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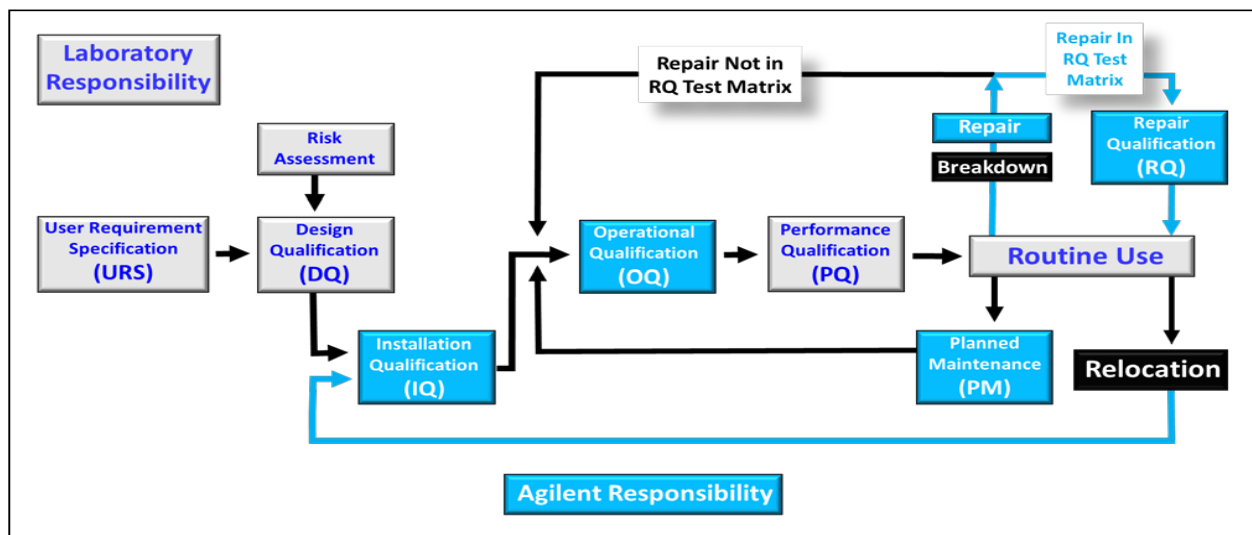
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Agilent CrossLab Compliance Services

Agilent CrossLab Compliance Services are designed to seamlessly integrate with traditional quality systems used by firms and recognized by regulatory agencies worldwide. Analytical instruments must be suitable for their intended use. This requirement is good science in all laboratories and a regulatory requirement in pharma and biopharma laboratories. A life-cycle process for documenting and testing the suitability of laboratory instruments should be followed and Agilent recommends the life cycle framework defined in USP General Chapter <1058> on Analytical Instrument Qualification (AIQ). USP <1058> defines the governing framework and requirements that need to be satisfied, but the laboratory is responsible for how they satisfy these requirements.

- The United States Pharmacopeia (USP) is the only major pharmacopeia with a general chapter dedicated to analytical instrument qualification, making <1058> an important global regulatory reference. The information is provided in a scientific, risk-based approach to analytical instrument qualification (AIQ). However, the life-cycle framework contained within USP <1058> is not prescriptive in its implementation, making the embedded scientific and risk-based principles flexible and universally applicable.
- The scientific process followed by CrossLab uses the Agilent's Automated Compliance Engine (ACE) to deliver paperless electronic qualification. The life-cycle stages Agilent perform are highlighted in the life-cycle diagram below. As part of this life-cycle, Agilent can configure the qualification tests performed to align with user requirements.



USP <1058> AIQ Framework

NOTE: RQ services, described later in this document, can be added to standard qualification services.

ACE Workflow and Equipment Qualification Plans (EQPs)

Overview

Within the ACE workflow, the qualification tests, setpoints, and limits are defined in an EQP that can be configured to ensure that testing satisfies user requirements. When the qualification work is complete, an Equipment Qualification Report (EQR) is issued. The electronic workflow used within ACE has significant data integrity advantages over traditional paper or Excel-based qualification protocols, as validated calculations can be performed directly using electronic data such as chromatograms and metrology test values. Several of the instrument life-cycle stages are the responsibility of the laboratory, Agilent can provide compliance consultancy services and documentation which can help customers satisfy these requirements. These additional services are not included in our typical qualification offering.



