



# Quality Management System Manual

Quality System Manual Revision Index

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## **Introduction**

McLoone has made the Strategic Business Decision to develop and implement the McLoone Business System (MBS). The MBS System will improve and sustain the overall performance of our business and products. Benefits include:

- Consistently provide products and services that meet or exceed customer requirements.
- The ability to plan and develop our annual Strategic Plan.
- Facilitating opportunities to enhance customer satisfaction.
- Address risks and opportunities.

The McLoone Business System Manual in compliance to ISO9001:2015 requirements and how they apply at McLoone. The manual can be used to introduce the elements of our MBS to our customers and other interested parties.

## **4 Context of McLoone**

McLoone Management has determined the internal and external issues and items that are relevant to achieve the results of the MBS. McLoone utilizes and embraces the Rockefeller Habits.

### **Related Documents:**

- One Page Strategic Plan – 2019

### **4.2 Interested Parties**

McLoone understands the effect and requirements of Interested Parties, so we have determined the interested parties along with the requirements and risks to ensure they are managed in the MBS. Operational Risk Management is not going to look at every possible risk that impacts an asset or employee. Rather, we look at the subset of risks that are Operational in nature.

### **Related Documents:**

- CF 241 Risk/Process Matrix
- MCD 363 Risk Procedure

### **4.3 Scope of the McLoone Business System**

McLoone has determined the scope of the MBS and is committed to applying all applicable requirements of the ISO 9001:2015 to our Business system.

The scope of our MBS is available to internal and external parties. The MBS covers the following Scope:

- Full Service manufacturer of product identification for OEM's and printers. Materials include metal and plastic nameplates, overlays, ID plates.
- Sub-Assembly of Components

**Exclusion of the MBS:****8.3 – Design and Development of Products and Services****Justification:**

McLoone does not perform design activities so the fulfillment to the requirements of this Clause are not applicable to our MBS.

**4.4 Quality Management Systems and Processes**

McLoone has established, documented and implemented our MBS in accordance with the requirements of ISO 9001:2015. Documented Procedures support the processes. The MBS is maintained and improved on using the following:

- Quality Policy
- Embracing the Rockefeller Habits
- One Page Strategic Plan
- KPI's
- Audit Results
- Analysis of Data
- Corrective and Preventative Actions
- Continual Improvements (ROCKS)
- Addressing Risks and Opportunities
- Management Review

**Related Documents**

CF 243 Process Matrix

**5 Leadership**

McLoone Leadership is actively involved in maintaining the MBS and is accountable for its overall effectiveness. Leadership is committed to continually improve the system by providing direction to the integration of the MBS requirements into each business process of our organization.

**5.1.2 Customer Focus**

McLoone ensures customer requirements and expectations are defined and achieved. We are committed to achieving 100% customer satisfaction, by mitigating risks that may affect the conformity of products. We also ensure that Statutory and Regulatory requirements are met.

**Related Documents:**

- MCD 17 – Customer Satisfaction
- MCD 5 – Management Review

## **5.2 Quality Policy**

McLoone Business Policy is defined and driven by the follow principles and behaviors:

- Continual Improvement
- Customer Satisfaction
- Competency

The Quality Policy is included in this manual and is provided to each employee. It is available on line in Entropy and strategically posted within the plant.

McLoone Business Policy Our Business Policy is defined and driven by the following principles and behaviors:

- **Continual Improvement:** Drive continual improvement and innovation throughout our company.
- **Customer Satisfaction:** Build mutually profitable relationships by providing quality products on time that meet our customers' needs.
- **Competency:** Develop team member competencies for people to learn and grow.

McLoone strives to make a positive impact. Using these guiding principles, everyone at McLoone is accountable for growing internal and external customer satisfaction. We are committed to our Core Values and those of JSJ Corporation: Earn Trust, Learn by Doing, Work Together & Steward is our Legacy.

## **5.3 Roles, Responsibilities and Authorities**

McLoone Leadership is actively involved in maintaining the MBS and is accountable for the overall effectiveness of the system. Leadership has initiated and fully supports the vision and strategic direction for the company and the MBS. Support through the Quality Policy, Core Values, Rockefeller Habits and Quality Objectives will improve the effectiveness of the system. Leadership provides direction and support into each process and is committed to promoting Continuous Improvement, Risk -Basked Thinking and motivation thought the organization.

