# ProCal Direct

by TMA Systems

TMA Systems has just been named as a representative vendor in the **2024 Gartner Market Guide for Enterprise Asset Management Systems**. This recognition is a testament to our commitment to providing quality asset management solutions across a range of asset-intensive industries.

ProCal Direct offers best fit for achieving highest compliance for ISO 17025 compliance.

Life sciences, Chemical Production & Processing, Power, Petrochemical Refining, Gas Production/Custody Transfer, Food & Beverage, Pulp & paper, Semiconductor, Aerospace, Mining, Military, Hospitals/Universities, Metals, Process Manufacturing, Transportation, Municipal Utilities, R&D, Metrology Laboratories, Instrument Service Companies & Others.

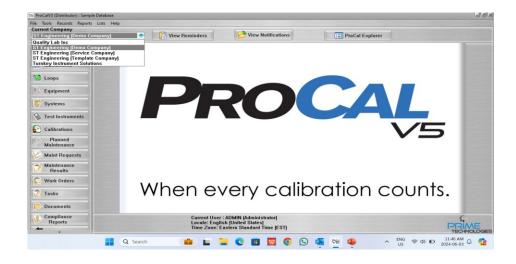
- Full control of Calibration, Maintenance and Asset Management Operations supported with alerts, reminders and warnings.
- Improve Quality controls by automating and tracking every asset, test specification, test calculation, certificate, asset trend, documents, reports and more...
- Efficiently complete quality and regulatory audits and eliminate surprises by tracking and managing compliance events, processes and documentation automatically.
- Eliminate human errors in calculations and work processes through automation
- Drive productivity up by over 100% with easy setup workflows

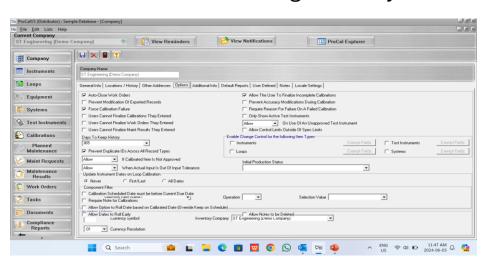


procalsystems.com

# Easy Single/Multi-Site Setup & Configurations

- ProCalV5 (On-premises) / ProCal Direct (Cloud) is a pre-validated GAMP5 system that supports multi-company and multi-site setup.
- ProCal Direct supports compliant record management dictated for cGxP operations per USFDA 21
  CFR Part 11, EU GMP Annex 11, ISO 9001-2015, QS 9000, ISO 13485, ISO 17025, ANSI 254 and others.
- Each location/site can setup their own site quality and operations configurations to manage instruments, test instruments, calibrations, maintenance, work orders, quality processes etc.
- Each location/site can have their own user group, user and third-party vendor setup.
- Each location/site will have control rights over their own assets via secure login.
- Each location/site can integrate ProCal Direct to their site's ERP or Plant Management System.





## Eliminating Manual Data Entry

Easily import each site's asset data into ProCalV5 Direct...

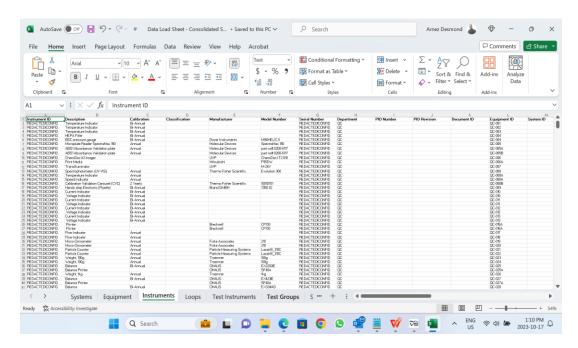
#### **Option 1:**

- We use a pre-validated ProCalV5 Data Load Template (DLT) to organize your asset data.
- Easily copy & paste data into the ProCalV5 DLT.
- The ProCalV5 Data Load Utility (DLU) check the ProCalV5 DLT for errors before importing your data into ProCalV5 Direct.

or

#### Option 2:

• Integrate ProCalV5 / ProCal Direct to your ERP or PMS via the ProCal Data Exchange & Connector to create a seamless IT & CMMS system.

