



# McLoone Business System Manual

MCD0364 Revision 4.1

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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 with 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 achieving the results of the MBS. McLoone utilizes and embraces the Rockefeller Habits.

### Related Documents

One Page Strategic Plan

### 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

**MCD363** 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 of the requirements of this clause is 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 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

Map Process

#### 5 Leadership and Commitment

McLoone Leadership is actively involved in maintaining the MBS and is accountable for its overall effectiveness. Leadership is committed to continually improving the system by providing directions 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

**MCD17** Customer Satisfaction

**MCD5** Management Review

##### 5.2 Quality Policy

McLoone Business Policy is defined and driven by the following 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 online in SharePoint 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: Earn Trust, Learn by Doing, Work Together & Steward 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 -Based 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 Risks and Opportunities

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 363 Risks  
Risk and Opportunity Matrix

### 6.2 Quality Objectives and Planning

McLoone's Objectives are strategic and are integrated into our MBS. The 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

### 6.3 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, how it will impact the organization, and potential risks associated
- The integrity of the MBS

- Availability of resources
- The allocation or reallocation of responsibilities and authorities

Changes could relate to any of the following: processes, equipment, personnel, suppliers, MBS, work instructions

#### **Related Documents**

**MCD345** Competence

**MCD372** Process Change Procedure

## **7 Support**

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

- Competent employees
- Equipment
- Work environment
- Financial resources

### **7.1.2 People**

McLoone has determined the roles and responsibilities required and provided the resources necessary for the business, this includes:

- Personnel needs – assessing required skills, knowledge, and qualifications for each role
- Ensure personnel are in roles that match their existing skills
- Provide the necessary training for skills, knowledge, and qualifications
- Evaluate the effectiveness of the training – ensuring competence
- Provide appropriate tools, equipment, work environment, and other resources

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**

ADP

Job Descriptions

**MCD345** Competence

### **7.1.3 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**

**MCD351** Contingency Plan-Security

**MCD358** Contingency Plan-Flood

### **7.1.4 Operation Environment**

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

### **7.1.5 Monitoring and Measuring Resources**

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

- Determining and providing resources (equipment, tools, software, personnel)
- Monitoring and Measurement Equipment
- Documented Procedures, Work Instructions, and Forms
- Competent and Qualified Personnel

#### **Related Documents**

**MCD305** Using GagePACK Calibration Software

**MCD110** Preventative Maintenance

### **7.1.5.2 Measurement and Traceability**

Documented procedures outline the processes that control Monitoring and measurement equipment used to accept products. We assure you:

- 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**

**MCD14** Measurement and Traceability

**MCD06** Internal Calibration

### **7.1.6 Organizational Knowledge**

McLoone determines the necessary knowledge for their processes (roles/responsibilities), understands importance to maintain, and addresses how to acquire or access additional knowledge when needed. It can include:

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

### **7.2 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**

**MCD345** Competence

McLoone Employee Handbook

### **7.3 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

#### **Related Documents**

**MCD362** Awareness

### **7.4 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 with?

#### **Related Documents**

**MCD341** Communication

### **7.5 Document and Data Control**

McLoone maintains a documented MBS to ensure that products conform to specified requirements and for the effectiveness of the system. The 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 protection
- Retention and disposition

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

#### **Related Documents**

**MCD1** Control of Documented Information

**MCD4** Control of Records

ADP

McLoone Intranet



## 8 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
- Maintain documented information when necessary (identification, traceability, etc.)
- Control changes and review consequences of unintended changes
- Mitigate potential risks associated with production and delivery
- Minimize errors and defects
- Handling customer feedback, addressing complaints, and providing necessary support

### 8.2.1 Customer Communication

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

- We have all the necessary information relating to the product
- Review of inquiries, contracts, and orders including changes
- Obtain customer feedback - including complaints, surveys, satisfaction measurements
- Handling and controlling customer property
- Contingency Plans

