Implementing RTPM Infrastructure for a Validated Environment

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Overview

- Drivers and Objectives
- Vision
- Infrastructure Planning
- Architecture/Standards
- Implementation Strategy
- Futures
- Summary

Drivers and Objectives

- PI Infrastructure in an FDA Compliant Environment
  - Help Facilitate Validation of Other Areas
- Serve as a Model for Other sites
- Balance Implementation to Maximize Cost Effectiveness and Resource Utilization
- Leverage Emerging OSI technologies to Expose Process Data
- Position PI Infrastructure for the System of Record

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Vision

- Compliant OSIsoft Infrastructure – Full Validation Documentation
- Provide Enterprise Access to Real Time Manufacturing Data
- Browser-Based Tools (Thin Client)
- Proactive Notification
- System of Record
- Rapid, Reliable and Informed Decision Making

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Infrastructure Planning

- **Phased Implementation**
  - **Phase I: Validation & Batch Configuration**
  - **Phase II: System of Record and Flexible Reporting/Notification**
  - **Phase III: Enterprise Integration**

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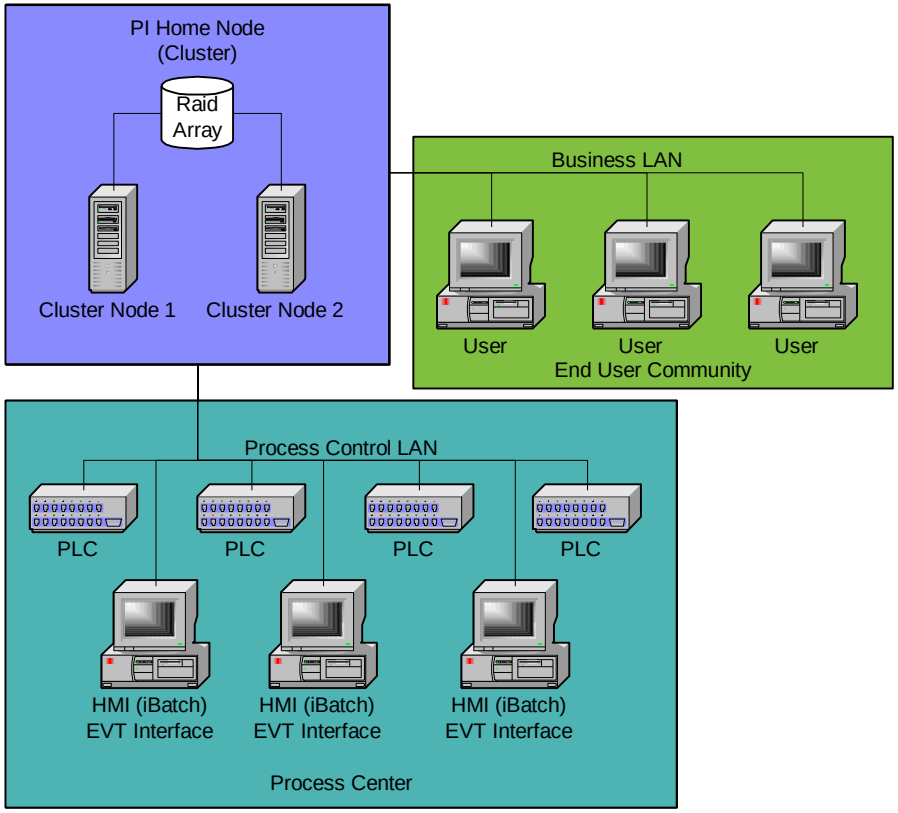
Architecture/Standards



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Naming Conventions

- PI Tags
  - Implement a well-defined naming convention
    - Utilize SCADA tag names as the core
    - Prefix tags with area abbreviation
    - Ensure naming convention makes it easy for users to find things via wildcard searches
  - Consolidate from previously used conventions

Module Database Hierarchy

- Design a flexible hierarchy
- Ensure compatible hierarchy with other components:
  - Event File Interface
  - PIBaGen
  - RTreports
- Make the structure “repeatable”
  - Ease report generation issues by enabling the “general case” reporting

PI System Security

- PI Points
  - The Interface User to own the data
    - Only interface can write data
    - Even PIAdmin cannot write/edit/delete data without first editing security attributes of the point
  - PIAdmin to own the point (attributes)
  - Interface Admin Group associated with point and data
    - Group to have read/write access to attributes but read/only to data

PI System Security

- PI Users
  - All users will have their own PI User ID
  - SOP's developed for User ID administration
    - Procedures for adding/deleting/changing users

PI System Security

- **Custom Application Security**
  - **Utilize Windows NT/Netware Security to determine access rights**
  - **Utilize AppName Trust to "proxy" user into PI to allow read/write access for manual data applications**

PI System Security

- **Backup**
  - **Create custom cluster version of PISRVSTART and PISRVSTOP batch files**
  - **SOP to address backup and recovery**

PI Message Log Audit Trail

- Allows auditing of:
  - Edits or Deletes to the Data Archive
    - Does not support logging BLOB auditing
  - PI Batch Database Changes
- Audit trail is written to the PI Message Log
  - Message logs typically are purged after 15 days
    - A backup procedure will accommodate longer retention of message log (audit trail)

Real-Time Data Collection

- OPC Interface
  - Multiple OPC Interfaces
    - Provide a level of fault-tolerance
    - Logical delineations of data collection
  - Data in PLC's is accessed directly from the PLC's via RSLinx
  - Data in SCADA are accessed via the SCADA's OPC server

