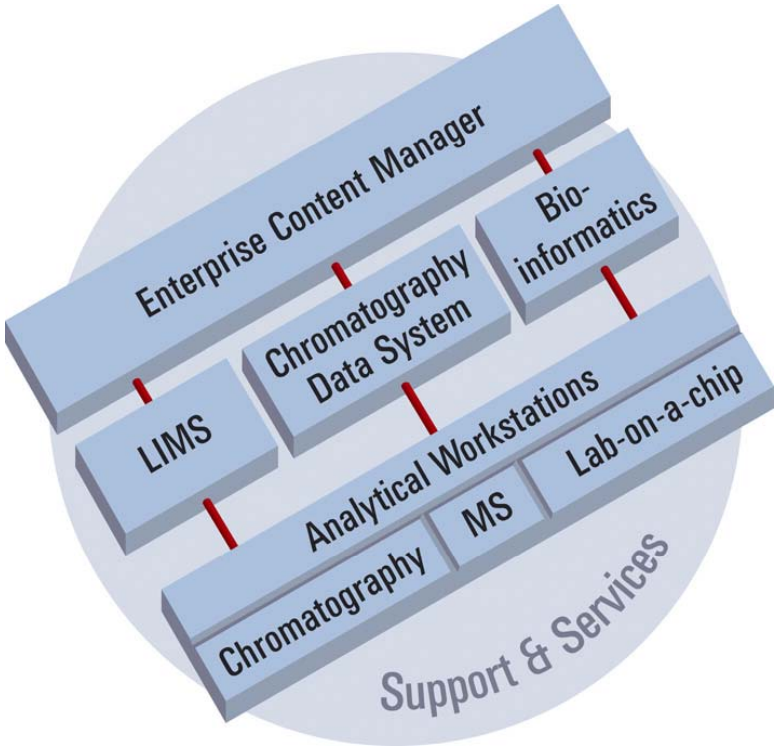
# The Use of an Automated Compliance Engine (ACE) with an Automated Business Process Manager (BPM) to Ensure Instrument Compliance

Abstract Number: 2790 - 6P

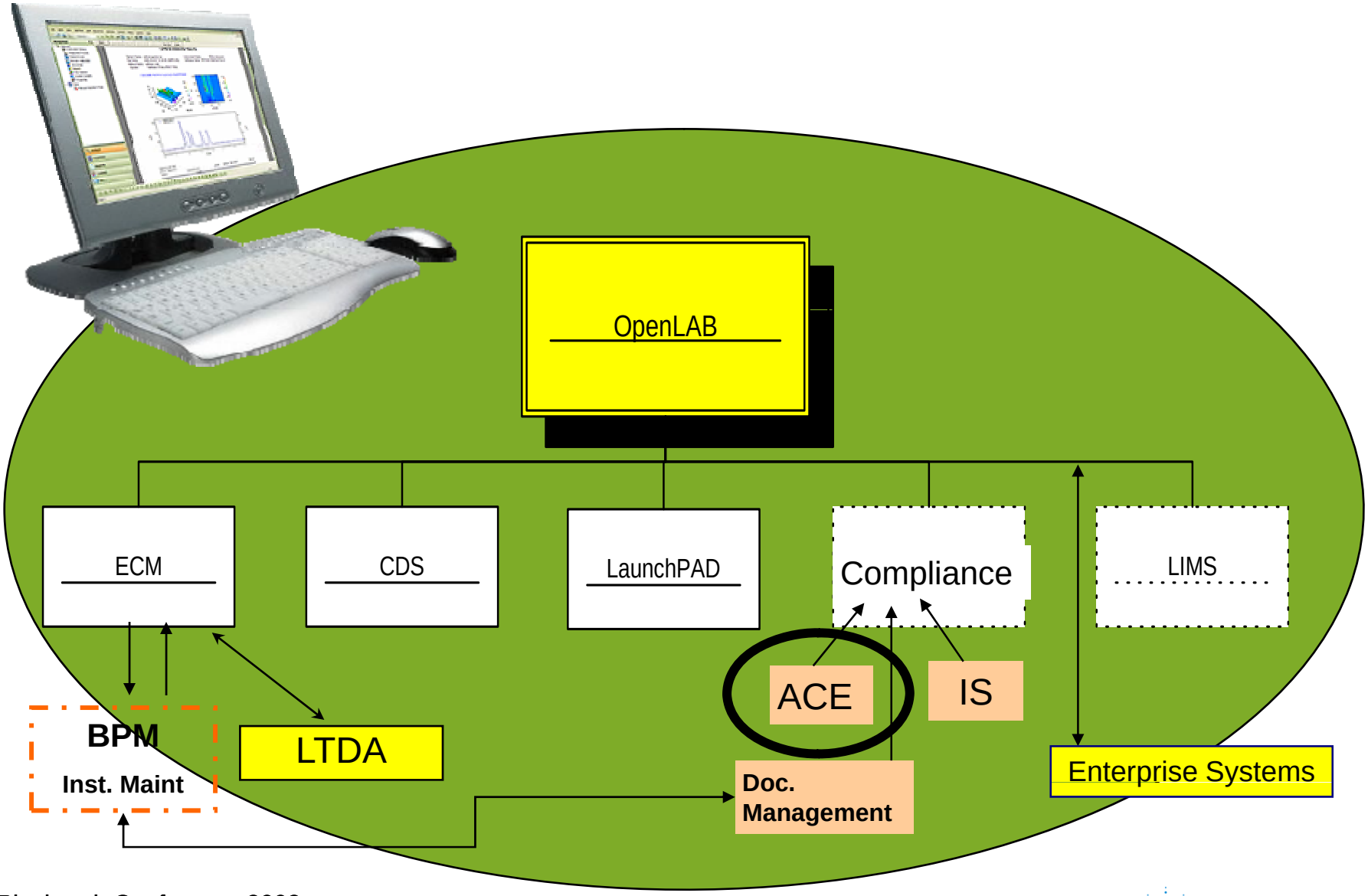
***Laboratory data collection, analysis, interpretation and management***

# Agilent Informatics




*OpenLAB ECM is the core of Agilent Lab Informatics*

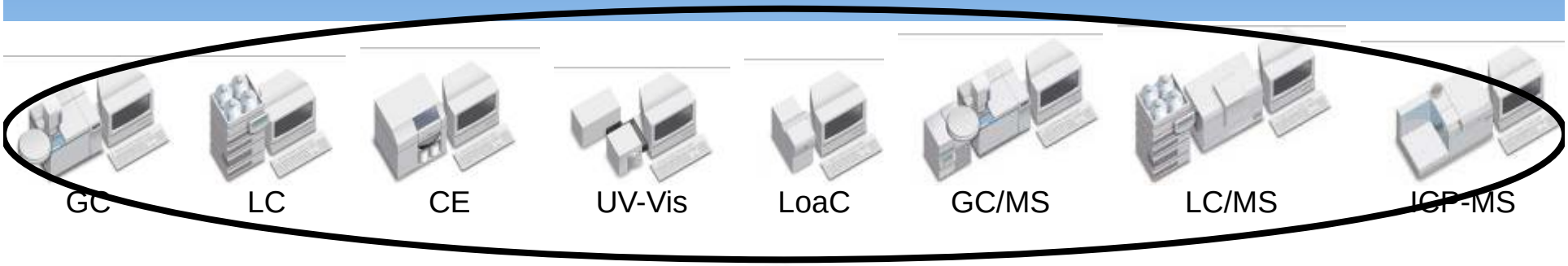
# What is OpenLAB?



# What Is Openlab ECM?

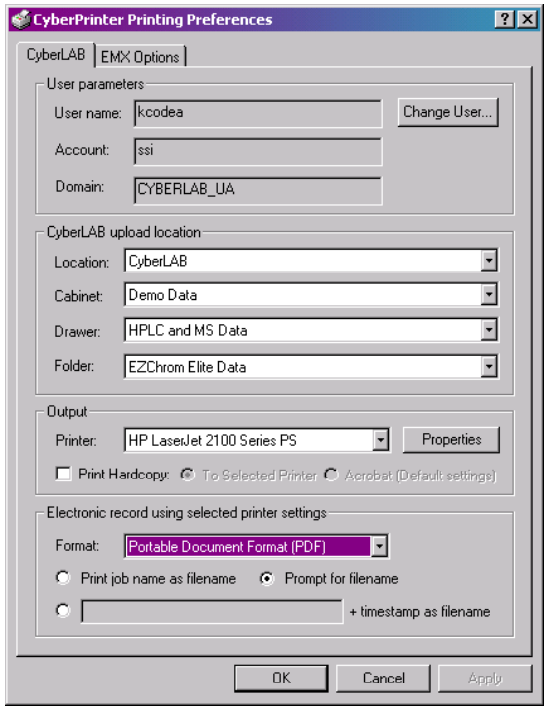
- **Enterprise Content Manager**
- is a web-based electronic library that collects, organizes, indexes, stores, archives, and shares any electronic file – from analytical raw data and lab reports to compliance records, molecular drawings, Adobe Acrobat documents, Microsoft Office documents, web pages, pictures, video and audio.
- ECM allows users to easily search and review all of their data. ECM automatically extracts searchable metadata from files and provides powerful search capabilities
- Backend DB of ORACLE / SQLServer

# Why Agilent OpenLAB ECM?




# How Data is imported into Openlab

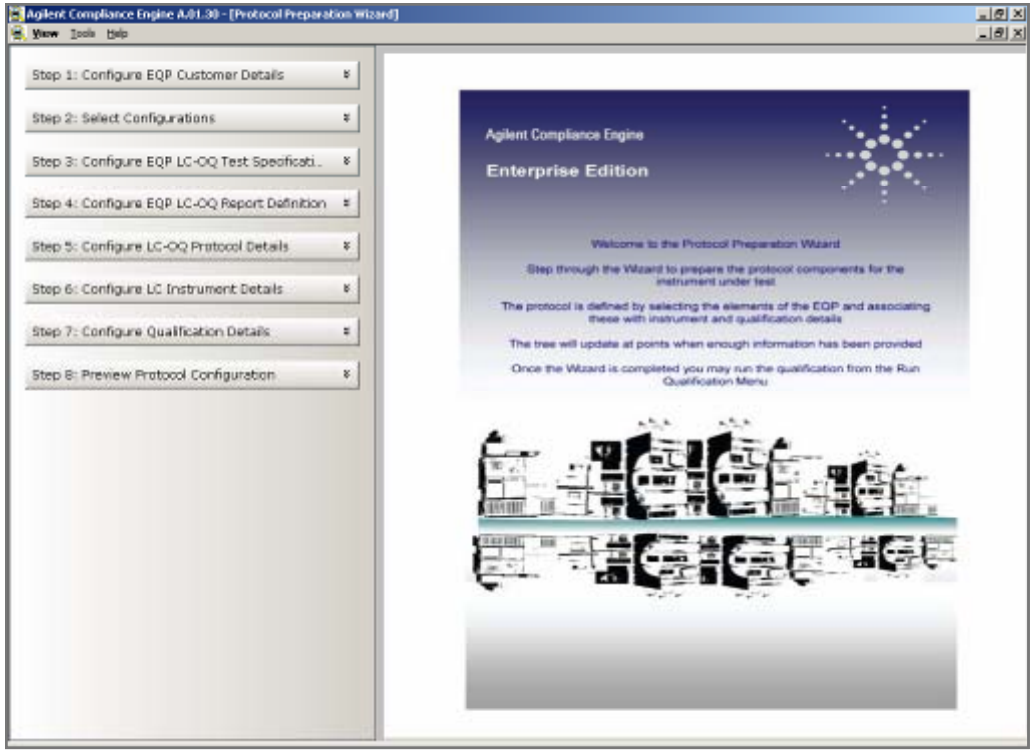
- Manually
  - Add Files (explorer right mouse click)
  - Office integration (Excel, Word, PowerPoint, Outlook, Explorer)
  - Tool Bar (Microsoft)
- Scheduler
  - Push or Pull
  - Configurable on options for data collection
- Cyberprinter
  - Acts as a printer driver
  - Transparent
  - Adobe pdf format (ACE Reports)