### 8.2.2 Determining the Requirements for Products

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

- Effective communication to understand needs and expectations
- Statutory and regulatory requirements
- Review of customer requirements – ensuring feasibility
- Requirements deemed necessary by McLoone

### 8.2.3 Review Requirements related to Products

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

- Requirements specified by the customer include delivery
- 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

#### Related Documents

**MCD197** Order Entry for Repeat Parts

### 8.2.4 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 including, but not limited to:

- Updated product specifications
- Revisions to purchase orders

#### **Related Documents**

**MCD219** Engineering Change Notification

**MCD34** Order Change Process

### **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 purchased 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

#### **Related Documents**

**MCD7** Supplier Evaluation

**MCD147** Setting up a New Supplier

**MCD387** Supplier Manual

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

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

#### **Related Documents**

**MCD8** Property Belonging to Customer or External Provider

**MCD42** Process Outsource Orders

**MCD63** Process Outsourced Dies

#### **8.4.3 Information for External Providers**

McLoone Purchase Orders define the product or service required. Purchasing documents are reviewed and approved by the Buyer/Planner. Examples include:

- Clearly defined product requirements (including quality and delivery expectations)
- Specific certifications (material certification, certificate of compliance, safety data sheet, etc.)

#### **Related Documents**

**MCD147** Setting up a New Supplier

**MCD145** Generate and Release Purchase Orders

**MCD387** Supplier Manual

## 8.5 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 are 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

**MCD345** Competence

**MCD303** Release of Products and Services

**MCD130** Scheduler

### 8.5.2 Identification and Traceability

McLoone identifies products throughout production. This includes:

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

### Related Documents

**MCD222** Identification and Traceability

### 8.5.3 Customer and External Owned Property

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

### Related Documents

**MCD8** Customer Supplied Material

### 8.5.4 Preservation

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

### 8.5.5 Post Delivery Activities

McLoone maintains documented information of all products delivered to our customers. The post-delivery activities include customer requirements and feedback. Including providing repair, replacement, or refund services for defective products within the warranty period.

### Related Documents

**CF7** McLoone Standard Terms and Conditions

### 8.5.6 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**

**MCD219** Engineering Change Notification

**MCD34** Order Change Process

### **8.6 Release of Products**

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

#### **Related Documents**

**MCD303** Release of Products and Services

**MCD85** Packing

### **8.7 Control of Nonconforming Material**

McLoone ensures product that does not meet specification is identified and controlled. We take appropriate action based on 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**

**MCD19** Control of Nonconforming Product

## **9 Performance Evaluation**

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

### **9.1.2 Customer Satisfaction**

McLoone monitors our customers' perceptions. This is accomplished by:

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

#### **Related Documents**

**MCD17** Customer Satisfaction

### **9.1.3 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.

- Management Review
- Internal Audits
- Continuous Improvement List

## 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 are impartial to the audited process
- Reviews result 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

**MCD226** 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
- Action taken or opportunities to address risk.
- Continuous Improvement

The outputs from the Management Review include:

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

### Related Documents

**MCD5** 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

## 10 Improvement

McLoone continually improves processes and performance to meet customer requirements and enhance customer satisfaction.

### Related Documents

ROCKS  
Continuous Improvement List

## 10.2 Nonconformances and Corrective Actions

McLoone documents all internal, supplier and customer nonconformities. Each concern is evaluated (rating system) for the need for 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, Nonconformance report, work instructions.

### Related Documents

**MCD21** Nonconformance and Corrective Action  
KPI Matrix

## 10.3 Continual Improvement

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

### Related Documents

Continuous Improvement List  
ROCKS  
Management Review (includes customer feedback, scorecards, KPI results, etc.)  
Internal Audits  
Risk and Opportunity Matrix  
KPI Matrix  
SQPD Boards

## Revision History

Date	Description of Document Change
3/27/2019	Last Revision Date in Entropy.
10/11/2021	Removed Year OPSP. No change to process – no training required.
5/6/2022	Updated format. No change to process – no training required.