2019 3-A SSI EDUCATION PROGRAM

Modernizing Food Manufacturing Reporting

CYBERTROL ENGINEERING

Presenter: Tim Barthel – Vice President - Automation Solutions

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Automation · Controls · Industrial IT · Manufacturing Intelligence

Agenda
Modernizing Food Manufacturing Reporting

- Introduction: Why We Are Here
- Traditional Data Recording Methods
- Comparison: Traditional vs. Electronic
- 21 CFR Part 11 Data Recording Compliance
- Q&A

Cybertrol Engineering: Why We Are Here

- System Integrator with experience in process control of sanitary systems
- Food and Beverage Committee & Board members
- Automation, Information and IT services
- UL508 panel shop
- Thousands of projects for over 400 clients
- Multiple certifications in industrial products
- Food & Beverage industry expertise
- Industrial IT Solution Partner

Rockwell Automation Solution Partner
Control • Process • Information

Ignition by inductive automation

Wonderware CERTIFIED SYSTEM INTEGRATOR SYSTEM PLATFORM

SIEMENS

CISCO Partner

vmware PARTNER PROFESSIONAL SOLUTION PROVIDER

CISCO CERTIFIED CCDA

ISA/IEC 62443 CYBERSECURITY FUNDAMENTALS SPECIALIST ISA

THINMANAGER A Rockwell Automation Technology

Sanitary Design · Electronic Reporting Experience

- Dairy · Meat Production · Process Cheese · Powder Handling · Sour Cream · Cottage Cheese · Ice Cream · Creamer · Infant Formula · Pet Foods · Sauces · Liquid Blending· Medical Device · Pharma
- Plant operations: Intake · HTST · CIP · Vats/Coagulation · Filtration · Evaporation · Drying · Powder Conveying · Bagging · Mixing/Batching · Cookers · Product Handling · Packaging Line Integration · Utilities · Wastewater Treatment

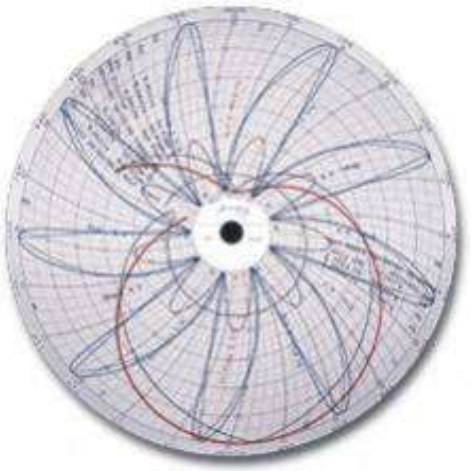
LAND O'LAKES, INC. · Hormel · DFA Dairy Farmers of America · Unilever · Popsicle · Ben & Jerry's · Klondike · PEPSICO

Saputo · Daisy Brand · KraftHeinz · Medtronic · Grande Cheese Company

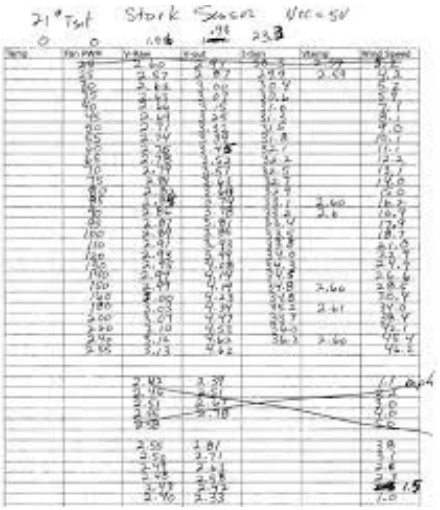
Boston Scientific · ConAgra Foods · Valley Queen Cheese Factory · FNA · Lloyds Barbeque

Traditional Data Recording Methods

Clipboard charts and circular chart recorders are commonly used to acquire and report critical data.



Electronic data recording systems are available to capture and display critical process data, with capabilities which far exceed traditional recording methods.



