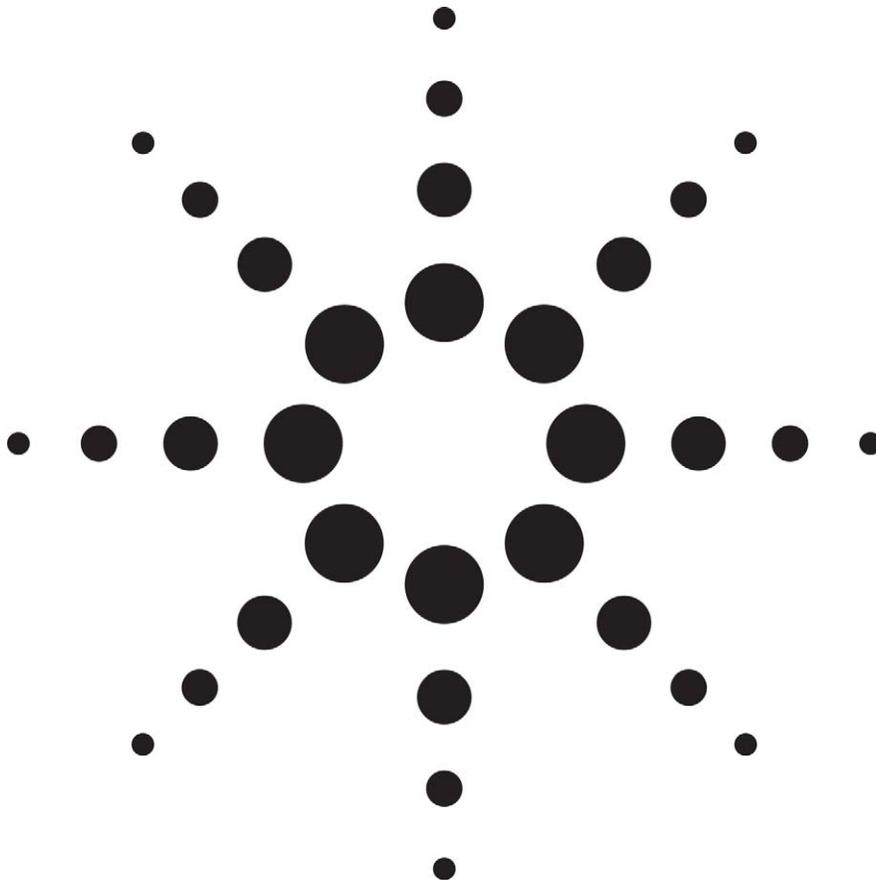


Agilent OL with Business Process Manager

*Automated System Performance
Verification*

White Paper



By Dario Fiore

Agilent Technologies
Laboratory Informatics
Life Sciences & Chemical Analysis Group

Agilent OL with Business Process Manager

Automated System Performance Verification

Introduction

Verification of instrument performance is a routine task that all analytical laboratories must perform on a periodic basis. This is particularly important if the instruments are used for mission-critical applications, in regulated environments, or critical sample analysis.

Routine Operational Qualification (OQ) may be done on the basis of a periodic service cycle. Every six months or so, the instruments may be taken off-line for a period of time while the testing and servicing is performed. Ideally, however, the extent of maintenance could be reduced if key portions of Performance Verification (PV) can be conducted more frequently or in the course of routine analysis. A concern with this approach is that the response to a failed PV test may be considered too time consuming to be done on a routine basis.

Although modern analytical data systems may offer automation to conduct the PV tests, most do not tie into or facilitate the necessary follow-up steps required to take corrective actions such as:

- Automated assessment of performance criteria
- Notifying appropriate individuals of required steps, corrective actions and approval process
- Ensuring correct management, versioning, and routing of administrative and laboratory documentation

Agilent OL manages this combination of technical, administrative, scientific, and business process requirements. This tightly integrated operating system combines the ability to control and acquire data from over 260 instrument models, manage any electronic content, and uses a Business Process Manager (BPM) that does not require programming. Agilent OL brings together people, content, and processes to improve the operation in the enterprise.

This white paper illustrates a business case that reflects actual needs in today's laboratory and serves as an example of how Agilent OL facilitates the entire process from data acquisition, to automated assessment of instrument performance, to taking appropriate actions defined by the individual enterprise.