High-level ACE Qualification Workflow

Standard and User-defined Limits

(Hardware qualifications only)

EQPs are available for download and approval as standard documents with Agilent recommended tests, setpoints, and limits, or they can be electronically configured by approved personnel to align with user requirements and intended range of use requirements. The degree of configuration depends on the analytical technology, but most EQPs can be configured to some degree, and one feature that can typically be changed is test limits.

EQPs are designed to be configurable (dependent on the analytical technology and standard requirements), but including additional tests or setpoints can impact the qualification time and associated cost. If a test limit is changed, ACE includes the capability to report results against the Agilent approved limit and any customer required limits (that is, both can be reported simultaneously).

If a user-defined test limit is more stringent than an Agilent recommended limit, Agilent makes no guarantee or obligation regarding the instrument passing the tighter test specification requirements. It is important to appreciate that tests performed under conditions of use (that is, to satisfy pharmaceutical monograph and application requirements) can have different limits than those defined in the QQ. It is the continuum of the combined QQ, PQ, and any point of use testing performed each time the instrument is used that together satisfy regulatory requirements.

User Requirements Specification (URS)

The purpose of user requirements is to document the intended use of the instrument within the life-cycle process and quality management system (QMS) being followed. Therefore, the URS is a customer / laboratory responsibility. Defining user requirements is often used to guide the customer in instrument selection and is stated as the first activity that should be followed in <1058>. The URS is important for two main reasons.

- It is a regulatory requirement for FDA and EU GMP that the intended use of the instrument and any software must be specified.
- Investment protection perspective means getting the right instrument for the right job.

Qualification protocols should test the instrument against any limits or specifications listed in the URS, which should document the intended range of use. Depending on the instrument complexity and how it is classified, a separate URS document may not be needed, but the URS requirements of the <1058> framework must be satisfied. A separate URS is almost always recommended for computerized systems.

An instrument performance specification is a product of the instrument development process by the supplier. It typically documents the performance the instrument can achieve. The URS should be based on intended use of the instrument and not the instrument specification. Additionally, if the intended use of a system changes, this may trigger a need to review the URS and associated qualification testing (for example, to ensure range of use is tested if used with a new analytical procedure).

Agilent offers compliance consultation services and documentation that can help customers address URS requirements.

Design Qualification (DQ)

The main function of the DQ stage of the laboratory instrument life-cycle process is to document why the selected instrument is suitable. Typically, this includes consideration of the instrument specification, how the instrument will be qualified, and the QMS followed by the instrument manufacturer. All together, these confirm that instrument performance is capable of satisfying user requirements. Depending on laboratory instrument life-cycle policy or SOPs being followed, instrument requirements and the relationship between the URS and DQ stages may vary – but as long as the <1058> framework principles are satisfied, this is not a problem, as it is left to each laboratory to justify and document its specific approaches.

The responsibility for satisfying DQ requirements primarily lies with the laboratory, with support from the supplier.

Agilent's approach to satisfying DQ requirements of USP <1058> includes the following.

- All Agilent hardware and software laboratory products, including the ACE software used to deliver qualification services, are designed, manufactured, and tested according to Agilent internal quality life-cycle development procedures.
- Certificates of Agilent testing, validation, and conformance to standards are provided with new Agilent instruments and similar certification can be provided for ACE software.
- Agilent is capable of installation, support, preventive maintenance, on-going qualification, and re-qualification after repair and user training worldwide.

Agilent offers a compliance consultation service that can help customers with DQ documentation.

Installation Qualification (IQ)

The main functions of the IQ stage are to document that laboratory is suitable (for example, critical systems typically include a site inspection / checklist), that the instrument is installed correctly in the environment, and IQ checks such as module start up are completed. IQ is provided and automated by ACE, which collects, checks, and tests Agilent hardware and software products for the following.

1. Purchase Order Details: Allows the customer to verify that the instrument being qualified matches their design requirements (if available) and purchase order.
2. Preparation and Installation Details: Gathers and records information about preparation and installation documents.
3. Documentation: Gathers and records information about reference and user manuals for initial installations.
4. Product Quality Assurance Details: Collects and records certificates and other forms that verify that the vendor has developed and built the product according to internal standards.
5. Startup: Verifies that all modules/components start up properly.
6. Installation Verification (software only): Verifies the correctness of all installation-related files.