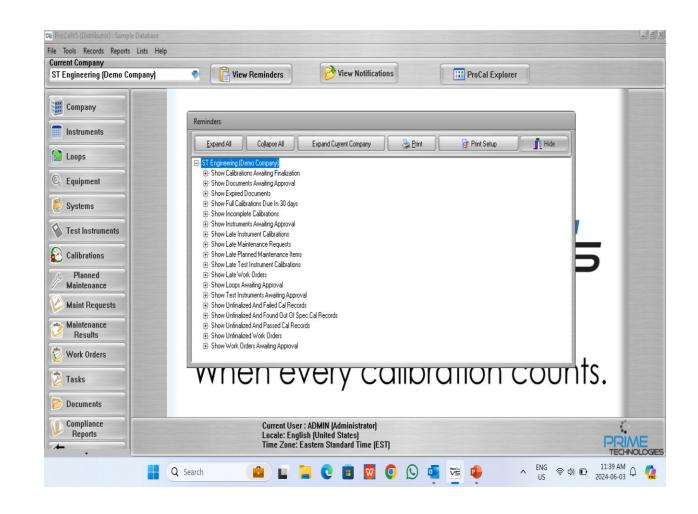


Data Load Template

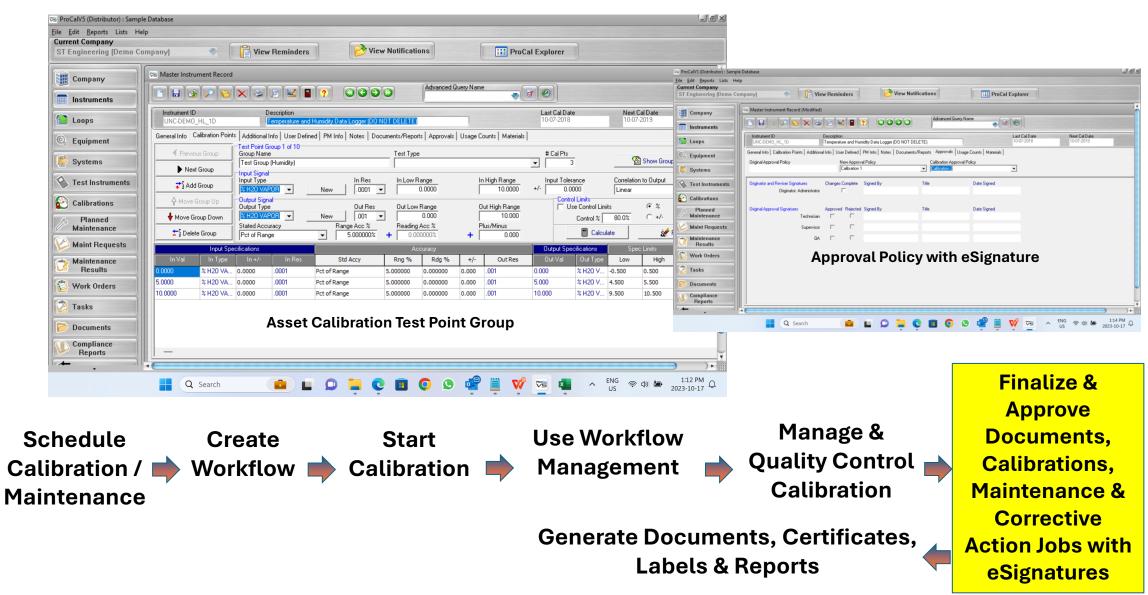
## Reminders, Alerts & Warnings

- ProCal Explorer provides a snapshot of all the assets under a company account.
- Get automatic reminders for Assets, Planned Maintenance, Work Orders, Documents.
- Get Alerts & notifications for Failed /Late/Non-Compliance Calibration & Work events.
- ProCal provides Warnings for Pass/Fail status, Non-Approved Assets

& More...

