

Product Containment System Guidelines

The following list summarizes recommendations for the implementation of an effective product containment system:

General

- Material flow through manufacturing, containment and shipping shall be documented on a Process Flow Chart and accompanied by a floor layout of the containment stations
- The containment area shall be set-up separate from the manufacturing area, but close enough to allow efficient communication between the two.
- Material leaving the manufacturing area and entering the containment station should be marked so that it is clearly understood that the material is not suitable for shipment
- The material leaving the containment area adequately marked or labeled to indicate its status
- Production planning shall consider the time required to process product through the containment process to ensure shipping schedules are not jeopardized
- A labeling or tagging system shall be in place to ensure inspection status of material through manufacturing, containment, storage and shipping is known. This system shall follow the standard documented in the quality system as close as possible
- Method used to identify certified product shall be reviewed by the customer

INSPECTION INSTRUCTIONS

- All quality issues shall be identified, clarified, and listed on an inspection checklist
- Detailed instructions and visual aids shall be made available for all items on the inspection check-list
- Inspection instructions shall be posted at appropriate areas including production and containment stations.
- The inspection checklist and instructions shall be submitted to customer for review and approval
- Exit criteria shall be established for each item on the inspection check-list and shall be approved by the customer.
- Time or quantity based exit criteria are acceptable only after corrective action has been implemented and validated or after capability has been demonstrated
- The inspection instructions shall include the re-inspection of all material (including product in transit at the customer's site or intermediate site) when a

new problem, or a problem not listed on the inspection checklist is found

VISUAL AIDS

- Samples or visual aids shall be posted at appropriate areas including production and inspection stations
- Samples or visual aids shall be clear to avoid misunderstanding of the standards
- Samples and visual aids depicting acceptable conditions shall be approved by the customer
- Are samples and visual aids given a unique identifier and tracked in the gage control system

TOOLS AND GAGES

- All tools, gages and shall be identified in the inspection instructions at minimum
- All gages shall be verified with a standard GR&R study. AIAG MSA standards shall apply
- Tolerances shall be adjusted inward for gages with a GR&R of 10% to 30%

INSPECTOR TRAINING

- Inspectors shall be adequately trained to perform the inspection, and a record of the training shall be maintained and summarized in a training matrix
- The containment operation shall be adequately staffed to meet the required volumes and shipping schedules
- Back-up inspectors shall be trained and available to cover for absenteeism, or other unforeseen problems
- Inspectors at all stages of the process (i.e. manufacturing, in-house containment and 3rd party containment) and across all shifts, shall be “calibrated” to ensure the inspections and acceptance criteria are carried out equally by all inspectors

DATA COLLECTION, SUMMARY AND REVIEW

- Defect information shall be collected and summarized to allow statistical analysis
- Defect data shall be posted at the containment area and at appropriate manufacturing areas
- Defect data shall be reviewed with appropriate containment and manufacturing personnel

CUSTOMER RETURNS

- Returned product shall be thoroughly reviewed by quality and manufacturing engineers, line supervisors, operators, and inspectors
- Defect information shall be recorded and summarized to allow statistical analysis
- Data shall be analyzed to identify weaknesses in the system and to identify improvement opportunities

- A system shall be in place to clearly show the identity of the person who inspected a part that 'slipped' through the system
- Inspector identification shall be recorded when returned parts are reviewed in order to identify training needs

CORRECTIVE ACTION

- A procedure shall be in place to initiate root cause analysis and corrective action for defects found
- A system shall be in place to review inspection needs based on performance data and discontinue inspection when exit criteria has been met and approved by customer
- A system shall be in place to review and update FMEA's, Control Plans, Operator Instructions and other relative documents with new information

MANAGEMENT REVIEW

- Management reviews shall be carried out. The meetings shall review status against goals or targets; costs associated with the containment; system effectiveness, and improvement needs
- Management shall take an active role in inspecting product returned from the customer and also in certifying product to be shipped to the customer