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

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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

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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

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Common Requirements for Regulated Industries

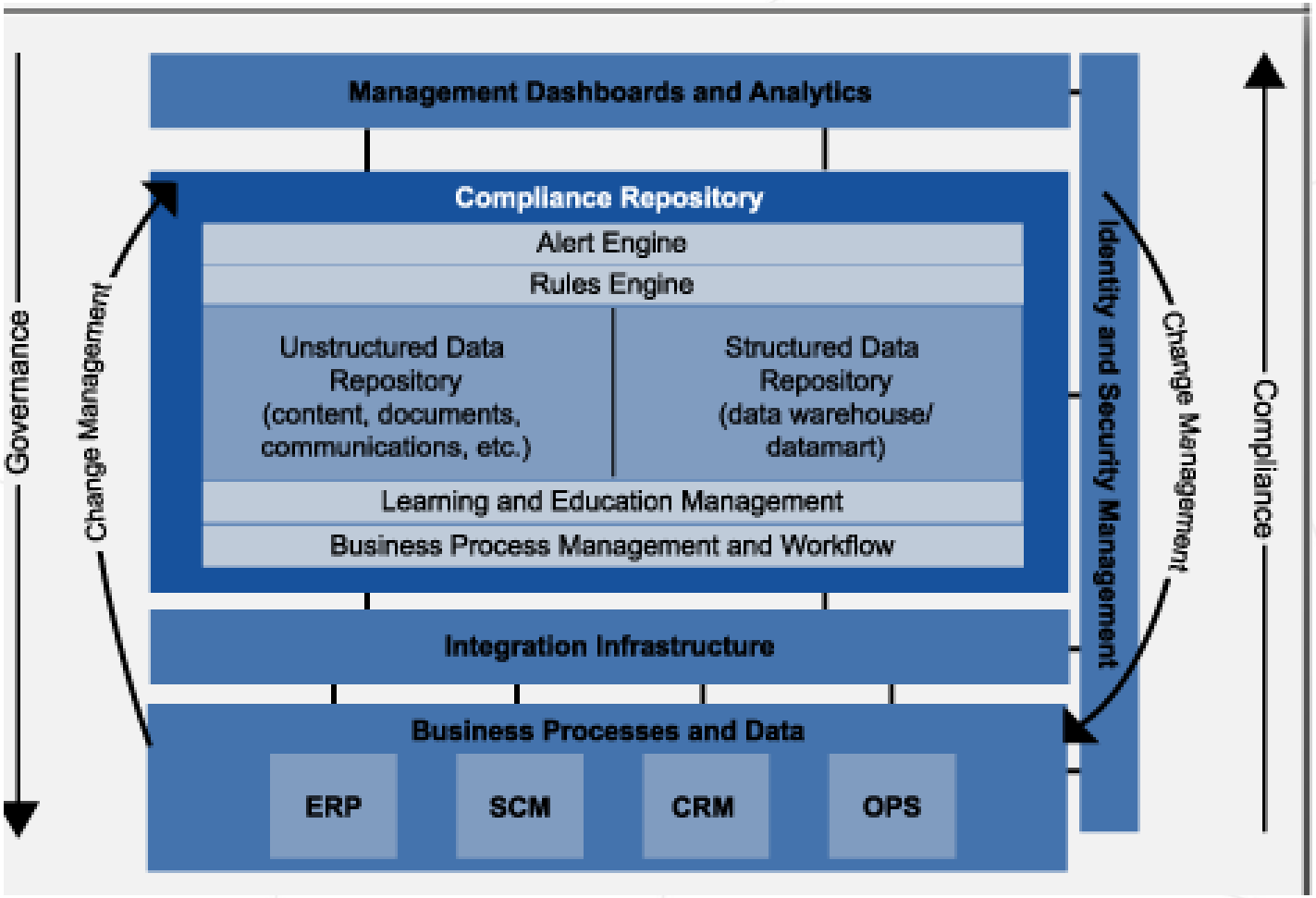
- Data integrity and trusted data are fundamental
- Security and privacy are key constructs
- Archiving for a retention period is expected
- Documentation and reporting considerations are paramount
- Most areas require sophisticated analytical capabilities
- Virtually all compliance mandates are driven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