# Regulatory Compliance Features

- 21 CFRPart11
- Password Protection
- Complete Access Security by User/Roles
- Data can be locked down
- Electronic Signatures / Signoff
- Audit Trail (System and Data)
- Data Versioning (Can never delete data)
- Complete Document Chain of Custody (with Adobe Forms)
- Complete integration with office products
  - Word, Excel, PowerPoint, Outlook, Explorer
- Compare multiple versions
- Composite Reports with traceability

# What is ACE?

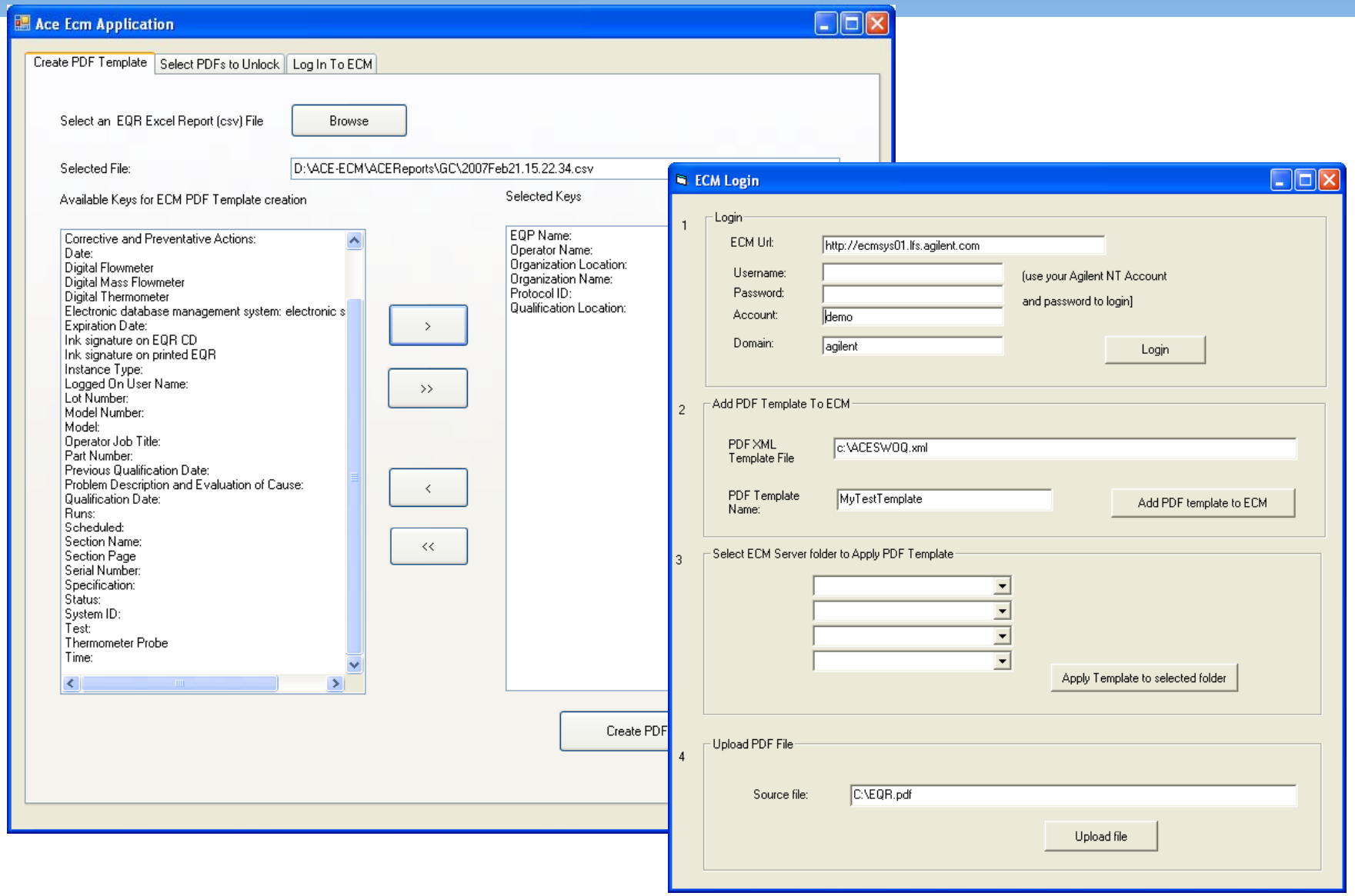



A software to manage the protocols, work-flow, raw data & reports involved in lab instrument qualification programs (IQ, OQ, RQ, PM, repair)

# Key aspects of ACE

- ACE is a standalone application that links with OpenLAB, ECM
- Self-contained software on laptop/tablet PC for portability
- Connect the laptop to any network connection or wireless connection to CDS and ECM components
- XML, pdf, EZChrom, .net
- E-sigs provided by Acrobat Digital Signature or ECM

# ACE/Openlab configuration



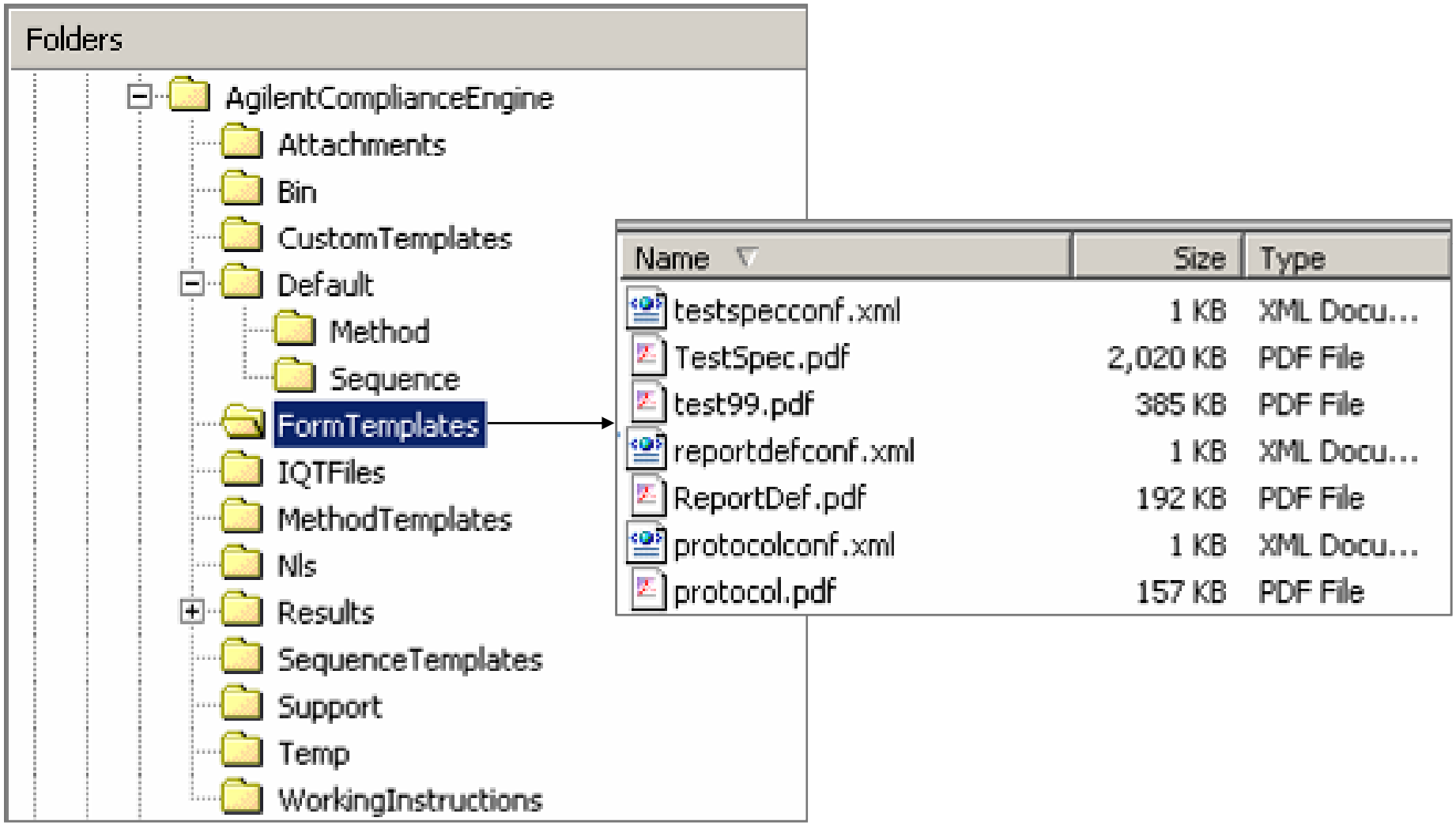
# Laboratory Objectives

- ✓*A totally paperless system used to perform validation on; computer systems,* ***laboratory instruments,*** *facilities, and even process.*
- ✓*The application would manage the validation life cycle for any of the mentioned validation systems.*
- ✓*Users would create validation documents based on approved templates in the system. These documents would then be routed for approvals via electronic signature.*
- ✓*Protocols and test cases would be created as well. The system would not permit the execution of a protocol prior to approval.*
- ✓*Execution of the approved protocol can be performed electronically. Screen captures or evidence of execution can be electronically attached to the executed protocol*
- ✓*Executed documents are routed for review/approval electronically.*
- ✓*Incidents are managed electronically.*
- ✓*There is some type of management feature to view the status of a validation exercise while underway.*
- ✓*The system would manage the periodic system review scheduling.*

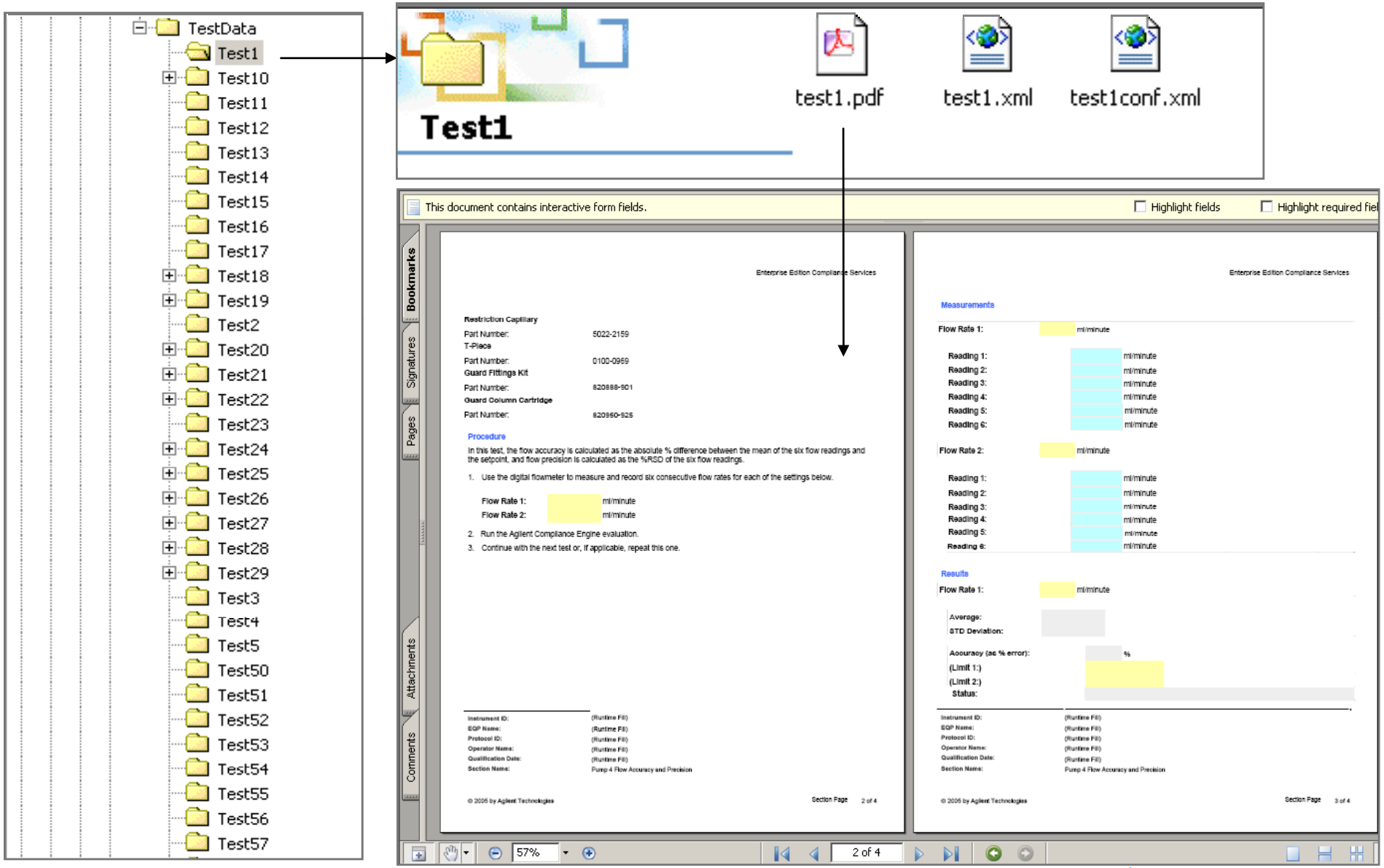
# Key aspects of ACE

- Data integrity provided by application security, locked pdf's, ECM database security
- Post-event data analysis of instrument qualification results provided by ECM using pdf 'reading' or .csv tables
- PM and repair records included in ACE for export to ECM
- Working instructions and other utilities contained in ACE
- ACE is fully validated by vendor, all instances have IQ and OQ of the ACE application. Automated IQ&OQ of ACE software can be performed anytime.