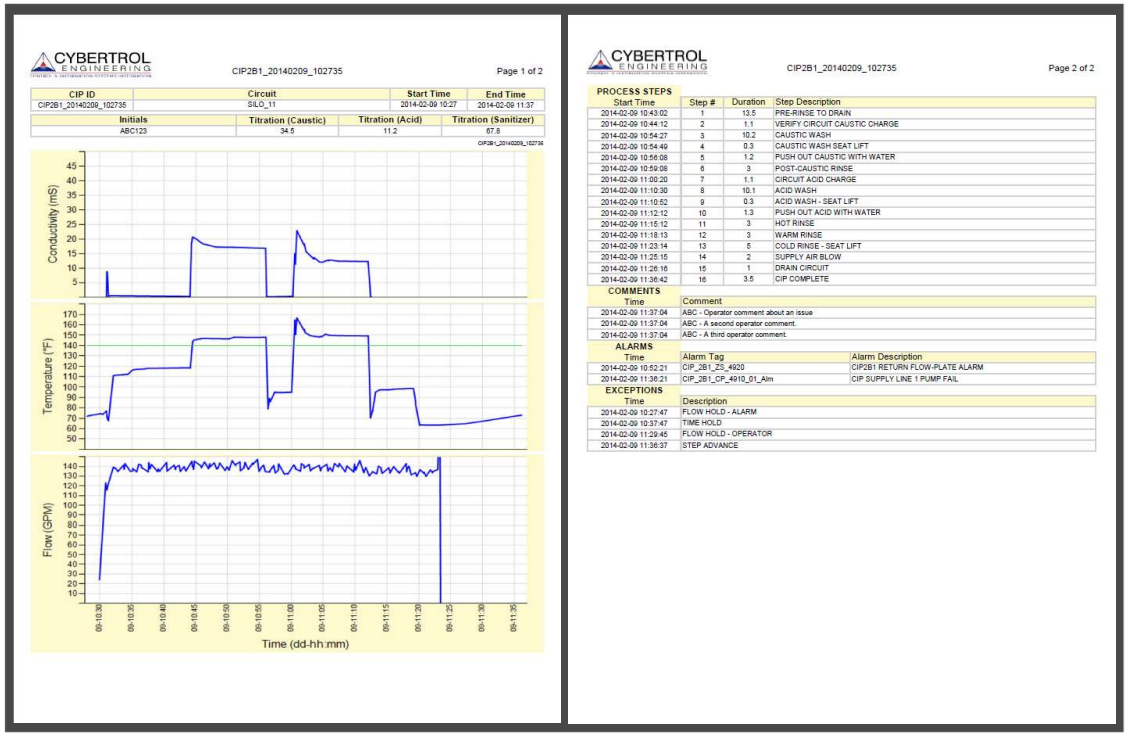
Traditional Chart Recorder CIP Report

- 3 Pen circular chart for Flow, Temperature, & Conductivity on a common scale
- Operator initials & date
- Handwritten recorded titration values
- Handwritten operator comments
- Paper record
- Stored in filing cabinet.

CIP Report Comparison

Traditional CIP

Electronic CIP



CYBERTROL ENGINEERING

CIP2B1_20140209_102735

Page 1 of 2

CIP ID	Circuit	Start Time	End Time
CIP2B1_20140209_102735	SILO_11	2014-02-09 10:27	2014-02-09 11:37

Initials	Titration (Caustic)	Titration (Acid)	Titration (Sanitizer)
ABC123	34.5	11.2	67.8

CYBERTROL ENGINEERING

CIP2B1_20140209_102735

Page 2 of 2

PROCESS STEPS

Start Time	Step #	Duration	Step Description
2014-02-09 10:43:02	1	13.5	PRE-RINSE TO DRAIN
2014-02-09 10:44:12	2	1.1	VERIFY CIRCUIT CAUSTIC CHARGE
2014-02-09 10:54:27	3	10.2	CAUSTIC WASH
2014-02-09 10:54:49	4	0.3	CAUSTIC WASH SEAT LIFT
2014-02-09 10:56:08	5	1.2	PUSH OUT CAUSTIC WITH WATER
2014-02-09 10:59:08	6	3	POST-CAUSTIC RINSE
2014-02-09 11:00:20	7	1.1	CIRCUIT ACID CHARGE
2014-02-09 11:10:30	8	10.1	ACID WASH
2014-02-09 11:10:52	9	0.3	ACID WASH - SEAT LIFT
2014-02-09 11:12:12	10	1.3	PUSH OUT ACID WITH WATER
2014-02-09 11:15:12	11	3	HOT RINSE
2014-02-09 11:18:13	12	3	WARM RINSE
2014-02-09 11:23:14	13	5	COLD RINSE - SEAT LIFT
2014-02-09 11:25:15	14	2	SUPPLY AIR BLOW
2014-02-09 11:26:16	15	1	DRAIN CIRCUIT
2014-02-09 11:36:42	16	3.5	CIP COMPLETE

