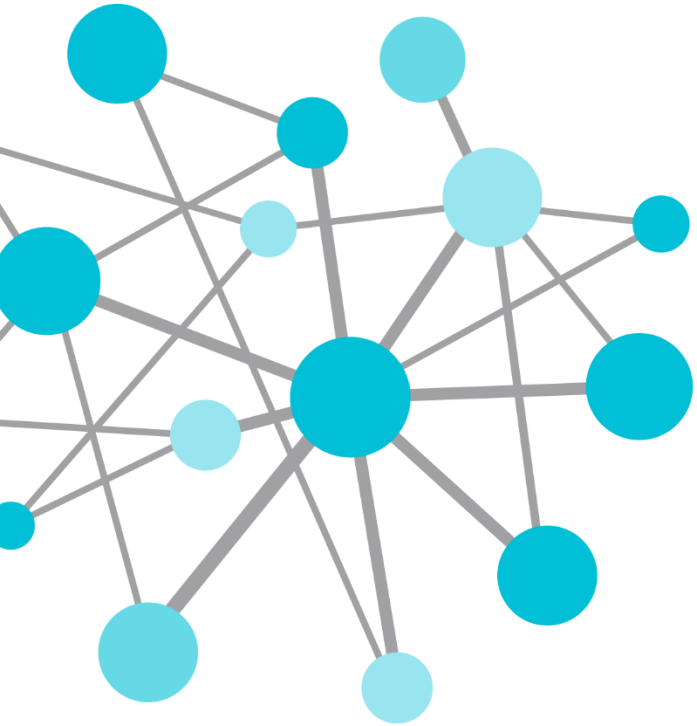


What is RtReports and how is it used in Pharma?

Presented by **Brent Punt**

© Copyright 2014 OSIsoft, LLC.

Agenda

- What we did before PI Server and RtReports
- Focus on RtReport Compliance Edition
  - Create a RtReport: RtReports Editor
  - Using RtReports: RtReport Generator
- RtReports Examples

© Copyright 2014 OSIsoft, LLC.

Before we implemented PI Server / RtReports

- Operators Monitor Equipment
  - Manual Data Gathering
  - Record data every hour in some cases
- Local Skid based vendor reports
  - Often with poor report design
- Reports with lengthy data dumps
  - Long data review times

© Copyright 2014 OSIsoft, LLC.

RtReports General Introduction

Template-Based Enterprise Reporting System that:

- Produces configurable and repeatable reports without programming
- Stores the templates centrally in PI Server
- Uses a web-based interface (Generator)
- Provides reports for real-time and historical data
- Provides reports for batches, time ranges or PI AF cases
- Provides access to PI System data (and external data)
- Meets eSign and auditing requirements for 21 CFR Part 11 electronic records and e-Signatures

© Copyright 2014 OSIsoft, LLC.

RtReports – Two Tools

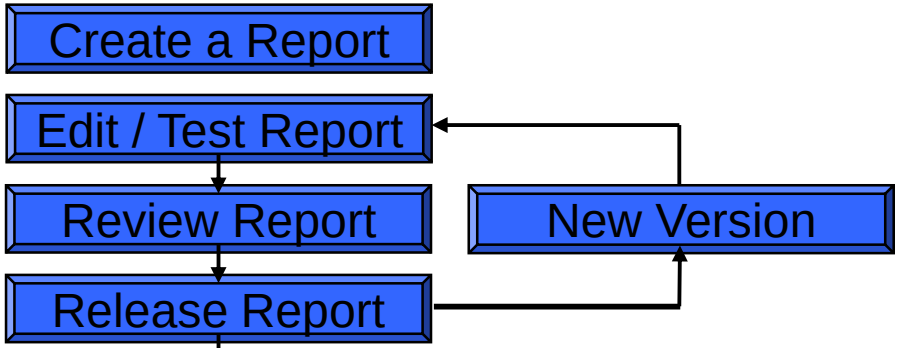
- Editor
  - Client / server based tool for RtReport Development
- Generator
  - Web Based User Interface

© Copyright 2014 OSIsoft, LLC.

RtReport Compliance Workflow

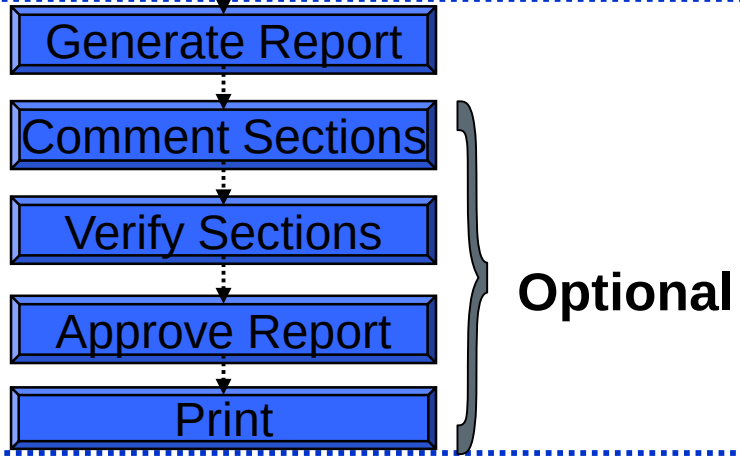
RtReports Editor

The Administrator creates a report template



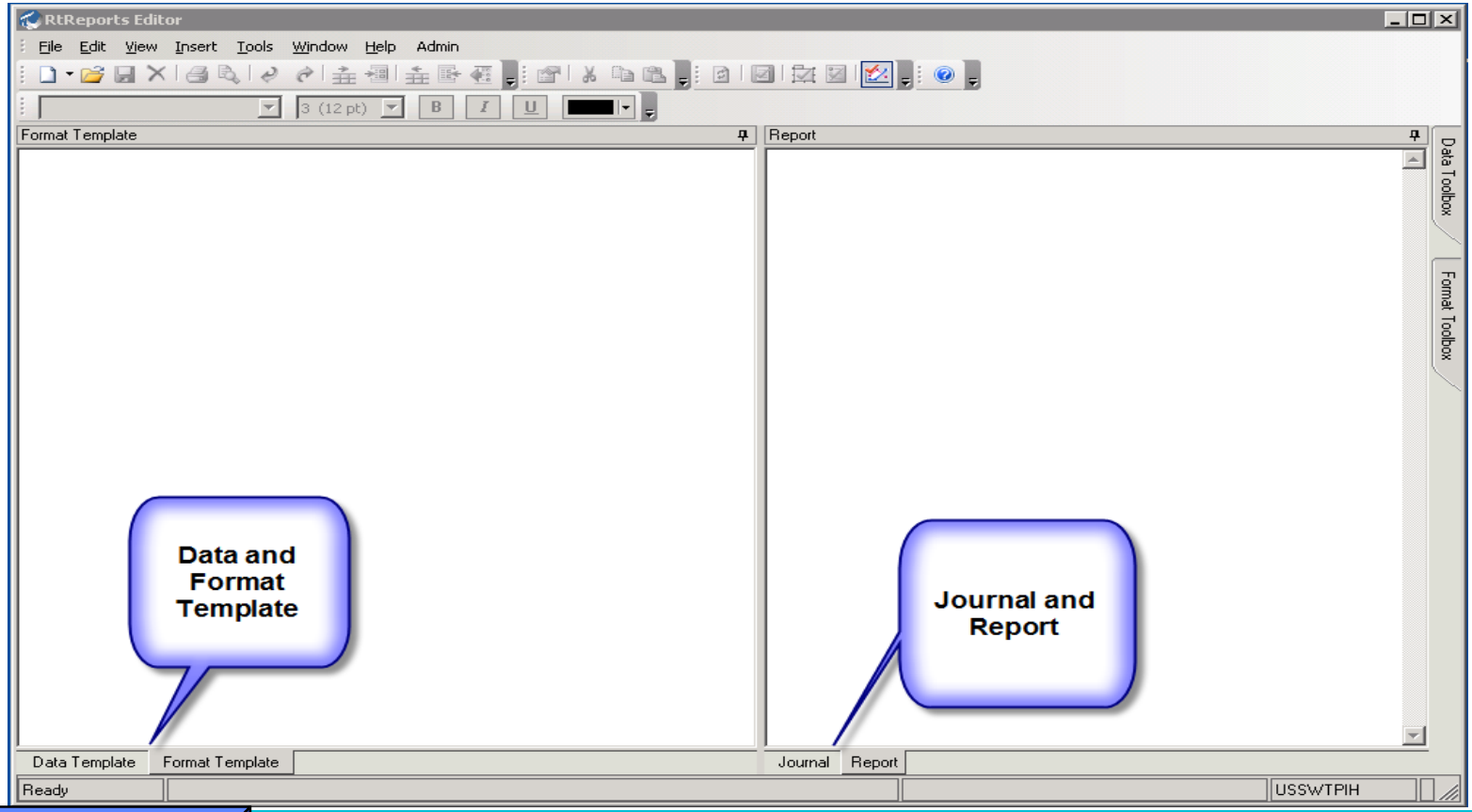
RtReports Generator

The user generates the template based on a batch or other context: PI Batch, Time, PI Asset Framework (PI AF) Case



© Copyright 2014 OSIsoft, LLC.

