



# **Demonstrating Compliance: Meeting Reporting Challenges**

**Tony Fenn - OSISOFT**

# What we have found working with you on Compliance Reporting:

1. Customer Reporting Challenges
2. An Infrastructure for Compliance
3. Requirements specific to reports
4. Use of our reporting product
5. A Recommended Project Approach

VALUE NOW, VALUE OVER TIME



# Customer Challenges

- All of our customers are all facing some requirement for reporting
  - Production reports, quality, environmental, etc.
- Data must be pulled together from many sources:
  - Multiple PI Servers across the Enterprise
  - External relational databases
  - Web services

VALUE NOW, VALUE OVER TIME



# Regulated Manufacturers Face More Challenges

- Compliance is a high level corporate imperative
- Now corporations must be both profitable and accountable
- Companies today may have to comply with multiple regulations or requirements (EPA Title V, FDA 21 CFR Part 11, Sarbanes Oxley, NERC 1300, HACCP)

Visibility and a single version of the truth  
are required to demonstrate compliance

**VALUE NOW, VALUE OVER TIME**



# Common Requirements for Regulated Industries

- Data integrity and trusted data are fundamental
- Security and privacy are key constructs
- Archiving for a retention period is expected
- Documentation and reporting considerations are paramount
- Most areas require sophisticated analytical capabilities
- Virtually all compliance mandates are driven by rules, policies and procedures--internally generated or formally dictated

VALUE NOW, VALUE OVER TIME



# The Bottom Line:

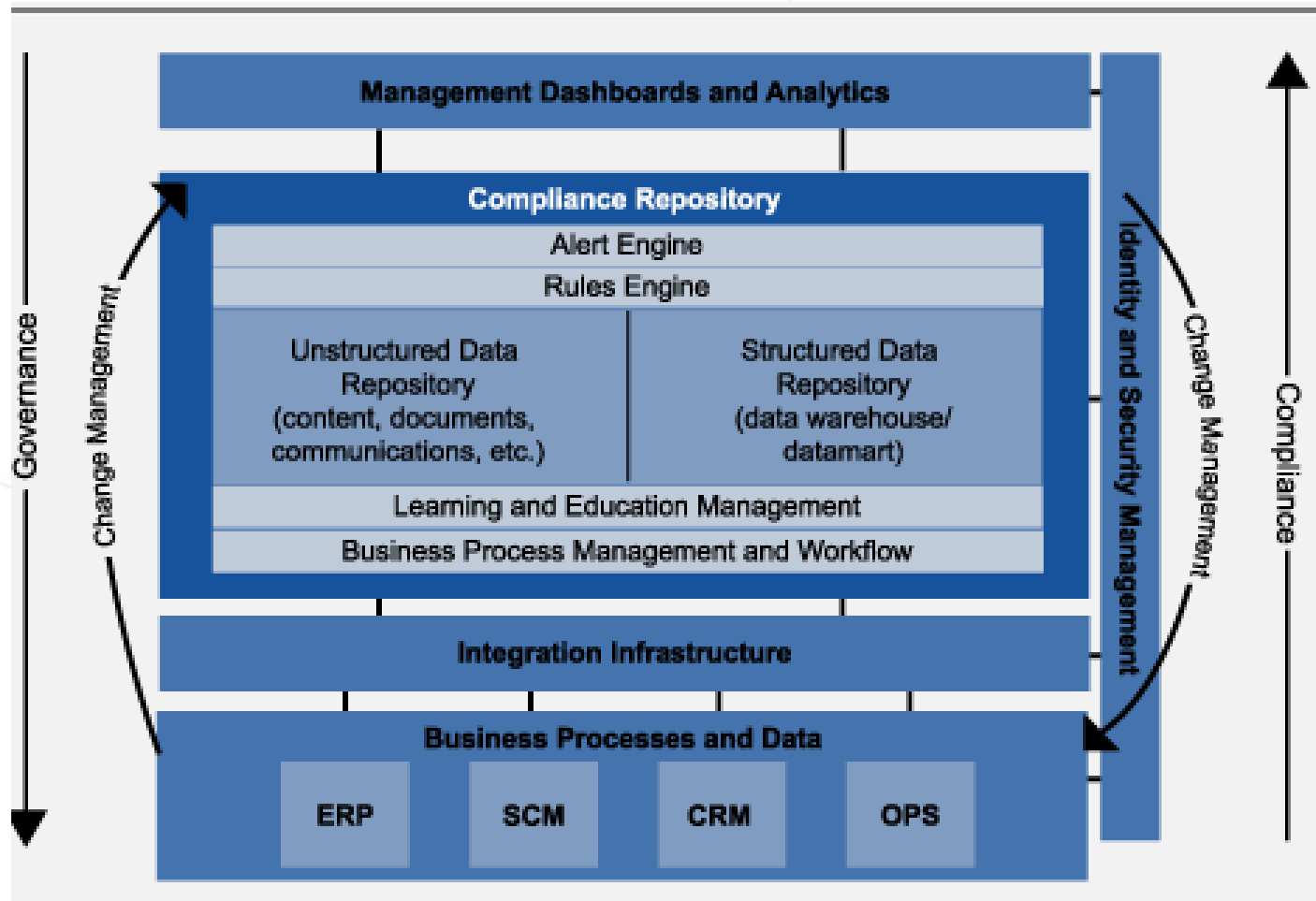
*As business and IT recognize the overlapping requirements of individual compliance mandates, leaders are taking steps to build out a sustainable architecture that minimizes time and cost while maximizing future reuse.*