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

Active Compliance Architecture



Source: AMR Research 2004

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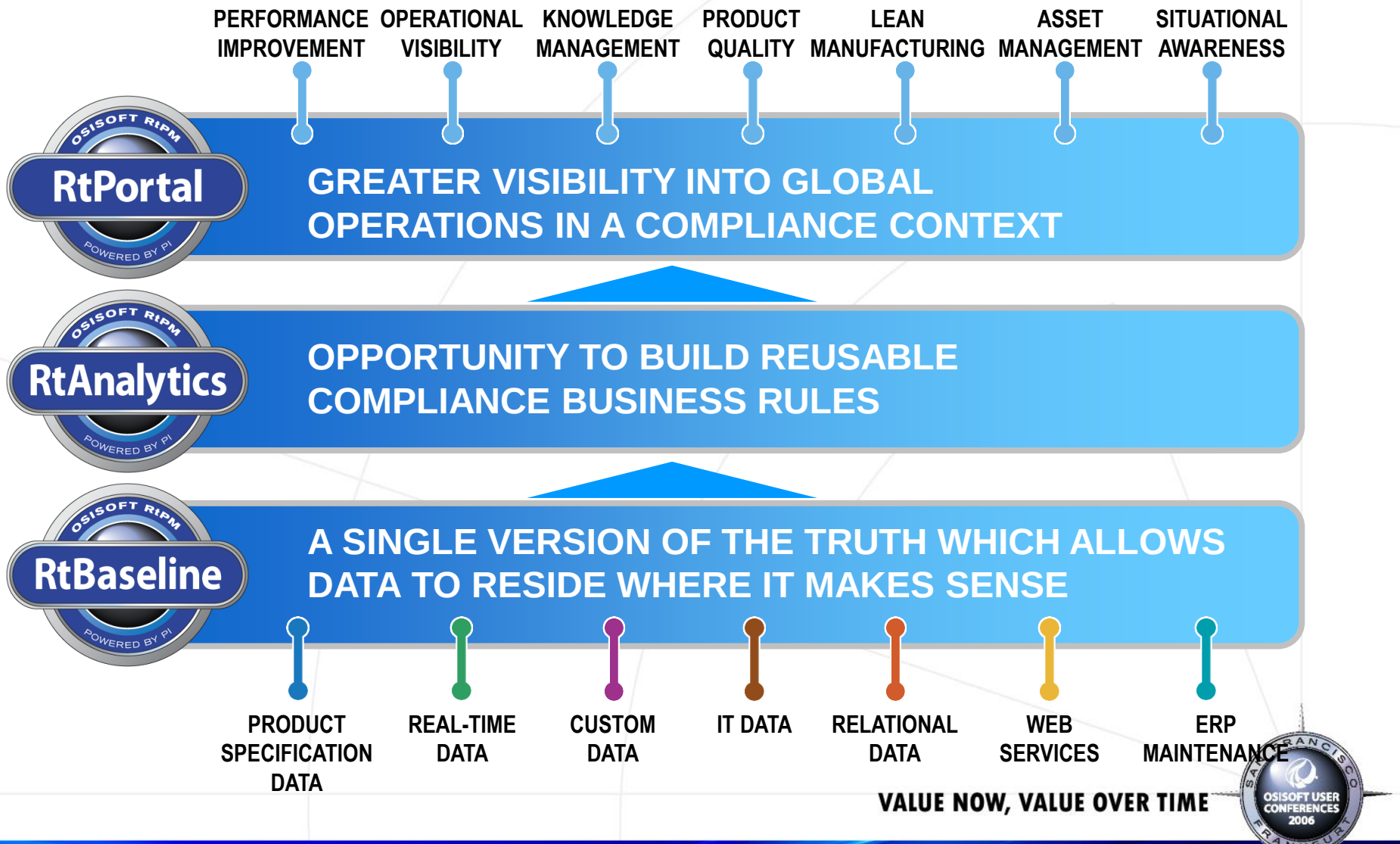
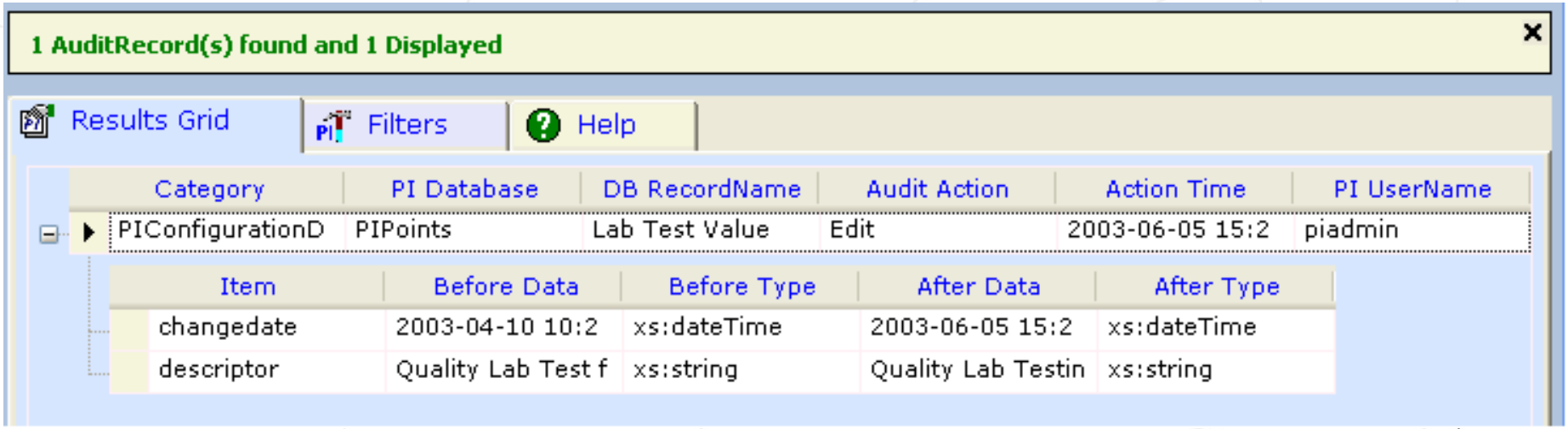
RtPM – A Corporate Infrastructure for Compliance