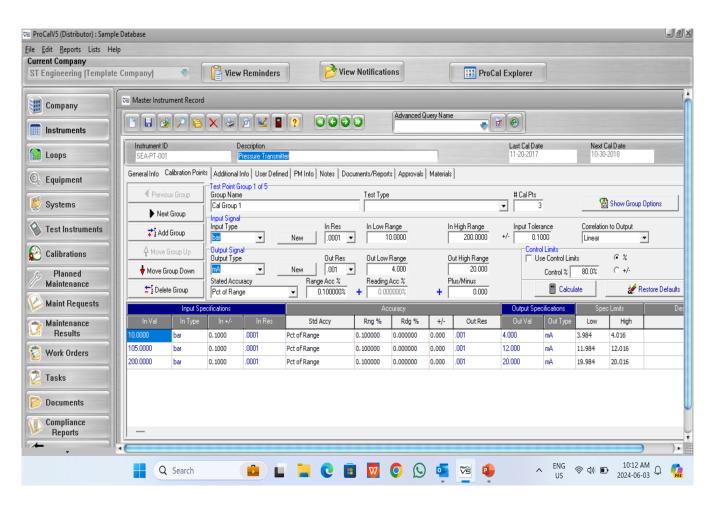


### Easy Asset & Workflow Management



### Instrument Master

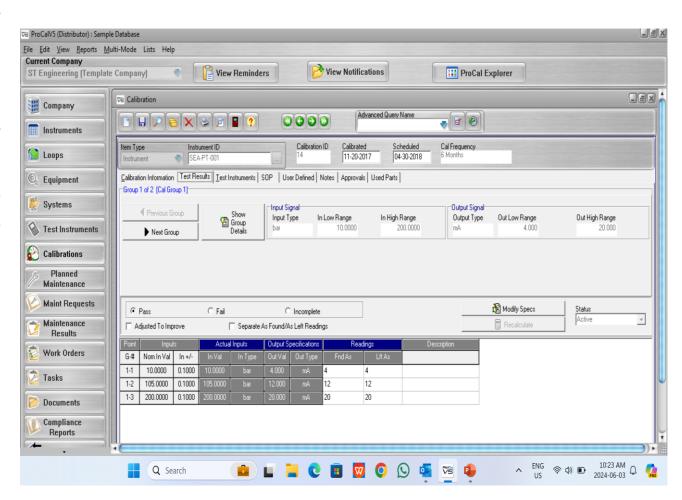
- General Asset Information
- View Calibration or Maintenance Work History
- Asset 1 or Multiple Test Specifications
- Handles all Types of Calibration Tests including (Temperature, Uncertainty Budget, Electrical, Scales & Balances, Mechanical, Radiation, Bio Cabinet, Dimensional etc.)
- Automatically link Assets to Planned maintenance activities
- Store before/after pictures
- Setup New Asset Calibration Policy
- Store SOPs/Work Instructions with Asset
- Setup Auto-Notifications for As Found/As-Left Failure
- Setup Auto-generate Compliance Report & More...



# Performing Calibrations as easy as 1-2-3

Whether Internal team or Third-Party Vendors, end-2-end calibration processes with documentation can be completed within minutes:

- Call the asset to enter the As Found or As Left or Both
- ProCal automatically performs all necessary calculations for pass/fail certifications
- Get e-Signatures according to the calibration approval policy (e.g., Technician, Third Party Vendors, Supervisor, QA, Manager etc.)
- Generates the reports and documents
  - Calibration Certificate
  - Calibration Label
  - Reverse Traceability
  - Instrument Trend Report