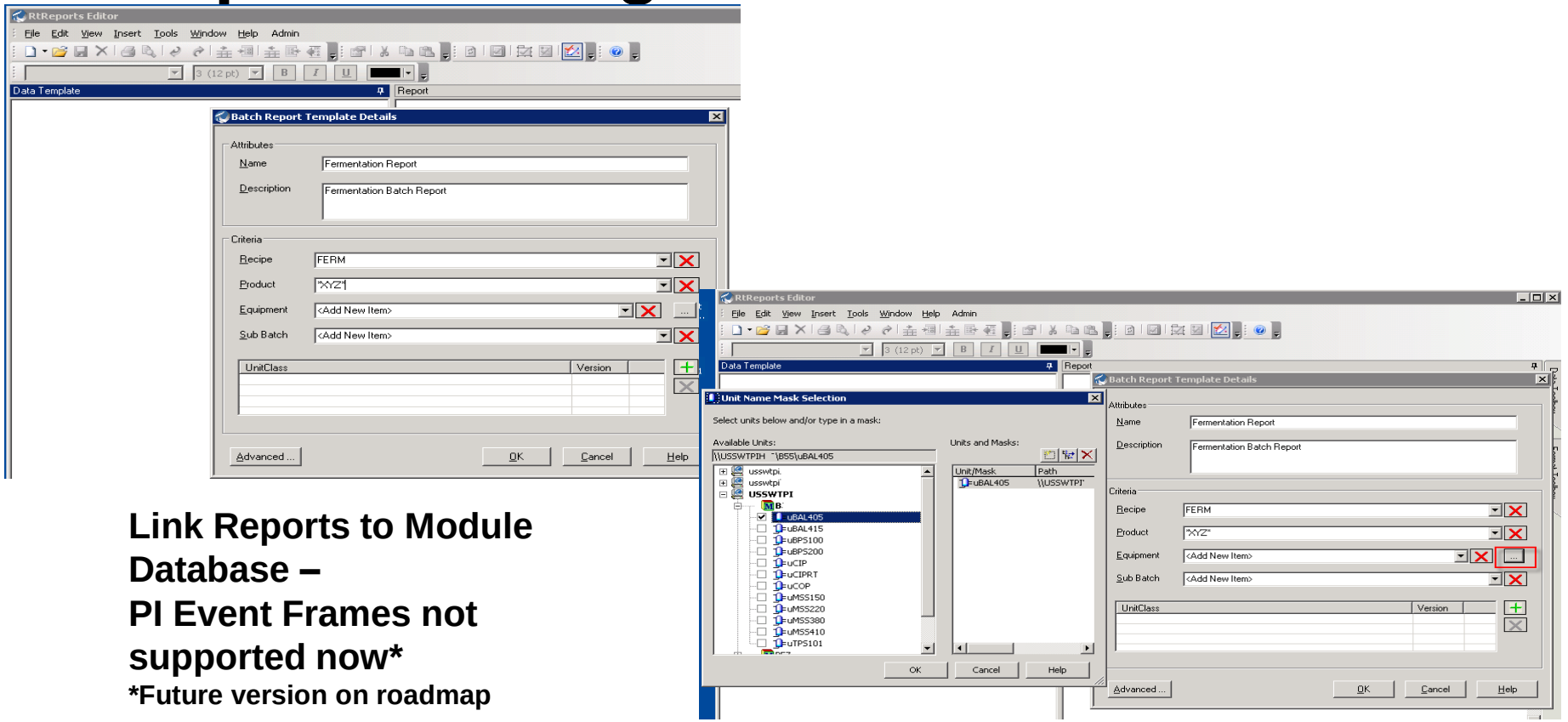
RtReports Editor: Four Windows



Create a Report

© Copyright 2014 OSIsoft, LLC.

Template Linking to Module Database

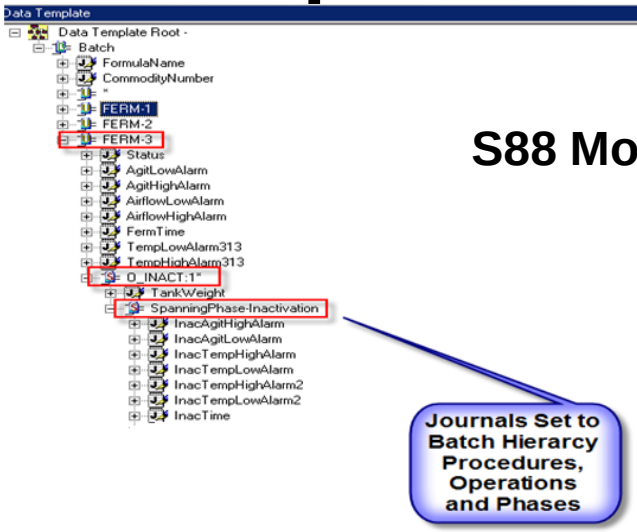


Link Reports to Module Database –
PI Event Frames not supported now*

***Future version on roadmap**

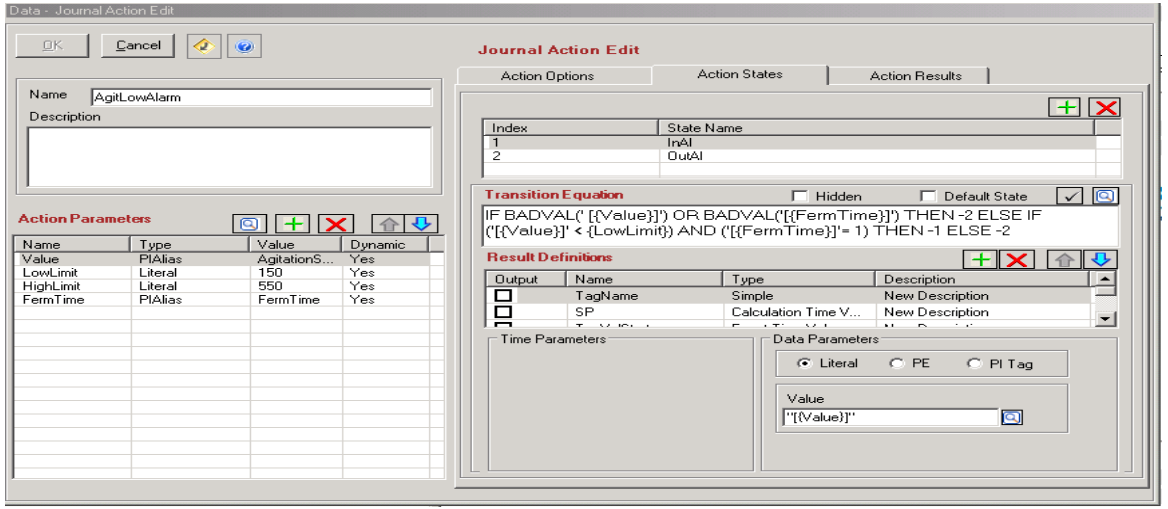
© Copyright 2014 OSIsoft, LLC.

