Marion Manufacturing Operating Procedures

Flow Down of Quality System Requirements for Sub-Contractors/Suppliers

1.0 Purpose

The purpose of this procedure is to prescribe and document the minimum Quality System requirements to be used by a subcontractor/supplier when performing for or supplying to Marion Manufacturing d.b.a. Marion Tool & Die, Inc.

2.0 Quality System Elements

2.1 The supplier shall have a Quality System that is structured and documented to meet the requirements of ISO 9001 as revised. (This does not require the supplier to be ISO 9001 Certified/registered.)

2.2 Marion Manufacturing or Marion Manufacturing's customers shall be afforded the right of access to quality and production records to verify at the sub-contractor's/supplier's premises and/or Marion Manufacturing's premises that sub-contracted/supplier product conforms to specified requirements.

2.2.1 Verification shall not absolve the sub-contractor/supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection by Marion Manufacturing's customer.

2.2.2 Sub-contractor/supplier shall maintain inspection and test result records for and be made available to Marion

Manufacturing, Marion Manufacturing's customers or regulatory authorities for retention periods of three (3) years, minimum.

2.2.3 Sub-contractor/supplier shall supply with every shipment objective evidence of the conformity of the processes, products and services from the sub-contractor/supplier (e.g., accompanying documentation, certificate of conformity, test documentation, material analysis, statistical documentation, process control documentation, and results of production process verification)

2.3 The sub-contractor/supplier shall maintain traceability of materials and product furnished by Marion Manufacturing. Notification shall be given of any nonconforming material or product.

2.3.1 Sub-Contractor/supplier shall notify Marion Manufacturing of materials that have been positively determined nonconforming but not realized until after shipment. Communication shall be documented and submitted to Marion Manufacturing Quality department within 7 days.

2.3.2 When material is found to be non-conforming the problem is reviewed by management and communicated with the customer and the supplier to determine whether the material still meets the required specifications.

2.4 When a purchase order references an instruction which include a specification and that specification requires qualification; the sub-contractor/supplier shall insure that proper and current qualifications are in place.

2.5 Where applicable, Sub-Contractor/Supplier shall flow down to sub-tier suppliers the applicable requirements in the purchase documents, including key characteristics where required.

2.5.1 Where applicable, Sub-Contractors/Suppliers shall use Marion Manufacturing customer approved special process sources.

2.5.2 When applicable, where Marion Manufacturing delegates verification activities to the suppler, requirements of delegation shall be defined by Marion Manufacturing and a register of the approved delegation activity shall be maintained.

2.6 When a significant/special process is being performed by the sub-contractor/supplier, it will become the responsibility of the sub-contractor/supplier to fix his/her process to ensure that no significant changes are made to that process or parameters of that process which could affect product quality.

2.6.1 Significant/special process is defined as a process which affects physical properties of product which cannot be inspected by normal receiving inspection (i.e.…heat treat, welding, coatings, EDM…etc.)

2.6.2 A significant change is defined as a change to process or parameters of that process which could adversely affect product quality.

2.6.3 The sub-contractor/supplier shall notify Marion Manufacturing in writing, of changes in product/process definition and obtain approval prior to implementation of any changes affecting significant/special processes.

2.7 Purchase Orders shall reference:

2.7.1 The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data.

2.7.2 Requirements for design, test, examination, inspection and related instructions for acceptance by supplier, where applicable, and that may differ from prescribed specifications.

2.7.3 Requirements for test specimens (e.g., production method, number, storage conditions) design approval, inspection, investigation or auditing, where applicable, and that may differ from prescribed specifications

2.8 Sub-contractor/supplier shall plan, implement and control processes, appropriate to the organization and the product for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products delivered to Marion Manufacturing.

2.8.1 Counterfeit part prevention processes should consider:

− training of appropriate persons in the awareness and prevention of counterfeit parts

− application of a parts obsolescence monitoring program

− controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources

− requirements for assuring traceability of parts and components to their original or authorized manufacturers;

− verification and test methodologies to detect counterfeit parts;

− monitoring of counterfeit parts reporting from external sources

− quarantine and reporting of suspect or detected counterfeit parts

2.9 Sub-Contractor/supplier shall deliver 100% of confirmed purchase order to Marion Manufacturing by the promised delivery listed on the sub-contractor/supplier order acknowledgment.

2.9.1 Sub-Contractor/supplier shall have exception to 2.9 delivery requirements if any or all the following apply:

− An event that is defined under force majeure