John Hagerty, AMR Research Staff

VALUE NOW, VALUE OVER TIME



# Active Compliance Architecture



Source: AMR Research 2004

VALUE NOW, VALUE OVER TIME





# RtPM – A Corporate Infrastructure for Compliance

PERFORMANCE  
IMPROVEMENT

OPERATIONAL  
VISIBILITY

KNOWLEDGE  
MANAGEMENT

PRODUCT  
QUALITY

LEAN  
MANUFACTURING

ASSET  
MANAGEMENT

SITUATIONAL  
AWARENESS

**RtPortal**

GREATER VISIBILITY INTO GLOBAL  
OPERATIONS IN A COMPLIANCE CONTEXT

**RtAnalytics**

OPPORTUNITY TO BUILD REUSABLE  
COMPLIANCE BUSINESS RULES

**RtBaseline**

A SINGLE VERSION OF THE TRUTH WHICH ALLOWS  
DATA TO RESIDE WHERE IT MAKES SENSE

PRODUCT  
SPECIFICATION  
DATA

REAL-TIME  
DATA

CUSTOM  
DATA

IT DATA

RELATIONAL  
DATA

WEB  
SERVICES

ERP  
MAINTENANCE

VALUE NOW, VALUE OVER TIME





# PI Server Changes tracked by the Audit Trail

The Audit Trail is one of the key features which ensures that the core server is compliant

## PI Audit Viewer

The screenshot displays the PI Audit Viewer application window. At the top, a yellow status bar indicates "1 AuditRecord(s) found and 1 Displayed". Below this, a navigation bar contains three tabs: "Results Grid" (selected), "Filters", and "Help". The main content area shows a table with the following data:

Category	PI Database	DB RecordName	Audit Action	Action Time	PI UserName
PIConfigurationD	PIPoints	Lab Test Value	Edit	2003-06-05 15:2	piadmin