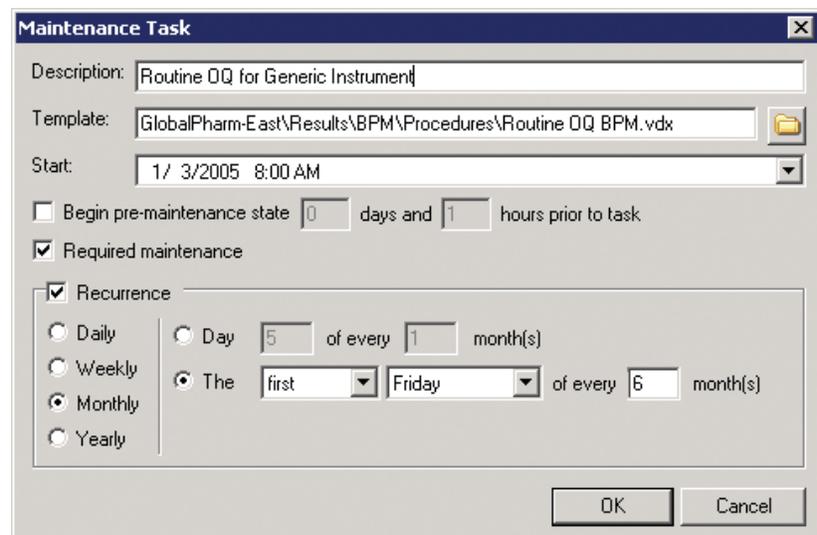


Figure 1: Agilent OL's Instrument Maintenance Task.

Routine Monitoring of Instrument Performance – Business Case

In this example we continue to reference the hypothetical organization called General Pharmaceutical Products, Inc. (GPP), producers of tablets for the OTC market.

To ensure that quality data is produced from each of their instruments, GPP performs a full OQ on a regular 6-month cycle; this is managed within Agilent OL's Instrument Maintenance feature illustrated in Figure 1.

GPP scientists, however, have determined that certain key performance indicators can be monitored more frequently offering the following benefits.

- Increase overall output from each instrument by reducing the extent of service required at each interval.
- Reduce the downtime and expense involved in maintenance by responding earlier to changes in performance.
- Reduce costs by performing only required repairs

The analytical method is also being monitored as part of this PV. This provides an added bonus because the analyst can be routinely reminded when mobile phases and standards need to be refreshed.

As described elsewhere, Agilent OL addresses all these needs by integrating CDS, ECM and BPM functionality. Below we describe the details and user experiences once the system is deployed.

Details

PV Test Criteria

The 4 criteria for routine PV are:

- **Asymmetry (Asy):** This assesses peak shape of a key component in routine standards. Acceptable asymmetry must be 1.1 or less.

- **Resolution (Res):** This assesses efficiency of separation between 2 key components in routine standards. Acceptable resolution must be 1.5 or greater.
- **Repeatability (Rep):** This assesses the autosampler performance. Acceptable repeatability must be less than or equal to 0.80%
- **Detector Performance (Det):** GPP has determined that an early symptom of detector lamp failure manifests in STD1 to STD2 ratio that is below 0.875 due to relative molar absorptivity of the key standards.

Criteria: P = Pass, F = Fail

Asy	Res	Rep	Det	Diagnosis / Action
P	P	P	P	System performance is acceptable, no action required.
P	F	P	P	Mobile phase or Standard mix should be made fresh.
F	F	P	P	Column needs to be replaced and a spare re-ordered.
P	P	F	P	Autosampler maintenance must be performed.
P	P	P	F	Lamp performance is degrading, replace lamp.

Table 1: Abbreviated PV Assessment Criteria

These criteria are associated with a Responsibility Matrix defined in GPP's SOP document as indicated in the table below:

Asy	Res	Rep	Det	Analyst Action	Approver Action
P	P	P	P	None	None
P	F	P	P	Replace Mob. Phase and Standards.	Approve action in Instrument Log.
F	F	P	P	Purchase new column, submit form for approval.	Approve action in Inst. Log and E-Sign Purch. Order request.
P	P	F	P	Complete Serv. Order for approval.	Approve action in Inst. Log and E-Sign Serv. Order request.
P	P	P	F	Purchase new Det. Lamp, submit form for approval.	Approve action in Inst. Log and E-Sign Purch. Order request.

Table 2: Responsibility Matrix

Mapping the Business Process to Agilent OL

The criteria, reports, responsibility matrix, and forms associated with this business process are mapped to Agilent OL in the following manner:

1. The CDS portion of Agilent OL is used to analyze data and generate the ad-hoc abbreviated PV report.
2. BPMs are designed to automatically and transparently evaluate the PV reports, as they are placed in specific locations.
3. Anomalous reports immediately trigger the appropriate user actions that include:
 - a. Require the analyst to review a responsibility matrix in an SOP
 - b. Update an instrument log within Agilent OL's ECM
 - c. Fill out a standard Purchase Order or Service Request depending on the criterion

PV Report Generation

Agilent OL's Advanced Report Designer is used to create a template for PV Testing. This results in a single page report that summarizes each of the test criteria as shown in the figure below.

Agilent OL's SmartSequence™ technology is used to create and run sequence or reanalyze previously acquired data. The appropriate records are tagged as Summary Runs and the PV Report Template is invoked within this sequence.

The sequence produces a result package called an OL.SSIZIP file that is placed in a predetermined location in the ECM. This fully indexed package contains all the data, templates, methods, sequence, and report files that generated the result

Business Process Design

The PV report file is contained in the OL.SSIZIP. All the files contained in the package are indexed. In this example, we are only interested in the 4 keys extracted from the PV Summary Report that reflect the business criteria for performance verification.