COMMENTS

Time	Comment
2014-02-09 11:37:04	ABC - Operator comment about an issue
2014-02-09 11:37:04	ABC - A second operator comment.
2014-02-09 11:37:04	ABC - A third operator comment.

ALARMS

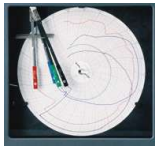
Time	Alarm Tag	Alarm Description
2014-02-09 10:52:21	CIP_2B1_ZS_4920	CIP2B1 RETURN FLOW-PLATE ALARM
2014-02-09 11:36:21	CIP_2B1_CP_4910_01_Alm	CIP SUPPLY LINE 1 PUMP FAIL

EXCEPTIONS

Time	Description
2014-02-09 10:27:47	FLOW HOLD - ALARM
2014-02-09 10:37:47	TIME HOLD
2014-02-09 11:29:45	FLOW HOLD - OPERATOR
2014-02-09 11:36:37	STEP ADVANCE

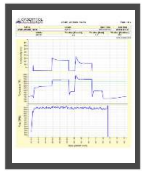
CIP Data Collection Comparison

Traditional CIP



- 3 Pen circular chart recoding Flow, Temperature, & Conductivity on a common scale.
- Operator signature & date.
- Handwritten recorded titration values.
- Handwritten operator comments.

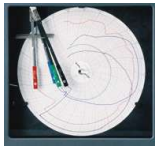
Electronic CIP



- Database automatically recording Flow, Temperature, & Conductivity, each uniquely scaled.
- Visual min./max. limits.
- Time-stamped Operator initials and date.
- Time-stamped entered titration values.
- Time-stamped typed comments.
- Time-stamped record of process steps.
- Time-stamped record of alarms.
- Time-stamped record of exceptions.

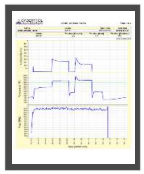
CIP Operator Comparison

Traditional CIP



- Operator monitors pen plots during CIP.
- Operator records start time.
- Operator adds notes to charts as CIP progresses.
- Operator reviews pen plots during the CIP
- Operator reviews and confirms final CIP report and signs and dates circular chart.

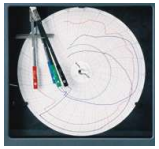
Electronic CIP



- Operator initiates CIP from HMI.
- Mandatory data must be entered before the CIP can progress.
- Operator data entries are clearly typed into the HMI.
- Operator comments can be added throughout the CIP and are time-stamped.
- Operator monitors data collection on HMI screen.
- Operator reviews and confirms final CIP report, and is prompted to verify and electronically sign the report.

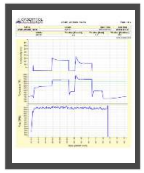
CIP Report Comparison

Traditional CIP



- Single paper record stored in a file cabinet.
- Potentially unclear hand written initials, dates, and notes.
- Potentially erroneous operator entered dates.
- Difficult to read circular charts.
- Results viewable by only one person at a time.