Link Report to PI System Data using Journals



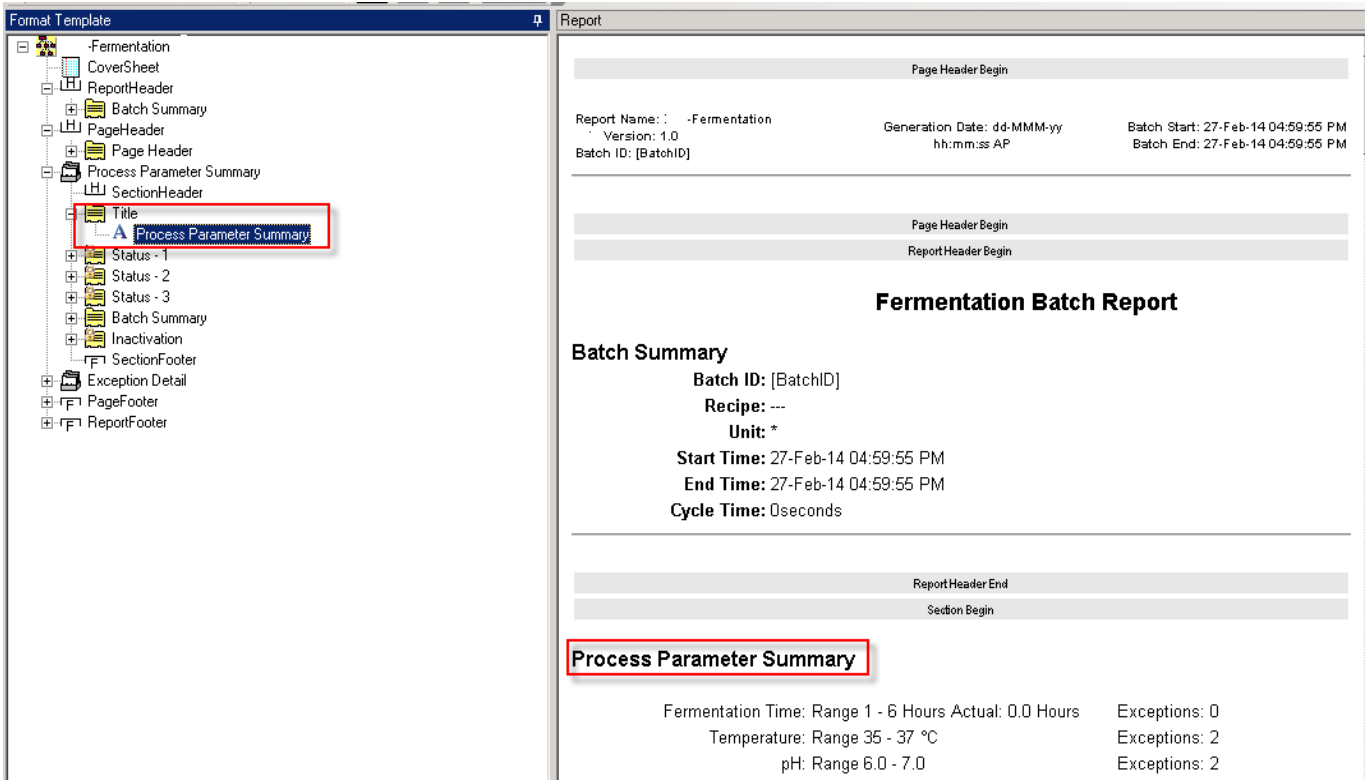
S88 Model for Batch Structure

Link Reports to PI System Data Directly or through MDB Aliases (preferred method)



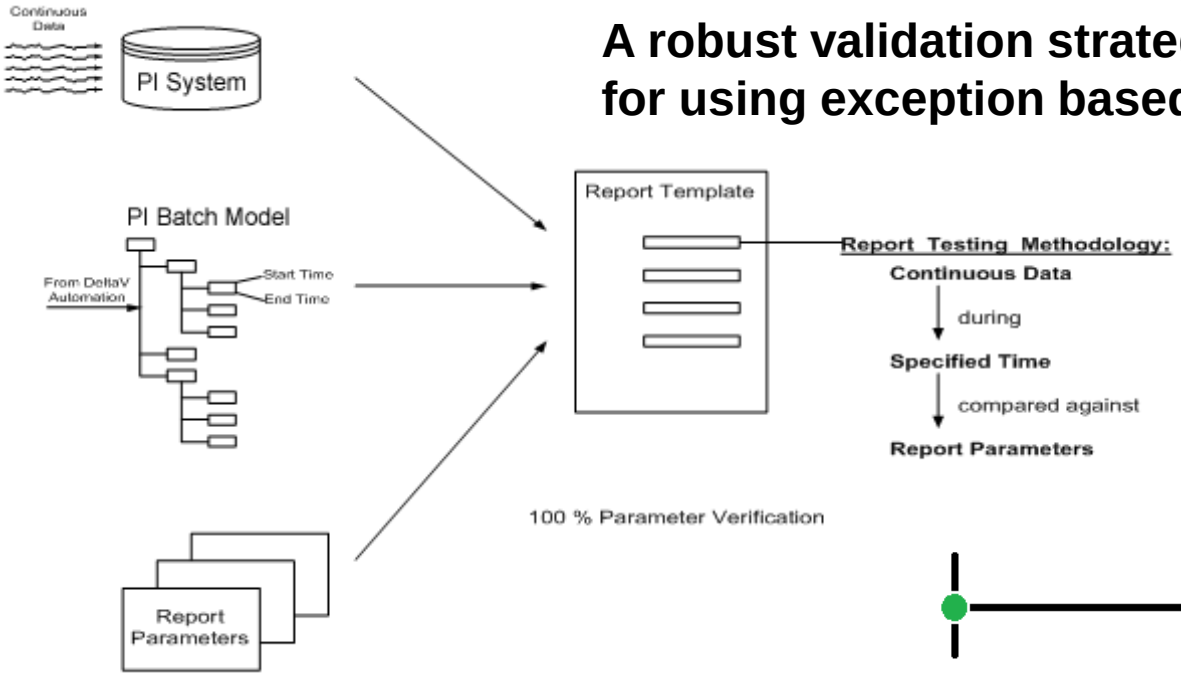
© Copyright 2014 OSIsoft, LLC.

Format the Data

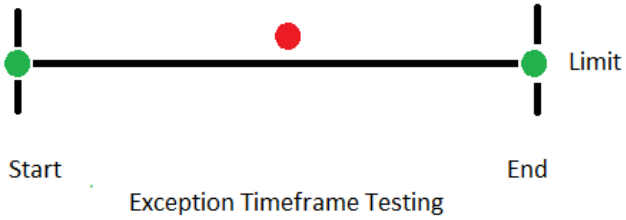


© Copyright 2014 OSIsoft, LLC.

RtReport Validation Methodology



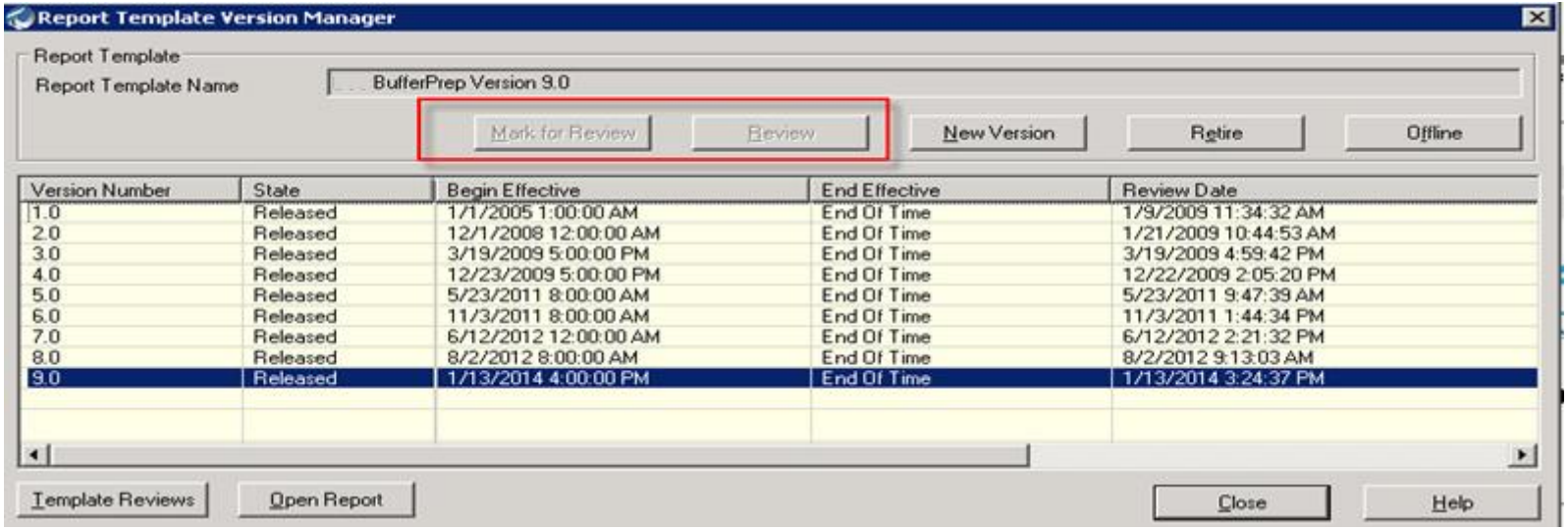
A robust validation strategy is critical for using exception based reporting.