Because multiple criteria are being evaluated, GPP chose an embedded BPM approach. The top-level process performs the initial evaluation of metadata of the PV Summary report. If one of the failure criteria is encountered, an embedded process that contains user activities, forms and requires user actions then treats the report.

The top-level process is transparently triggered by the appearance of the OL.SSIZIP package generated by the instrument sequence. This is one benefit of the seamless interaction between the data system and content management parts of Agilent OL.

OpenLAB™ Performance Verification Report

Instrument name:	Acceptance Criteria	Test 1	Test 2
Sequence name:	SysSut_Val.rst	Asymm 10%	1.1
Analyst:	DFAdmin (BUILT-IN)ad...	USP Resolution	1.5
Date printed:	03-May-05	AS Repeatability	0.80%
		Det. Intensity	0.875
31000			
Criterion 1		Asymmetry Compound	
Data file name	Compound	Asymm 10%	
1 SysSut001.dat	CaF	1.0028	
2 SysSut002.dat	CaF	1.0031	
3 SysSut003.dat	CaF	1.0037	
4 SysSut004B.dat	CaF	1.0040	
5 SysSut005.dat	CaF	1.0020	
6 SysSut006.dat	CaF	1.0014	
Max:		1.0040	
Mean:		1.0028	
Std Dev:		0.0010	
%RSD:		0.10%	
STATUS:		PASS	
Criterion 2		Resolution Compound	
Data file name	Compound	USP Resolution	
1 SysSut001.dat	CaF	1.8930	
2 SysSut002.dat	CaF	1.7026	
3 SysSut003.dat	CaF	1.8957	
4 SysSut004B.dat	CaF	1.8620	
5 SysSut005.dat	CaF	1.8612	
6 SysSut006.dat	CaF	1.8307	
Min:		1.8612	
Mean:		1.8792	
Std Dev:		0.0157	
%RSD:		0.84%	
STATUS:		PASS	
Criterion 3		Repeatability	
Data file name	PK2	PK1	Comb. Stats
1 SysSut001.dat	44948	34752	
2 SysSut002.dat	44928	34874	
3 SysSut003.dat	44804	34825	
4 SysSut004B.dat	35417	45716	
5 SysSut005.dat	44850	34914	
6 SysSut006.dat	45088	35064	
Mean:	43339	36858	39908
Std Dev:	3582	4440	4161
%RSD:	8.26%	12.11%	10.54%
STATUS:		FAIL	
Criterion 4		Deterior Performance	
Data file name	PK2	PK1	PK1:PK2
1 SysSut001.dat	44948	34752	0.773
2 SysSut002.dat	44928	34874	0.776
3 SysSut003.dat	44804	34825	0.773
4 SysSut004B.dat	35417	45716	1.291
5 SysSut005.dat	44850	34914	0.778
6 SysSut006.dat	45088	35064	0.778
Mean:			0.862
STATUS:		PASS	

5/3/2005 10:35:08 AM Prepared by Scientific Software, Inc. 1/1 - 7

Figure 2: Agilent OL's Performance Verification Report output.

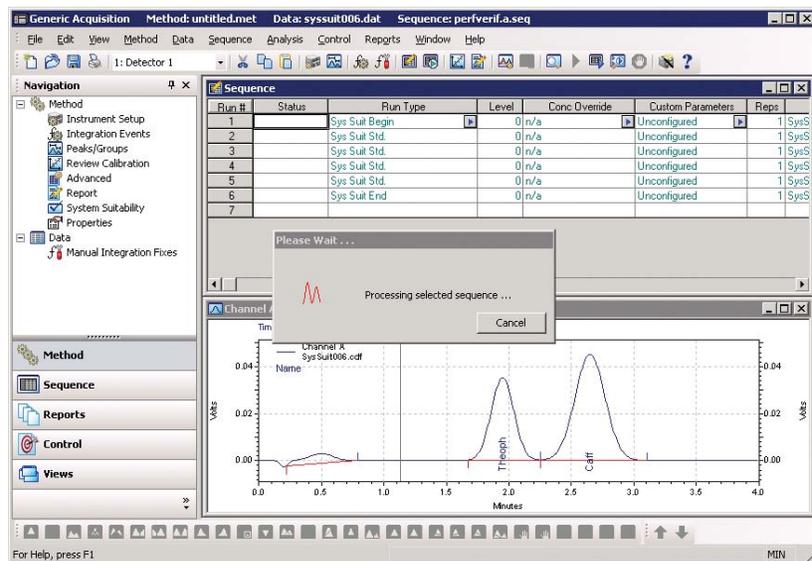


Figure 3: Agilent OL's sequence engine generates PV reports.

