are members of the Material Review Board.

There are four possibilities for the disposition of nonconforming product. They include the following:

6.1 *Rework/Repair* - The nonconforming product is placed back into the manufacturing process to be reworked or repaired. The rework or repair must be completed successfully before its associated nonconforming tag or form is removed. The individual performing the rework or repair shall indicate completion on the tag or form. The reworked/repaired item is subject to re-verification to demonstrate conformity to existing standards. This disposition shall be authorized by Material Review Board members.

6.2 *Scrap* - The nonconforming product is discarded. This disposition shall be authorized by Material Review Board members.

6.3 *Use As Is* - The nonconforming product is used in the manufacturing process without being reworked or repaired. When required by contract, the customer is contacted to obtain permission to use the nonconforming product. This disposition shall be authorized by QA. Sales provides a second disposition signature when the form, fit, or function is affected and when the customer must be contacted. The rationale for the use of the nonconforming product must be stated with the disposition.

6.4 *Return* - The nonconforming product is returned to its supplier. It is accompanied by return paperwork which, among other things, specifies the reason for the return. It may also be accompanied by a Supplier Corrective Action Request. This disposition shall be authorized by Material Review Board members.

There also is a fifth, interim disposition, Re-Test. Product is marked this way if the condition is uncertain and the product must be evaluated again. Ultimately, one of the above four dispositions will be assigned.

A rejection tag or nonconforming form may be marked VOID if the rejection was in error.

All members of the Material Review Board have the authority to involve other personnel as necessary in the disposition of nonconforming product.

One month from the date of rejection shall be allowed for the disposition of nonconforming product. If no disposition can be reached within one month, the individual responsible will note why on the rejection form.

7.0 Customer Supplied Nonconforming Product

Any customer supplied product that is found to be nonconforming is handled in the manner described above with one addition: Sales shall be involved in the disposition of the nonconforming product and shall authorize the disposition. This is as described in 90-2000-7.5.4, Customer Property.

8.0 Documentation and Record

Reject tags and Nonconforming Material Forms, and Supplier Corrective Action Requests are preserved as Quality records. Reject tags and Nonconforming Material Forms are serialized by QA. In addition, copies of Use As Is dispositions are saved as part of the job order documentation. The storage location and retention period of these documents are specified in 90-2000-4.2.4, Control of Records.

9.0 Post-Shipping Notification and Action on Nonconforming Product

If it is determined that nonconforming product has been shipped, the actions that Product Resources takes depends on the both the nature of the product (regulated or not) and whether or not Product Resources is acting as a contract manufacturer of another company's product. The Management Representative is responsible for the customer and/or regulatory body communication.

If Product Resources is acting as a contract manufacturer, Product Resources will, as soon as the nonconformance is identified, notify the customer of the nonconformity and, as required, provide the identify of the affected product by serial number, lot, or date code as is applicable to the specific product. If the product is a regulated product, in this scenario it is the responsibility of the customer to notify the regulatory body. The customer, along with the regulatory body as required, makes the determination of the need for end user or distributor notification or product recall.

If Product Resources is selling product directly to end users or distributors, Product Resources will notify the regulatory body as soon as it is detected of the nonconformance in the case of a regulated product. In this case, the regulatory body will take part in the impact determination. In all cases, Product Resources

Quality Assurance and Engineering Departments will review the impact of the nonconformance and, with the regulatory body if required, determine whether or not end user and distributor notification is required and whether or not a product recall is required.