PURPOSE

To establish and assign responsibility for the documentation, evaluation and control of changes initiated by Mingo Manufacturing or impacting Mingo Manufacturing that may have an impact on the quality of Mingo Manufacturing Customer's products.

To prevent incidents or losses through the identification and control of new or changed circumstances.

SCOPE

The process shall be applied to all products or services supplied by Mingo Manufacturing for customers.

Types of changes typically requiring a management of change but not all inclusive are:

- Addition of new process equipment or critical business system (including software)
- Replacement of process equipment or parts
- Modification or minor additions to process equipment
- Modifications or minor additions to infrastructure / non-process equipment
- Changes to process control and/or instrumentation
- Changes in critical process parameter operating limits
- Alterations to safety systems (interlocks, shutdowns, fire or explosion suppression, etc.)
- Revisions to standard operating procedures
- Changes in site-level organizational structure
- Changes to maintenance procedures
- Changes in raw material/component specifications or design
- Alterations or new connections to utility systems (air, electrical, gas, water, steam, etc.)
- Changes to QA procedures or critical test equipment

RESPONSIBILITY

The Mingo Manufacturing Quality Manager shall be responsible for the implementation and assurance that the management of change process used by Mingo Manufacturing provides an effective process for documentation, evaluation and control of changes and communication to the customer when applicable.

DEFINITIONS

Management of Change:

A method for systematically evaluating and responding to permanent or temporary change which may have an effect on products, processes, the control of health and safety hazards, security issues or environmental impacts. The objective of MOC is

A manner in which a change is described and implemented within both internal and external processes. Performance of analysis for hazards and tolerance to risk exposure or failure based on the proposed changes.

Risk Assessment:

A systematic procedure of evaluating potential, prospective risks that may be involved in a Supplier's process, practice, activity or undertaking.

Risk Management:

The identification, evaluation, and ranking the priority of risks followed by synchronized and cost-effective application of resources to lessen, monitor, and control the probability and/or impact of unfortunate events.

RISK ASSESSMENT

To perform a risk assessment a cross-functional team should engage in a what-if brainstorming session. Develop the definitions and examples that apply to your situation and the risks your workers, products, or processes will be exposed to. A risk assessment should be done early while still in the planning stage of a change.

Tools that may be used to identify risks and mitigate or eliminate the potential issue of a change are:

- Risk Assessment (Identification of cause, Consequence, Severity, and Probability of Occurrence)
- Process Failure Mode and Effect Analysis (PFMEA)
- Root Cause Analysis
- 5 – Whys
- Cause and Effect Diagrams
- Flowchart Diagrams
- Corrective and Preventive Actions
- Brainstorming
- Fishbone Diagrams

PROCEDURE

1. General Requirements

1.1 All change proposals shall have a unique tracking number and be maintained by the Mingo Manufacturing Quality Manager in a tracking system.

1.2 The individuals who perform the functions of initiation, review, approval, execution, implementation and closure of MOC proposals shall be adequately trained according to established procedures.

1.3 The originator of a MOC is considered the change owner and is responsible for providing general oversight and maintains a follow-up mechanism.

1.4 There shall be a documented record of all change proposals assessed by the MOC Reviewers that shall be maintained as part of Mingo Manufacturing MOC records.

1.5 If an MOC proposal is related to or requires another MOC, the later MOC shall include a reference to the original MOC number.

1.6 If a change affecting fit, form, or function of the product is identified, the Originator shall notify the customer prior to implementing the change with enough time to allow for a thorough review and response.

Request and obtain the most current version of the customer's Supplier Management of Change (SMOC) Form to fill out according to their procedure.

Note: If clarifications are required by the customer, the Originator shall provide a response within 5

working days.

2. Supplier Requirements

2.1 All suppliers are required to notify Mingo Manufacturing of changes to their:

- organizational structure,
- key personnel,
- critical sub-suppliers,
- critical materials,
- critical processes,
- manufacturing location,
- design,
- industry standard.

2.2 A copy of this procedure shall be provided to all suppliers.

2.3 The Mingo Manufacturing Quality Manager shall evaluate the MOC by reviewing the potential impact on Production Quality and Customer requirements (e.g. Production process, Supplier Quality, QC, Purchasing, Regulatory) to determine one of the following:

- If the change proposal is adequately explained and supported, accept the MOC by listing the necessary actions and/or requirements.
- If the change is determined to be unfeasible or unjustified, reject the MOC proposal, documenting the reason(s) for rejection, signing/dating the MOC form.
- If additional information is required, the customer will be notified and arrange for the information or put the MOC originator in contact with the customer for the additional information.

Note: The review shall consider the need for divisional review, interactions with other facilities, contractors, and any Regulatory impact of the proposed change.

2.4 Once the MOC review is completed, send the completed MOC form to the customer to inform them of the change.

3. Records

3.1 Records of management of change shall be retained in accordance with Records QF-15-01, Management of Change (Form)

4. Related Documentation

4.1 WI-15-01, Management of Change (Work Instruction)
4.2 SOP-01, Document Control
4.3 SOP-02, Record Control