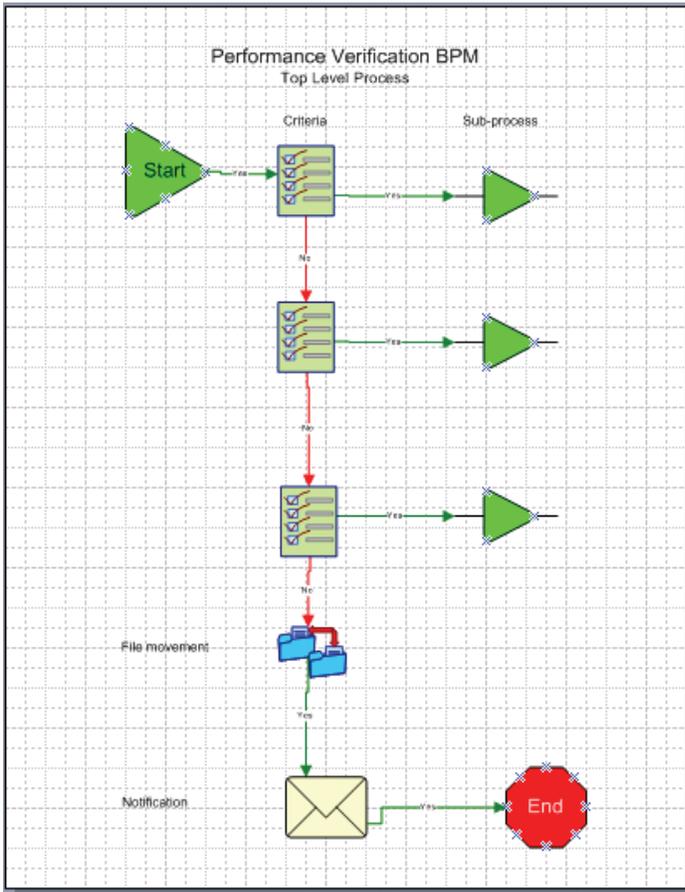


Figure 4a: Top level PV business process.

Top Level BPM

The top-level process is shown in figure 4a. It is assigned at a folder level of the content manager so that any file placed in that folder can be evaluated automatically. If a file or file package contains the appropriate metadata keys specified within this process, it will be either sent to an embedded process or moved to a different location.

Embedded BPMs

The more detailed activities occur in the embedded BPMs. These are designed to follow the assessment criteria and responsibility matrix summarized in Tables 1 and 2 on page 3. The structure of the processes is very similar. In figure 4b, we analyze the process designed to respond to the case where autosampler reproducibility is out of specification.

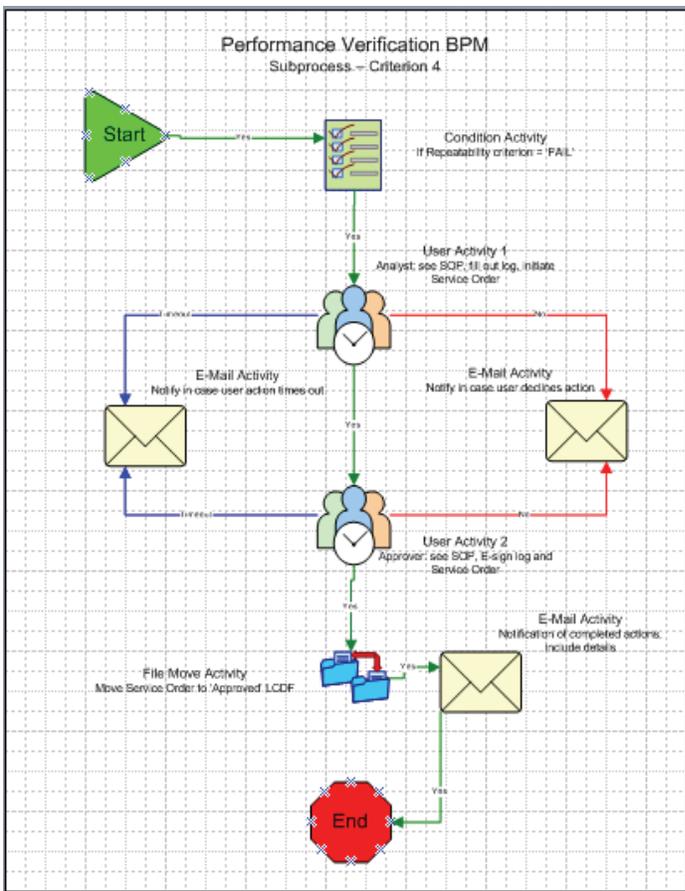
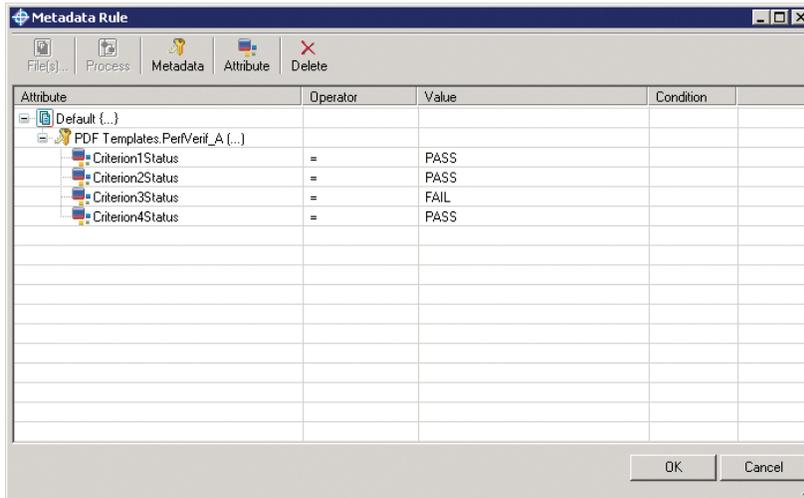