Electronic CIP

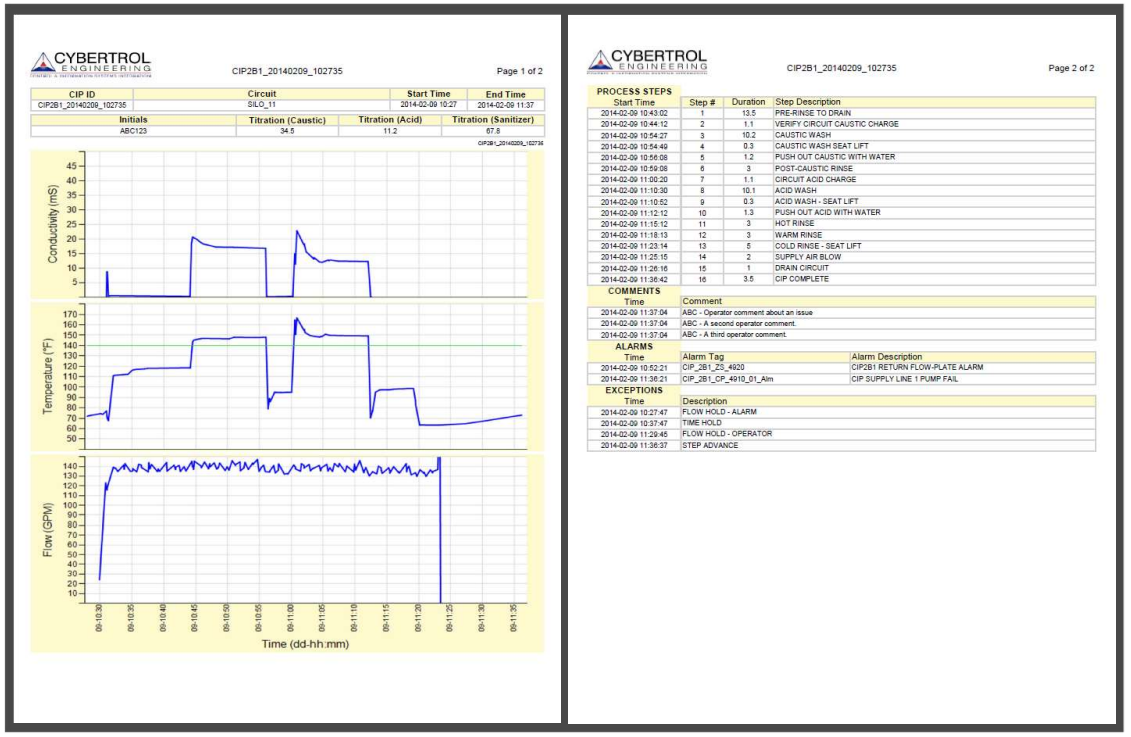


- Redundant electronic record with optional paper record.
- Clearly typed initials, dates and notes.
- Electronic time-stamps.
- Easy to read rectangular charts.
- Viewable by multiple people simultaneously at any location using any web browser.
- Easy to find specific reports using sorting and filtering criteria.
- A summary report showing all CIPs with quick access to any individual report.

CIP Report Comparison

Traditional CIP

Electronic CIP



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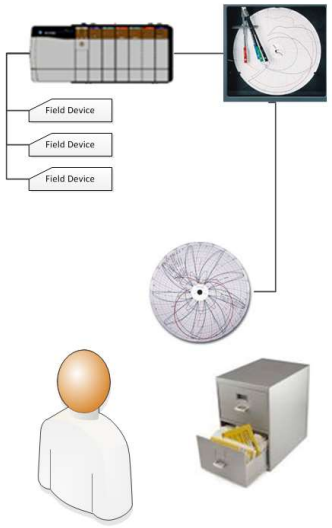
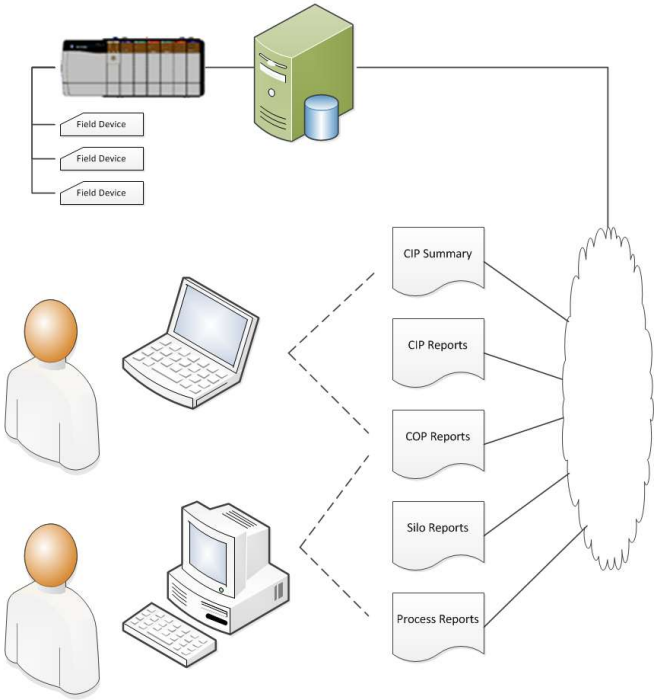
Data Flow Comparison