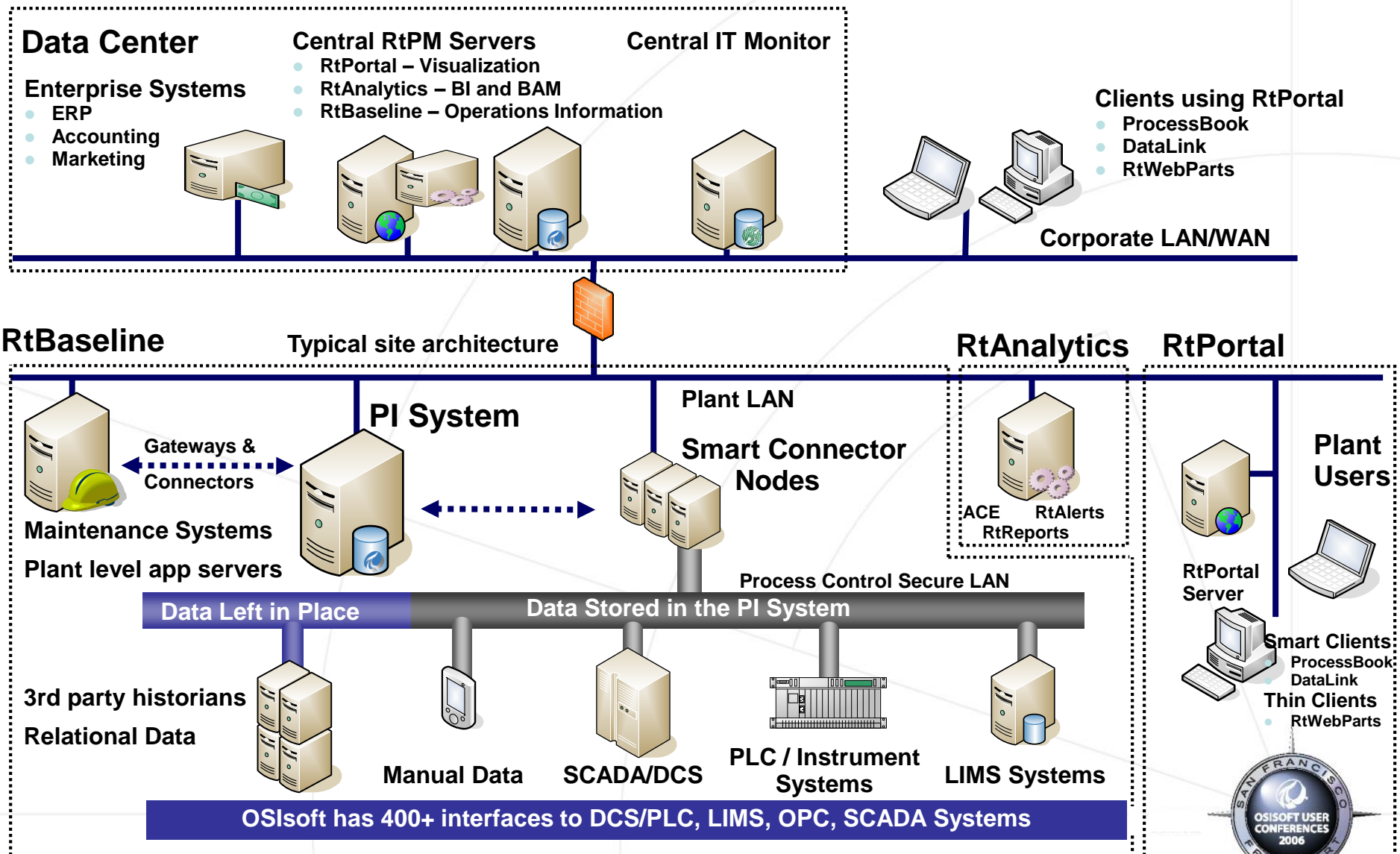
Below the main table, there is a detailed view of the configuration item changes:

Item	Before Data	Before Type	After Data	After Type
changedate	2003-04-10 10:2	xs:dateTime	2003-06-05 15:2	xs:dateTime
descriptor	Quality Lab Test f	xs:string	Quality Lab Testin	xs:string

VALUE NOW, VALUE OVER TIME



# Detailed Enterprise Compliance Architecture



# Compliance Reporting Requirements

Microsoft Excel is arguably the most widely used reporting tool used by our customers

- Excel has long been the host environment for PI DataLink
- Together they are excellent for Adhoc reporting

*but*

- These type of reports tend to have complex macros behind making them difficult to support
- It is hard to pass a 'Compliance Integrity Test'

VALUE NOW, VALUE OVER TIME

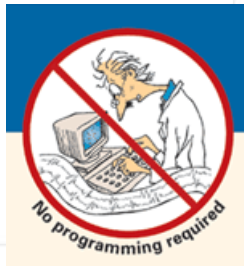


# Compliance Reporting Requirements

1. A Compliance Reporting System should provide the means to produce secure, version-controlled reports.



2. Reports should be built by configuration with no programming, driven by a set of rules that are an integral part of the compliance strategy.