Edit / Test Report

© Copyright 2014 OSIsoft, LLC.

Review / Release Reports



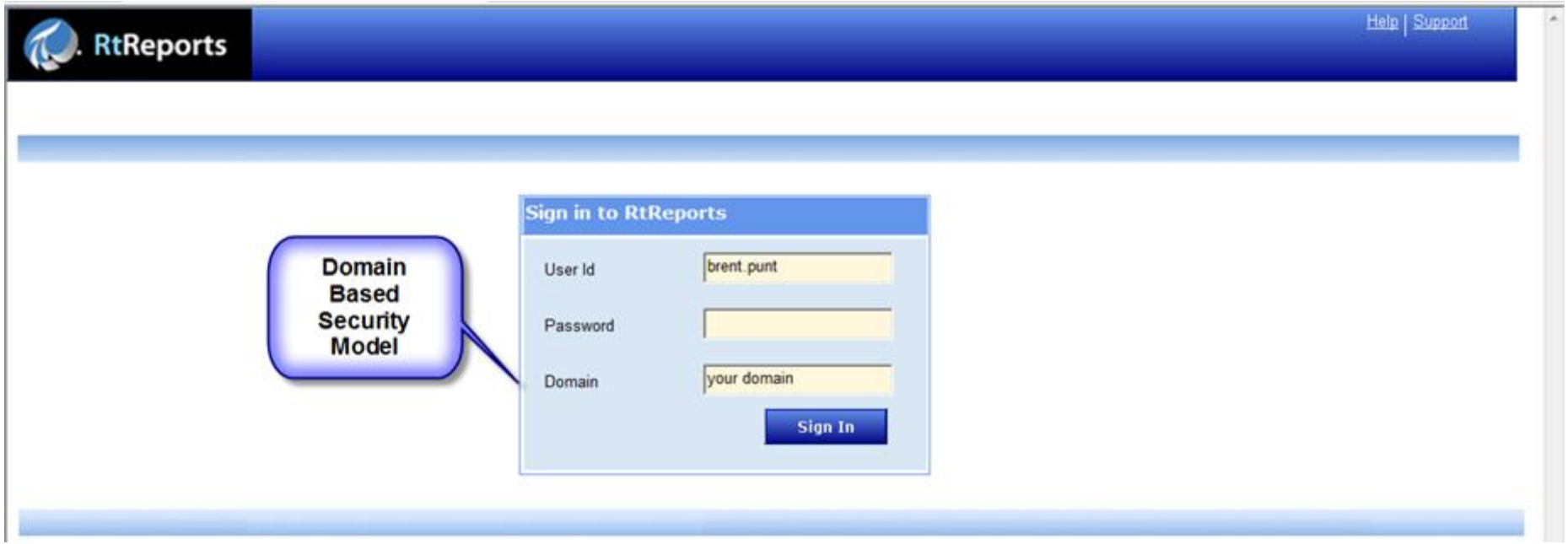
Review Report

Release Report

Strong Version Control

© Copyright 2014 OSIsoft, LLC.