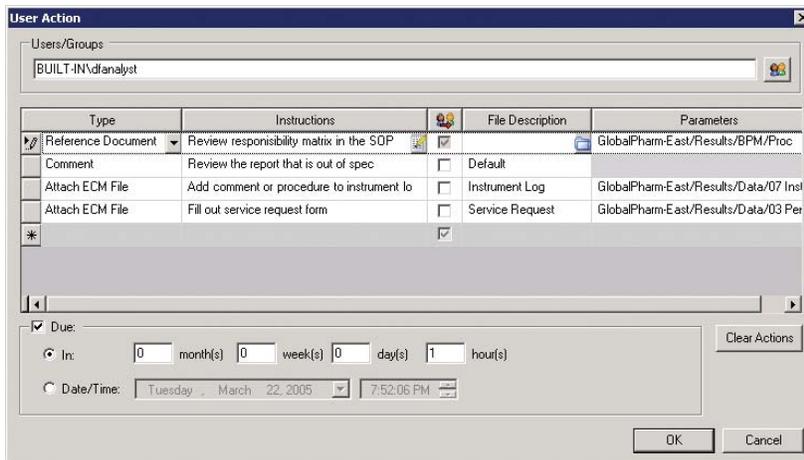
Figure 4b: One of the subordinate business processes.

The BPM performs the following tasks:

- **Criterion Activity:** This is used to confirm that the PV Report is properly evaluated.

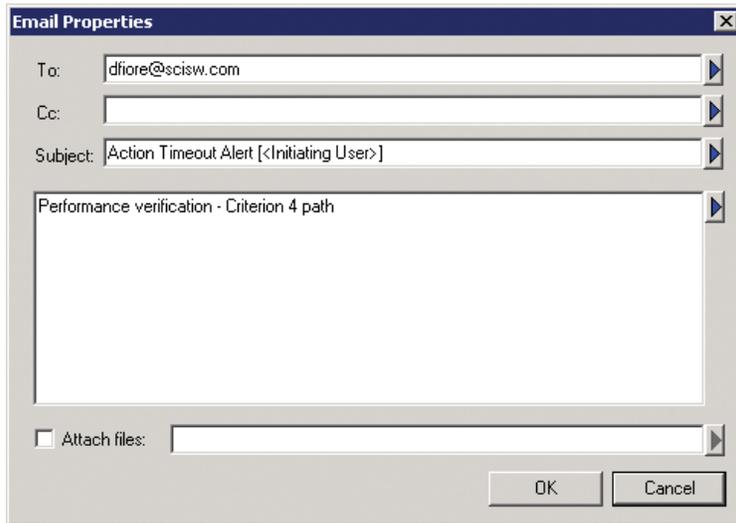


- **User Activity 1:** The user is required to:
 - **Review an SOP:** this is supplied as part of the process. From this he/she will know exactly what is expected.
 - **Review the PV Report:** This is also conveniently supplied.
 - **Update and attach an Instrument Log:** this readies the log for sign-off by an approver.
 - **Fill out and attach a Service Order request:** this readies the service request for sign-off to an approver.

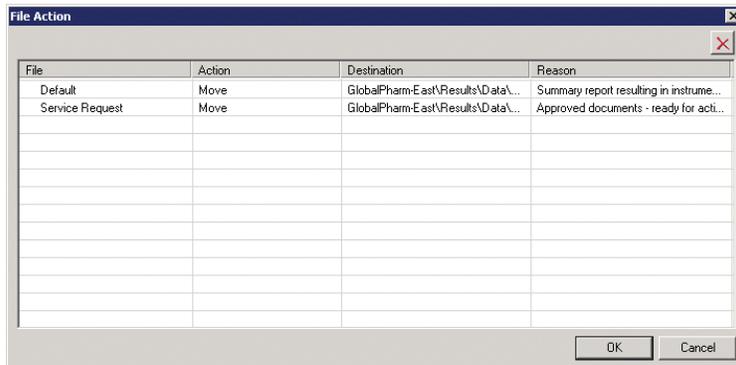


- **User Activity 2:** The approver receives the same SOP and OL.SSIZIP package as the analyst, and is required to assess the analyst's evaluation. If agreeable with the assessment, e-sign with approval, decline if a change is required, or e-sign with rejection.

