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#### 1.0 PURPOSE

Establish a schedule and criteria for auditing production, administration and quality control procedures that are specified on various product Data Lists, Mfg/QA Travelers, Operation Sheets, Inspection Instruction Sheets, Manufacturing Control Documents, Engineering Drawings and established Policies and/or Procedures for work functions that affect a deliverable product.

#### 2.0 GENERAL

The auditing operation shall be conducted at least once every calendar year; more frequently as directed by the Quality Group. The audit personnel shall determine procedural conformance to each manufacturing, administrative and quality control operation referenced on the applicable Data List or contained within a referenced document found on the Data List. A General Practice policy or procedure that is not referenced on a Data List is subject to audit if the process affects a deliverable product. Processes, procedures and policies that do not directly affect a deliverable product are exempt from audit.

### 3.0 REQUIREMENTS

# 3.1 Written Policies and/or Procedures; Product Line Specific

Prepare form Mfg/QA Process Survey (Your #) to exhibit a paragraph by paragraph data entry for each directive in the procedure and/or policy referenced on the applicable document that is directly or indirectly referenced therein.

- 3.1.1 In the event an audit cycle cannot be observed, prepare a suspense file that re-activates every 10 working days until a cycle can be observed.
- 3.1.2 Procedure paragraphs of a non-directive nature are not recorded on the Mfg/QA Process Survey (Your #).
- 3.1.3 Procedures that are found in compliance and are duplicated on several Product Data Lists are qualified for all applied products.

# 3.2 General Practices (Unwritten Policies and/or Procedures)

An unwritten, sound business practice, policy and/or procedure that affects a deliverable product must be recorded on the Mfg/QA Process Survey (Your #) to the fullest extent practicable at the time of discovery.

- 3.2.1 A practice that is not recorded in procedure format requires the process to be reviewed by the Quality Group to determine the impact on product quality. Record your recommendations to appropriate management using the Quality System Impact Analysis (Your #).
- 3.2.2 The impact on product quality is the only criterion used to determine the necessity for converting a general practice into a procedure format. Depending upon the impact, a written procedure is conceivably not applicable. Specific criteria for risk analysis are inherently subjective; however, specific examples to establish the fundamental guideline follow.
- 3.2.3 Sample practices that *do not* require written procedures include specific elements of many disciplines. Specific elements are those understood to be germane to subjects such as, but not limited to:

Geometric dimensioning and tolerancing as a basis for a drafting discipline

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Complex math knowledge as a basis for the engineering design discipline

Inspection station setup to measure part compliance

Computer literacy to operate software

Daytime planning to utilize valuable resources

Other intrinsic or germane departmental policies and/or procedures practiced as a means to achieve mandated requirements.

3.2.4 Sample practices that *do* require written procedures include specific elements of many disciplines. Specific elements are those understood to be germane to subjects such as, but not limited to:

Preparing accounting records to meet specific reporting criteria

Preparing purchase orders to meet specific regulatory agency requirements

Operation of simple or complex equipment to deliver a product to commerce or comply with safety regulations

Employment practices to meet State and/or Government laws

Other intrinsic or germane, departmental policies and/or procedures practiced as a means to achieve mandated requirements.

#### 3.3 Product Conformance Records

Records produced to provide evidence of deliverable product conformance shall be examined for comparison to the latest Document Control Center (DCC) record or applicable product procedure.

- 3.3.1 Forms are exempt from DCC control; however, consistently applied forms are necessary to objective management of many processes.
- 3.3.2 Forms that depart from unwritten, routinely updated practices are not indicative of a consistent application and generally detract from the original purpose unless supplemented with appropriate and generally sound business practices.
- 3.3.3 Record departures from Form revision levels on the Mfg/QA Process Survey (Your #).
- 3.3.3.1 Evaluate the change in an unwritten business practice that prompted the Form to be revised to determine the impact on the affected product.
- 3.3.3.2 Record the product impact and the recommendations to appropriate management on the Quality System Impact Analysis (Your #).
- 3.3.3.3 Perform risk analysis according to paragraph 3.2

### 4.0 WORKMANSHIP

Adherence to applicable federal, state, local, and (Your Co) environmental, health, and safety requirements is mandatory.

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