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**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:**

Reactions 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. Cause Analysis of Occurrence and Non-Detection**


Cause analysis is required on any defect that MACI issues a Quality Failure Notice (QA-SM-13). The cause analysis should be based on the process flow and review each process for any potential causes, both Occurrence and Detection of the process should be included in the cause analysis.

**III. Implementation of Countermeasures**

Countermeasures are required for any concerns and problems from each process and 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.