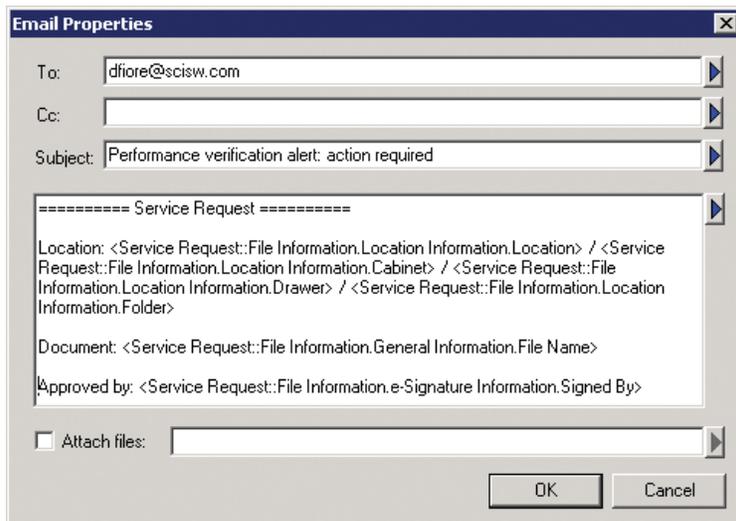
- **Email Activities:** These come into play in the event that a user is inactive or declines the required tasks. The messages can be sent to the appropriate individual or group to merely alert or initiate an escalation process. A significant amount of information may be included in the message because of the available keys extracted by the ECM.



- **File Action:** this now moves the files into appropriate locations based on file type.



- **Final E-Mail Activity:** This is the notification that is sent to appropriate managers and includes enough high-level information to inform them of what occurred. This message may contain a very detailed collection of metadata tags for the associated files in the content repository.



Instrument Log Files: in this example, each instrument log file is a separate Excel® spreadsheet. Because these too are managed within Agilent OL, all entries, modifications, and E-Signatures are tracked within the ECM for supervisory or regulatory review.

These ancillary forms are shown in the figure below:

HPLC-ANALG-15-UV Instrument Log		
Date	Comment / Action	Approver
2/12/2005	Instrument placed in service	N/A
3/1/2005	Replace D2 lamp and reorder spare	DFApprover
4/6/2005	Replace D2 lamp and reorder spare [bad supplier]	DFApprover
4/10/2005	Initiated service request for autosampler maintenance	DFApprover

Figure 7: Sample Instrument Log.

Content Management and BPM Deployment

Assignment of Special metadata keys: Agilent OL provides a PDF Template generation tool that is used when unique report formats need to be managed beyond simple text indexing. PDF Template Keys need only be created once for a given report format. In this example 4 key pairs were designed so that a description and a value could be recognized in any PV Report generated.

Report generation and Packaging Results: each report generated by the CDS portion of Agilent OL is a summary of the chromatographic analyses as described above. Agilent OL's sequence engine automatically produces the reports in PDF format, packages all the content in an 'OL.SSIZIP' file containing raw data, reports, and all files associated with the execution of the sequence.

Report Indexing: the OL.SSIZIP package is automatically placed in the folder specified by the Analyst and indexed. During the indexing process, any special tags designed with Agilent OL's template tool or user defined keys are also extracted and associated to the indexed file as metadata. The steps described occur completely automatically and do not require user intervention other than launching a sequence (set-and-forget).

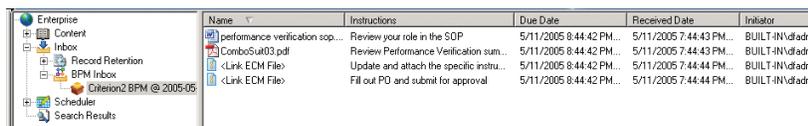
Deployment: GPP has chosen to deploy the PV assessment BPM described above as a folder-level process. This enables the unattended monitoring of results as they are being generated by Agilent OL's CDS engine. Only the pertinent summary reports are flagged for user action, other content is routed transparently to a folder location for approved results.

User Experience

Agilent OL eliminates issues that represent significant time drains such as those summarized in the section below called 'Efficiency Gains'. As a result of the well-structured mapping of GPP's business process and the powerful tools available in Agilent OL, the user experience is simple and well directed. Below we describe the experience of the 2 users types involved in this process: the Analyst and the Approver. Remember that these users need only respond to PV results that have been automatically flagged by the BPM engine.