# Test Type Packages (Calibration Tests)

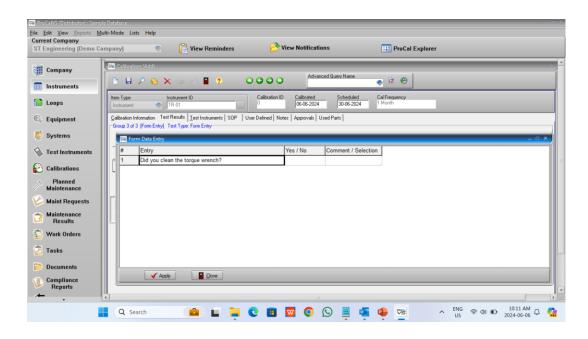
- ProCal Direct Calibration Test templates support all types of calibration tests.
- ProCal Direct has over 50+ Test Type Packages (TTP Customized Test Routines) to enhance quality and accuracy of calibration testing. We also offer custom TTP development to meet your unique testing requirements. Here are some of our TTP examples:

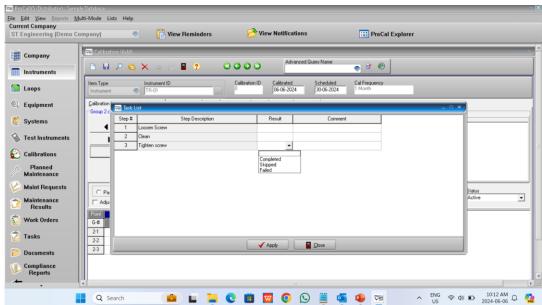
Dissolution Suite	Linearity Test	Scales & Balances	
HPLC Suite	Manual Pass/Fail	Test Omission	
Air Flow & Filter Suite	Pipette Calibration	Timer Test	
Bio Containment	Radiation	Uncertainty Budget	
Bio Safety Cabinet	Reproducibility	Vibration Probe	
Fluke Switch Test	RTD Curve	Temperature	
Fume Hood Certification	HEPA Filter Integrity	Pressure Safety Valves	
Gas Analyzer Cylinder & Test	Glove Box Certification	Pipette Calibration Z Factor	

# Form Entry & Task List

Easily create checklists and forms as part of the maintenance or calibration activities.

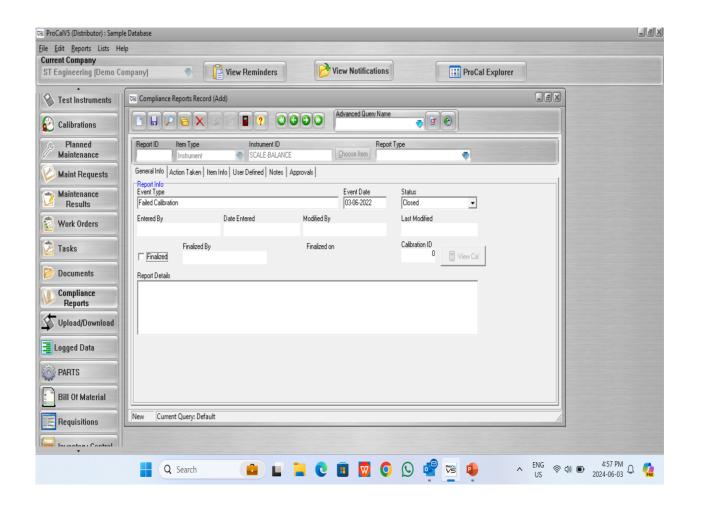
Define the mandatory or optional conditions for the activities in forms and checklists that may require or may not user input.





# Compliance Reporting

- Calibration management compliance reporting is very important in the Pharmaceutical, Life Science and Food & Beverage industry.
- ProCal Direct automatically tracks failed/late/non-compliant events and allows quality professionals to take corrective actions.
- Easily generate new compliance reports that include correction of processes, compliance documents, reports, notes, pictures and e-signed approvals.
- Easily pull up compliance reports during quality and compliance audits.



### Planned Maintenance

- Easily create planned maintenance jobs in ProCal Direct.
- Planned Maintenance jobs tracked with reminders and alerts.
- Planned Maintenance activities cover maintenance and calibrations tasks.
- For calibration jobs which are part of a planned maintenance, test specifications get automatically included.
- Materials required for iobs (Parts/Materials from Inventory) are also automatically loaded.