# Structure of ACE



# Structure of ACE



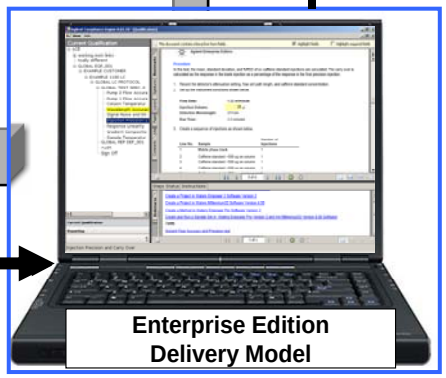
# Structure of ACE

## test specification (acrobat form)

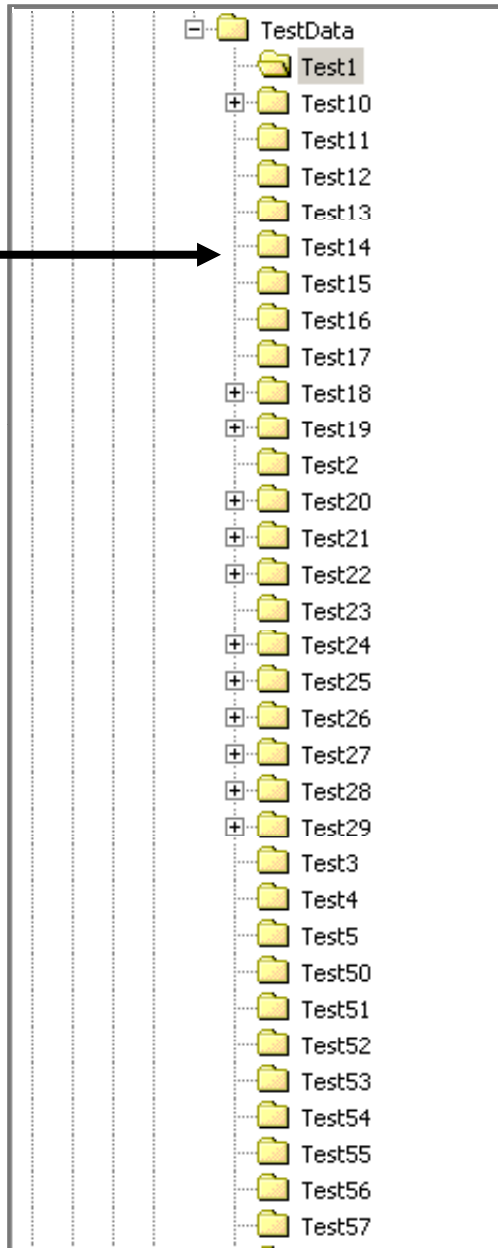
**Column Temperature Accuracy and Stability**

This test uses a calibrated digital thermometer to determine the accuracy and stability of column temperature.
Column temperature accuracy is calculated as the absolute difference between the measured temperature and setpoint
Temperature stability is calculated as the absolute difference between the highest and lowest measured temperatures.

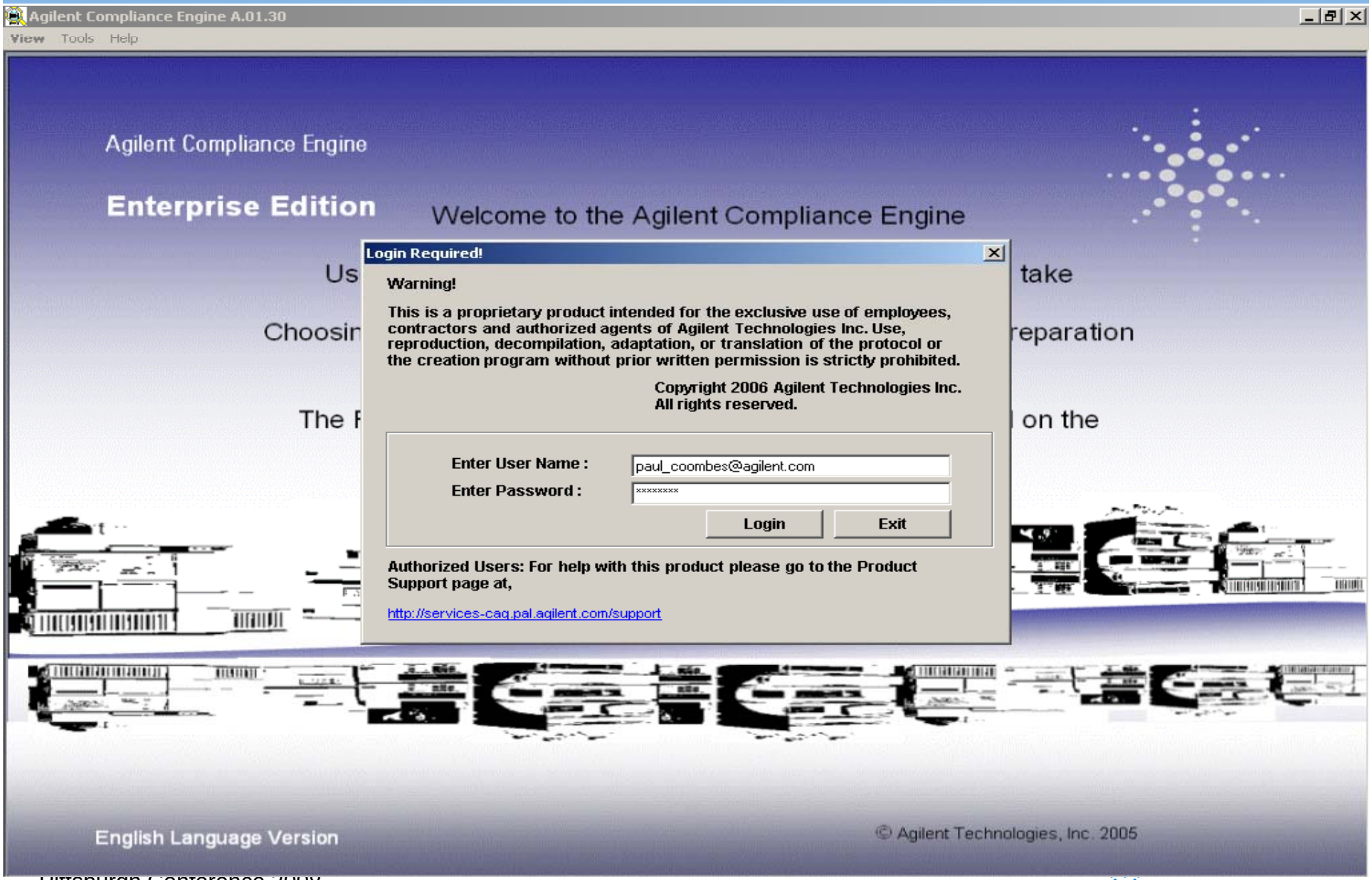
| | | | | |
|---|---|---|---|---|
| **Run the test?:** | Run | | | |
| **Customer Reference:** | Equivalent to GSK_Cork_TestSpec01 but for A.1.30 forms plus FLD tests | | | |
| **Temperature 1:** | 60.0 | °C | | |
| **Accuracy** | | | | |
| **(Limit 1:)** | | <= | 2.0 | °C |
| **(Limit 2:)** | | <= | 3.0 | °C |
| **Temperature 2:** | 35.0 | °C | | |
| **Accuracy** | | | | |
| **(Limit 1:)** | | <= | 2.0 | °C |
| **(Limit 2:)** | | <= | 3.0 | °C |
| **Stability** | | | | |
| **(Limit 1:)** | | <= | 0.5 | °C |
| **(Limit 2:)** | | <= | 1.0 | °C |



