



# Agilent OpenLAB Instrument Control Manager

## Comprehensive System Validation Service

### Agilent OpenLAB Installation Qualification Service

The Agilent OpenLAB Installation Qualification (IQ) Service validates that your system, as purchased, is installed as designed and specified. The Agilent OpenLAB IQ Service documents that your system has been properly installed into your environment, and that this environment is suitable for the proper operation of the system.

The purpose of the IQ is to ensure the following:

- The products that you have purchased from Agilent Technologies have been received as purchased.
- Your environment meets the environmental specifications as set by Agilent Technologies.
- The software that you purchased is completely installed on the server and client computers.
- The Agilent OpenLAB system functions properly in your environment.
- All the equipment (hardware and software) that you purchased is documented.

### Deliverables

- Agilent Technologies will prepare an IQ document that includes the configuration of the system being implemented and send it in electronic form for approval prior to the qualification.
- As the customer, you will review and approve the IQ protocol as assembled by Agilent Technologies Analytical Validation Services. This protocol will reflect the current Agilent Technologies qualification procedures for the product.
- Agilent personnel will execute an IQ with the predefined protocol prepared by Agilent Technologies.
- The IQ tests to ensure the components of the Agilent OpenLAB system are installed properly including (depending upon your specific configuration):
  - Enterprise Content Management (ECM)
  - Business Process Management (BPM)
  - ECM Options
  - Instrument Control Manager (ICM)
  - Instrument control options
  - One ECM Desktop Client



- Remediation Services
- ECM Print Services
- Agilent Technologies will deliver the executed IQ paper document upon completion of the execution for final review and approval. All data collected by the Agilent representative will be signed and dated as per the protocol instructions.

### **Acceptance criteria**

Acceptance of the entire Agilent OpenLAB IQ Service is complete when the IQ documentation is reviewed and signed by both responsible parties.

### **Limitations and assumptions**

- The customer assumes responsibility for the review, acceptance, archiving, and security of the delivered record of qualification.
- Any requested modification to the IQ will be considered a change order to the project.
- The customer plans to purchase IQ for the acceptance and production systems.
- The Agilent IQ Service covers once instance of an Agilent OpenLAB system, such as the Validation instance. Additional instances can be validated for an extra fee.
- The IQ for the acceptance and production systems covers one client computer. Additional client computers can be validated for an extra fee.
- Screen captures are not included in the IQ execution.

### **Customer obligations**

Responsible for maintaining all hardware/software associated with this system under change-control management.

## **Agilent OpenLAB Operational Qualification Service**

The Agilent OpenLAB Operational Qualification (OQ) Service validates that your system, as purchased, meets functional specifications as designed. The Agilent OpenLAB OQ Service documents that your system (both hardware and software) as purchased meets functional specifications and performs as intended throughout representative or anticipated operating ranges.

The OQ protocol was developed using the methodology outlined below:

- The server and client functions were defined in advance.
- Test cases were developed with expected results and acceptance criteria by Agilent Technologies.
- The OQ protocol is jointly approved prior to the execution of the protocol.
- A certified Agilent representative will execute the tests.
- The results of each test will be compared with the expected results and the acceptance criteria.
- The resulting document will be jointly approved by the customer and Agilent Technologies.

### **Deliverables**

- Agilent Technologies will prepare an OQ document that is tailored to the configuration of the system being implemented.
- As the customer, you will review and approve the OQ protocol as assembled by Agilent Technologies Analytical Validation Services. This protocol will reflect the current OQ procedures for the product.
- Agilent personnel will execute an OQ for the server (or servers) and one client computer covered by the installation with the predefined protocol prepared by Agilent Technologies. The OQ tests to ensure the components of the Agilent OpenLAB system are operating properly including (depending on configuration):
  - ECM
  - BPM
  - ECM Options
  - ICM
  - Instrument control options
  - ECM Desktop Client
  - Remediation Services
  - ECM Print Services
- Agilent personnel will deliver the executed OQ documents to the customer upon completion of execution for review and approval. All data collected by the Agilent representative will be signed and dated.

## **Acceptance criteria**

Acceptance of the entire Agilent OpenLAB OQ Service is complete when the OQ documentation is reviewed and signed by both responsible parties.

## **Limitations and assumptions**

- The customer assumes responsibility for the review, acceptance, archiving and security of the delivered record of qualification.
- Any requested modification to the OQ will be considered a change order to the project.
- The Agilent OQ Service covers once instance of an Agilent OpenLAB system, such as the Validation instance. Additional instances can be validated for an extra fee.
- The OQ for the acceptance and production systems covers one client computer. Additional client computers can be validated for an extra fee.
- Screen captures are not included in the OQ execution.

## **Customer obligations**

Responsible for maintaining all hardware/software associated with this system under change control management.

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