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Subject: Reaction to Defective Material	

PURPOSE:

This procedure outlines the response suppliers are expected to make when supplier defects are found at MACI or at MACI's customer.

SCOPE:

This procedure applies to suppliers when defective products from suppliers are found at MACI or MACI's customer.

CONTENT:

Reaction to defective materials involve containment, root cause analysis of occurrence and non-detection, implementation of countermeasures and standardization.

I. Containment of Defects.

MACI Quality Assurance Department will determine the level of containment required. Containment may involve separation / sorting of the defect at MACI's customer, MACI's finished parts warehouse, MACI's inventory and the supplier's inventory. Positive containment will be required for any defect that may cause a failure at MACI's customer, regardless of the reject quantity.

II. Root Cause Analysis of Occurrence and Non-Detection


Thorough analysis is required on any defect that MACI issues a Quality Failure Notice (QA-SM-13). The analysis that is done by the suppliers must include occurrence and non-detection root cause.

III. Implementation of Countermeasures

The severity of the defect will dictate the level of countermeasures required for a defect. If the defect is ranked as high on the QFN, physical/mechanical countermeasures (i.e. more than retrain associates) will be expected. Both occurrence and non-detection should be addressed with countermeasures.

IV. Standardization

All documentation affected by implemented countermeasures including Quality Assurance Control Plans, FMEA's, and work instructions are to be updated by the supplier. Countermeasure activity also must be cross-lined to all other part numbers and processes. Defect history also must be considered when new tooling or lines are designed and implemented.

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V. Costs

The supplier is responsible for any nonconformance to blueprint or other agreed standards shipped to MACI.

Costs which may be incurred may include sorting of warehoused parts, work-in-process parts, finished MACI products, as well as processing costs, value added costs, rework costs, return shipping costs, and any incidental scrap costs generated by reworks. When supplier defects are found at MACI, MACI will contact the supplier to discuss disposition. Defects found on off-shifts or weekends may require immediate sorting to protect MACI production. MACI will then inform the supplier the next business day of the occurrence.