Batch Data Collection

- EVT Interface for Batch Execution System batch files
- PI Batch Generator Interface
  - New version is currently in development
  - Provide for down-stream processing hierarchical batch generation
  - Only be used where a Batch Execution System does not generate the batch information

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Fault-Tolerance

- Server
  - Use Microsoft Windows Clustering
  - Validation Test Strategy includes testing failure modes

Fault-Tolerance

- Interfaces
  - Use multiple OPC Interfaces
  - Failure of a single interface will stop data from being collected from a section of the facility rather than the whole facility
  - Run the interfaces on a Windows 2000 cluster to provide high reliability
  - Use Buffering to protect against network outages and PI server outages

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Alarming and Notification

- PI-ACE Based
  - Use Module Database for Configuration
    - Allow multiple instances of the same code
    - Each instance runs in a context (module) and uses the Aliases defined in that context
  - Use PI-SQC and PI-ALARMS for more complex triggering of notifications

Reporting Tools

- **PI-DataLink**
  - **Possible add-ins for things such as:**
    - **Cycle time analysis**
    - **Batch Hierarchy Reporting**
      - Note: Next Version of the Excel portion of BatchView will not access Batch Database
  - **Training to provide users with Ad-hoc query capabilities**

Reporting Tools

- PI-ProcessBook
  - Next Version of BatchView will support
    - Batch Database
    - Hierarchical Batches
    - Batch Trends
    - Gant Charts

Reporting Tools

- **PI-ICE**
  - **Web based access to PI Data, Trends, and Diagrams**
  - **Uses "Web parts" to allow end-user customization**
  - **Extensible via PI-ICE SDK**
    - **Build custom Web parts such as:**
      - Batch Cycle Time
      - Batch Hierarchy
      - Batch Discrete Data Reporting

Reporting Tools

- RTreports
  - Early Adopter Program
  - Key batch reporting tool
  - Supports
    - PI Batch Database
    - Hierarchical Batches
    - Custom Calculations
  - Designed to be 21CFR11 Compliant

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Implementation Strategy

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Phase I

- Validation & Batch Configuration
- First Half of 2003
  - Define Architecture/Standards
  - Compliant PI Server Installation
  - Interface Consolidation and Validated Implementation
  - Batch Infrastructure Implementation (EVT)
  - System of Record Prototype (ICE, ACE, RTreports)
  - Quality Reporting
  - cGMP Training

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Phase I

- Server Validation
  - Build Cluster as the Validated Server Using PI 3.3 SR2
  - Generate Validation Plan
  - Generate URS, FRS, GDS
  - Requirements Traceability Matrix
  - Generate and Execute IQ/OQ
  - Generate SOPs (Backup, Administration, Operations, Audit)
  - Generate Traceability Matrix

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Phase I

- Validated Implementation
  - OPC Interface Design
    - Multiple Interfaces Providing a Level of Fault-tolerance
  - Generate DDS (Detail Design Document)
    - Specific Implementation
    - Appendix Listing All Tags
  - Generate and Execute
    - IQ/OQ
    - Functional Test Specification (FTS)
    - Structural Test Specification (STS)

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Phase I

- Batch Infrastructure Implementation (EVT)
  - Generate DDS
  - EVT Generates Tags/MDB so DDS does not Have Tag List
  - Generate and Execute
    - IQ/OQ
    - Test Plan

Phase I

- **Manual Data Entry Yield Application**
  - **Separate Validation**
  - **Validation Plan, FRS, DDS, IQ/OQ, Unit Test Plan, Integration Test Plan, System Acceptance Test Plan, Traceability Matrix, PQ**
  - **Leverage MDB for Correlation**

Phase I

- System of Record Proof of Concept
  - Non-validated, Read-only, Demonstrates Capabilities
  - Installation of PI-ICE and Configuration of Screens
  - Installation of PI-ACE and Generation of Notifications
  - Installation of RTreports and Generation of Reports

Phase I

- Quality Reporting Foundation
  - Shaped by Feedback from Proof of Concept
  - Generation of URS and FRS

Phase I

- cGMP Training
  - PI Client Tools
  - PI-ICE
  - Administration

Phase II - System of Record

- Central Repository
  - Reliable Decision Making
  - Fully Validated - End to End
  - Quality Data – Batch Release
  - 21 CFR Part 11 Compliant

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Phase II - System of Record

- Quality Needs
  - Specification Compliance
  - Analysis Tools
  - Internal Audits
  - Batch Release Criteria
  - Certificates of Analysis
  - Root cause analysis
  - SQC

Phase II - System of Record

- **Regulatory Needs**
  - **Exception Reporting**
  - **Exception Analysis**
  - **Regulatory Compliance Reports**
  - **Environmental**

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Phase II - System of Record

- Manufacturing Needs
  - Batch Summary
  - Utility Reports
  - Detail by Unit, Product, etc.
  - Yield, Efficiency, Throughput
  - CIP/SIP

Phase II

- July 2003 - March 2004
  - MDB & PIBAGEN for non-iBatch
  - Validated Implementation
    - PI-RTreports
    - PI-ICE
    - Notification/PI-ACE
  - Other Automation Areas
  - Communicate Findings to Other Sites

Phase III (futures)

- Packaging & Enterprise Integration
  - March 2004 - September 2004
  - Evaluations Integration/Migration
    - SAP RLINK
    - Maintenance Management System
  - Automation Integration of Packaging
  - Evaluate PLM Integration
  - Other Site Implementations

Questions & Answers

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