View Notifications ProCal Explorer ST Engineering (Demo Company) Planned Maintenance Company Instruments Instrument ID Loops Temperature and Humidity Data Logger (DO NOT DELET) UNC-DEMO\_HL\_1D Equipment Use Default Calibration Specs Scheduled battery replacement and contact clean Maintenance Calibration Specs | User Defined | Notes | Materials Systems Responsible Employee Entered By Date Entered Mike McClain ▼ New 09/08/2018 10:58:43 PM Ken Wachs Test Instruments Modified By Document ID ▼ 08-04-2018 26/09/2019 09:58:08 AM **Calibrations** Responsible Vendor 26-09-2019 31-10-2019 Planned Maintenance Worksheet Report Override ▼ Keep On Schedule Maint Requests Exp Man Hrs Maintenance Results Separate As Found/As Left Readings Failure Alert Maintenance Type Work Orders Failure Alerts Due 0 Days After Event Found Out of Cal Alert Maint Type Tasks Found Out of Cal Alerts Due Days After Event **Documents** Compliance Reports Q Search

View Reminders

& More...

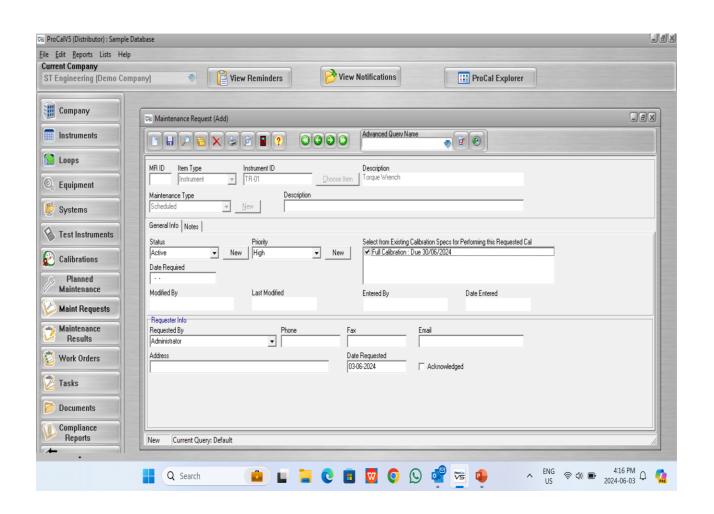
ProCalV5 (Distributor): Sample Database

File Edit Reports Lists Help

### Ad Hoc Maintenance

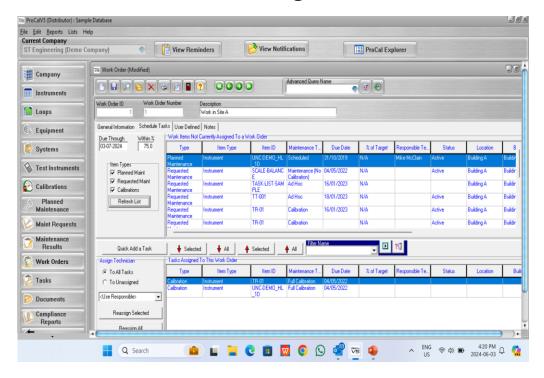
- Easily create ad-hoc maintenance jobs in ProCal Direct.
- ProCal Direct lists existing Planned Maintenance jobs including due dates which allows managers and supervisors to make more efficient and informed decisions.