McLoone ensures that customer requirements and expectations are clearly defined and understood at all levels of the organization. We are committed to achieving 100% customer satisfaction by mitigating risks and assure Statutory and Regulatory requirements are identified and achieved.

### **Related Documents**

- One Page Strategic Plan
- ROCKS

## **6 Planning**

McLoone considers all issues and determines the risk and opportunities that need to be addressed to:

- Ensure that the MBS achieves the intended results.
- Enhance desirable effects
- Prevent or reduce undesirable effects
- Continual Improvement

McLoone has planned actions to address risks and opportunities that have the potential to impact the Quality of our products. Opportunities are taken to adopt new practices, equipment, and technology to enhance our organization and meet the needs of our customers.

### **Related Documents**

MCD 6.1 Risks

MCD 363 Risks/Process Matrix

## **6.2 Quality Objectives**

McLoone's Objectives are strategic and are integrated into our MBS. Objectives are in line with our Quality Policy and relevant to the conformity of our products and customer satisfaction. Objectives are in the form of KPI's and ROCKS, they are measurable and communicated. Objectives have responsibility, actions and goals. .

### **Related Documents**

- KPI Matrix
- ROCKS
- Management Review

## **Planning of Changes**

If changes to the MBS are necessary, we ensure the change will be carried out in a planned manner. We consider:

- The purpose of the change and potential consequences
- The integrity of the MBS
- Availability of resources
- The allocation or reallocation of responsibilities and authorities

### **Related Documents**

MCD 372 Process Change

## **7 Support**

McLoone is fully committed to provide adequate resources required for the implementation, maintenance and continual improvement of the MBS. Our committed resourced include:

- Competent employees
- Equipment, Work environment and financial resources

### **People**

McLoone has determined and provided the resources necessary of the business this includes:

- Personnel training needs
- Provide the necessary training
- Evaluate the effectiveness of the training

Employees are made aware of the importance of their activities and how they contribute to the business objectives. Records of personnel qualifications are maintained.

### **Related Database**

Entropy

### **Infrastructure**

McLoone maintains our infrastructure to ensure the conformity of our products. This includes:

- Buildings, workspace and associated utilities
- Equipment – including hardware and software
- Transportation Resources
- Information and communication technology

### **Related Documents**

MCD 351 Contingency Plan-Security

MCD 358 Contingency Plan-Flood

### **Environment for the operation of processes**

Leadership manages the human and physical factors of the work environment considered to be important to control processes and ensure conforming products. Evaluations include:

- Social
- Physical Environment
- Psychological

### **Related Documents**

McLoone Employee Handbook

### **Monitoring and measuring resources**

McLoone has determined the monitoring, measurement and resources required across our MBS. The structure includes:

- Monitoring and Measurement Equipment
- Documented Procedures, Work Instructions and Form
- Competent and Qualified Personnel

### **Related Documents**

MCD 305 Calibration Software

### **Measurement and Traceability**

Documented procedures outline the processes that control Monitoring and measurement equipment used to accept product. We ensure:

- Equipment is calibrated at a specified interval
- Equipment is properly identified along with the status of calibration
- Safeguarded from adjustments, damage or deterioration
- The validity of measurements results and if found unfit corrective measures are taken
- **Related Documents**
- MCD 14 Measurement and Traceability
- MCD 16 Internal Calibration

### **Organizational Knowledge**

McLoone considers the specific knowledge necessary for each operation or function. It can include:

- Gained Experience
- Lessons Learned – Best Practice
- External Sources – Standards, Conferences, Customers



## **Competence**

McLoone determines to the extent necessary the competence for people performing work that may affect the effectiveness of the MBS and its products.

- Employees are competent, based on education, training or experience
- Job descriptions
- Job performance for each employee
- Provide job and career training
- Assist employees that exhibit less than desirable results

### **Related Documents**

MCD 345 Competence

McLoone Employee Handbook

## **Awareness**

McLoone has ensured that people working are aware of:

- Quality Policy
- Core Values
- Quality Objectives
- Employee contribution to objectives
- The consequence of not conforming to the MBS requirements

## **Communication**

McLoone Leadership has determined the internal and external communications that are relevant to the MBS, the includes:

- What will be communicated and who will communicate
- When to communicate
- How to communicate and who to communicate to.