VALUE NOW, VALUE OVER TIME



# Compliance Reporting Requirements

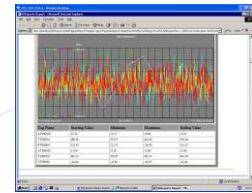
3. Templates should be used for repeatable reports and data retrieval
  - Templates house compliance business rules (Actions)
  - Templates are a collection of queries built from the rules
  - Templates also contain the style and formatting
  - Templates should be versioned like pieces of equipment
  - Templates should be stored and backed up on a server together with all the process data

VALUE NOW, VALUE OVER TIME



# Compliance Reporting Requirements

4. Basic actions or rules will support many simple reports – for example - list values, draw trends, find max, min, average, total, stdev.
5. But rules and actions must be user-extensible to create more complex company specific report queries.



VALUE NOW, VALUE OVER TIME





*For any batch of 'Never Be Sick' drug that ran in the blue mixing vessel last year:*

***Check if the vessel temperature exceeded QC high limits, but only in the 3rd iteration of the agitation operation, but not if the vessel was in testing, or in maintenance...***

***If it did then report when it went back below limit and calculate max, min and average temperature and trend the pressure and pH starting 10 mins before***

***If it did not then report 'No Exception'***

VALUE NOW, VALUE OVER TIME





# Standards for Style and Formatting Rules

**VALUE NOW, VALUE OVER TIME**



# Standards for Style and Formatting Rules

## Cover Page

Report Name,  
Version, Context Summary



**OSI**soft

Batch Summary Report

Revision: 1.0

Batch ID: BID04251C

Production Order: BIDRTS95

Batch Start:

Batch End:

July 21, 2004 06:14:23

July 21, 2004 06:53:12

**VALUE NOW, VALUE OVER TIME**



# Standards for Style and Formatting Rules

## Cover Page

Report Name,  
Version, Context Summary



**OSI**soft

Batch Summary Report

Revision: 1.0

Batch ID: BID04251C

Production Order: BIDRTS95

Batch Start:

Batch End:

July 21, 2004 06:14:23

July 21, 2004 06:53:12

## Page Header

Production Order Number: BIDRTS95

Batch Summary Report

Report Version: 1.0

**VALUE NOW, VALUE OVER TIME**



# Standards for Style and Formatting Rules

## Cover Page

Report Name,  
Version, Context Summary



Batch Summary Report

Revision: 1.0

Batch ID: BID04251C

Production Order: BIDRTS95

Batch Start:

July 21, 2004 06:14:23

Batch End:

July 21, 2004 06:53:12

## Page Header

Production Order Number: BIDRTS95

Batch Summary Report

Report Version : 1.0

## Report Header

Report Name,  
Version, Release Date,  
Author, Generation Date,  
Print History

### Report Summary

Report Name: Example Production Summary Report

Report Generation Date 06-Jul-05  
03:21:00 PM

Report Version 1.0

Release Date 31-Dec-69  
07:00:00 PM

Report Author OSINTFenn

Creation Date 06-Jul-05  
02:57:21 PM

Disclaimer: This report has been printed for  
informational purposes only.

### Batch Summary

Production Order Number:  
BIDRTS95

Procedure Start Time :	12-Apr-05 01:16:50 AM	Procedure End Time :	12-Apr-05 02:41:52 AM	Duration :	1 hour 25 minutes 2 seconds
------------------------	--------------------------	----------------------	--------------------------	------------	-----------------------------------

Recipe Name: RCSPB85

Product Name: PrDEK72

# Standards for Style and Formatting Rules

## Details Sections:

- Timed Values
- Limit violations
- Ramp rate violations
- Tables of data values
- Statistics
- Expression results
- Etc.....