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



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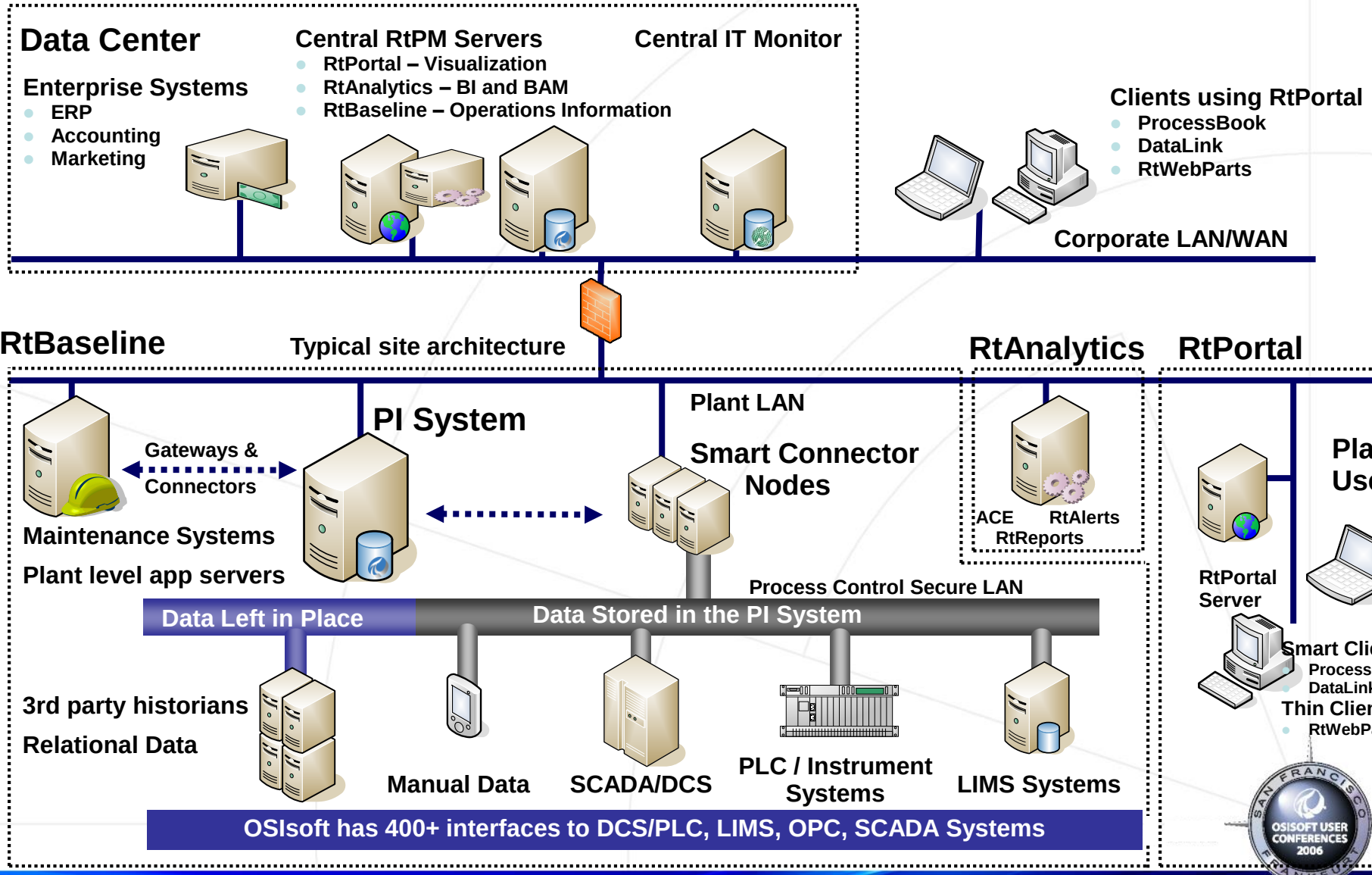
Detailed Enterprise Compliance Architecture



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’

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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.

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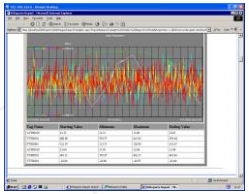
Compliance Reporting Requirements

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

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.

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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'*

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Standards for Style and Formatting Rules

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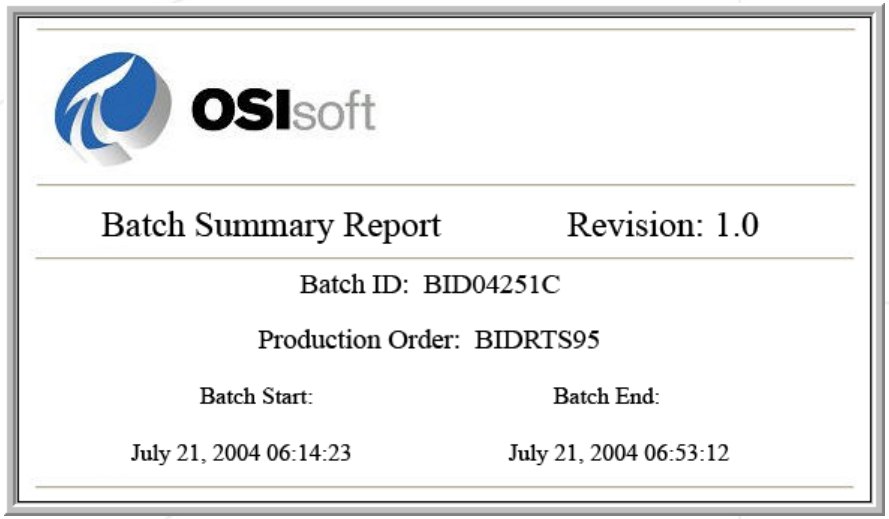
Standards for Style and Formatting Rules