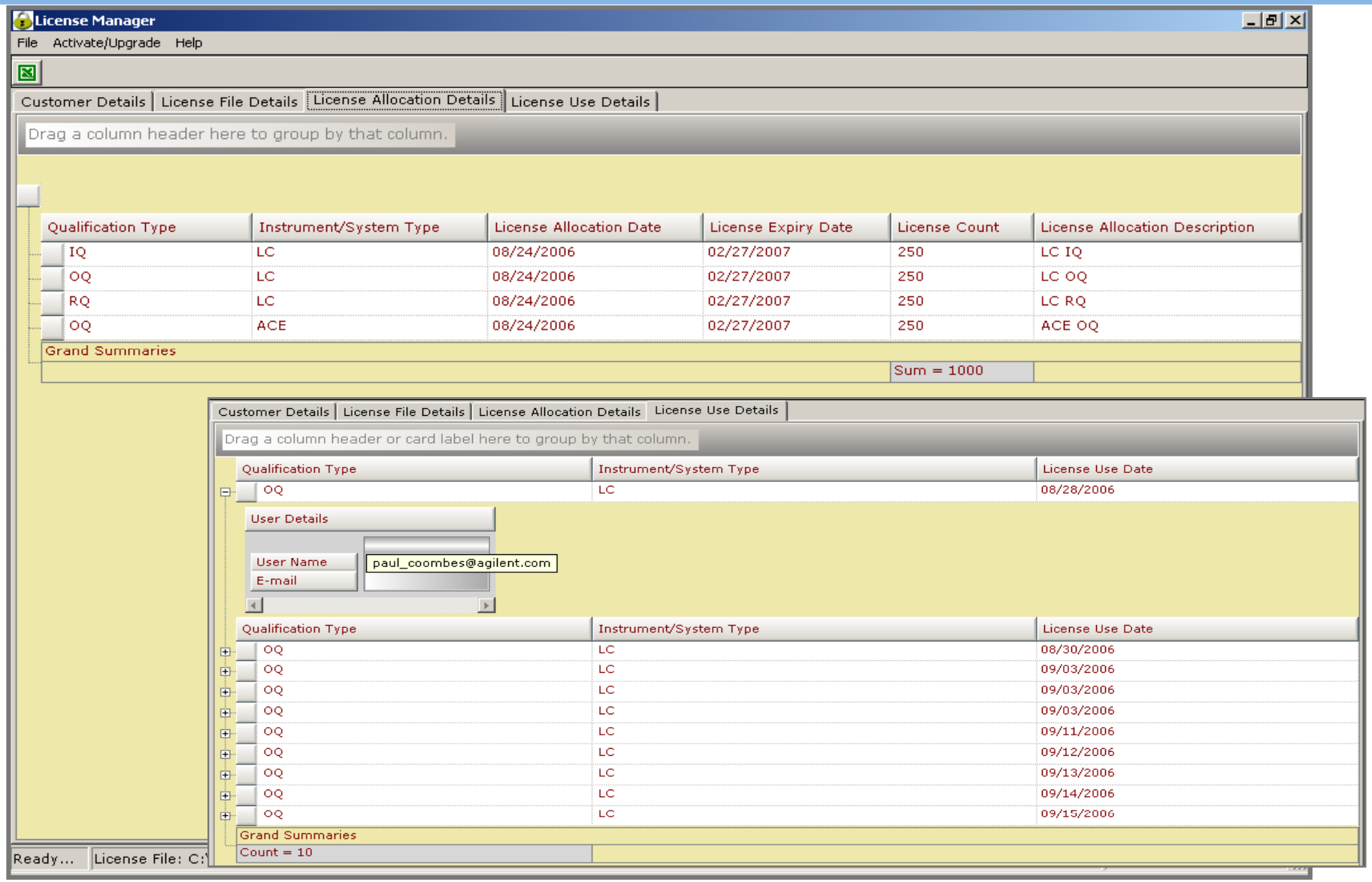
**Enterprise Edition Delivery Model**



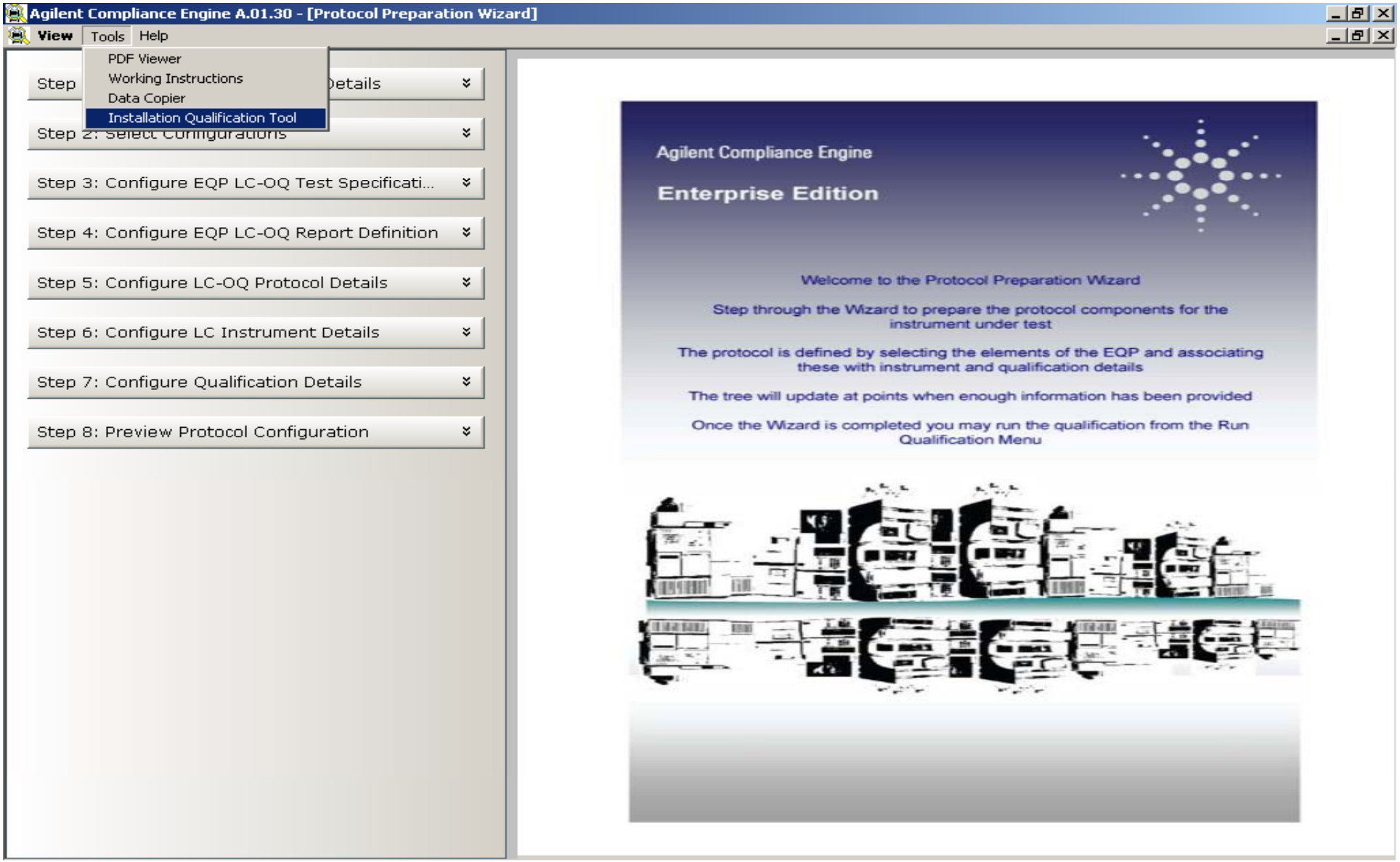
# User Authetication



# License module



# Ace Enterprise Edition



# Qualification Report


## Installation Qualification Report

| | | | | | |
|---|---|---|---|---|---|
| **Date:** | 16, Sep 2006 | **Time:** | 17:59:16 GMT | **Host Name:** | A0053209 |
| **Windows User Name:** | pcoombes | **Revision Number:** | A.01.30 | **Product Name:** | Agilent Compliance Engine |
| **Install Type:** | N/A | **Additional Packages:** | None | | |