Operational Qualification (OQ)

The main function of the OQ stage is to evaluate and document instrument performance at the intended operational range of use. OQ protocols should include a mix of metrology, functional, and operational tests. ACE qualification protocols include information about the test description and rational, setpoints, and the limits (acceptance criteria) for each technique, category, and instrument configuration.

OQ is provided and automated by ACE. ACE checks and tests for Agilent hardware and software products include the following.

- Metrological tests such as flow, temperature, pressure, and so on that ensure that the system is performing within Agilent (or user) specifications.
- Qualification results are reported in the EQR, which can include details of all test certificates, standards, and training information for the engineer performing the work. (Note that the EQR can be configured to customer requirements.)
- System or "holistic" tests verify the combined functions of the various system components
- The qualification testing can be configured to ensure URS requirements, such as range of use are tested.

For software qualification, the OQ consists of automated diagnostics regression testing and verification of the software installation. This supports continued use of the software in regulated environments (at install and as part of supporting periodic review).

In line with regulatory requirements, the EQPs should be approved before work is performed and the EQR should be reviewed and approved when the work is complete (as illustrated in Figure 2). The EQR contains all the raw data, results, and relevant information and attachments for complete compliance and traceability.

Mechanical Qualification (MQ)

(Dissolution systems only)

The main function of the MQ stage is to document that the mechanical performance of the instrument meets specifications and is functioning properly.

Performance Qualification (PQ)

The main function of the PQ stage is to document that the instrument is fit for purpose under conditions of intended use and to create an approved framework that ensures the instrument continues to perform as required. Because instrument range of use is tested within the OQ stage, it is usually not necessary to test this during PQ. It should be noted that requirements for instrument maintenance and repair fall within the PQ life cycle stage within the USP <1058> framework, as they are components of ensuring the continued performance of the instrument.

The customer is responsible for satisfying PQ requirements. (NOTE: Agilent can provide a PQ for Dissolution systems only.)

It is important to note that PQ is a lifecycle activity and not a one-time event. PQ tests may include activities such as method validation or system suitability tests (SST), but in Agilent's opinion, SSTs contribute towards ensuring continued performance of the instrument (that is, PQ testing), but do may not fully satisfy <1058> PQ requirements.

Repair Qualification (RQ)

After an instrument is repaired, tests should be performed to evaluate the effectiveness of the repair and document that repaired instrument satisfies performance requirements. Agilent offers a service called Repair Qualification (RQ), which refers to the requalification of laboratory instrument hardware after a repair. For some laboratory systems, to document the performance after repair may require a full OQ. However, for some modular or component-based systems, such as HPLC and GC for example, partial qualification testing can be justified. This is accomplished by performing the qualification tests that are applicable to only the module or system component related to the repair, reducing the time the instrument is out of service. Re-qualifying the instrument after repair is a regulatory requirement defined in USP <1058>.

Because of the modular/component-based dependency of RQ service, it is only available for the following instrument platforms: GC, GC/MS, LC, LC/MS, GPC, and SFC.

Agilent offers service contracts to repair and requalify an instrument during the period between scheduled annual OQs. The level of retesting is prescribed in the RQ section of ACE: a form is displayed for the operator showing all types of repairs possible and the retesting required. Part of an example form for an LC system is shown below.

Re-Qualification After Repair		
Pump Strategies		
Repair/Replace Strategy	Modules	OQ Testing
Internal pump head parts, active inlet valve (or AIV cartridge), (parts of) check valves, reference valves, inlet manifold or pump drive, or taking pump head apart to clean (versus repair)	Any pump	Flow Accuracy & Precision
Pulse damper, pressure transducer	Any pump	Flow Accuracy & Precision
Multi-channel gradient valve	Quaternary	Flow Accuracy & Precision Gradient Composition

The full list of RQ repair and retest guidance is available for customer review.

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Overview

Agilent recommends use of **Network ACE** for CrossLab qualification services that are enabled using the Agilent Automated Compliance Engine (ACE) software. Network ACE and Local ACE both access data directly (default methods) and are considered equivalent from a data integrity and data traceability perspective (see below). To provide additional flexibility in qualification service delivery, an alternative method is also available that accesses data indirectly. Use of the alternative method requires customer pre-approval using this form.