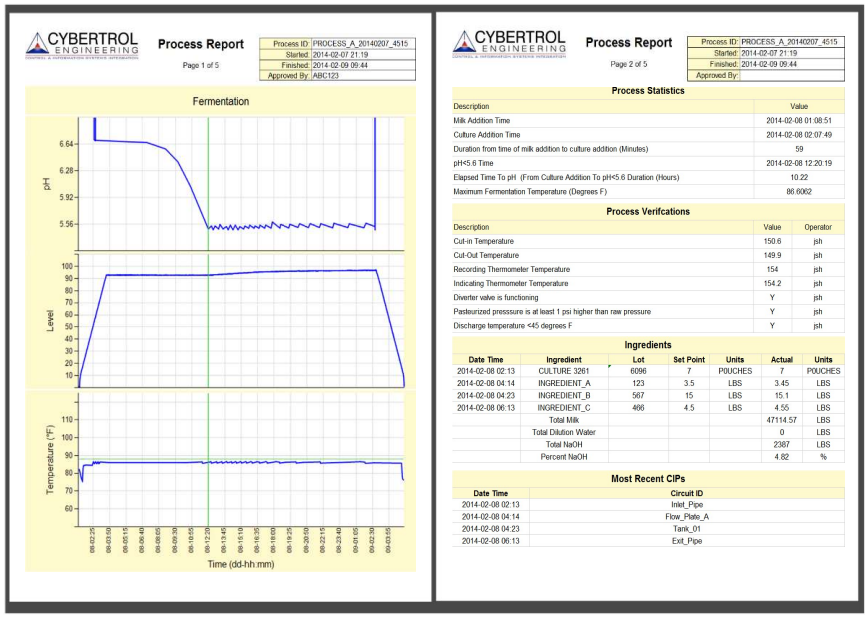
Traditional Chart Recorder

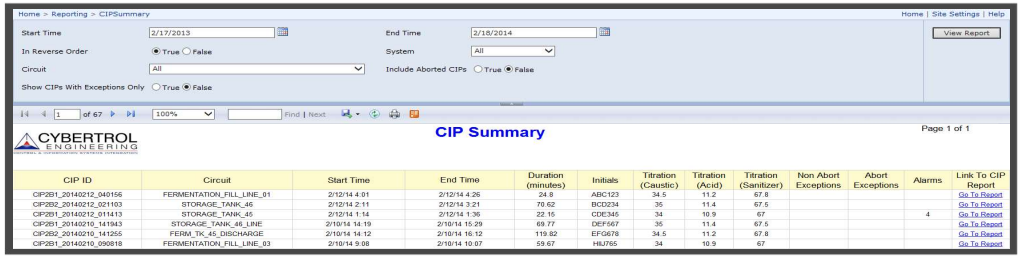


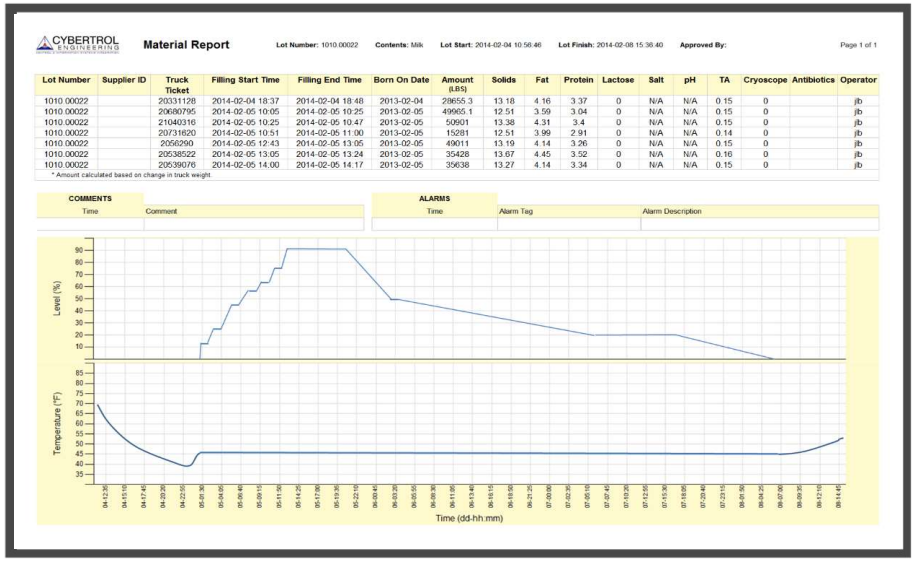
Electronic Reporting



Production Report Examples

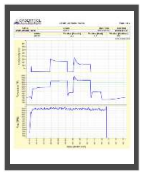






21 CFR Part 11 & Security

	Traditional CIP	Electronic CIP
Signatures	• Handwritten signatures and dates	• Time-stamped electronic signatures authenticated by user name and password
Comments	• Handwritten and dated post process comments and approvals.	• Time-stamped post process comments with electronic signatures authenticated by user name and password
Tampering	• No protection against post process report modifications and tampering	• Fully controlled data acquisition preventing any data modifications or tampering
Validation	• Data validation by periodic comparison of gage readings for Temperature, Flow and Conductivity against recorded chart values	• Data validation by continuous side by side comparison of Temperature, Flow and Conductivity data recorded in Historian to the sensor values displayed on the HMI.

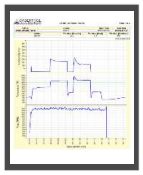


21 CFR Part 11 & Security

	Traditional CIP		Electronic CIP

		Redundancy	• Redundant electronic records
			  • SQL Server & Historian Data
			  • Reports in PDF format in a file folder
			  • Optional paper reports

	• Access to records is controlled by lock & key	**Security**	• Access to records in SQL Server, Historian, and File Folder is controlled by authenticated user name and password
	• Offsite record retention requires periodic manual intervention to copy and transport records	**Backups**	• Offsite record retention is automatic and immediate



21 CFR Part 11 & Security – PMO Requirements

V. CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE AND REPORTING

1. Manual Records and Chart Recorders are Visual in Nature:

- PMO Statement: *Milk plant employees and regulatory personnel can see and physically hold the records and place them in files for safe keeping.*
- Electronic Method: Data Immediately visible on the HMI that Operator is interacting with. Data is backed up incrementally on a time period to avoid any data loss

2. Manual Records and Chart Recorders are Physical in Nature:

- PMO Statement: *Milk plant employees and regulatory personnel can physically record on and actually sign the records and; therefore, become responsible for the required public health activity*
- Electronic Method: After each procedure that requires validation, the operator is required to review the report to validate the information was recorded, and then electronically signs off on the report

3. Manual Records and Chart Recorders are Typically Hard Wired Directly to Dedicated Instrumentation:

- PMO Statement: *Very little complexity exists between the sensor, such as a temperature or flow sensor, and the final recording device. This allows routine maintenance and compliance monitoring and inspection of manual records and chart recorders to be relatively simple*
- Electronic Method: Trends are built that are visible on the HMI for comparison to the values displayed on the operations screens and for calibration purposes to validate the data being stored is accurate

21 CFR Part 11– Electronic Requirements

Limit Physical Access to computer hardware

The physical hardware capturing the information must be installed in a secure server room. Typically, with virtual images, only administrators have access to the server environment, and this is controlled through active directory.

Use NTFS or other secure file system

All virtual machines built have a Microsoft Server OS which is NTFS

Take advantage of operating system security and domains

Security on the HMI is associated with Windows Linked Users/Groups maintained in the Production Domain Controller

Prohibit access to HMI programming application and other software programs

Programs are not loaded on the operator computer/thin client. The thin client has no way to interact with the server when properly configured.

21 CFR Part 11– Electronic Requirements

Use a password-protected screen saver, Automatic Logout

If a client has not been used for a predetermined amount of time, default is 10 minutes, the system will log-out, or can be configured for login of a read-only user. If security at a button level is not enough a password-protected screen saver can be added to displays.

Use log on requirements for HMI clients

The ReadOnly user is logged onto the HMI system when the client first runs. That user has minimal rights and cannot change information in the system.