**Base Reference File Name :** agilentcomplianceengine_a.01.30.xml

### Summary

Overall Evaluation of Installation Check: PASS

File Report Summary

- No missing files or invalid files found
- No system file differences found

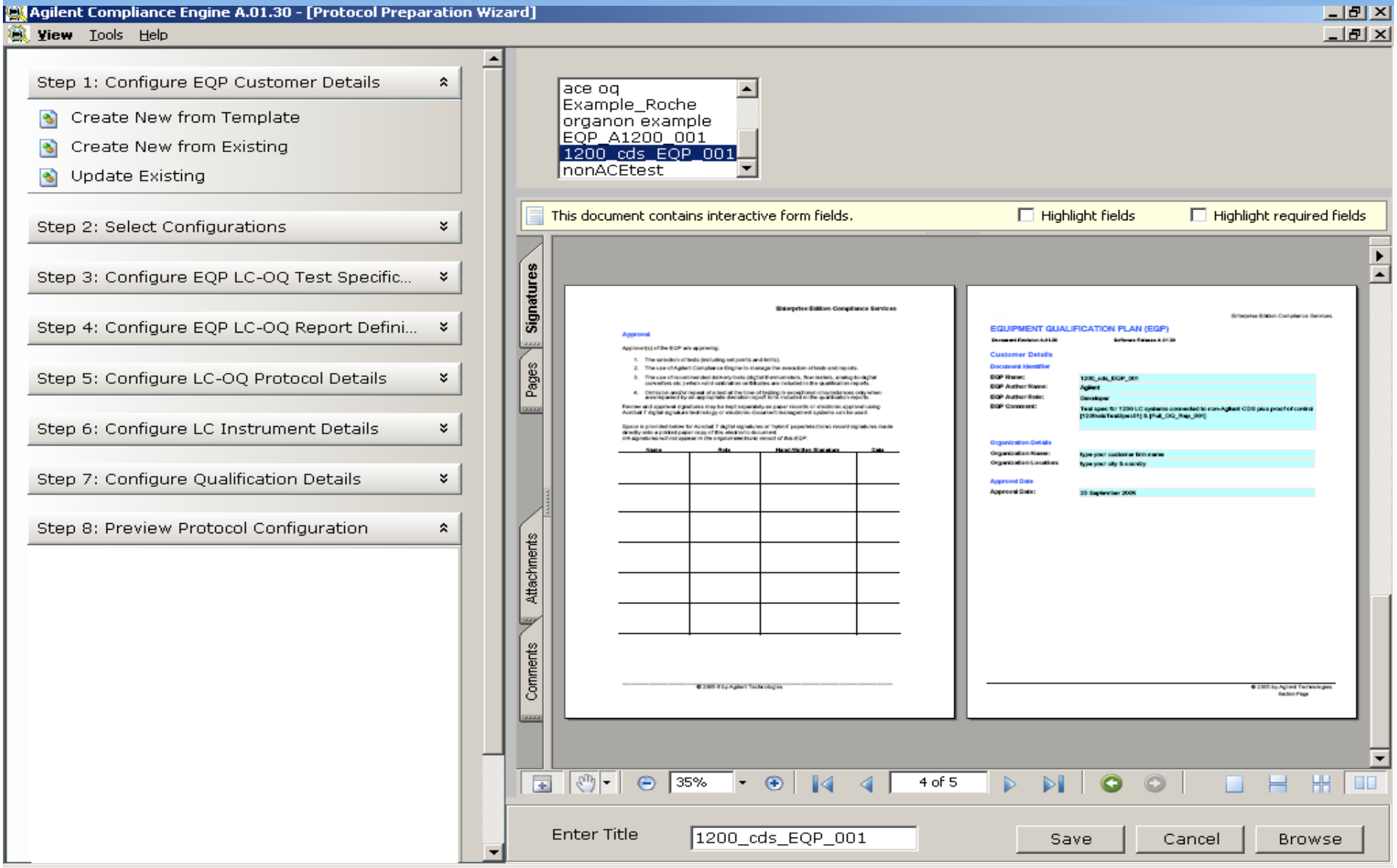
Registry Report Summary

- No invalid registry entries found

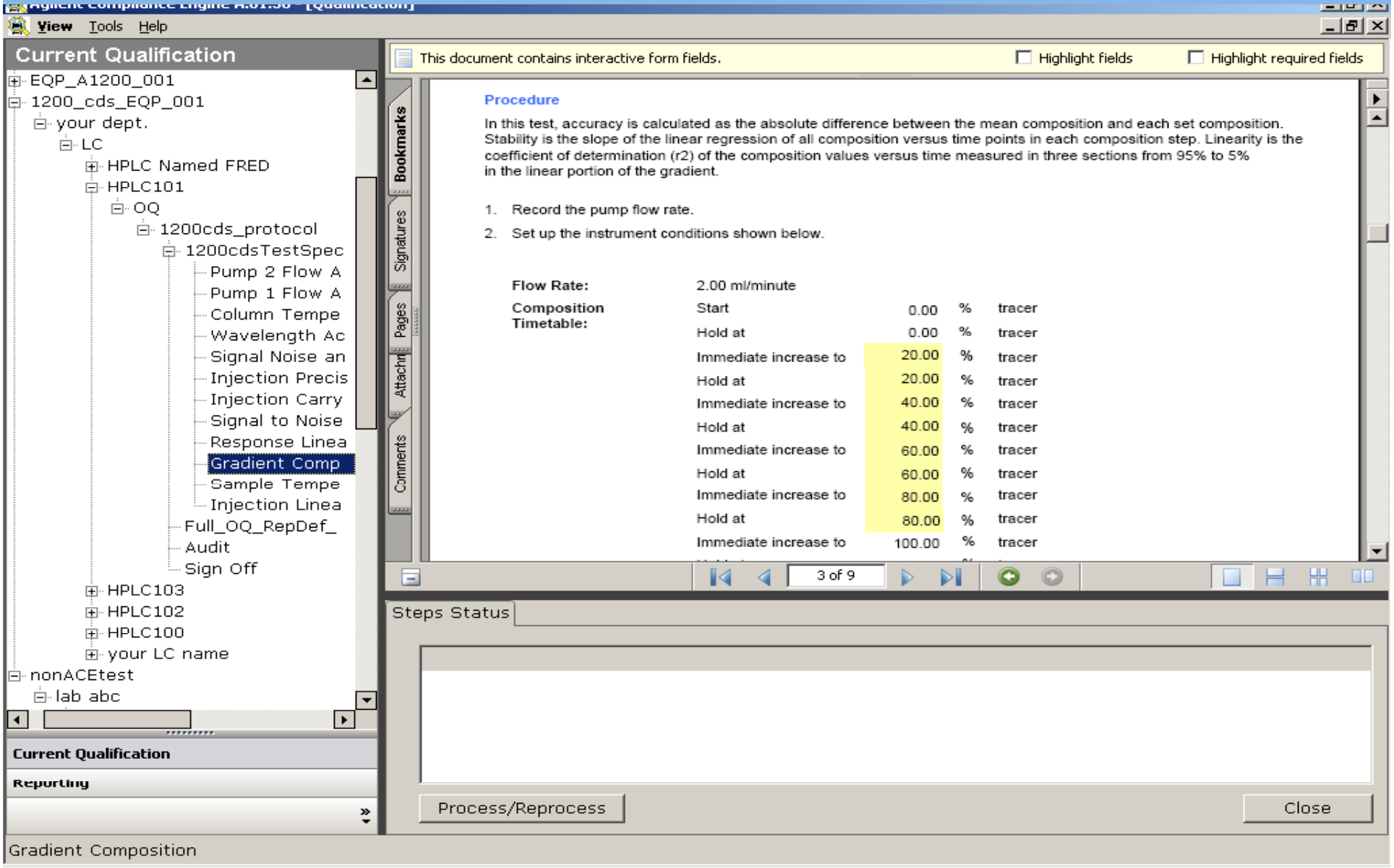
Files Registration Report Summary

- Not registered files: NONE

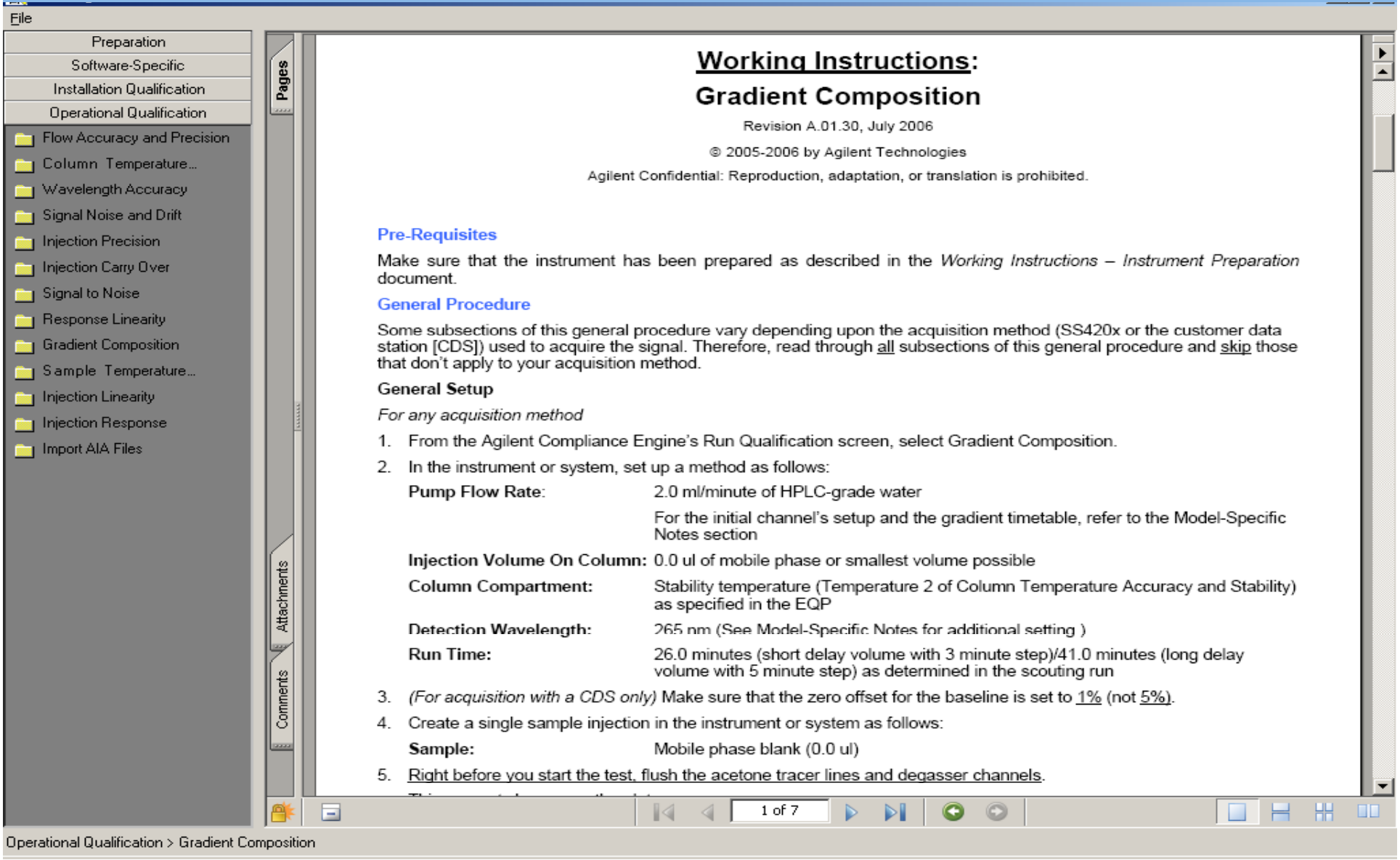
# Use Preset Templates



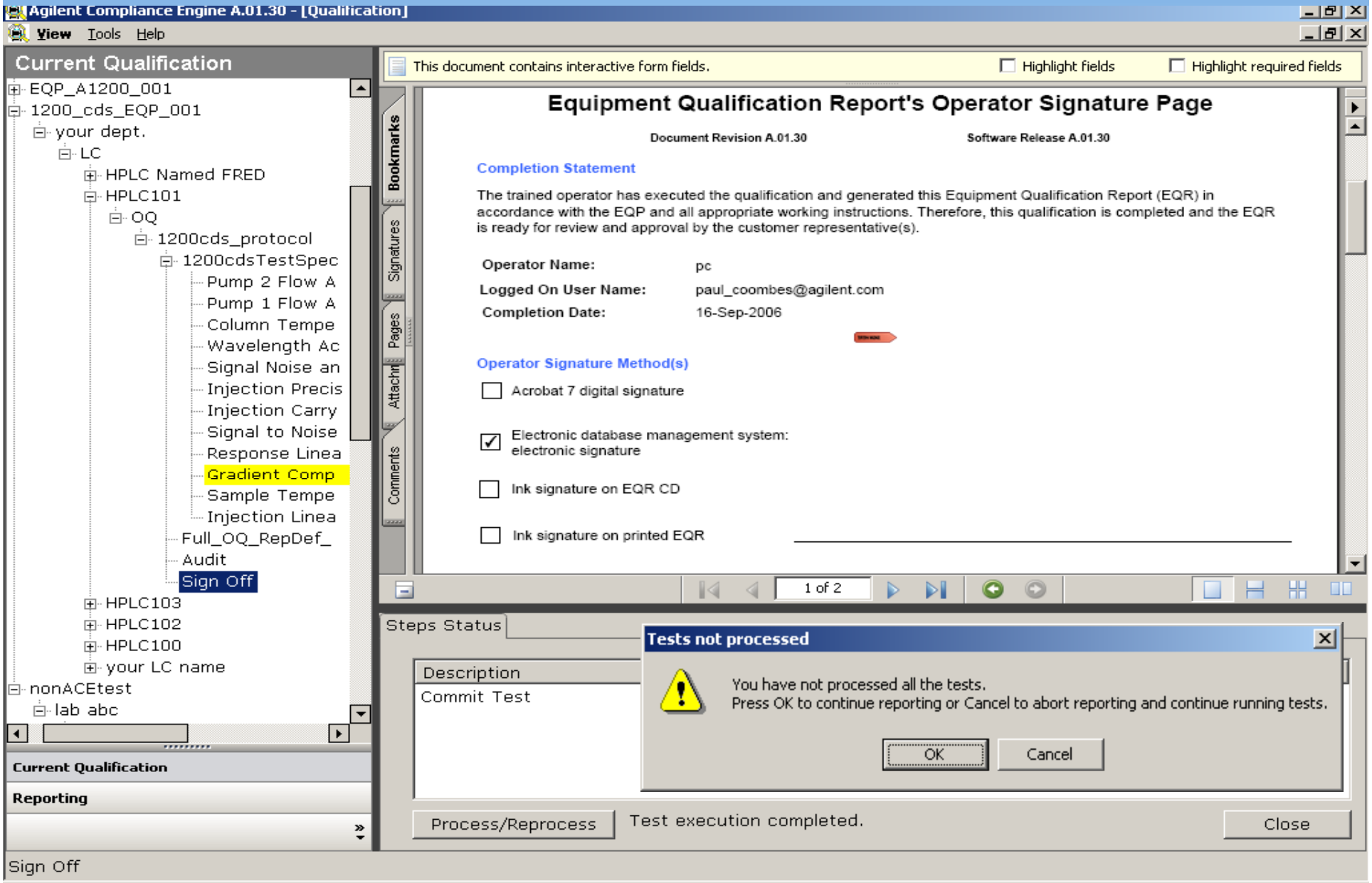
# Ace May Use Customer Protocols



# Users May Given Detailed Protocols



# Protocols Checked for Completeness

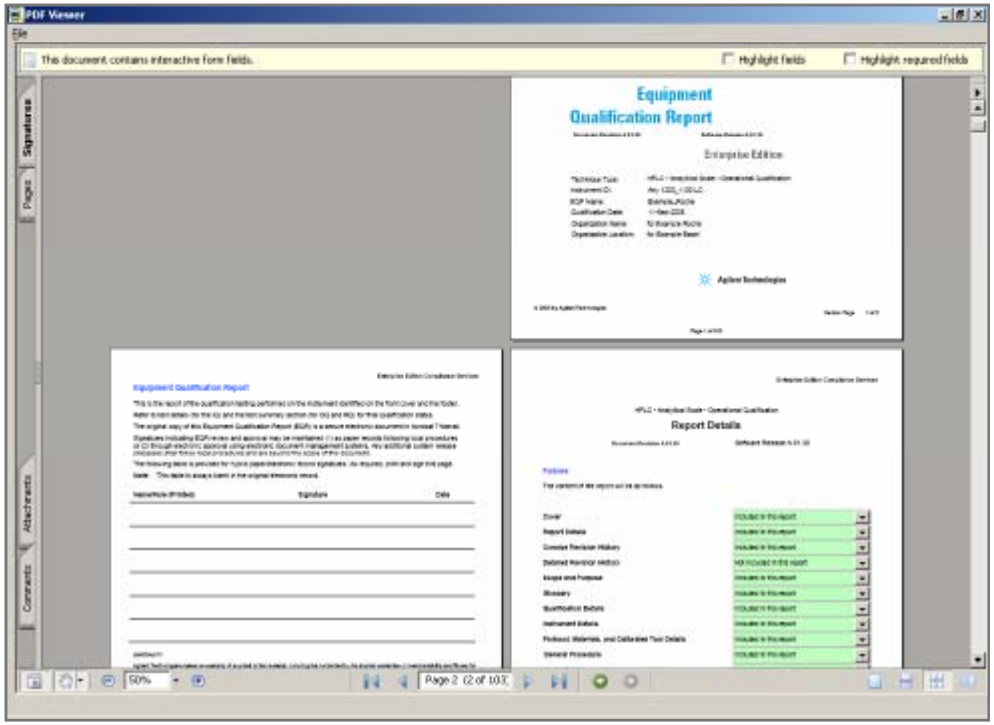


# Completed Reports Automatically Moved Into Openlab

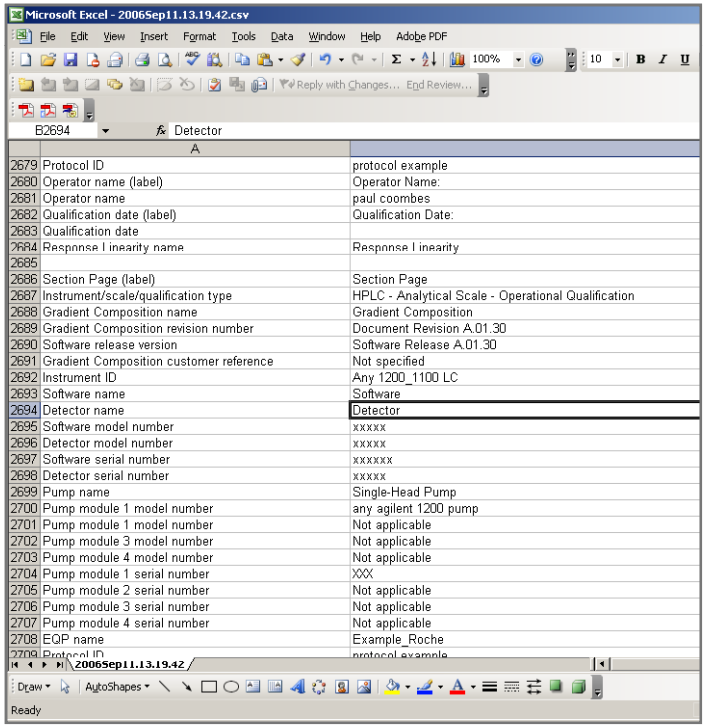
| Name | Size | Type | Modified |
|---|---|---|---|
| 2006Sep11.13.19.42.csv | 172 KB | Microsoft Office Exc... | 9/11/2006 1:20 PM |
| 2006Sep11.13.19.42.pdf | 7,045 KB | PDF File | 9/11/2006 1:32 PM |