Available Methods

Method	Definition
Network ACE (Agilent recommended)	ACE software is installed on a network node within the laboratory LAN infrastructure. Raw data locations are always captured in the equipment qualification report (EQR), which provides end to end traceability and a fully characterized data workflow in the delivery. This method requires collaboration with the customer to load ACE behind the customer firewall.
Local ACE	ACE software resides on an independent external drive that can be driven from the system controller, where the customer data system (CDS) resides. Because the external drive is connected to the CDS, the data integrity of this method is equivalent to that of the Network ACE delivery method. Raw data is imported directly into ACE by the Data Manager tool, with the data paths always captured in the report, which provides data traceability assurance.
Alternative (Requires pre-approval)	<p>This method requires customer pre-approval due to data integrity implications. <u>Only choose this option in scenarios like the following:</u></p> <ul style="list-style-type: none">ACE software is not run from a PC directly connected to the customer CDS, such as the FSE’s laptop. System data files are transferred indirectly from the CDS to the FSE laptop instead of directly as done with Network and Local ACE methods.Data is acquired using a CDS on the FSE’s laptop and transferred directly to ACE. The CDS used in this method is qualified for data collection purposes.

EQR Storage

Select the checkbox below to authorize Agilent to store copies of the EQRs generated by ACE for Agilent internal assessments. The intention of the assessment is to evaluate the delivery of the qualification service, with a focus to improve delivery and assess the appropriateness of data integrity measures. The storage is exclusively for the internal assessment by Agilent and is not shared with other organizations. It is not to be considered a backup for the EQR provided at qualification delivery.

Customer Approval of Alternative Method and EQR Storage

Authorize Agilent to use the alternative method (check for approval): ☐

Authorize Agilent to store EQRs for their internal assessment (check for approval): ☐

Approved By/Title:

Date Approved:

Comments:

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Introduction

With heightened scrutiny of data integrity, the Agilent Automated Compliance Engine (ACE) software must be able to access instrument-generated raw data files one of two ways: directly, using the connection between network nodes or with the server; and indirectly, through storage in a secure transfer location. (In this document, data integrity refers to the who, what, and where of data used in generating an ACE equipment qualification report, or EQR.)

ACE includes three main service delivery methods that address data integrity requirements; the rest of this document provides details to determine which one best fits a customer's needs.

Regardless of the delivery method, ACE features and delivery procedures are compatible.

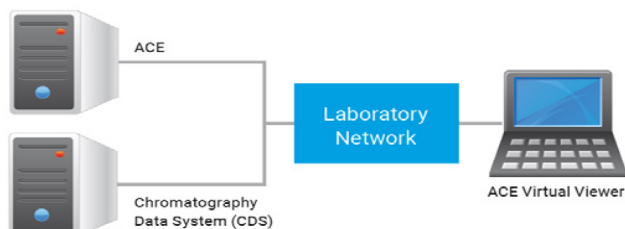
Network ACE (Agilent Recommended)

Overview



ACE software is installed on a network node within the laboratory LAN infrastructure, which requires collaboration with the customer to load ACE behind their firewall. Raw data locations are always captured in the EQR, which provides end-to-end traceability and a fully characterized data workflow in the delivery.

Details



Typical Network ACE installation diagram

Installing ACE in a separate node (a.k.a. the host PC) on the same network as the system controller offers data traceability that is equivalent to an installation on the system controller itself. The system controller (where the CDS resides) and the ACE host PC are identified and seen by the server and subject to the customer's data access controls and general IT policies. The CDS's audit trail records data movements between nodes or between the client and server, and ACE's data traceability features identify the original data directory and therefore ensures end-to-end data traceability

The ACE host PC has a separate/partitioned drive for ACE software. During ACE's installation, two services are setup on the operating system (OS): one for security and the other as a watchdog. Because the ACE host PC sits on the network as a shared drive, engineers access ACE through the networked drive: ACE is not installed on ACE Virtual Viewer PCs.