Cover Page

Report Name,
Version, Context Summary



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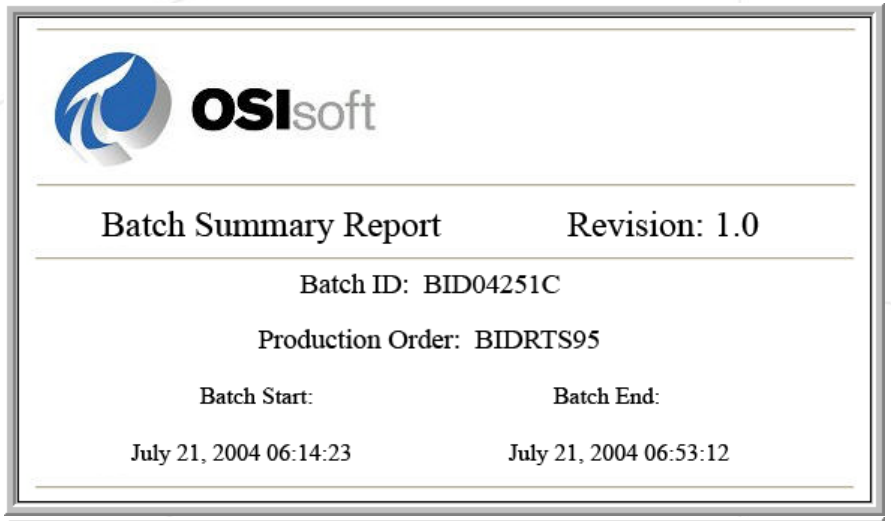

Page Header

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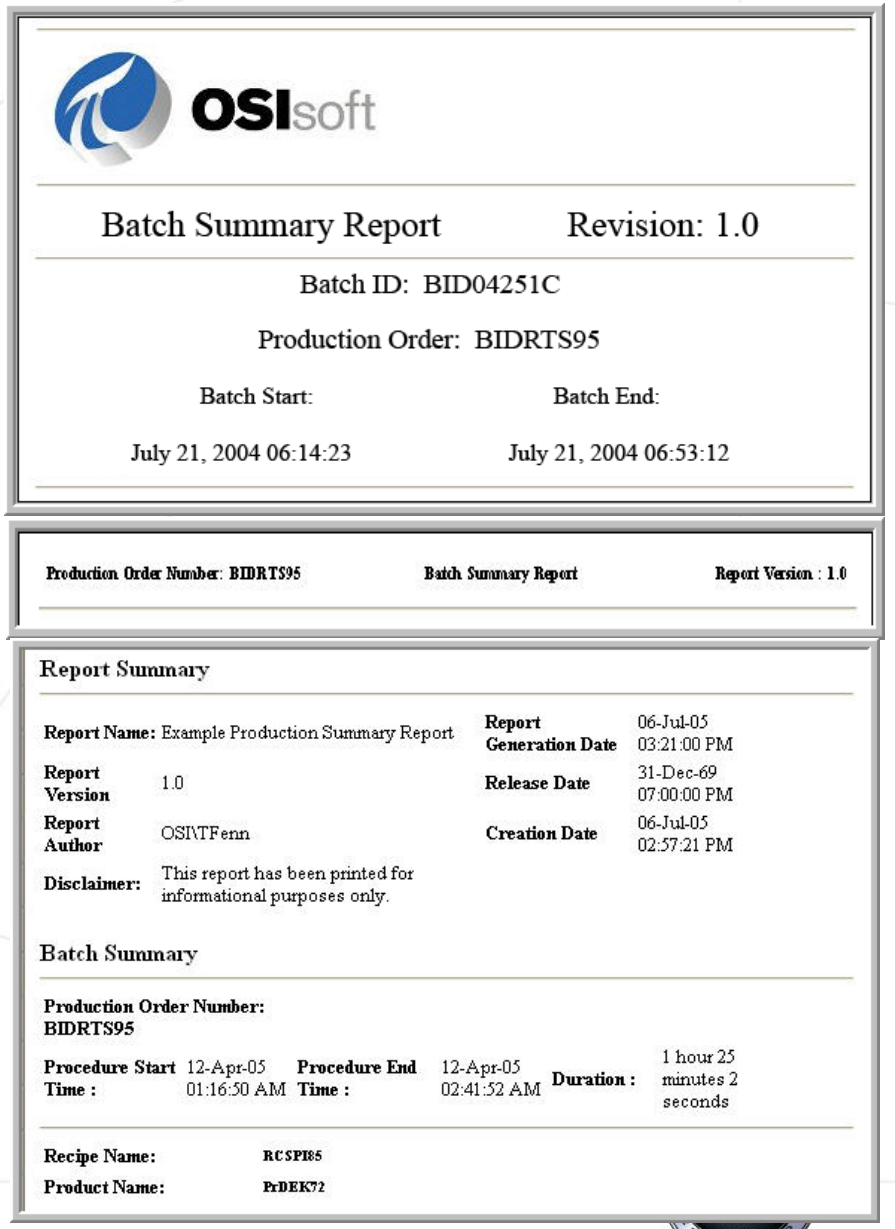
Standards for Style and Formatting Rules