## **7.5 Documented Information**

McLoone maintains a documented MBS to ensure that products conform to specified requirements and for the effectiveness of the system. Documents are:

- Formatted, identified, have an owner, and revision level
- Reviewed and approved initially and when changes occur.
- Controlled and available for use, easy access
- Storage, preservation, and protected
- Retention and disposition

External documentation deemed necessary for the planning and operation of the NMS system is identified and controlled. Documented information can include customer drawings, artwork, specifications.

#### **Related Documents**

MCD 1 Control of Documented Information

MCD 4 Control of Records

Entropy Database

### **8 Operations – Operation Planning and Control**

McLoone defines the necessary operational control(s) for our processes, this includes:

- Establishing criteria and control for processes and outsourcing for the acceptance of products
- Ensuring resources are available
- Maintaining documented information when necessary
- Demonstrate conformity of products
- Control changes and review consequences of unintended changes
- Mitigate any adverse effects as necessary.

#### **Customer Communication**

McLoone is a partner with our customers and communication is an essential part of meeting and exceeding customer expectations. We ensure:

- That we have all the necessary information relating to the product
- Review of enquires, contracts and orders including changes
- Obtain customer feedback including complaints
- Handling and controlling customer property
- Contingency Plans

#### **Determining the Requirements for Products**

McLoone ensures that we can meet customer requirements for products and services, this includes but is not limited to:

- Statutory and regulatory requirements
- Requirements deemed necessary by McLoone
- Acceptance that McLoone can meet the products and services provided

## **Review Requirements related to Products and Services**

McLoone's ensures we can meet requirements offered to our customers for products and services. Contract and product review are performed prior to committing to supply products or services. The review process at a minimum includes:

- Requirements specified by the customer including delivery and post-delivery activities.
- Requirements that may not be specified by the customer, but necessary for the specified or intended use.
- Requirements specified by McLoone.
- Statutory and Regulatory Requirements for the products.
- Contract or order requirements differing from those previously expressed, reviewed and resolved.
- Records of review and requirements are retained.

## **Changes to Requirements for Products and Services**

McLoone's ensures that all documented information is amended when need and affected personnel are made aware of those changes.

### **Related Documents**

MCD 55 Review of Customer Drawings

MCD 219 Engineering change Notification

MCD 245 Processing Customer Order Checklist

## **8.3 Design and Development of Products and Services**

The following sections are not applicable to McLoone.

- 8.3.1 General
- 8.3.2 Design and Development Planning
- 8.3.3 Design and Development Inputs
- 8.3.4 Design and Development Controls
- 8.3.5 Design and Development Outputs
- 8.3.6 Design and Development Changes

## **8.4 Control of Externally Provided Processes, Products and Services**

McLoone maintains responsibility and control for the quality of all products purchase from external providers, including customer designated sources. Controls are established to ensure that products and services provided by suppliers will conform to our customer and McLoone requirements. Controls include:

- Approved Supplier List
- Review of Supplier Performance

### **Type and Extent of Control**

McLoone ensures that our externally provided products, services do not adversely affect our ability to deliver conforming product to our customers. Suppliers with poor performance may or could be replaced unless corrective actions are taken to satisfy the concerns.

#### **Related Documents**

MCD 8 Property Belonging to Customer or External Provider  
 MCD 42 Process Outsource Orders  
 MCD 63 Process Outsourced Dies

### **Information for External Providers**

McLoone Purchase Orders define the product or service required. Purchasing documents are reviewed and approved by the Purchasing Manager.

### **Production and Service Provision**

McLoone plans and implements production under controlled conditions. Examples of controls include:

- Documentation for the characteristics and results of the products to be produced.
- Monitoring and measurement of activities to verify that controls for the process is achieving acceptable results.
- Suitable infrastructure and environment for our processes.
- Trained and competent personnel, along with specific job training criteria.
- Understand and implement where necessary the validation of planned results where output cannot be verified.
- Error-proofing
- Implementation of release, delivery and post-delivery activities.

**Related Documents**

MCD 345 Competence  
 MCD 303 Release of Products and Services  
 MCD 130 Scheduler

**Identification and Traceability**

McLoone identifies product throughout production. This includes:

- Product on the manufacturing floor, conforming and non-conforming.
- Lot traceability
- Status of product

**Related Documents**

MCD 222 Matrix ID and Traceability

**Property Belonging to the Customers or External Providers**

McLoone exercises care with property belong to customers or external providers. We ensure the correct storage, maintenance and accounting of property.