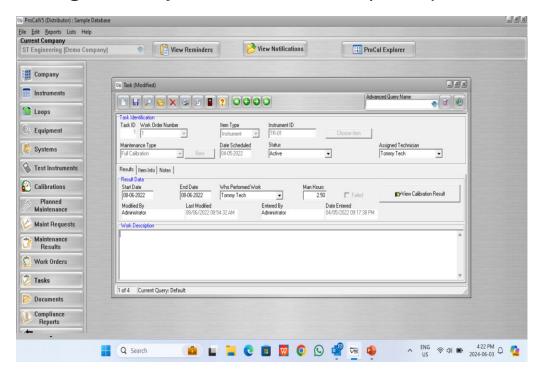
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### Work Orders & Tasks

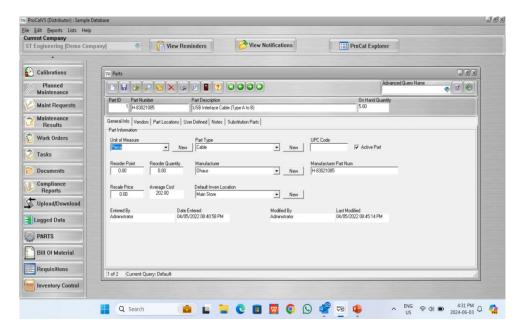
- Work Orders support Planned Maintenance, Ad-hoc Maintenance and Tasks.
- A Work Order can support unlimited tasks.
- Each task can be assigned to an individual, team or third-party vendor.
- Unlimited Tasks can be easily created to support either maintenance or calibration jobs.
- Work Orders can be integrated with ERP and Plant Management System work orders. (Example: Slide 18)

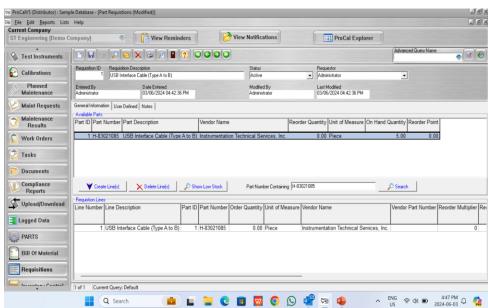




## Parts & Inventory

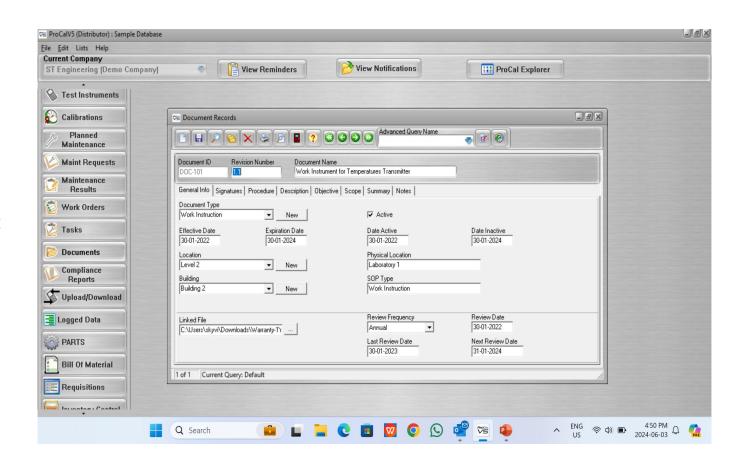
- Easily create parts and bill of materials in ProCal Direct.
- Parts and materials can be added to assets in ProCal Direct.
- These parts and materials are automatically loaded in Planned Maintenance & Work Order jobs.
- The Inventory module keeps track of the quantity of parts and materials.
- Efficiently generate requisition to better manage inventory for the engineering department.





## Document Management

- Documents can be attached to Assets in ProCal Direct. These documents can be referenced during maintenance and calibration jobs.
- The Document management module can be used to maintain:
  - SOPs
  - Work Instructions
  - Manuals etc.
- Each document can be quality managed with:
  - Version number
  - Review schedules
  - Document Status / Validity
  - E-Signatures



## Documenting Process Calibrators

#### Speed up the calibration process with:

- Download tags for calibration jobs and Upload results from DPCs to ProCal Direct
- User-defined test standard settings can allow specific standards to only be used for certain instrument types
- Reverse traceability for tracking affected instruments, if needed
- Links master records to standard operating procedures and other documents
- Automatically send reminders, alerts, and warnings
- Auto-recalculate high/low tolerances during actual field calibrations
- Upload logged data captured in the field
- Pre-structured associations for instruments to loops and/or equipment records are viewable in a hierarchical format which allows for multiple calibration test groups on a single instrument



### 70+ Reports - View / Print & Export

- Calibration certificates
- Calibration Worksheets
- Completed Planned Maintenance
- A3 Interval Analysis
- Calibration labels
- Instruments Due Reports
- Test Standards Due Reports
- Audit Trail
- Reverse Traceability
- Incomplete / Failed calibrations
- Compliance Reports
- Completed Work Order
- Document Reports
- Calibration Labels
- Completed On-Demand Maintenance
- Custom Reports & more...