Cover Page
Report Name,
Version, Context Summary

Page Header

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



OSIsoft

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

Production Order Number: BIDRTS95 | Batch Summary Report | Report Version : 1.0

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	OSI\TFenn	**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

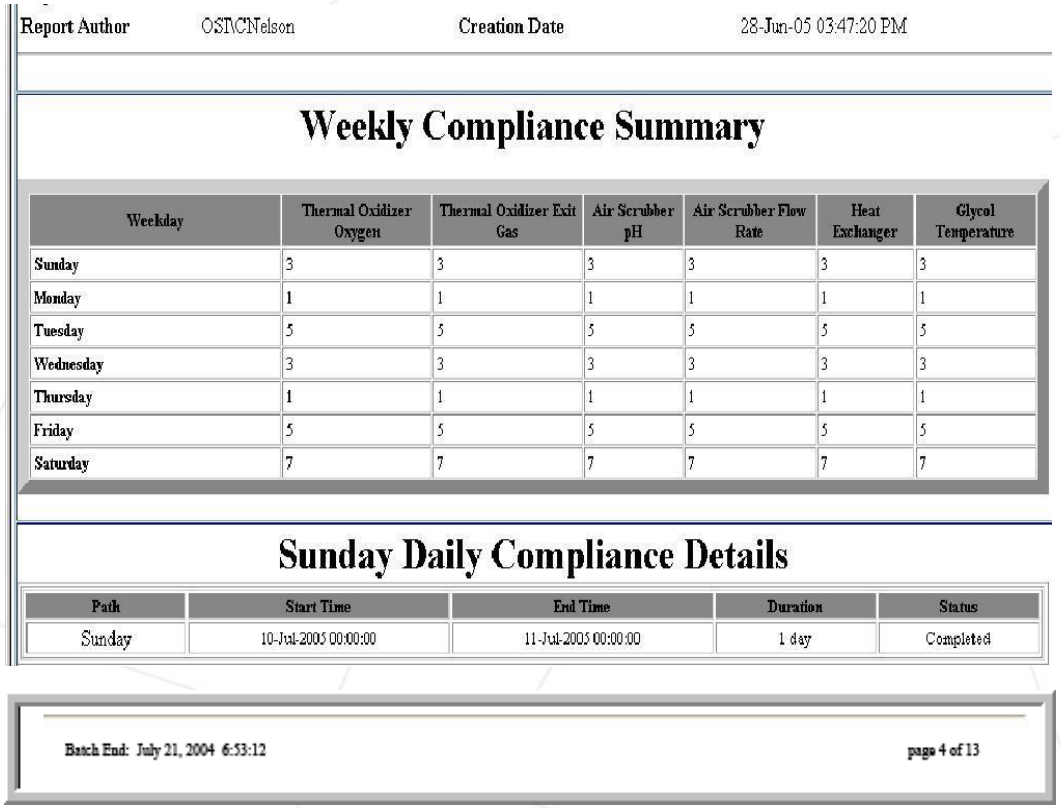
Recipe Name:	RCSPI85
Product Name:	PrDEK72

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 OSI\CNelson 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

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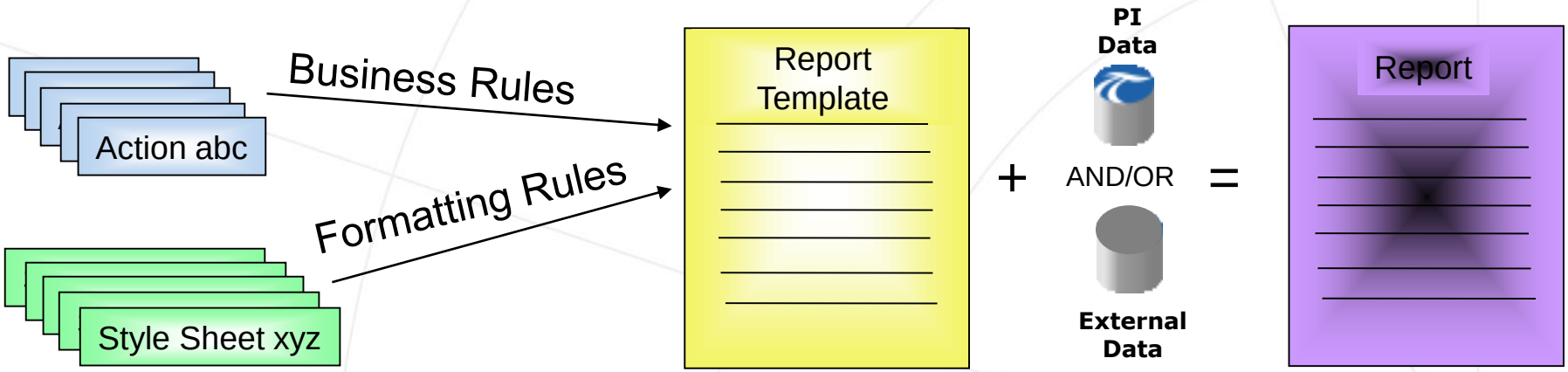
Action and Style Sheet Libraries