Requirements

Installation

- Install on a host PC with a separate drive (different from that of the OS)
- Attach to a network that clients can access
- 500 GB
- NTFS format
- User has local administration rights
- Customer installation instruction document is available

Operational

- User has an ACE node logon with a minimum of power user rights permissions; user also has a personal ACE account and password added through the ACE licensing tool
- Up to 5 users with 3 open sessions each can access the NDA simultaneously
- Exception to ports 11121-11141 on ACE node, clients, and switch's/Smart Hubs to be open on the network

Local ACE

Overview



ACE software resides on an independent drive that can be driven from the system controller, where the CDS resides. Because the drive is connected to the CDS, this method's data integrity is equivalent to preferred 1 method's. Raw data is imported directly into ACE by ACE's Data Manager tool, and data paths are captured in reports to provide data traceability.

ACE software resides on an independent drive that can be driven from the system controller, where the CDS resides. Because the drive is connected to the CDS, this method's data integrity is equivalent to the Network ACE method. Raw data is imported directly into ACE by ACE's Data Manager tool, and data paths are captured in reports to provide data traceability.

Details

ACE is designed to run from a dedicated drive, without leaving a footprint on the host PC. Therefore, it can be connected directly to the system controller (where the CDS resides) without altering the system's qualification status. For additional protection, the drive can be driven by another host PC on the same network; also, the drive can remain on site with the customer for use by the Agilent Field Service Engineer (FSE) during service deliveries only.

Alternative Method

This method requires customer pre-approval due to data integrity implications and only applies in scenarios like the following:

- ACE software is not run from a PC directly connected to the customer CDS, such as the FSE's laptop. System data files are transferred indirectly from the CDS to the FSE laptop instead of directly as done with Network and Local ACE methods.
- Data is acquired using a CDS on the FSE's laptop and transferred directly to ACE. The CDS used in this method is qualified for data collection purposes.

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00 Test Suite and Optional Tests

This document describes the test program for qualifying UV-Visible systems. Generic models refer to unspecified UV Systems other than the Agilent Cary and 8453/8454. (Consult your Agilent representative for compatibility questions.)

This section lists all models' OQ tests and allows you to select optional tests.

Note: Optional tests are NOT INCLUDED in the standard OQ but can be ordered as EXTRA COST TESTS. Select the check boxes in the table and attach this document to your OQ EQP documentation for a record of qualification conditions. Configurations with older software versions may not be able to be qualified.

Key: Standard core tests Optional tests Applicable pharmacopeia

Test	8453, 8454	Cary 50, 60	Cary 100, 300	Cary 4000, 5000, 6000i, 7000	Generic	USP	Ph. Eur.
CDS Logon Verification	✓	✓	✓	✓	✓		
Baseline Flatness	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
* Baseline Flatness (Cary UMA)	N/A	N/A	N/A	✓	N/A		
Maximum Resolution	N/A	N/A	N/A	<input type="checkbox"/>	N/A		
Photometric Accuracy – NIST Glass Filters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		✓
Photometric Accuracy – Potassium Dichromate	✓	✓	✓	✓	✓		✓
Photometric Linearity – NIST Glass Filters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	✓
Photometric Linearity – Potassium Dichromate	✓	✓	✓	✓	✓	✓	✓
Photometric Noise	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
* Photometric Noise (Cary UMA)	N/A	N/A	N/A	✓	N/A		
** Photometric Reproducibility – NIST Glass Filters	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A	✓	
** Photometric Reproducibility – Potassium Dichromate	✓	✓	✓	✓	✓	✓	
Photometric Stability	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Stray Light – Acetone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	
Stray Light – Potassium Chloride	✓	✓	✓	✓	✓	✓	✓
Stray Light – Sodium Iodide	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	✓
Stray Light – Sodium Nitrite	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	✓
Stray Light Ratio – Acetone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	
Stray Light Ratio – Potassium Chloride	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	
Stray Light Ratio – Sodium Iodide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	
Stray Light Ratio – Sodium Nitrite	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	
Toluene/Hexane Resolution	✓	✓	✓	✓	✓	✓	✓
Wavelength Accuracy – Didymium	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	✓
Wavelength Accuracy – Holmium Oxide in Perchloric Acid	✓	✓	✓	✓	✓	✓	✓

Test	8453, 8454	Cary 50, 60	Cary 100, 300	Cary 4000, 5000, 6000i, 7000	Generic	USP	Ph. Eur.
Wavelength Accuracy – Mercury Line	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	✓	✓
Wavelength Accuracy – Source Line	✓	✓	✓	✓	✓	✓	✓
Wavelength Accuracy and Reproducibility – Cerium Sulfate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓	✓
Wavelength Reproducibility	✓	✓	✓	✓	✓	✓	

* These tests are in addition to the Cary test suite when a UMA module installed.
** These tests also calculate the accuracy based on the average of six measurements.