**Related Documents**

MCD 8 Customer Supplied Material  
 MCD 10 Receive and Control Customer Supplied Material

**Preservation**

McLoone will preserve the outputs during production to ensure the conformity to requirements. This includes, handling, contamination control, packaging, storage, and transportation.

**Post Delivery Activities**

McLoone maintains documented information of all products delivered to our customers. The post-delivery activities include customer requirements and feedback.

**Control of Changes**

McLoone reviews internal and customer changes for production to the extent necessary to ensure conformity with customer requirements. We retain documented information describing the review of changes including the person(s) authorizing the change, and actions resulting from the review.

**Related Documents**

MCD 303 Release of Products and Services  
MCD 85 Packing

**Release of Products and Services**

McLoone monitors the characteristics of the product and process in receiving, in-process inspection, and final inspection to ensure the requirements for the product has been met. Records are maintained.

**Related Documents**

MCD 303 Release of Products and Services  
MCD 85 Packing

**8.7 Control of Nonconforming Outputs**

McLoone ensures product that does not meet specification is identified and controlled. We take the appropriate action based on the nonconformity, this applies to internal and external concerns. We deal with nonconforming in one or more of the following:

- Description of the nonconformity.
- Containment.
- Description of actions taken.
- Obtaining customer deviation.
- Identification of authority deciding the action.

**Related Documents**

MCD 19 Control of Nonconforming Product  
MCD 243 Control of Nonconforming Product

**9.1 Performance Evaluation**

The objectives of monitoring, measuring, and evaluation are , process criteria, product characteristics, performance of the MBS. Results are evaluated. Reports are presented to Management for review and decision making on opportunities for improvement.

## **Customer Satisfaction**

McLoone monitors our customer's perceptions. This is accomplished by:

- Customer Surveys
- On Time Delivery
- Customer Concerns
- Customer Supplied Report Cards

## **Analysis and Evaluation**

McLoone performs the necessary analyses and evaluates data and information initiated from monitoring and measurement and uses the results to evaluate conformity of products, customer satisfaction, the conformity and effectiveness of the MBS, the performance of suppliers. This data is used to continually improve our processes.

### **9.2 Internal Audit**

McLoone's schedules and conducts internal audits to ensure our system conforms to McLoone requirements along with the requirements of the ISO9001:2015 Standard. All Management Reviews are documented and retained.

- Defined audit intervals and criteria.
- Ensure auditors that are impartial to the audited process.
- Reviews results from previous audits.
- Take corrective actions.
- Audits and Nonconformances are reported in Management Review.
- Retain documented evidence of audits performed and the results.

#### **Related Documents**

MCD 226 Internal Audits

### **9.3 Management Review**

McLoone's Management Review process is planned and includes the following inputs:

- Status of actions from previous Management Reviews.
- Internal or external changes that are relevant to the MBS,
- Customer Satisfaction and feedback from interested parties.
- MBS Objectives (KPI Matrix), process performance, product conformity
- Nonconformities and corrective actions
- Audit results
- Supplier Performance

- Adequacy of Resources
- Actions taken or opportunities to address risk
- Continuous Improvement

The outputs from Management Review include:

- Opportunities for improvements.
- Changes to the MBS.
- Resource needs.

#### **Related Documents**

MCD 5 Management Review  
KPI Matrix

McLoone determines and selects opportunities for improvement and implements the necessary actions to meet McLoone and Customer Requirements. Examples include:

- Rockefeller Habits: ROCKS
- Continual Improvement Projects – Manufacturing, Management System
- Corrective Actions
- Risks/Opportunities

#### **Nonconformances and Corrective Actions**

McLoone documents all internal, supplier and customer nonconformities. Each concern is evaluated (rating system) for the need of permanent corrective action. All information is documented and retained.

- Interim Actions
- Analyzing the nonconformance, where can it occur
- Implement Actions
- Review effectiveness.
- Update appropriate documentation, Corrective Actions, 716 nonconformance report, work instructions.

#### **Related Documents**

MCD 21 Nonconformance and Corrective Action  
KPI Matrix

#### **Continual Improvement**

McLoone continually improves the suitability, adequacy and effectiveness of the MBS.