7.04 MB My Computer

***The pdf report and companion .csv file generated by ACE are automatically swept up by ECM***

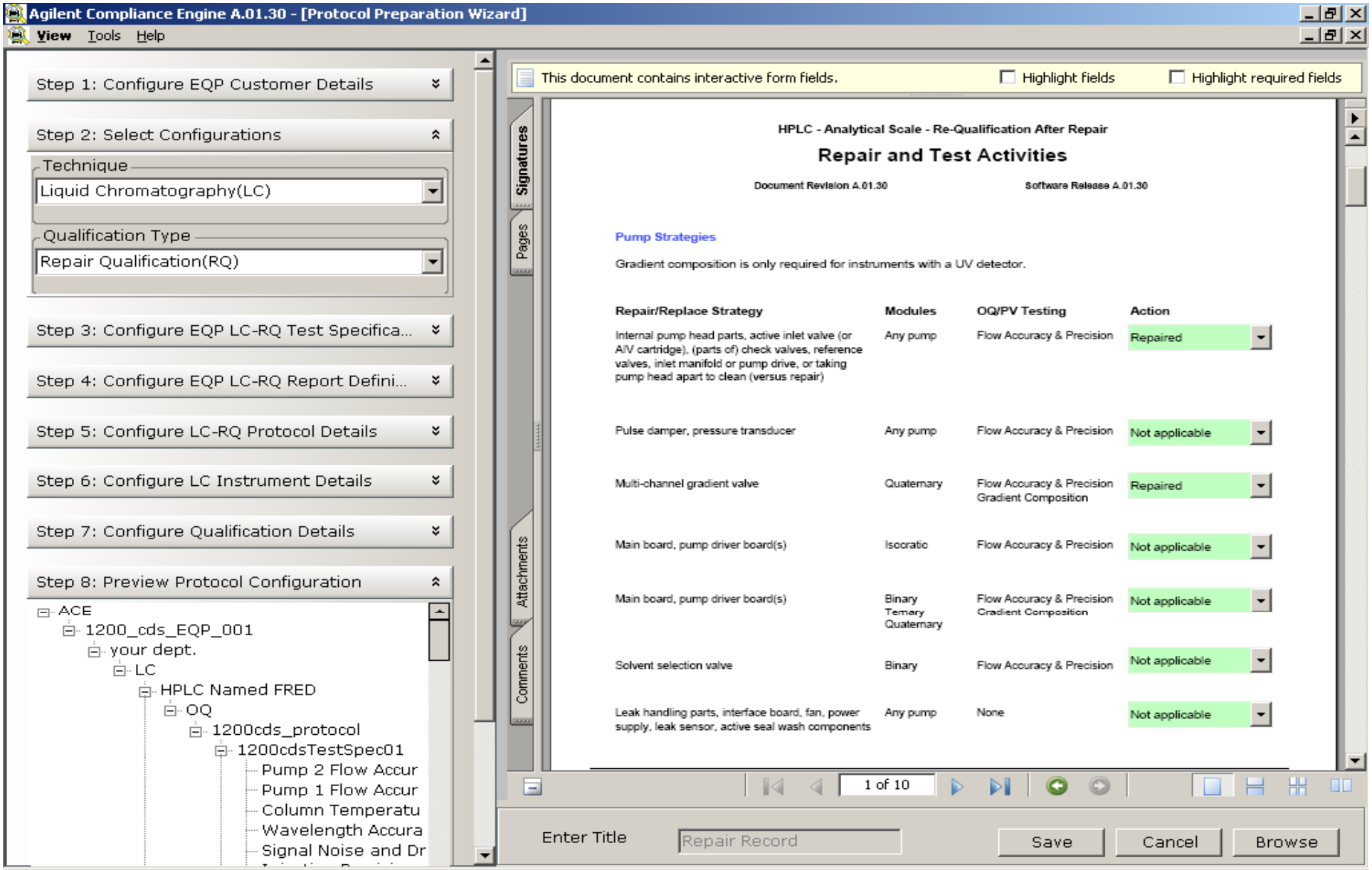



***FDA audit ready report in pdf***




***Database ready report in .csv***

# Repair & Test Results



# Value Proposition

Instrument Qualification.

Save 66% Review time.

No Risk.

# Reduce Instrument Downtime

Reduce the downtime to 1 day

*Get your analysts back to work*

5 to 6 hours work to deliver full OQ/RQ,
complete single pdf report provided to QA and/or system owner.
Parallel and remote review is possible, 30 minutes to 2 hours review & approval time.

With ACE Agilent engineer can achieve:
8 HPLC's fully OQ'd, reports reviewed
and systems released in 5 days Mon-Friday

**Reducing review time from 3 days to 1 day is 66% saving in review costs and downtime.**

# Minimize Risk

Validated, medium-risk configurable COTS ‘out-of-the-box’ solution – minimal validation effort for corporate computer validation team

20 months investment in protocol development & testing done by Agilent not the customer (typical competitor programs take 9-18 months to implement, validate and release for pilot use in one lab)

FDA and EMEA readily accept Agilent Compliance products

Automation ensures adherence to protocol, consistent execution in every lab, can be reviewed remotely – allows corporate oversight reduces risk of rogue labs/sites.

Can be executed by Agilent or 3rd party or firm’s personnel – eliminates risk of losing delivery capability and ensures the program’s longevity

This is Agilent’s new platform – industry standard acceptability world-wide.

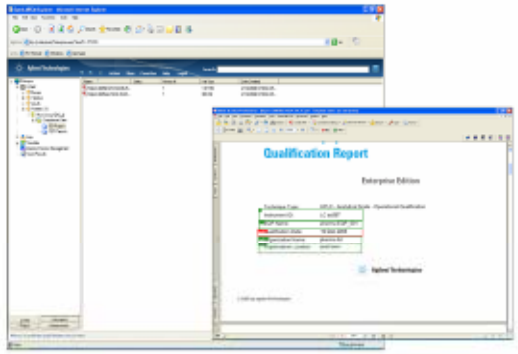
# Summary

## Agilent Compliance Engine (ACE)

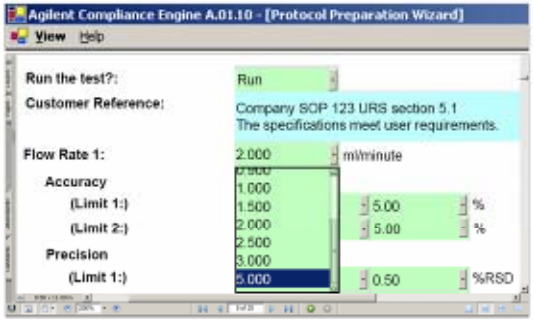
### Single Protocol for...

- Agilent Technologies
- Waters Corporation
- Thermo Electron Corporation
- Shimadzu Corporation
- PerkinElmer, Inc.
- Gilson
- CTC samplers and others

