



Micro Precision Calibration Inc.
22835 Industrial Place Grass
Valley, CA 95949, USA

SOFTWARE VALIDATION COMPLIANCE (MP Calibration Management System)

November 17, 2020

This system was developed exclusively for instrument calibration and instrument management. It was structurally validated following a Certified Quality System conforming to FDA CFR 21 Part 11.

The output of this Life Cycle includes the following documents.

- * The Product Description
- * The Software Quality Plan
- * The Functional Specification
- * The Test Cases
- * The Software Test Plan
- * The Software Release Notice and Revision Control
- * The Source Code Documentation

Optional Enhanced Security software package

The product Description and Functional Specification contains detailed information relative to the inclusion of FDA CFR 21 Part 11 features. The Software Quality Plan and the Test Cases demonstrate how these features were evaluated.

This FDA CFR 21 Part 11 feature set contains:

User Level Management

Security controls through different access permissions.

File Integrity


Electronic records are secured, versioned, and tampered files are detected.

Audit Trails

Automatic generation of secure time-stamped audit trails for all record changes (data, calibration, method, and system).

Electronic Signatures

User-definable electronic signature with customizable reasons list.


Stephanie Millo
Software Quality Assurance Manager
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MP Software Quality Assurance Checklist

Project Name: Calibration Management System V.1 (<http://cms.microprecision.com>)

- Equipment Information:
 - Add Equipment
 - Edit Equipment
 - View Equipment

- Events:
 - Upload Calibration
 - Receiving
 - Repair
 - Repair Evaluation
 - Calibration
 - 17025 Calibration
 - Z540 Calibration
 - Final Inspection
 - Shipping
 - Return As Is

- Viewing of Reports
 - Finance
 - Divisional
 - Sales
 - Repair

- Add/Edit
 - Companies
 - Division
 - Employee
 - Equipment Info
 - Locations
 - Parts
 - Templates
 - Order System List
 - Tax District

- Order System - Estimates:
 - Add Estimates
 - Edit Estimates
 - View Estimates
 - Delete Estimates

- Order System - Work Order:
 - Add Work Order

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- Order System - Invoices:
 - Add Invoice
 - Edit Invoice
 - View Invoice
 - Delete Invoice

- Purchase Order:
 - Add Purchase Order
 - View PR / PO

- Pick-up and Delivery
 - Add Schedule
 - Appointment List
 - Vehicle Management
 - Equipment Utilities
 - Cloning Wizard

- Equipment Company Transfer
 - Equipment Merge

- Multiple Equipment Editor
 - Select Equipment
 - Save Equipment

- Profile Manager
 - Add/Edit/Delete User
 - Add/Edit/Delete Profile

- Set Charges
 - Select Equipment
 - Upload CSV File

A handwritten signature in black ink that reads "Stephanie Millo".

Stephanie Millo
Software Quality Assurance Manager
Micro Precision Calibration, Inc.