Keystone Quality Assurance Program
Summary of Requirements

1/13/2012

General Requirements

- The licensee shall define & implement an ongoing quality management system meeting Keystone Quality Assurance Program requirements.
- The licensee quality management system shall be fully documented in a quality manual.
- The licensee shall designate an individual responsible for defining, implementing and for the ongoing operation of the quality management system.
- The responsibilities of the individual responsible for the quality management system shall be defined and documented in the quality manual.
- The licensee shall keep records that demonstrate the ongoing operation of the quality management system as documented in the manual.

Criteria Definition – the licensee shall define and list the following acceptance criteria in the quality manual:

- Raw Material / Component Requirements, including (where applicable) test specifications or other criteria stated in the evaluation reports used to qualify the product.
- In Process Inspection Requirements, define "go/no-go" criteria specific to the product components or sub-assemblies. Used to discover known deficiencies as early in production as possible.
- Finished Product Inspection Requirements define "go/no-go" criteria specific to the finished product. Used to prevent known deficiencies from being shipped to the customer.

Procedure Definition – the licensee shall define how the following activities are performed, including naming the employee position(s) responsible, to be documented in the quality manual:

- Work order processing describes how the customer order details are recorded and communicated to production. Requires the creation of a form or other method of communicating customer order details, such as customer name & address, identification of product model, quantities, sizes, & options (see Record Keeping Requirements below).
- Inspection of incoming materials describes how raw materials / components are evaluated for acceptance or rejection, to include action to be taken upon rejection. Requires the creation of a list of acceptance criteria for raw materials / components (see Criteria Definitions above).
- In-process quality inspections describes how work in process is evaluated for acceptance or rejection, to include action to be taken upon rejection. Requires the creation of a list of acceptance criteria for work in process (see Criteria Definitions above).
- Final product inspections describes how finished product is evaluated for acceptance or rejection, to include action to be taken upon rejection. Requires the creation of a list of acceptance criteria for finished products (see Criteria Definitions above).
- Documented quality audits describes how finished products are randomly and regularly evaluated versus finished product acceptance criteria. To include how often audits are to be performed, and how audit records are kept. Requires the creation of a form to demonstrate ongoing audits are performed (see Record Keeping Requirements below).
- Complaint handling describes how the licensee receives, records and resolves complaints from any party. Requires the creation of a form to record complainant name & address, the nature of the complaint, and action taken to resolve the issue and how recurrence was prevented (see below).

Record Keeping Requirements – as a minimum, the following records shall be maintained as a part of the quality management system and shall be available for inspection for a period of at least four (4) years:

- "Millcerts" or other documentation from suppliers indicating raw materials / components meet criteria.
- Work Order Forms (form to be created and filled out by licensee per Work Order Procedure).
- Quality Audit Forms (form to be created and filled out by licensee per Audit Procedure).
- Complaint Forms (form to be created and filled out by licensee per Complaint Procedure).
- Qualification Documents the latest versions of reports used for product approval.