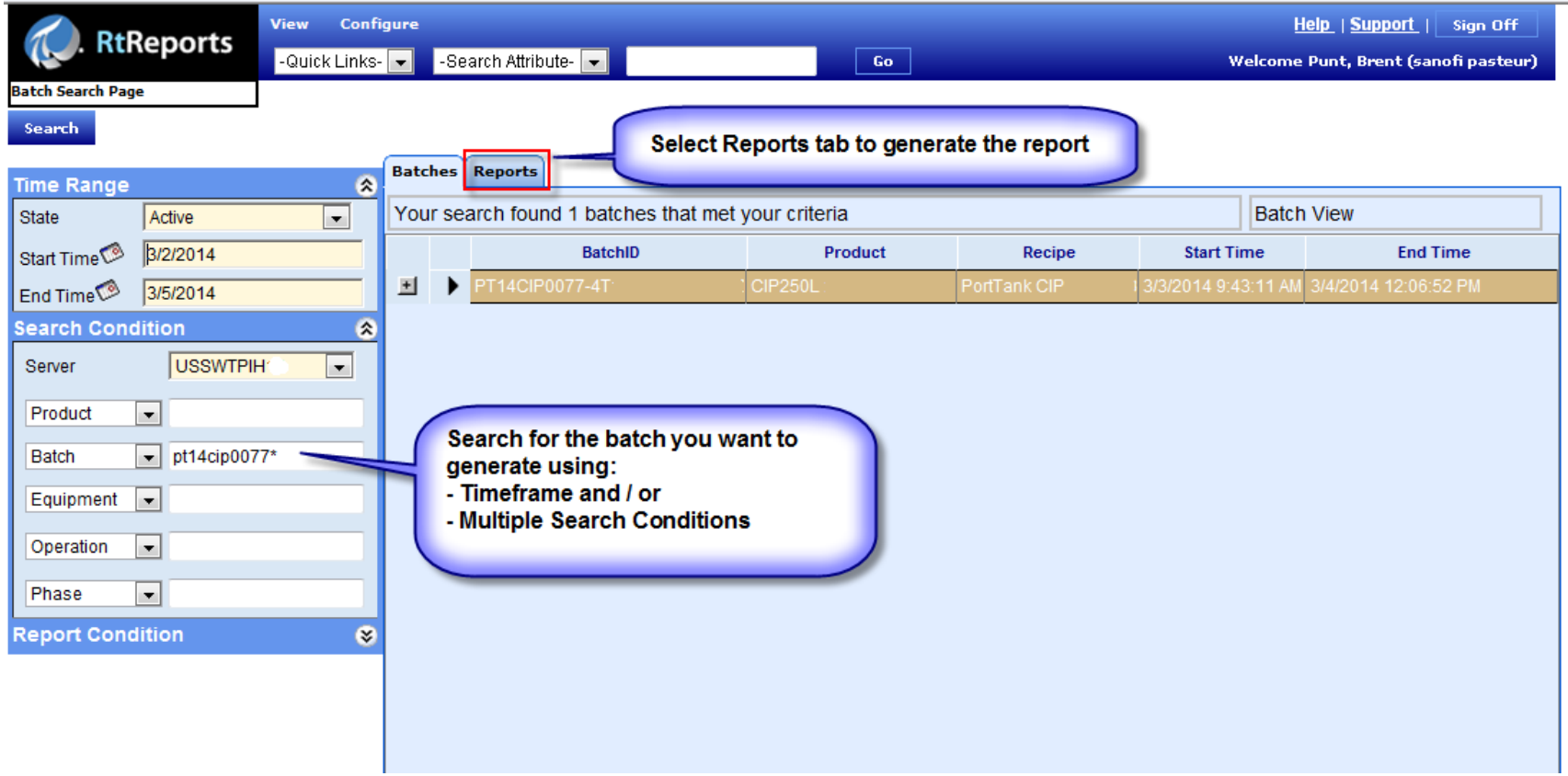
RtReports Generator



Generate Report

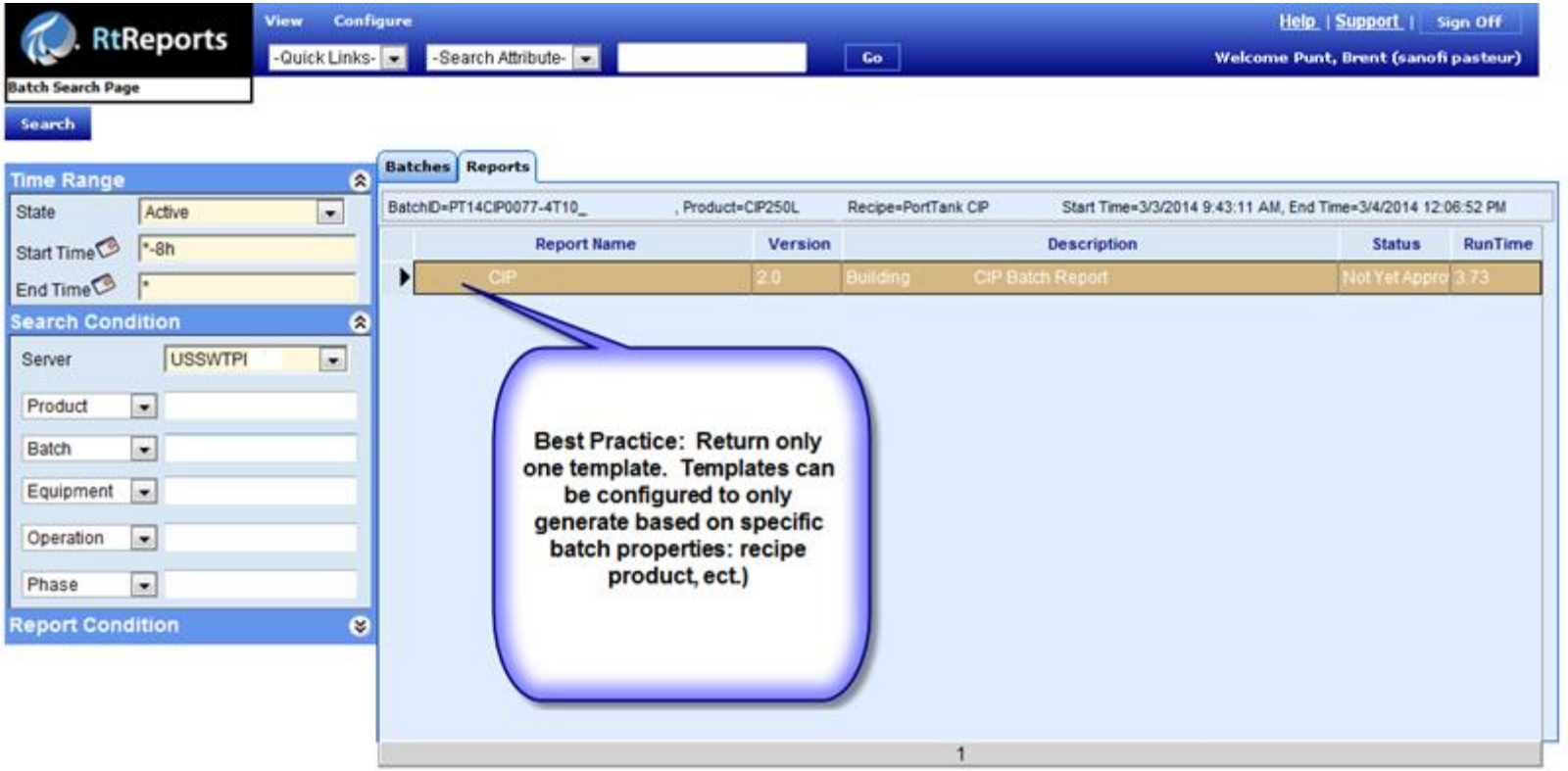
© Copyright 2014 OSIsoft, LLC.

Default Batch Search Page



© Copyright 2014 OSIsoft, LLC.

Report Template Selection



© Copyright 2014 OSIsoft, LLC.

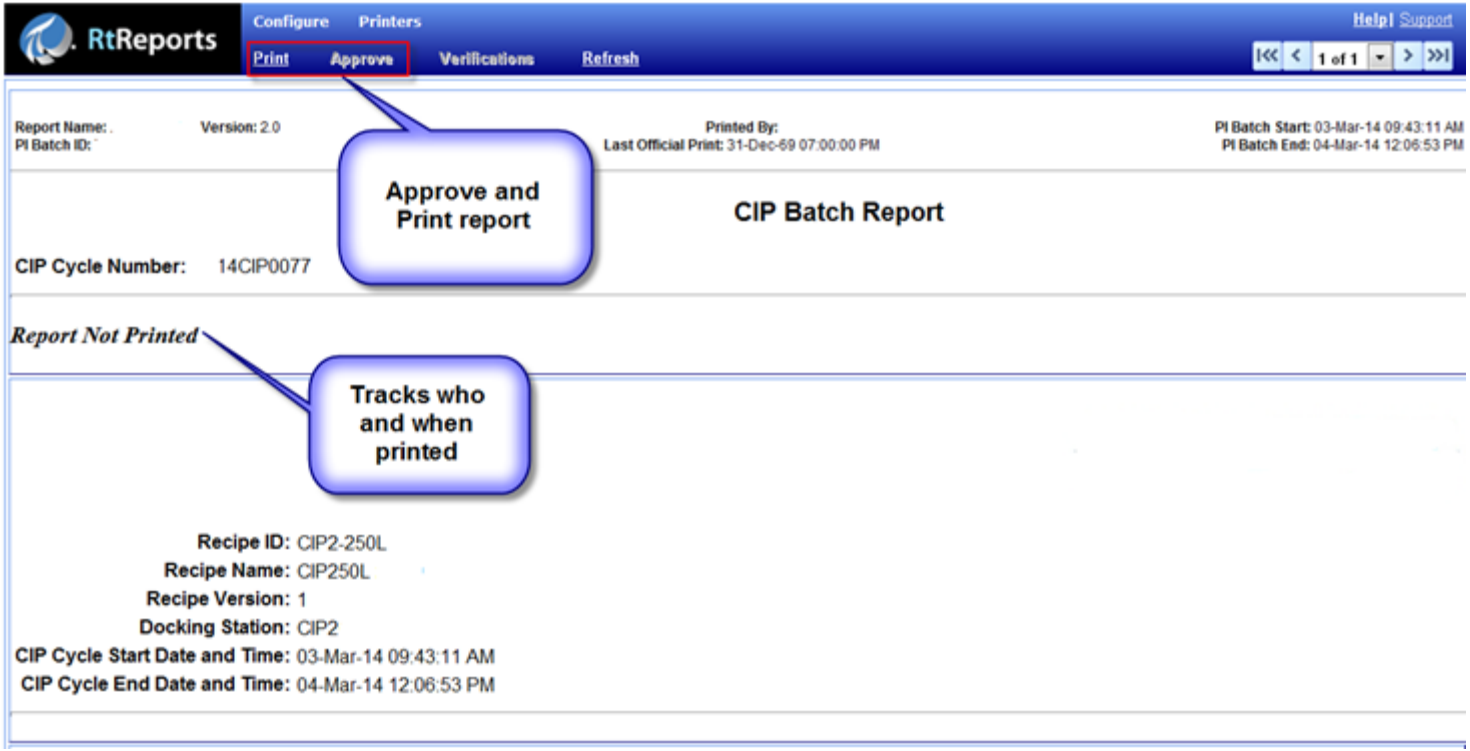
Generation Screen

BufferPrep

Running time is approximately 8.41 seconds....