Analyst Experience

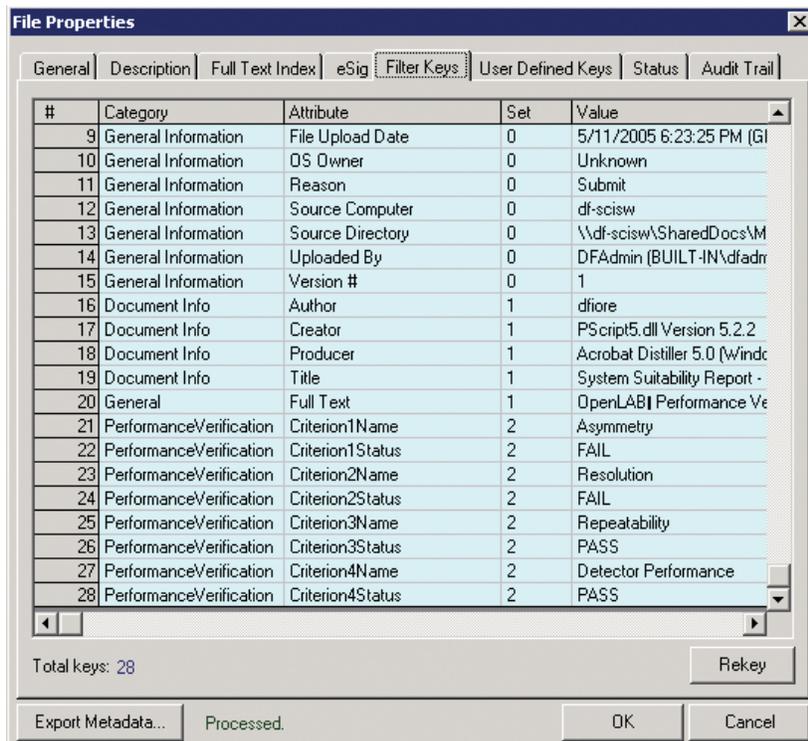
The analyst's tasks are significantly simplified, as they only need to be involved with initiating sample runs by launching sequences. Thereafter they simply monitor their Agilent OL Inbox for activities and instructions organized by the BPM engine.



Name	Instructions	Due Date	Received Date	Initiator
performance verification sop...	Review your role in the SOP	5/11/2005 8:44:42 PM...	5/11/2005 7:44:43 PM...	BUILT-IN\dfadm
ComboSut03.pdf	Review Performance Verification sum...	5/11/2005 8:44:42 PM...	5/11/2005 7:44:43 PM...	BUILT-IN\dfadm
<Link ECM File>	Update and attach the specific instru...	5/11/2005 8:44:42 PM...	5/11/2005 7:44:44 PM...	BUILT-IN\dfadm
<Link ECM File>	Fill out PO and submit for approval	5/11/2005 8:44:42 PM...	5/11/2005 7:44:44 PM...	BUILT-IN\dfadm

Figure 8: The user only has to follow supplied instructions and focus on specific tasks.

Assessment of PV report content can be done by either reviewing the report itself (seen in Fig. 2 above) or by the reviewing the extracted metadata found in the file properties.

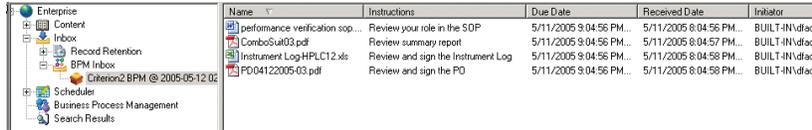


#	Category	Attribute	Set	Value
9	General Information	File Upload Date	0	5/11/2005 6:23:25 PM (G)
10	General Information	OS Owner	0	Unknown
11	General Information	Reason	0	Submit
12	General Information	Source Computer	0	df-scisw
13	General Information	Source Directory	0	\\df-scisw\SharedDocs\M
14	General Information	Uploaded By	0	DFAdmin (BUILT-IN\dfadm
15	General Information	Version #	0	1
16	Document Info	Author	1	dfiore
17	Document Info	Creator	1	PScript5.dll Version 5.2.2
18	Document Info	Producer	1	Acrobat Distiller 5.0 (Windc
19	Document Info	Title	1	System Suitability Report -
20	General	Full Text	1	OpenLAB Performance Ve
21	PerformanceVerification	Criterion1Name	2	Asymmetry
22	PerformanceVerification	Criterion1Status	2	FAIL
23	PerformanceVerification	Criterion2Name	2	Resolution
24	PerformanceVerification	Criterion2Status	2	FAIL
25	PerformanceVerification	Criterion3Name	2	Repeatability
26	PerformanceVerification	Criterion3Status	2	PASS
27	PerformanceVerification	Criterion4Name	2	Detector Performance
28	PerformanceVerification	Criterion4Status	2	PASS

Figure 9: Simply reviewing file metadata provides a convenient way to assess results.

Approver Experience

The Approver receives a BPM package after the Analyst's tasks are completed. The Approver sees the same PV results in addition to the Analyst's inputs in the Instrument Log and Purchase or Service Order. Approval of the Analyst's input is indicated by electronically signing both files. With Agilent OL, any electronic document may be e-signed even if the original application does not allow the display of signature watermark as with Adobe® PDF documents.