### Electronic records

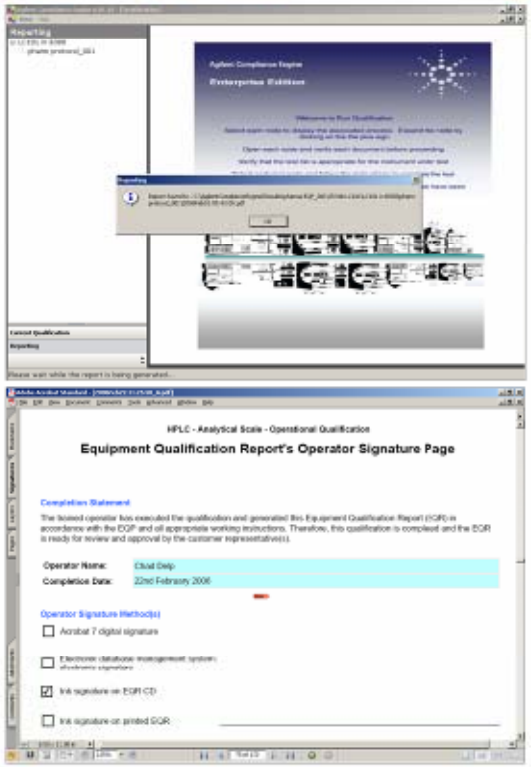



### Flexible tests...



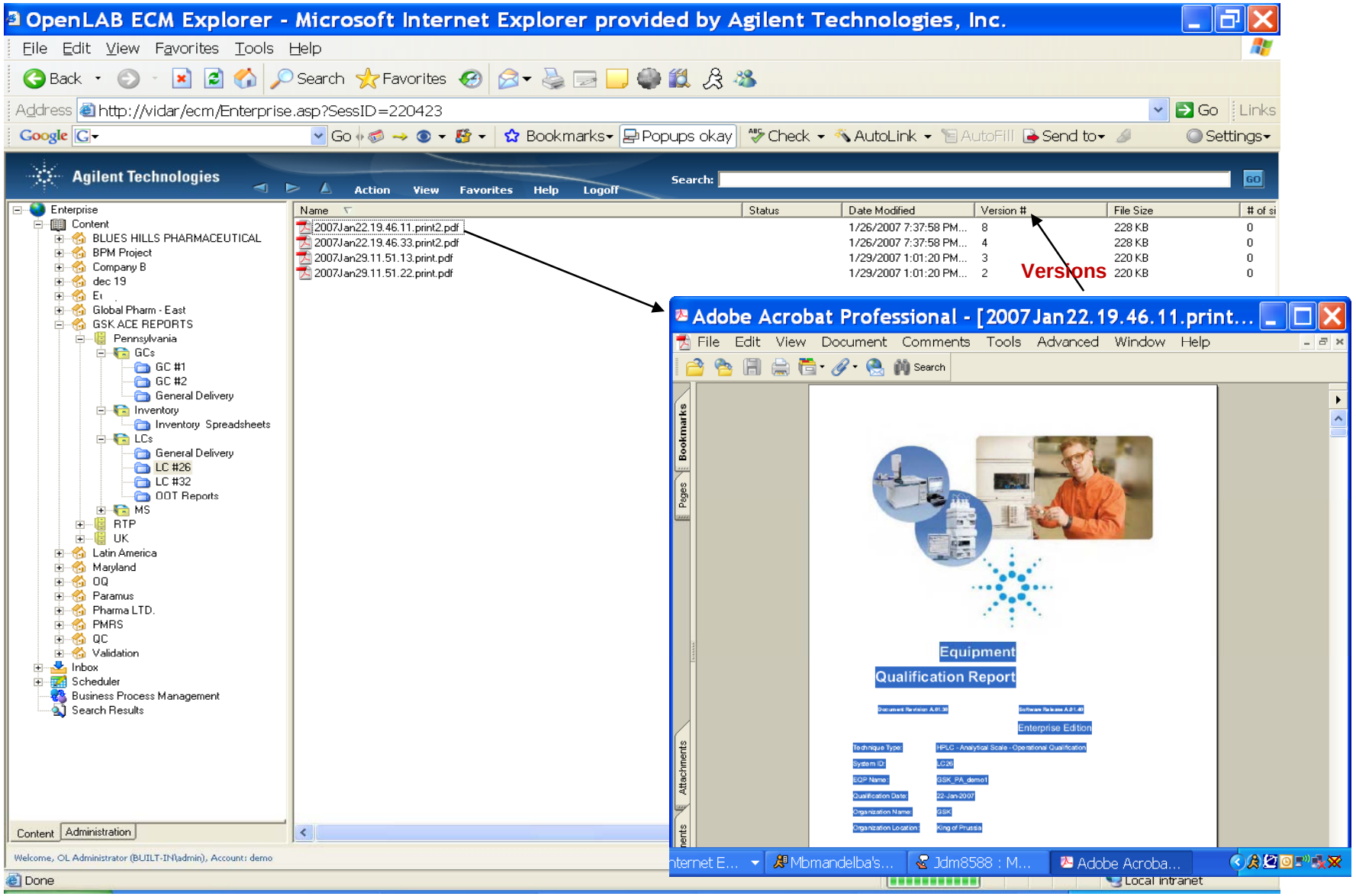

### Flexible reports...


### Single signature...

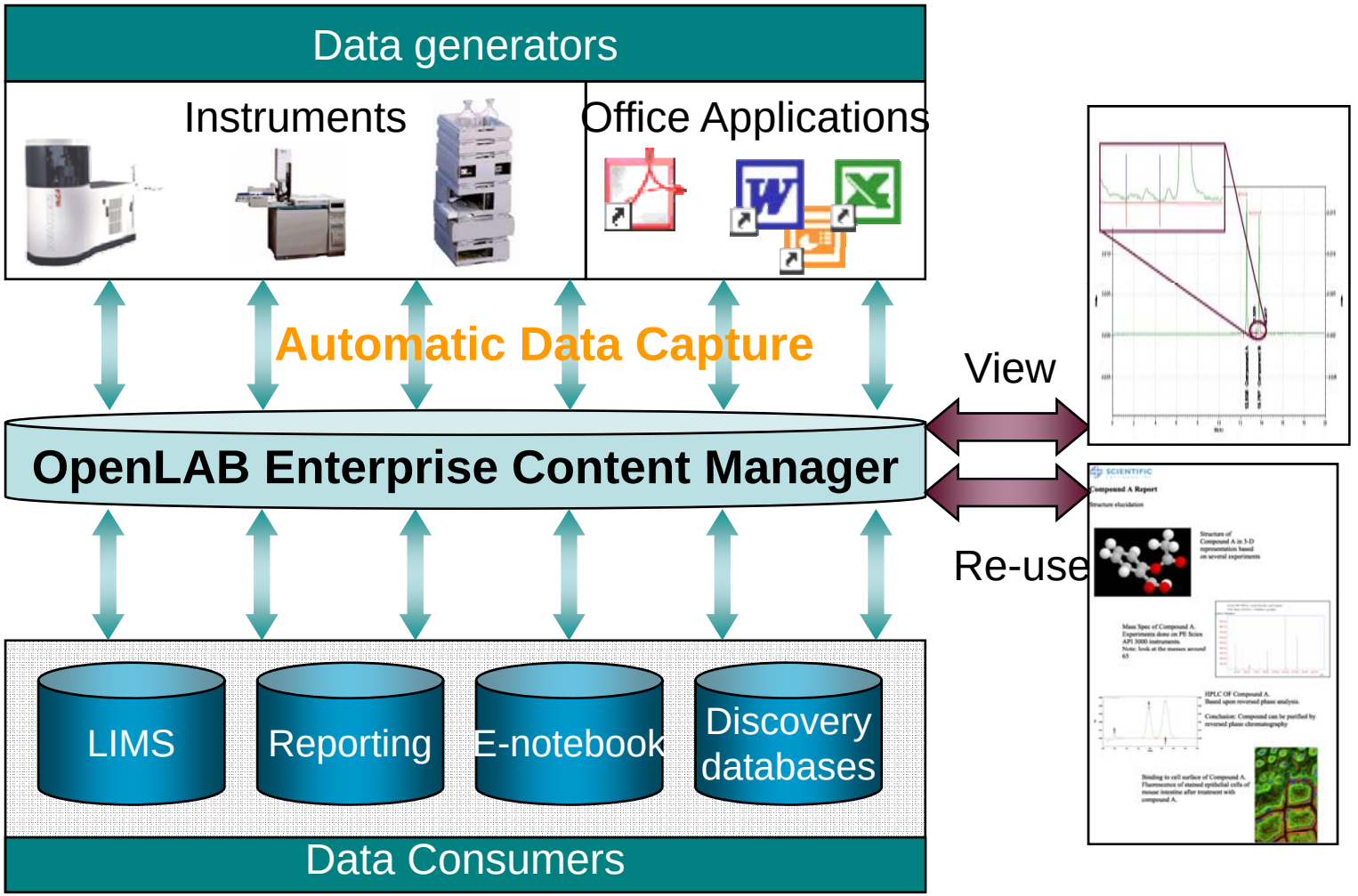



## Saves time & money ...

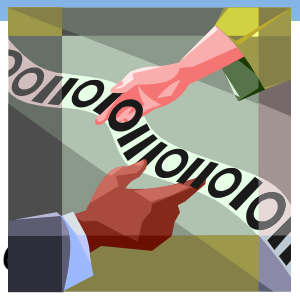
# Files Stored in Native Format in Openlab



# OpenLAB ECM Managing Data



# ECM Driven Solutions (just some of many examples)



- *Data Archiving*
- *Central Data Storage (PROTECTED), Methods, SOP, Documents…*
- *Regulatory Compliance (21CFRPart11, GALP, Sarbanes Oxley, HIPPA)*
- *Document Management*
- *SOP maintenance*
- *Legacy Data ! (viewers, TNF, data, CDS, LIMS…)*
- *Excel Remediation*
- *Validation/Compliance Documentation (i.e. ACE)*
- *ELN*
- *Data Management Searching and Reporting*
- *IP Protection*
- *Chain of Custody (reports, data…)*
- *Instrument and Training records*


# How Data is imported into ECM

- Manually
  - Add Files (explorer right mouse click)
  - Office integration (Excel, Word, PowerPoint, Outlook, Explorer)
  - Tool Bar (Microsoft)
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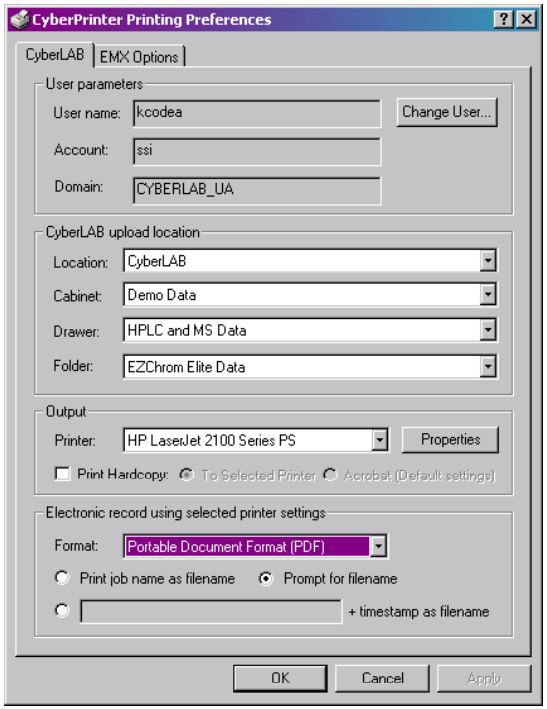
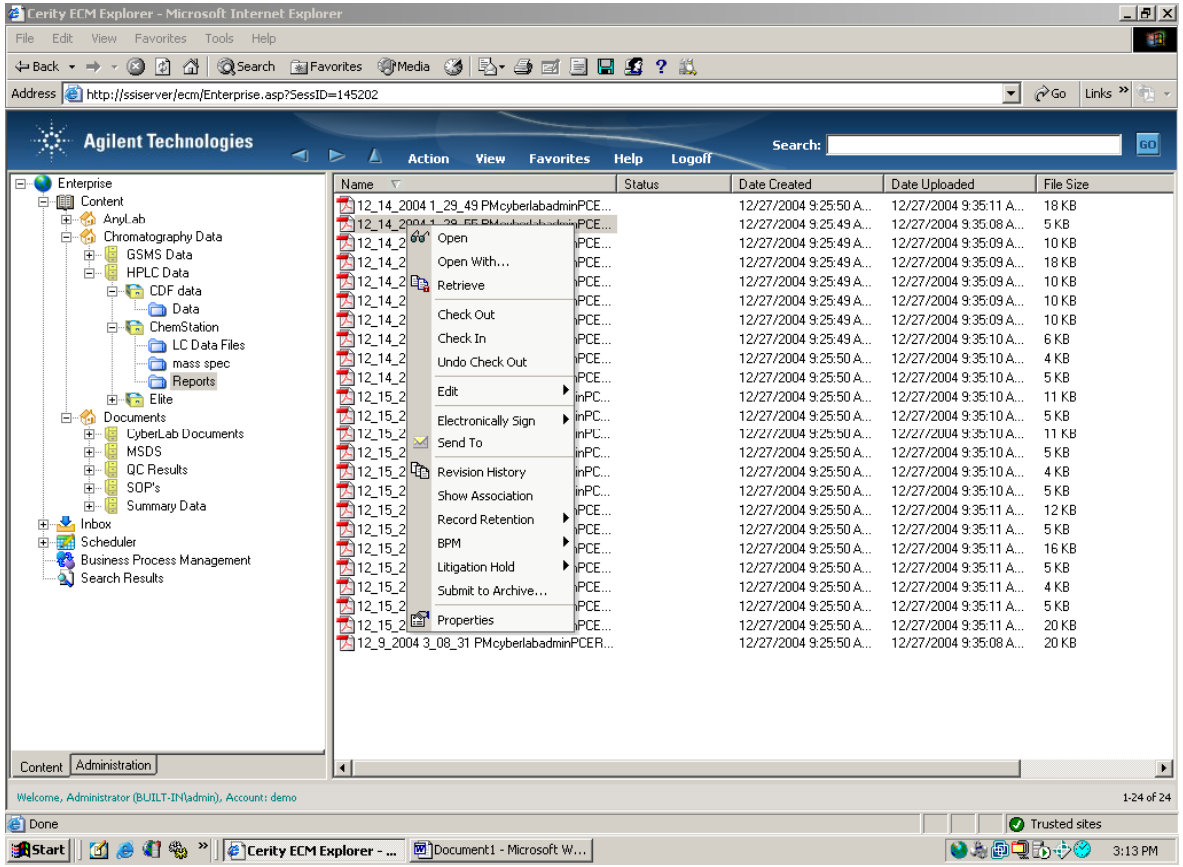