Type of Cal. In House



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#### FICATE of CALIBRATION

Certificate # 94396

#### Company Name

#### Instrument ID WT93217

Description	weight set	Type of Car	in House
Manufacturer	Troemner, LLC	Received Condition	In-Spec
Model Number	100g-500g	Returned	In-Spec
Serial Number	z1010234	Adjusted	No
Calibration Procedure	Manufacturer Spec	Calibration Frequency	ANNUAL
P.O. Number		Date Received	08/08/2013
Temp	71°F	Calibrated	08/08/2013
Humidity	34% RH	Due Date	08/08/2014

#### Calibration Specifications

	Group Name	Weight							
Test Point	Ref Standard	Tol	UUT As Found	P/F	UUT As Left	P/F	Dev	Uncertainty	
1	100.0 grams	+/-0.0010	100.0009 grams	P	100.0009 grams	P	0.0009	0.0441 mg	
2	200.0 grams	+/-0.001	200.000 grams	P	200.000 grams	P	0.000	0.132 mg	
3	300.0 grams	+/-0.001	300.001 grams	P	300.001 grams	P	0.001	0.139 mg	
4	400.0 grams	+/-0.001	400.001 grams	P	400.001 grams	P	0.001	0.187 mg	
5	500.0 grams	+/-0.0	500.0 grams	P	500.0 grams	P	0.0	$0.4~\mathrm{mg}$	

<u>Calibration Standards Used</u>					
Test Instrument ID	Manufacturer	Model Number	Traceability No.	Next Cal Date	
PMI 499	Sartorius AG	CCE1004		5/21/2014	
PMI 500	Sartorius AG	CCE106		5/21/2014	
PMI 727	Troemner, LLC	7223-1	697665-1	12/19/2013	

This instrument has been calibrated in accordance with the Precision Measurements Quality Assurance Manual and is traceable to the International Systems of Units (SI) through National Metrological Institutes, ratiometric techniques or natural physical contants. (NIST). Precision Measurements quality system is registered to ISO 9001-2008 and accredited to ISO/IEC 17025-2005. Precision Measurements is also compliant to ANSI/NCSL 2540-1-1994, ISO 10012-1, 10 CFR 50 App. B, 10 CFR 21, and MIL-STD-45602A. This report may not be reproduced, except in full, without the written approach of Precision Measurements. Unless stated otherwise, the expanded measurement uncertainty of the measurement process does not exceed 25% of the tolerance allowed for the individual characteristics measured, the measurement uncertainties for this calibration are based upon 95% (2 sizma) confidence limits.

#### Remarks or Special Requirements:

Print Date: 08/27/2013 QF-8 Rev. 2 Issued - 02/10/09

#### Precision Measurements

A Division of Instrumentation Technical Service, Inc.

20 Hagerty Boulevard, Suite 1 \* West Chester, PA 19382 \* (610) 436-9703 \* (610) 436-9097 Fax

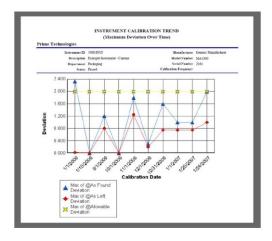
#### TEST INSTRUMENT REVERSE TRACEABILITY REPORT For the Period: 1/1/2017 - 10/5/2017

Test Instrument Owner	* Demo Model Numbe	r Class A
Test Instrument ID	T-005 Serial Number	r N/A
Description	Weight set Last Cal Dat	• 1/1/2017
Status	Active Next Cal Dat	e 1/1/2018