Name	Instructions	Due Date	Received Date	Initiator
performance verification sop...	Review your role in the SDP	5/11/2005 9:04:56 PM...	5/11/2005 9:04:56 PM...	BUILT-IN\dfad
ComboSul03.pdf	Review summary report	5/11/2005 9:04:56 PM...	5/11/2005 9:04:57 PM...	BUILT-IN\dfad
Instrument Log\HPLC12.xls	Review and sign the Instrument Log	5/11/2005 9:04:56 PM...	5/11/2005 9:04:58 PM...	BUILT-IN\dfad
PO04122005-03.pdf	Review and sign the PO	5/11/2005 9:04:56 PM...	5/11/2005 9:04:58 PM...	BUILT-IN\dfad

Figure 10: The Approver's Inbox.

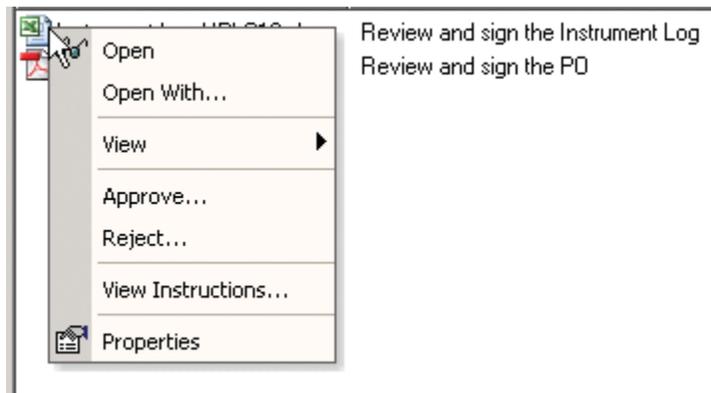
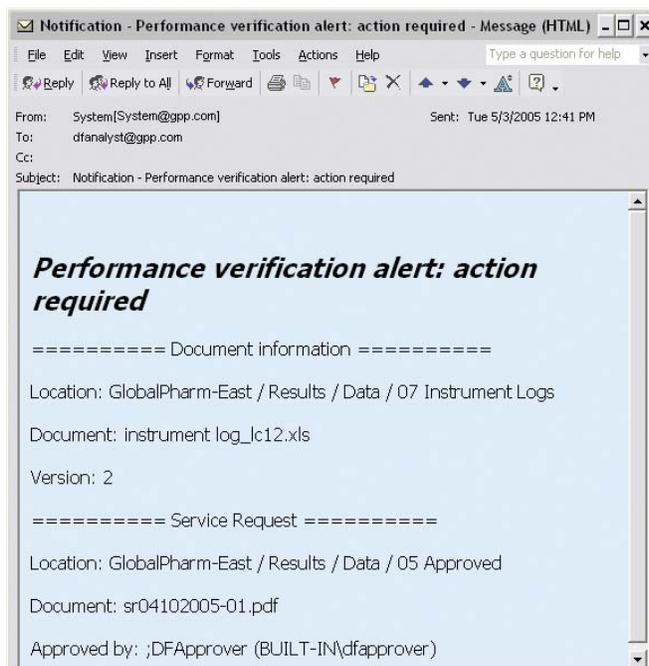


Figure 11: Simple E-sig process.

Notifications

As defined in the embedded BPMs, prior to completing a process, the designated people are notified via e-mail. The e-mails contain significant content detail obtained from Agilent OL and can be directed to desktop or mobile client devices.



Efficiency Gains

By integrating user and role management, CDS, ECM, and BPM functionality, significant efficiencies are gained in ways that perhaps many enterprises have not even calculated. The following are some benefits that are evident just in this example:

- **Analysts:** The time and expertise required for early detection of performance degradation is nearly eliminated. This can represent a significant financial benefit particularly if instruments are used by offsite, offshore, transient analysts or in a 'walk-up' environment where any user can access a particular instrument.
- **Time:** The time involved in administrative tasks such as locating the correct procedure, Service Report, Purchase Order template, Instrument Log, and approved versions of these documents is eliminated. This also represents an intangible benefit as well in environments where scientists prefer to focus on science with minimal time spent on administrative chores.
- **Laboratory Managers** are assured that any and all instruments managed by Agilent OL are working optimally or quickly attended to.
- **Administrative and Purchasing Managers:** are assured that submission of purchase orders is done correctly, according to established procedures, and routed correctly. Even submission of orders to vendors can be further automated by using e-mail and E-Fax submissions.
- **Informatics Group Managers** benefit from supporting a single scalable system that combines users, data of all kinds, and business processes while allowing connectivity to other enterprise systems.
- **Compliance Officers** benefit from knowing that users, raw data, results, and E-Signatures are all managed in an auditable, permission-based closed system.
- **Executives:** CFO and Division VP's can realize ROI benefits by assessing the net efficiency increase per FTE.

SUMMARY

In conclusion, enterprises such as GPP benefit tremendously from the collection of technologies within Agilent OL. A well-defined process, such as the System Performance Verification example described here, is easily and effectively handled by Agilent OL's ability to manage from instrument control to business response and user interactions. As a result efficiencies summarized in the previous section are gained at various levels in the enterprise.