Set up the DeskLock feature / Windows application restrictions

DeskLock is not necessary when using thin clients which can be configured the same way. Operations will login to the thin client as a User and will have restricted applications and rights. The thin client will also not be able to modify the server system as they are separate machines and only runs as a service on the server.

21 CFR Part 11– Electronic Requirements

Disable Windows Help

Windows help is not secured and gets disabled as part of configuration.

Log all Client Stations

Thin clients do not allow code debugging or switching to other applications, and interaction is automatically logged by the remote application server.

Set up re-verification of operator identity or supervisor signoff

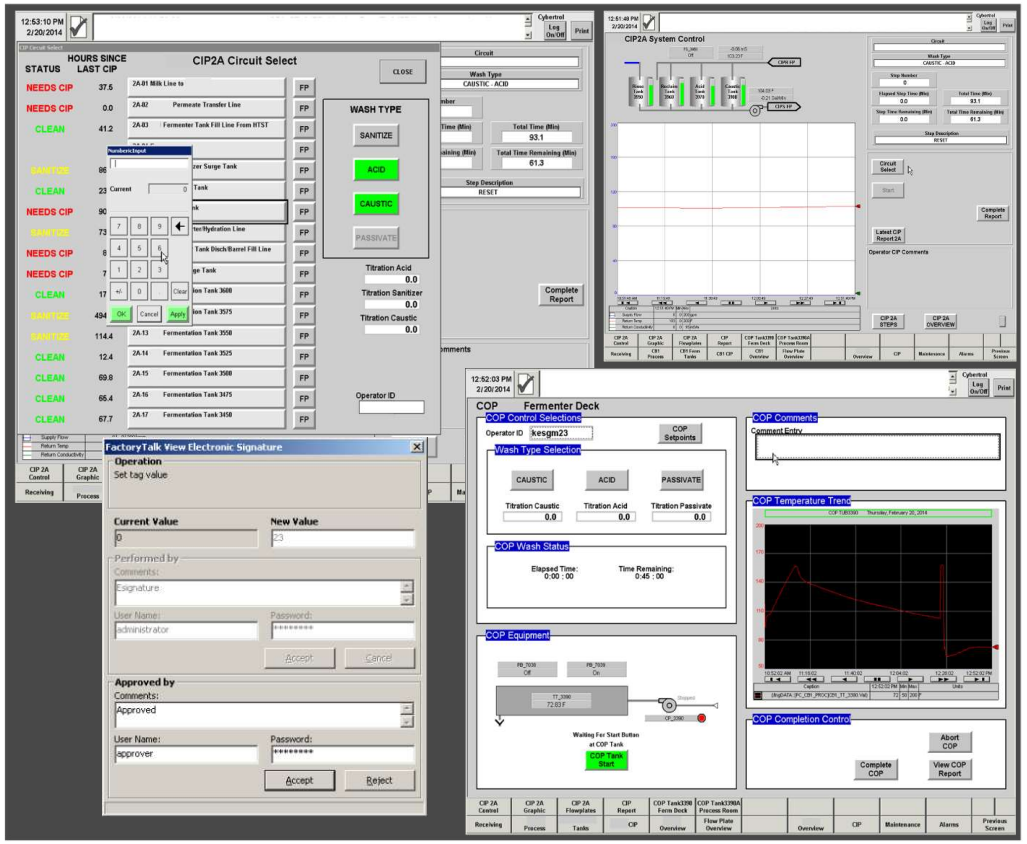
Using windows AD linked security signature entries, certain operations can be verified and limited to user groups. Security for this access is maintained within Active Directory which can only be accessed by an administrator

Use Version Control Software

FactoryTalk AssetCentre is one software application that is used to regulate and monitor changes in various Rockwell software products. The changes to the master PLC programs are monitored and documented so there is an audit trail

21 CFR Part 11– Electronic Requirements

- Operator Selections Automatically Recorded.
- Drop Down List Selections
- HMI Controlled Value Entry
- Clearly Typed Operator Comments
- Operator Authentication Required
- Programs protected by version control software and authorized access through Windows security
- Access to other software programs limited with use of Thin Clients and Windows security



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? Q&A Portion ?

Contact: Tim Barthel · tbarthel@cybertrol.com

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