	Company Name * Demo				
Item ID	Description	Manufacturer	Model Number	Serial Number	Calibrated
111	Temp & Humidity Transmiter	Vasila	RH/Temp-65	65464	10/5/2017
I-0001	New Gauge	Ashcroft	12345	YY876	8/14/2017
I-0001	New Gauge	Ashcroft	12345	YY876	8/15/2017
I-0002	New Gauge	Ashcroft	1234	TTR453	8/2/2017
I-002	100 PSI Pressure Guage	Ashcroft	1234	65465489	8/2/2017
I-002	100 PSI Pressure Guage	Ashcroft	1234	65465489	8/2/2017
I-002	100 PSI Pressure Guage	Ashcroft	1234	65465489	8/17/2017

LOOPS CALIBRATED							
Company Name							
Item ID	Description	Number of Loop Calibration	<u>Calibrated</u> ns for This Company	Using This Test Instrument:			
TEST INSTRUME! Company Name	NTS CALIBRAT	ED					
Test Instrument ID Description Manufacturer Model Number Serial Number Calibrated							
Number of Test Instrument Calibrations for This Company Using This Test Instrument:							

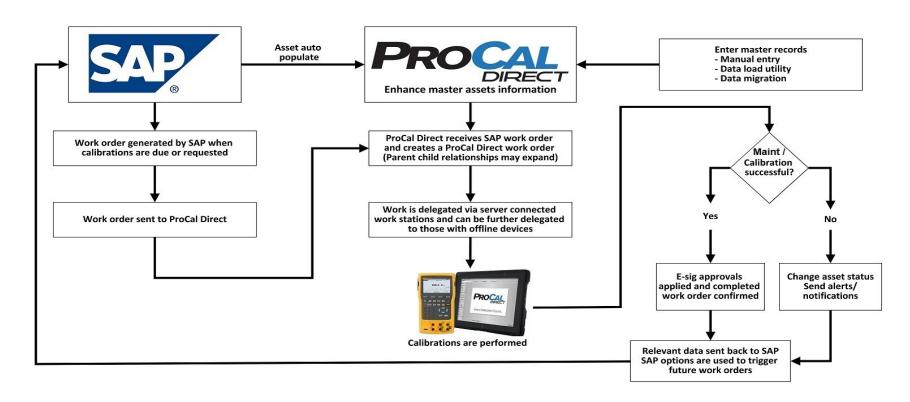
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# SAP / ERP Integration (Sample Workflow)

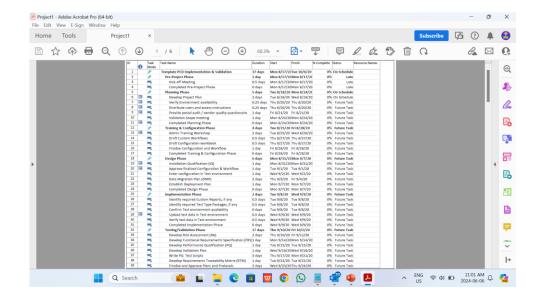
- Clients can choose to use ProCal Direct as a standalone system or integrated with their ERP or PMS systems.
- Clients may also choose to use only the calibration functionality and still integrate with ERP or PMS systems.

#### **SAP & Calibration Work Flow**



### Validation Services

- ProCal Direct is a pre-validated GAMP 5 Software. We can provide supporting Mail-In-Audit documentation.
- For On-Site Validation Requirements: We can support clients with validation scripts and consulting services.
- ProCal Direct consulting services are professionally executed under strict project management guidelines.
- ProCal Direct validation services can be completed in under 40 days. These are phases in our consulting support for IQ / PQ:
  - Pre-Project Phase
  - Planning Phase
  - Training & Configuration Phase
  - Design Phase
  - Implementation Phase
  - Testing / Validation Phase
  - Deployment Phase





#### Clients Currently Using ProCalV5













































Trusted by thousands of users trust since 1990.