- 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

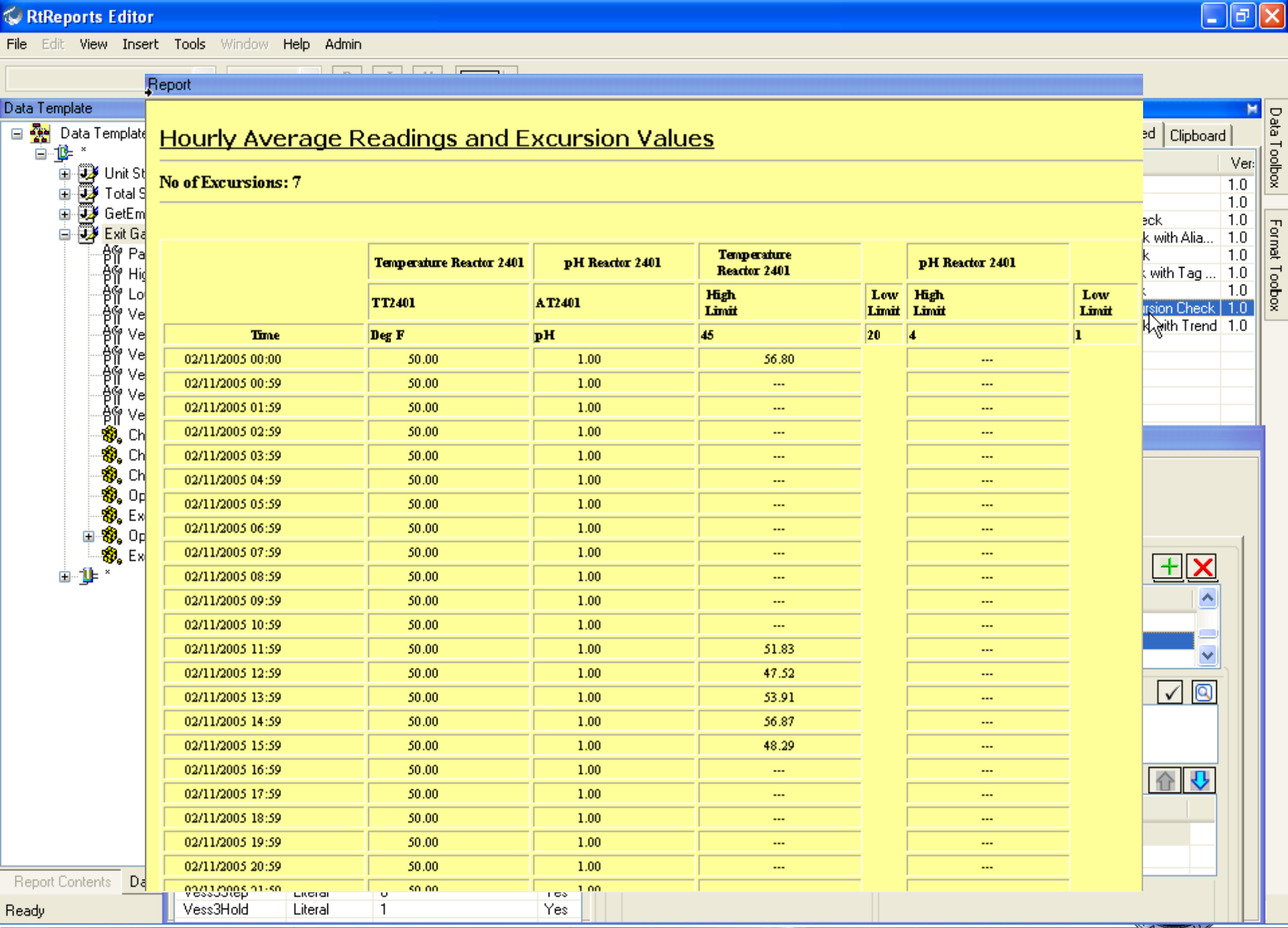
- Reports should be generated against a pre-defined report template that is version-controlled.
- Then they will accurately reflect the state of the operation at the time the data was stored.
- Reports cannot permit modification after they have been generated.
- ESig comments and approvals should remain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