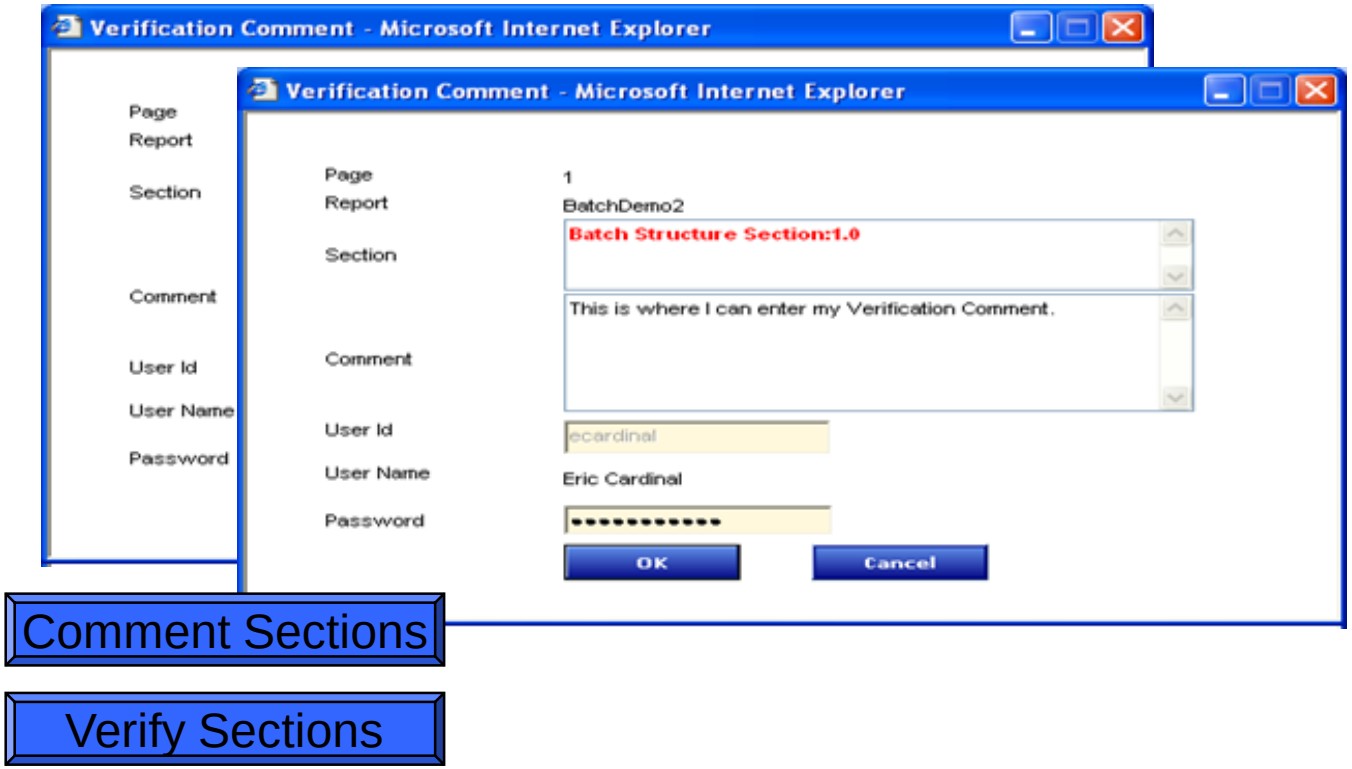
© Copyright 2014 OSIsoft, LLC.

RtReport Review Screen



© Copyright 2014 OSIsoft, LLC.

Adding Comments / Section Verification

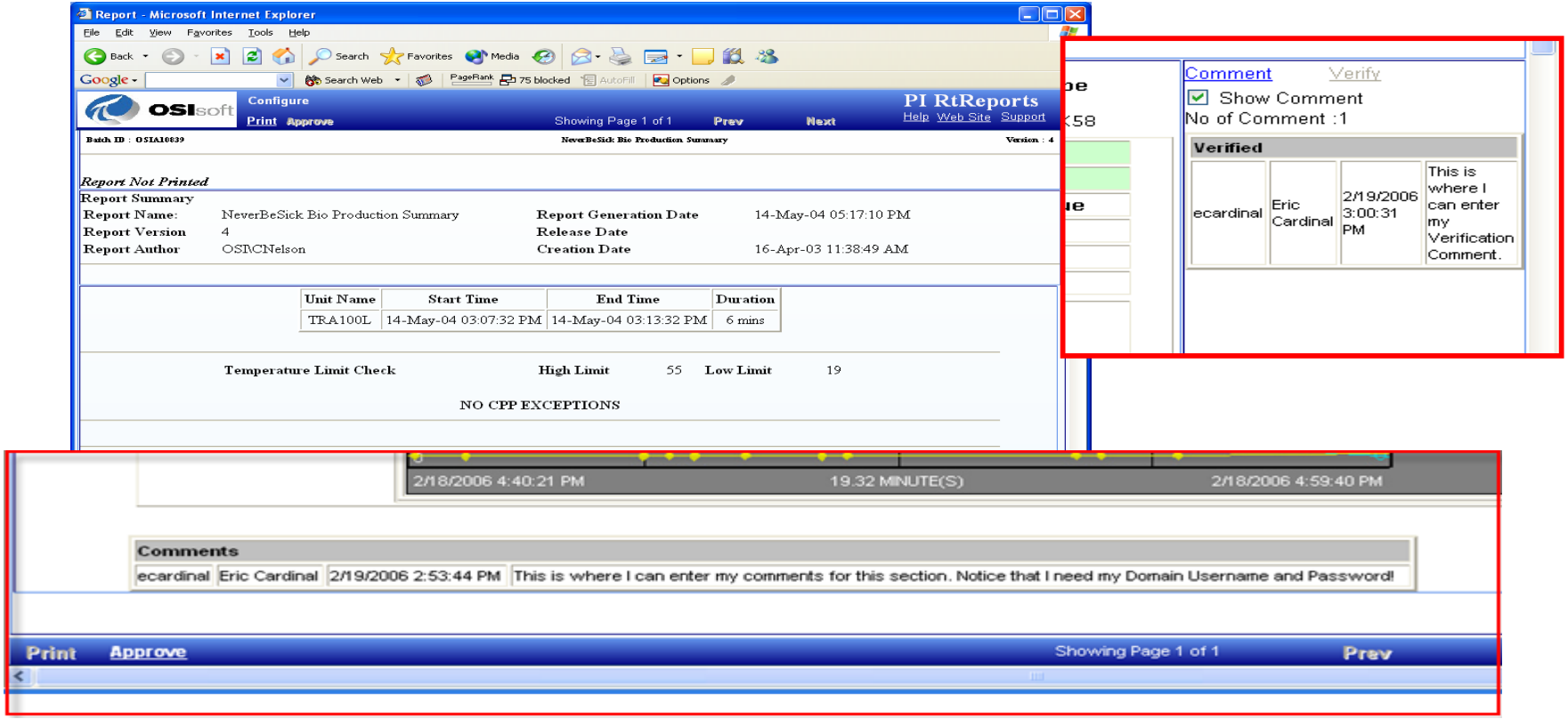


Username and password are always needed to enter comments

- Security Groups Set who can perform actions

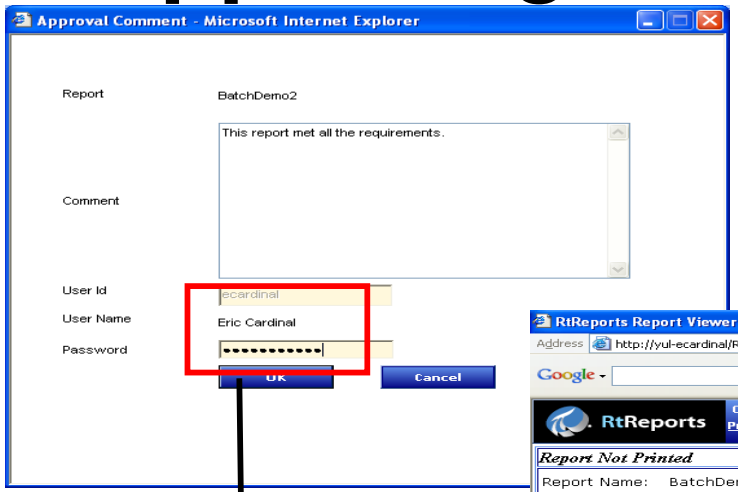
© Copyright 2014 OSIsoft, LLC.