## Page Footer

Report Author

OSTCNelson

Creation Date

28-Jun-05 03:47:20 PM

Weekly Compliance Summary

Weekday	Thermal Oxidizer Oxygen	Thermal Oxidizer Exit Gas	Air Scrubber pH	Air Scrubber Flow Rate	Heat Exchanger	Glycol Temperature
Sunday	3	3	3	3	3	3
Monday	1	1	1	1	1	1
Tuesday	5	5	5	5	5	5
Wednesday	3	3	3	3	3	3
Thursday	1	1	1	1	1	1
Friday	5	5	5	5	5	5
Saturday	7	7	7	7	7	7

Sunday Daily Compliance Details

Path	Start Time	End Time	Duration	Status
Sunday	10-Jul-2005 00:00:00	11-Jul-2005 00:00:00	1 day	Completed

Batch End: July 21, 2004 6:53:12

page 4 of 13

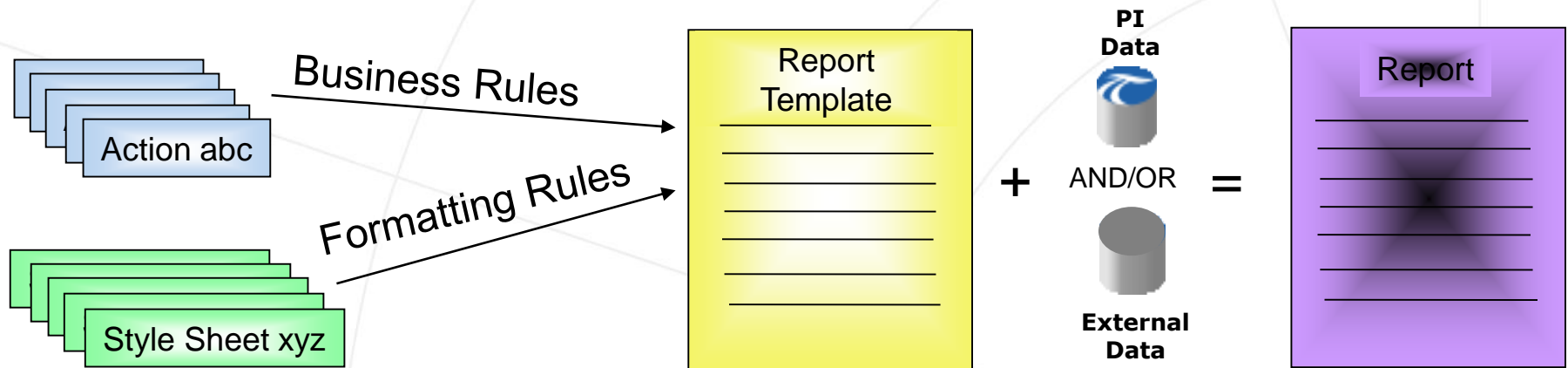
Section Comments and Approvals

VALUE NOW, VALUE OVER TIME



# Action and Style Sheet Libraries

- Report standardization is promoted through
  - A library of pre-defined actions (business rules)
  - A library of style sheets (formatting rules)
- Objects in both libraries should be imported and exported for rapid report building



*Modular Report Building Is Achieved Through A Standard Library of Business and Formatting Rules*



# Compliant Report Generation Summary

- Reports should be generated against a pre-defined report template that is version-controlled.
- Then they will accurately reflect the state of the operation at the time the data was stored.
- Reports cannot permit modification after they have been generated.
- ESig comments and approvals should remain with the electronic document record.

VALUE NOW, VALUE OVER TIME





# OSIsoft's product RtReports was developed with our regulatory customers

- An enterprise, web-based reporting application
  - Report standardization results in repeatable reports managed with configuration, not programming
- A comprehensive reporting tool
  - Specify the format, content and management of reports

VALUE NOW, VALUE OVER TIME



# OSIsoft's — RtReports

- Provides the flexibility to create reports based on:
  - Time frame
  - Batches
  - Analysis Framework cases
- Integrates internal and external data sources
  - Relational and web services data

VALUE NOW, VALUE OVER TIME



## Report

## Data Template

## Data Template

- Unit St
- Total S
- GetEm
- Exit Ga
- Pa
- High
- Low
- Ve
- Ve
- Ve
- Ve
- Ch
- Ch
- Ch
- Op
- Ex
- Op
- Ex