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

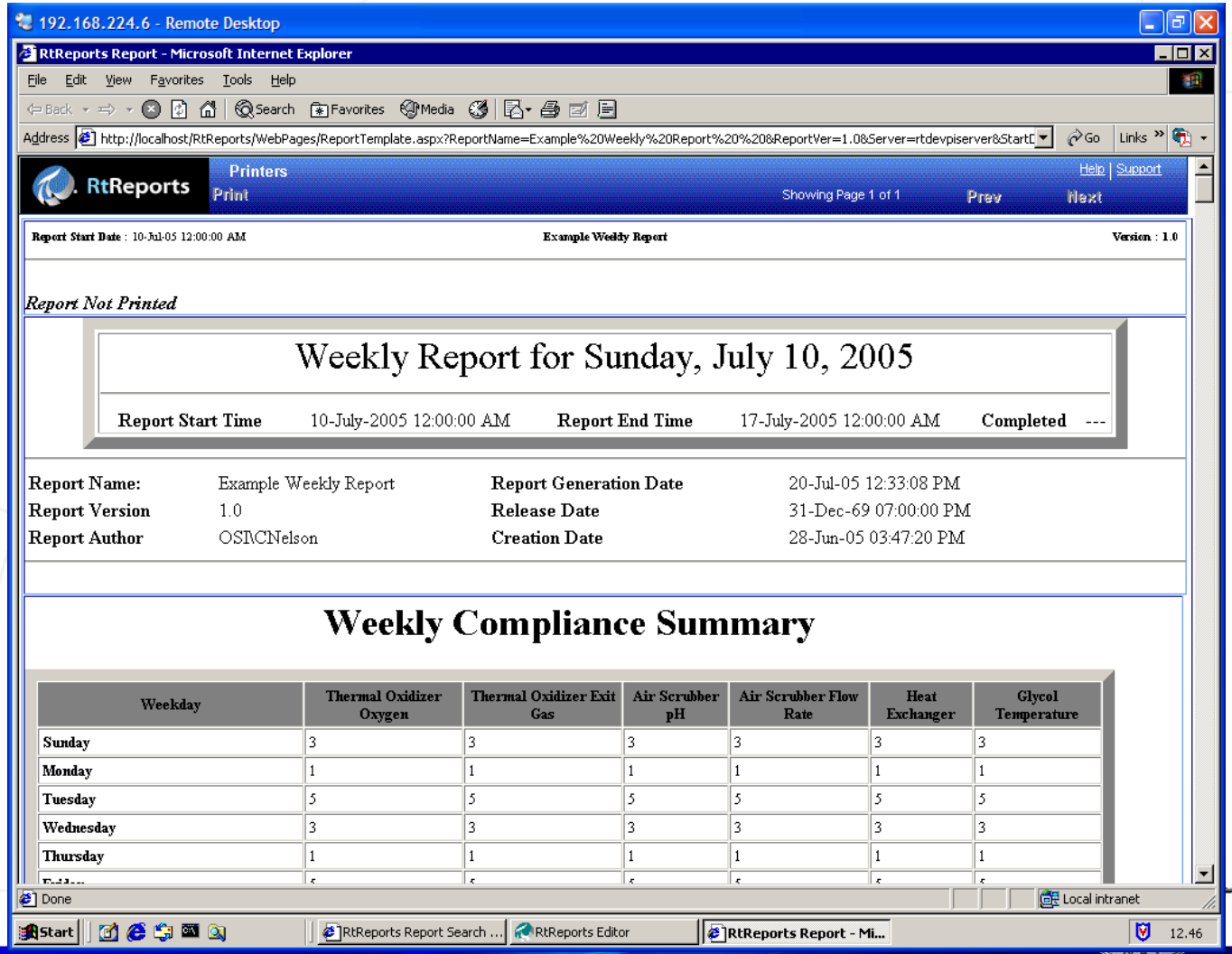
OSIsoft's — RtReports

- 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

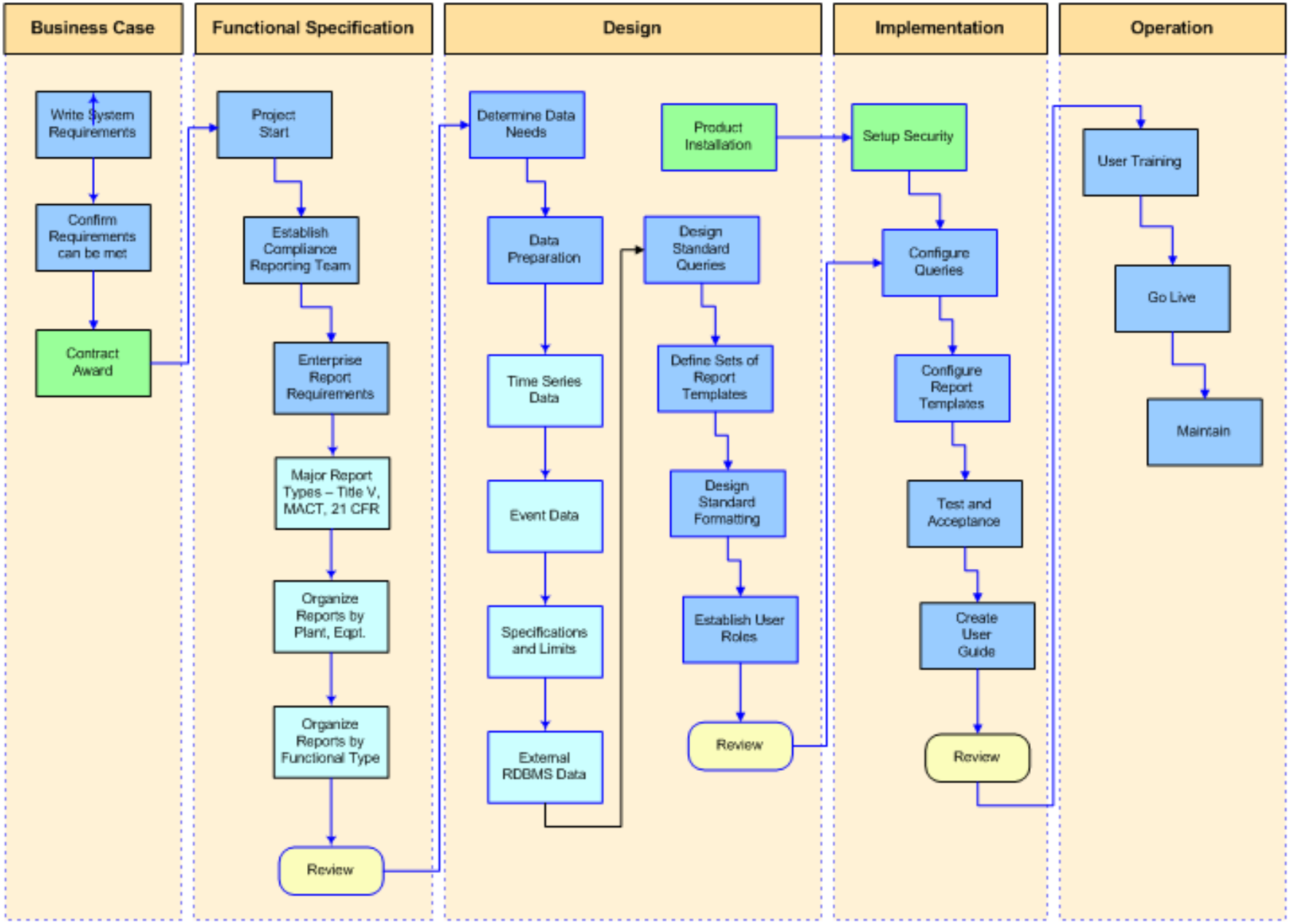


Weekly Title V Compliance Report

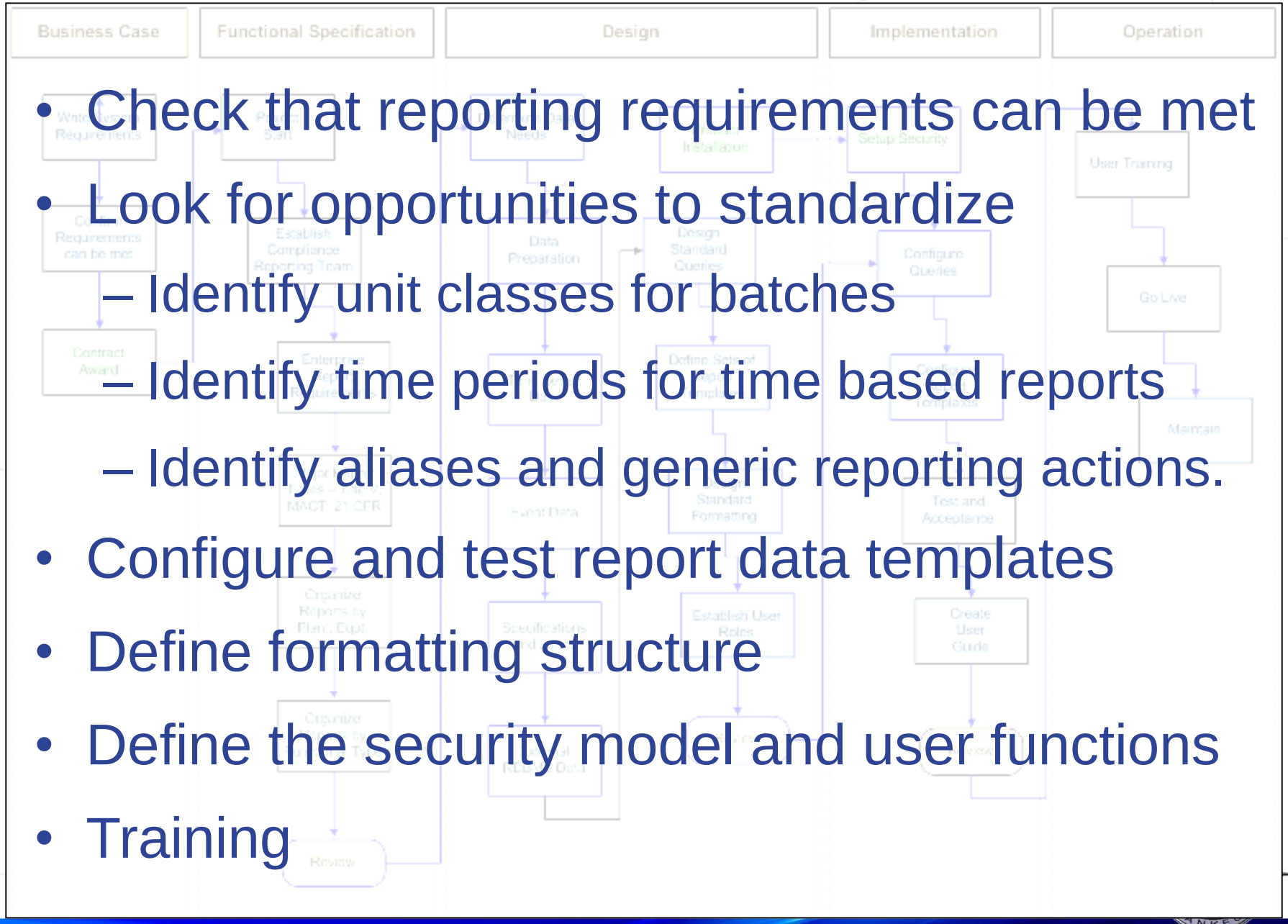
- Generated Report



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.

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

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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

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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

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