Report Example with Comments



© Copyright 2014 OSIsoft, LLC.

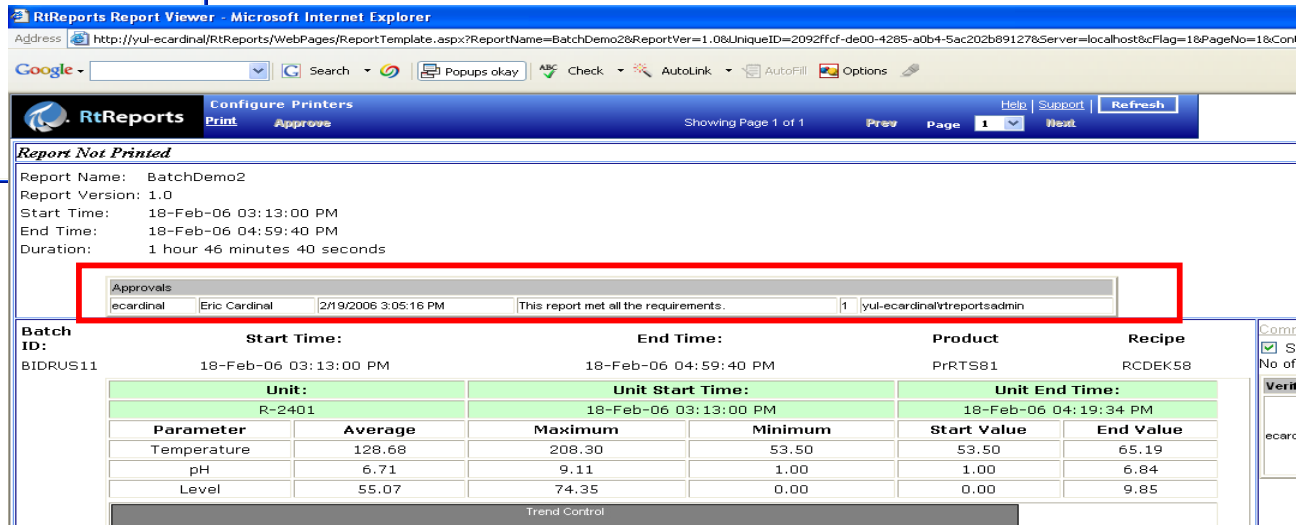
Approving a RtReport



Company Guidelines require meaning of signature. Not available in RtReports. A Procedural Control must be used.

Users must add meaning to the comment field.

Username and password Required



Approve Report

© Copyright 2014 OSIsoft, LLC.

Printing

- Draft Print
  - Using a list of printers
  - No watermark – not tracked
- Official Print
  - One and Only One Printer
  - Official Watermark
  - Tracked in system

Print

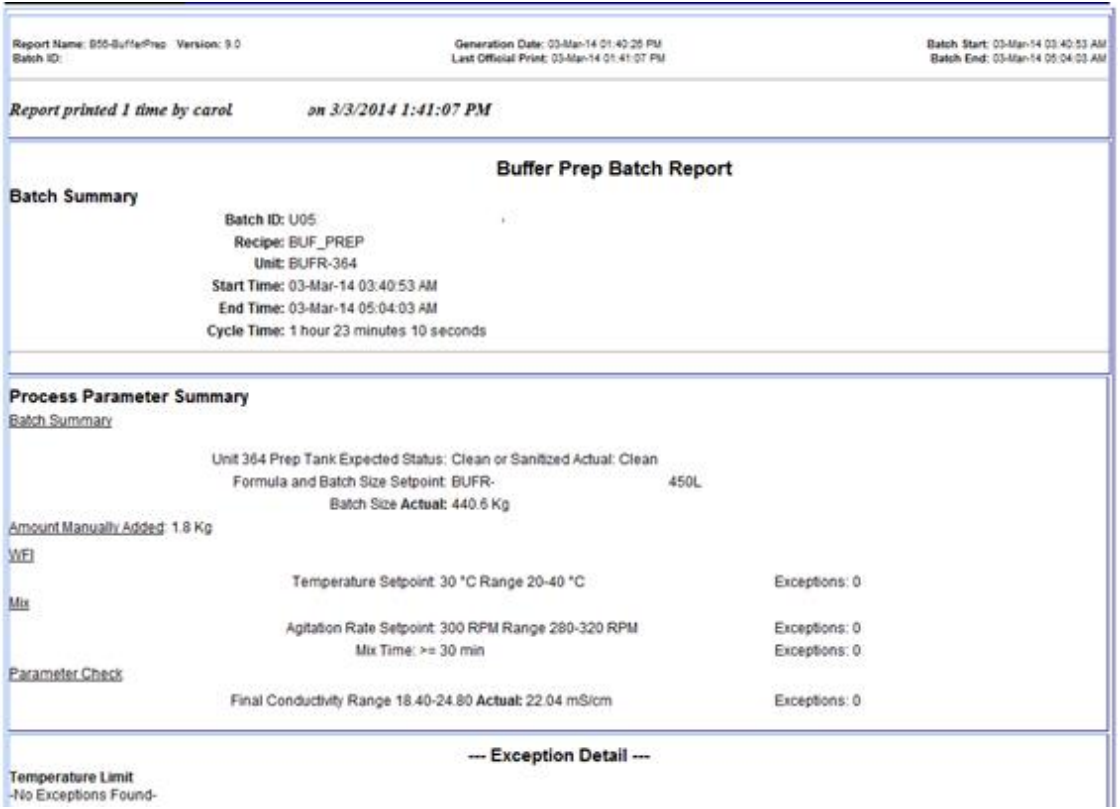
© Copyright 2014 OSIsoft, LLC.

How we use RtReports

- RtReports used for Real Time Batch Release of CIP, SIP, Media and Buffer
  - Zero Downtime is Expected
- Process RtReports printed and attached to paper batch record packet
  - CIP/ SIP not printed – verified on glass
- The following slides shows examples of RtReports used in production:

© Copyright 2014 OSIsoft, LLC.

Exception based report example



Report Name: B55-BufferPrep Version: 9.0
Batch ID:

Generation Date: 03-Mar-14 01:40:26 PM
Last Official Print: 03-Mar-14 01:41:07 PM

Batch Start: 03-Mar-14 03:40:53 AM
Batch End: 03-Mar-14 05:04:03 AM

Report printed 1 time by carol on 3/3/2014 1:41:07 PM

Buffer Prep Batch Report

Batch Summary

Batch ID: U05
Recipe: BUF_PREP
Unit: BUFR-364
Start Time: 03-Mar-14 03:40:53 AM
End Time: 03-Mar-14 05:04:03 AM
Cycle Time: 1 hour 23 minutes 10 seconds

Process Parameter Summary

Batch Summary

Unit 364 Prep Tank Expected Status: Clean or Sanitized Actual: Clean
Formula and Batch Size Setpoint: BUFR- 450L
Batch Size **Actual:** 440.6 Kg

Amount Manually Added: 1.8 Kg

WFI

Temperature Setpoint: 30 °C Range 20-40 °C — Exceptions: 0

Mix

Agitation Rate Setpoint: 300 RPM Range 280-320 RPM — Exceptions: 0
Mix Time: >= 30 min — Exceptions: 0