## Hourly Average Readings and Excursion Values

No of Excursions: 7

	Temperature Reactor 2401	pH Reactor 2401	Temperature Reactor 2401		pH Reactor 2401	
	TT2401	AT2401	High Limit		Low Limit	
Time	Deg F	pH	45	20	4	1
02/11/2005 00:00	50.00	1.00	56.80		---	
02/11/2005 00:59	50.00	1.00	---		---	
02/11/2005 01:59	50.00	1.00	---		---	
02/11/2005 02:59	50.00	1.00	---		---	
02/11/2005 03:59	50.00	1.00	---		---	
02/11/2005 04:59	50.00	1.00	---		---	
02/11/2005 05:59	50.00	1.00	---		---	
02/11/2005 06:59	50.00	1.00	---		---	
02/11/2005 07:59	50.00	1.00	---		---	
02/11/2005 08:59	50.00	1.00	---		---	
02/11/2005 09:59	50.00	1.00	---		---	
02/11/2005 10:59	50.00	1.00	---		---	
02/11/2005 11:59	50.00	1.00	51.83		---	
02/11/2005 12:59	50.00	1.00	47.52		---	
02/11/2005 13:59	50.00	1.00	53.91		---	
02/11/2005 14:59	50.00	1.00	56.87		---	
02/11/2005 15:59	50.00	1.00	48.29		---	
02/11/2005 16:59	50.00	1.00	---		---	
02/11/2005 17:59	50.00	1.00	---		---	
02/11/2005 18:59	50.00	1.00	---		---	
02/11/2005 19:59	50.00	1.00	---		---	
02/11/2005 20:59	50.00	1.00	---		---	
02/11/2005 21:59	50.00	1.00	---		---	

Report Contents

Ready

Vess3Hold Literal 1 Yes Yes

# Weekly Title V Compliance Report

- Generated Report

192.168.224.6 - Remote Desktop

RtReports Report - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address http://localhost/RtReports/WebPages/ReportTemplate.aspx?ReportName=Example%20Weekly%20Report%20%20&ReportVer=1.0&Server=rtdevpserver&StartC

RtReports Printers Print Showing Page 1 of 1 Prev Next Help Support

Report Start Date : 10-Jul-05 12:00:00 AM Example Weekly Report Version : 1.0

Report Not Printed

Weekly Report for Sunday, July 10, 2005

Report Start Time 10-July-2005 12:00:00 AM Report End Time 17-July-2005 12:00:00 AM Completed ---

Report Name: Example Weekly Report Report Generation Date 20-Jul-05 12:33:08 PM  
Report Version 1.0 Release Date 31-Dec-69 07:00:00 PM  
Report Author OSINCNelson Creation Date 28-Jun-05 03:47:20 PM