# OpenLAB ECM User Interface

- **OpenLAB ECM uses the standard MS Explorer look and feel to access content**

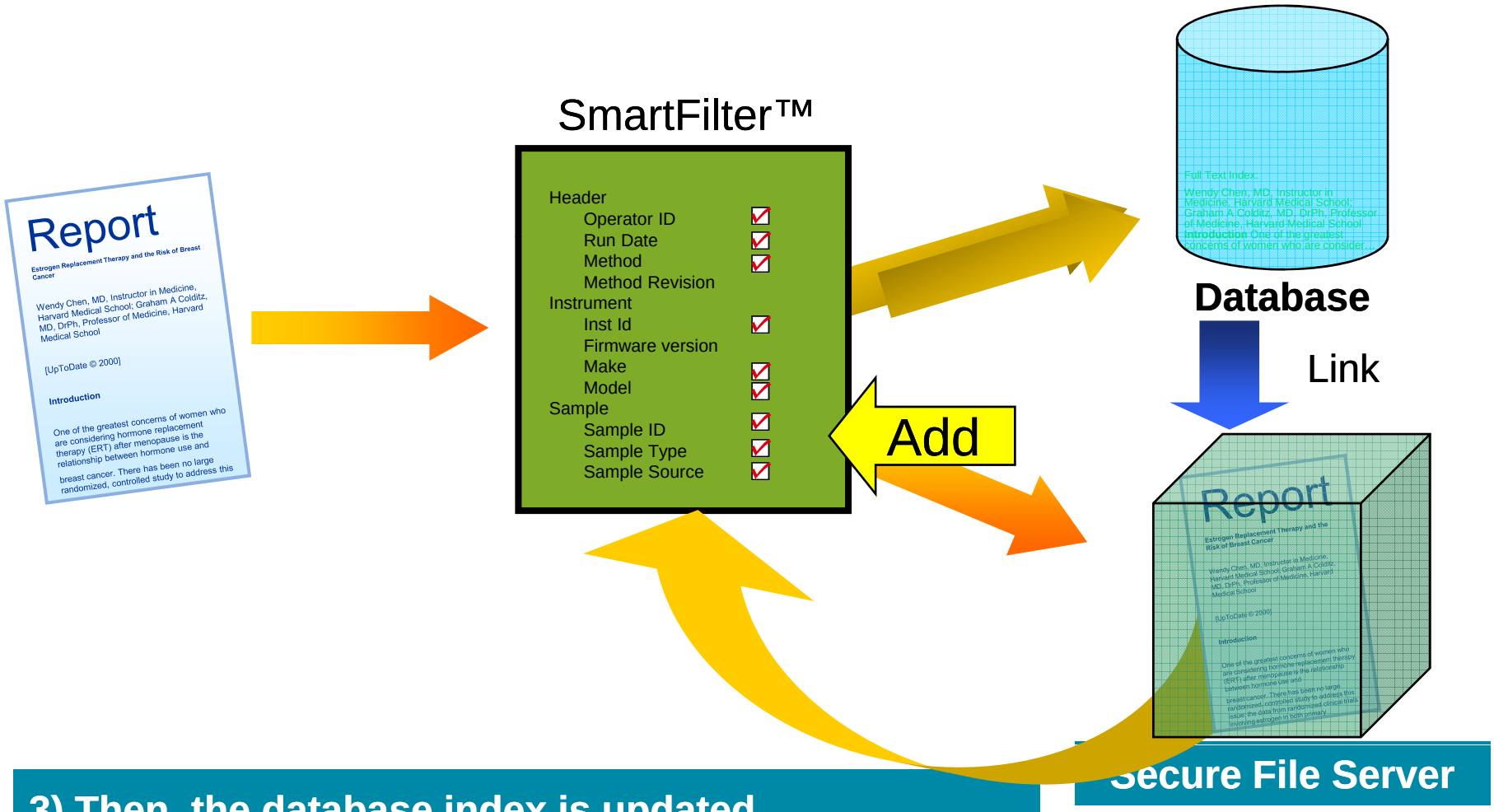
- Fully Web based – thin client
  - Not just running in a browser as a fat client
- Single Application – 1 login machine readable, human readable in same application
- LCDF concept - organize
- Account
  - Location
    - Cabinet
      - Drawer
        - Folder

- A visual organization of data
- Data is also searchable with "Google-like" or advanced search engines



# Intelligent Indexing for Advanced Searching

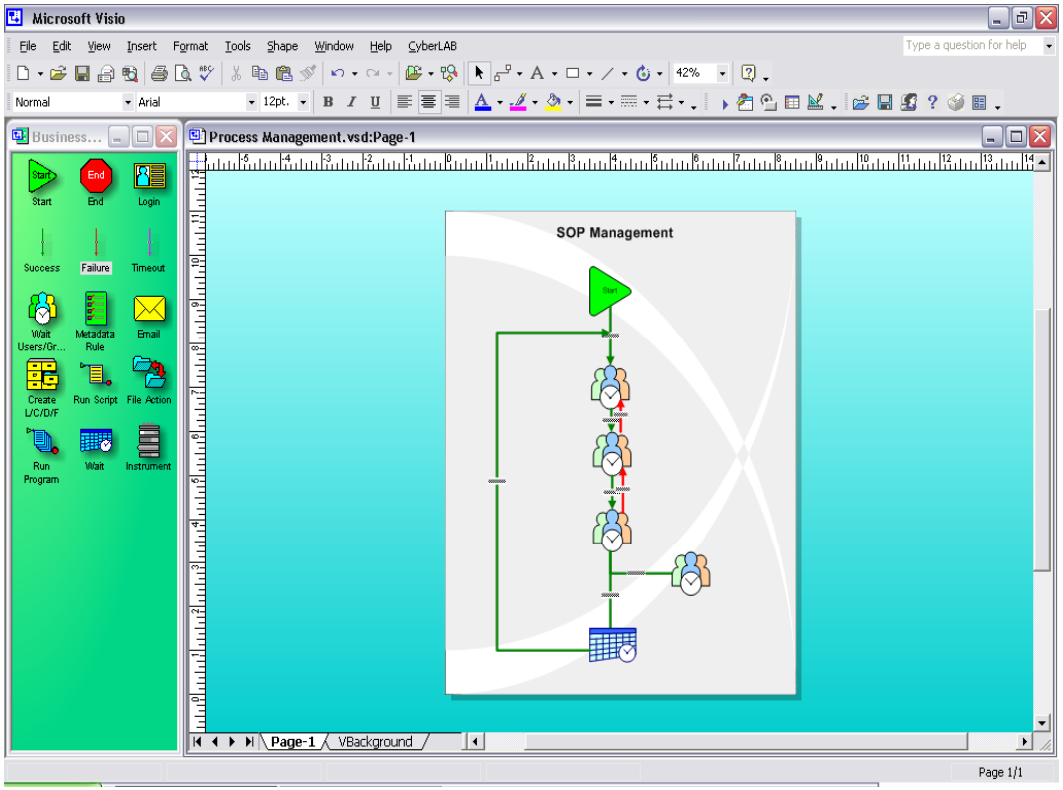
***For machine and human readable files***




**3) Then, the database index is updated**

# Business Process Management (BPM)

- **A plug-in for OpenLAB ECM**
- **Manage flow of work throughout the enterprise by:**
  - *Automating processes*
  - *Streamlining processes*
  - *Optimizing processes*



# BPM Template Design

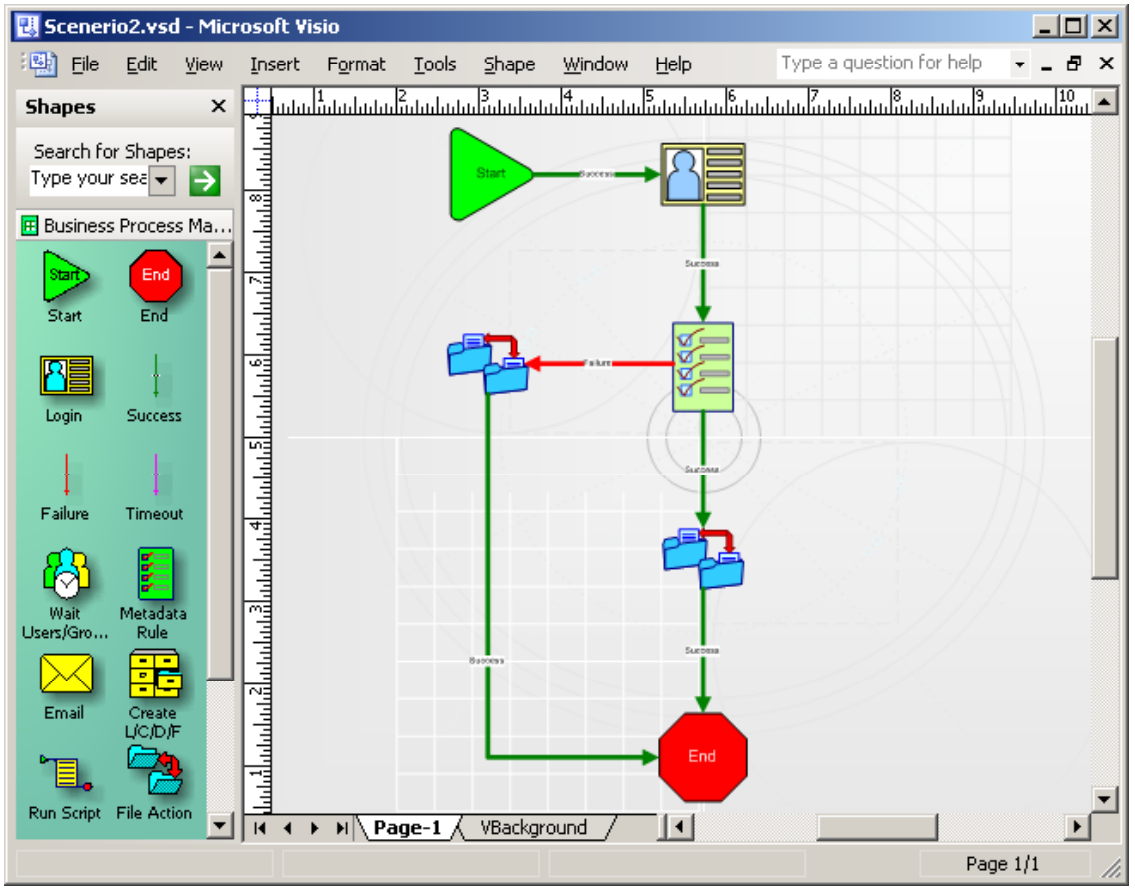
**Utilizes Microsoft Visio**

Provides Visio objects and tools for various business tasks

•Workflow modeling is frequently done with Visio now

These tasks have standard programmatic actions configured into them

Build and configure your own workflow based on document or file activities



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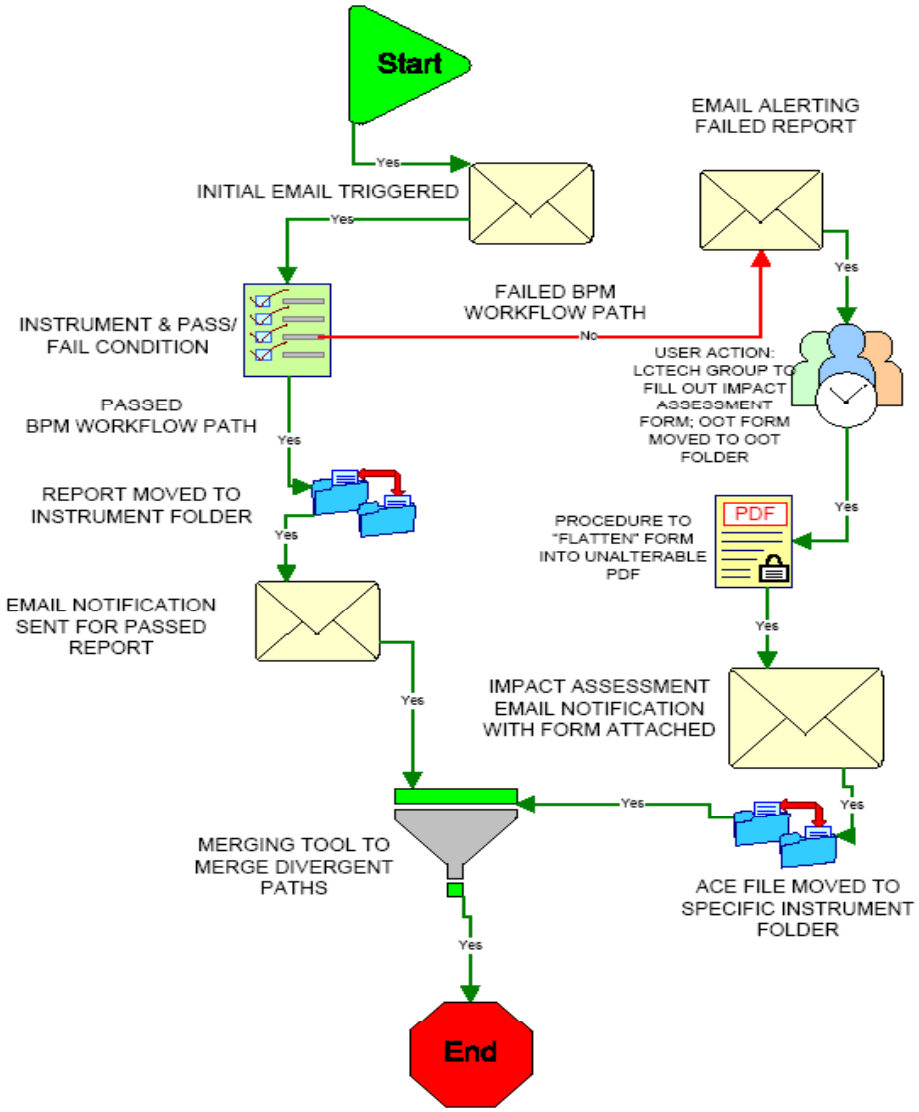

# WorkFlow: ECM with ACE