Parameter Check

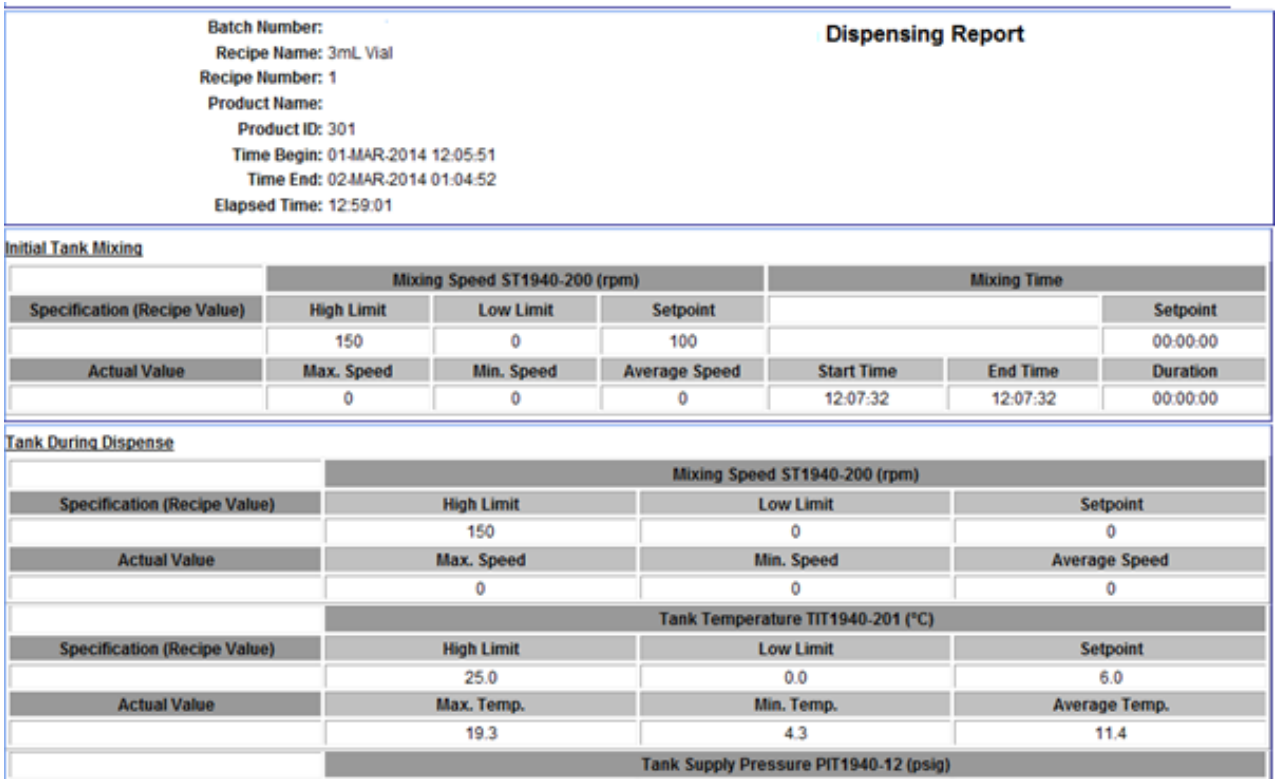
Final Conductivity Range 18.40-24.80 **Actual:** 22.04 mS/cm — Exceptions: 0

--- Exception Detail ---

Temperature Limit
-No Exceptions Found-

© Copyright 2014 OSIsoft, LLC.

Batch Summary Report example



Batch Number:
Recipe Name: 3mL Vial
Recipe Number: 1
Product Name:
Product ID: 301
Time Begin: 01-MAR-2014 12:05:51
Time End: 02-MAR-2014 01:04:52
Elapsed Time: 12:59:01

Dispensing Report

Initial Tank Mixing

	Mixing Speed ST1940-200 (rpm)			Mixing Time		
Specification (Recipe Value)	High Limit	Low Limit	Setpoint			Setpoint
	150	0	100			00:00:00
Actual Value	Max. Speed	Min. Speed	Average Speed	Start Time	End Time	Duration
	0	0	0	12:07:32	12:07:32	00:00:00

Tank During Dispense

	Mixing Speed ST1940-200 (rpm)		
Specification (Recipe Value)	High Limit	Low Limit	Setpoint
	150	0	0
Actual Value	Max. Speed	Min. Speed	Average Speed
	0	0	0
	Tank Temperature TIT1940-201 (°C)		
Specification (Recipe Value)	High Limit	Low Limit	Setpoint
	25.0	0.0	6.0
Actual Value	Max. Temp.	Min. Temp.	Average Temp.
	19.3	4.3	11.4
	Tank Supply Pressure PIT1940-12 (psig)		

© Copyright 2014 OSIsoft, LLC.

Daily Utility Release Report example

Time Summary

Building Daily WFI Release Report

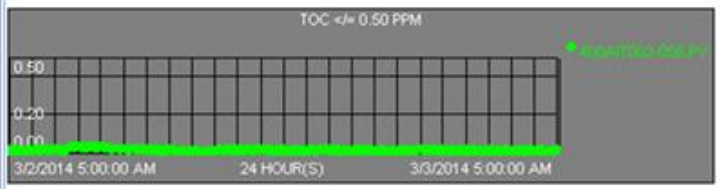
Start Time: 02-Mar-14 05:00:00 AM
End Time: 03-Mar-14 05:00:00 AM
Duration Time: 1 day

Conditional formatting reduces review time

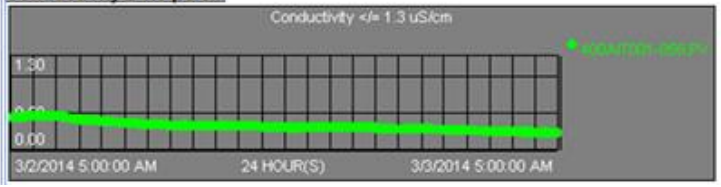
Trend Results

	Loop TOC	Conductivity
Alert Range:	≤ 0.10 PPM	≤ 0.3 µS/CM
Action Range:	≤ 0.50 PPM	≤ 1.3 µS/CM
Actual Max:	0.03 PPM	0.5 µS/CM
Result:	Pass	ALERT

TOC ≤ 0.50 PPM



Conductivity ≤ 1.3 µS/cm



© Copyright 2014 OSIsoft, LLC.

PI Server and RtReports Value Added

- Reduction in operator time: no manual data recorded
- Real Time Reporting reduces overall
  - Batch Cycle Time
  - Batch Release Time
- Exception based reporting
  - Largest reduction of Batch Release Time
- Utility reports reduces physical water samples req'd

© Copyright 2014 OSIsoft, LLC.

How Important is RtReports to our Business?

- RtReports in use since December 2008
- Using current Version 3.3.0.6
- 84 versions on 24 Templates
- ~11,000 PI Batches generated in 2013
  > 70% Batches require RtReports
- Used to release > $1 Billion in revenue

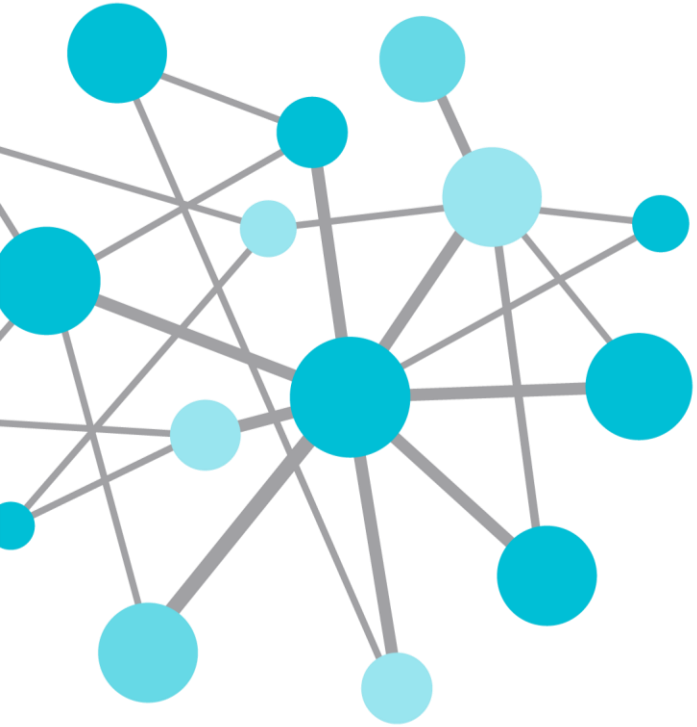
PI Server and RtReports are Integral and Essential to our Business

© Copyright 2014 OSIsoft, LLC.

Brent Punt

- Brent.punt@sanofi.com
- Information Solutions Swiftwater Industrial Site Head
- Sanofi Pastuer Swiftwater Site, Swiftwater, PA

© Copyright 2014 OSIsoft, LLC.



THANK YOU

Brought to you by OSIsoft.

© Copyright 2014 OSIsoft, LLC.