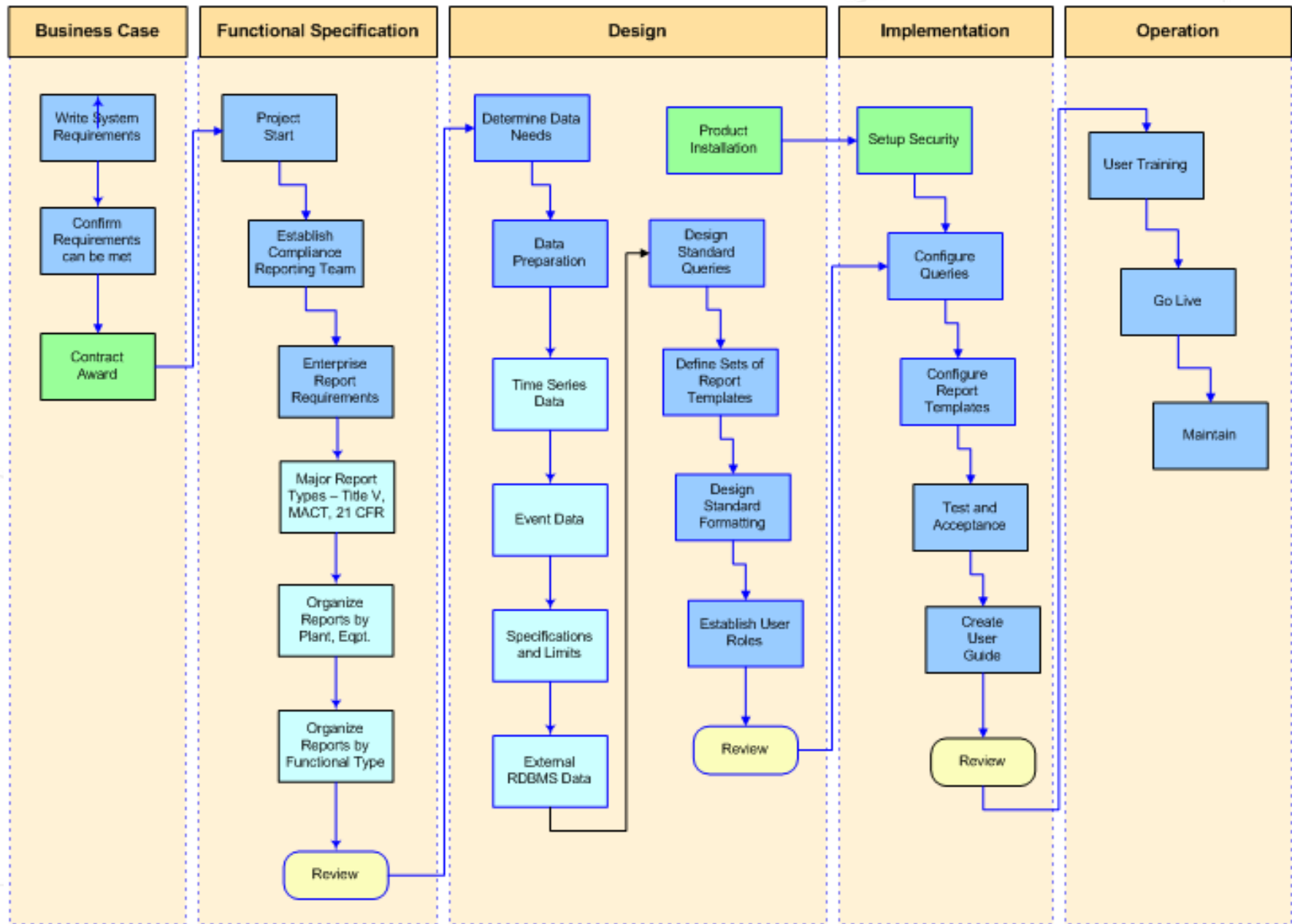
### Weekly Compliance Summary

Weekday	Thermal Oxidizer Oxygen	Thermal Oxidizer Exit Gas	Air Scrubber pH	Air Scrubber Flow Rate	Heat Exchanger	Glycol Temperature
Sunday	3	3	3	3	3	3
Monday	1	1	1	1	1	1
Tuesday	5	5	5	5	5	5
Wednesday	3	3	3	3	3	3
Thursday	1	1	1	1	1	1
Friday	1	1	1	1	1	1

Done Local intranet

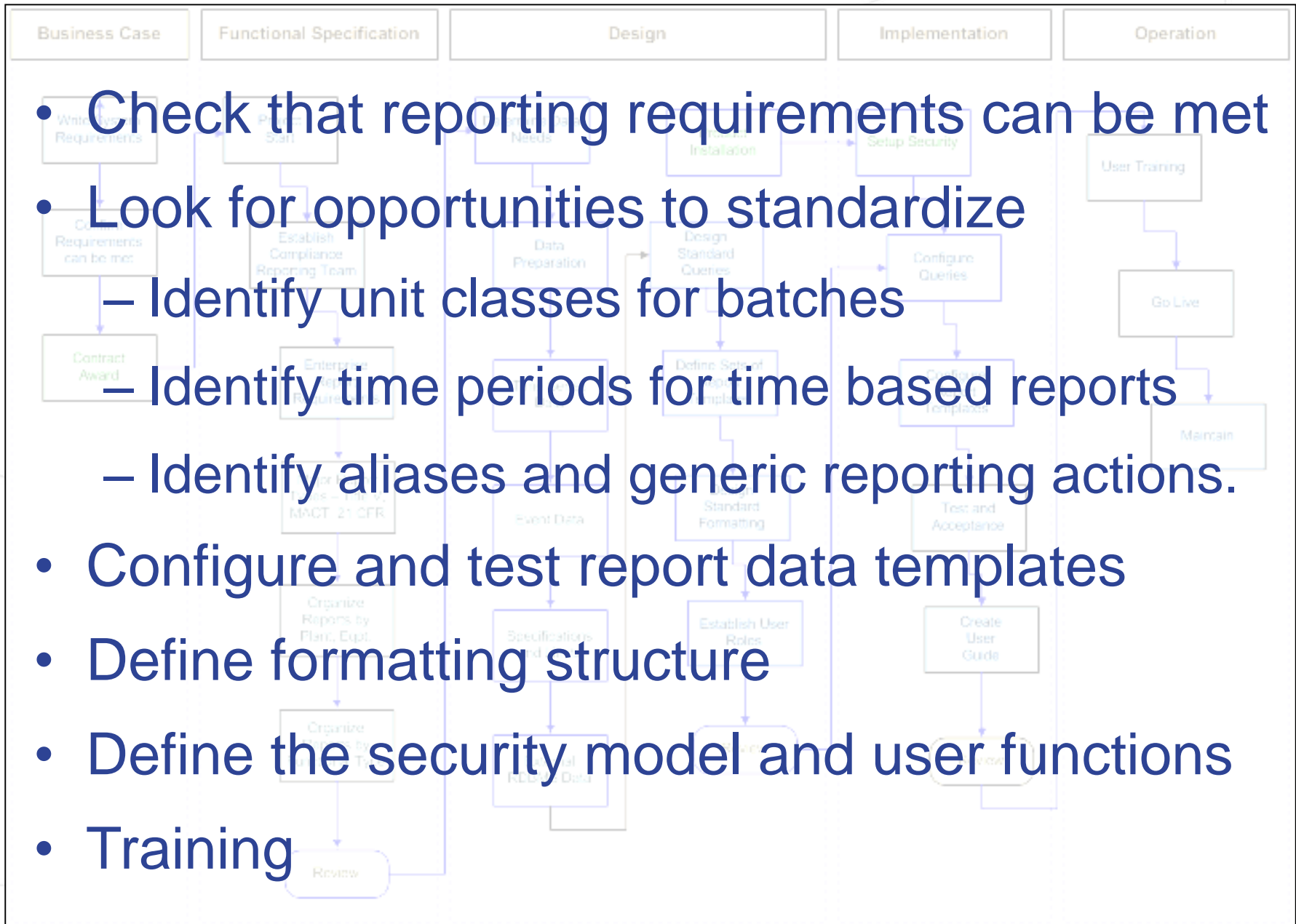
Start RtReports Report Search ... RtReports Editor RtReports Report - Mi... 12.46

# Planning for Compliant Reporting



# Planning for Compliant Reporting

- Check that reporting requirements can be met
- Look for opportunities to standardize
  - Identify unit classes for batches
  - Identify time periods for time based reports
  - Identify aliases and generic reporting actions.
- Configure and test report data templates
- Define formatting structure
- Define the security model and user functions
- Training



# Case Study: Confidential Customer

- **Goals**

- To generate real time reports for managing the utilities services for an extensive site which spans many buildings.
- A configurable product is needed which will allow for time based (hourly, daily, weekly, monthly, quarterly, yearly etc....) reports.

VALUE NOW, VALUE OVER TIME





# Case Study: Confidential Customer

- **Implementation**

- Data comes from many automation systems
  - MCS and BMS. Utilities include clean water, clean steam, glycol, N, O2, CO2, and process air.
- OSIsoft team designed 4 pre-defined actions and 1 general formatting stylesheet
  - Could be applied across over 70 reports.
- The initial installation and set of reports was completed in 3 days

VALUE NOW, VALUE OVER TIME



# Case Study: Confidential Customer

- **Implementation (cont)**
  - OSIsoft remotely refined reports and actions
  - A local integrator was trained on site by OSIsoft

*RtReports successfully adopted by operators and supervisors as a replacement for paper based systems*

VALUE NOW, VALUE OVER TIME



# Standardized Reporting Benefits

- **Improve employee efficiency**
  - Reports built and regenerated without programming
  - Library of processing rules and formatting rules allow for rapid report generation
- **Enhance knowledge management and collaboration**
  - Reports available on-demand, via the Web
- **Reduce variability in reporting**
  - Information workers retrieve information from the same source
  - Generate tamper-proof reports
- **Improve manufacturing agility**
  - Accelerate product release through automatic comparison with specification data and generation of C of A
  - Automate environmental reports

VALUE NOW, VALUE OVER TIME