Setpoints and Limits

Configuration lists models and, as applicable, abbreviations for lamp type and/or software version in parentheses.

Cary UMA is for tests in addition to the Cary test suite when a UMA module is installed.

D:	Deuterium lamp	W 5.0:	Cary WinUV 5.0
H:	Holmium perchlorate	W 5.1:	Cary WinUV 5.1 and >
X:	Xenon lamp	W 5.1.2:	Cary WinUV 5.1.2 and <
C 5.02:	ChemStation B.05.02 and <	W 5.1.3:	Cary WinUV 5.1.3
C 5.03:	ChemStation B.05.03 and >		

Configuration	Setpoint		Limits	
	Default	Allowable Range	Default	Allowable Range
Baseline Flatness				
8453 8454	0 Abs at 190 – 1100nm	N/A	> -0.00100 and < 0.00100 Abs	-0.01000 – -0.00100 and 0.00100 – 0.01000
Cary 50 Cary 60 Cary 100 Cary 300	0 Abs at 200 – 850 nm	N/A	≥ -0.0010 – ≤ 0.0010 Abs	-0.010 – 0.010
Cary 4000 Cary 5000 Cary 6000i Cary 7000	0 Abs at 200 – 850 nm 0 Abs at 200 – 3000 nm 0 Abs at 200 – 1700 nm 0 Abs at 200 – 3000 nm	N/A	≥ -0.00120 – ≤ 0.00120 Abs	-0.0120 – 0.0120
Cary UMA	0 Abs at 250 – 2500 nm	N/A	≥ -0.0018 – ≤ 0.0018 Abs	-0.018 – 0.018
Generic	0 Abs at 200 – 850 nm	N/A	≥ -0.0010 – ≤ 0.0010 Abs	-0.010 – 0.010
Maximum Resolution				
Cary 4000 Cary 5000 Cary 6000i Cary 7000	N/A	N/A	< 0.0480	0.0480 – 0.0960
Photometric Accuracy – NIST Glass Filters				
For Abs setpoint values > 1.00, the limit changes to ≤ 0.80% Abs.				
8453 (C 5.02) 8454 (C 5.02)	1.0000 Abs at 440.0 nm 1.0000 Abs at 465.0 nm 1.0000 Abs at 546.1 nm 1.0000 Abs at 590.0 nm 1.0000 Abs at 635.0 nm	N/A	≤ 0.008 Abs	N/A
8453 (C 5.03) 8454 (C 5.03)	1.0000 Abs at 440.0 nm 1.0000 Abs at 465.0 nm	N/A	≤ 0.008 Abs	N/A

Configuration	Setpoint		Limits		
	Default	Allowable Range	Default	Allowable Range	
Cary 50	1.0000 Abs at 546.1 nm	N/A	≤ 0.008 Abs	N/A	
Cary 60	1.0000 Abs at 590.0 nm				
Cary 100	1.0000 Abs at 635.0 nm				
Cary 300	0.7000 Abs at 440.0 nm				
Cary 4000	0.7000 Abs at 465.0 nm				
Cary 5000	0.7000 Abs at 546.1 nm	N/A	≤ 0.008 Abs	N/A	
Cary 6000i	0.7000 Abs at 590.0 nm				
Cary 7000	0.7000 Abs at 635.0 nm				
	0.5000 Abs at 440.0 nm				
	0.5000 Abs at 465.0 nm				
	0.5000 Abs at 546.1 nm				
	0.5000 Abs at 590.0 nm				
	0.5000 Abs at 635.0 nm				
Photometric Accuracy – Potassium Dichromate					
For Abs setpoint values > 1.00, the limit changes to ≤ 1.0% Abs.					
All models	Std. Conc.				
	40 mg/L	0.492 Abs at 235 nm 0.572 Abs at 257 nm 0.192 Abs at 313 nm 0.426 Abs at 350 nm	N/A	≤ 0.010 Abs	N/A
	60 mg/L	0.747 Abs at 235 nm 0.867 Abs at 257 nm 0.292 Abs at 313 nm 0.644 Abs at 350 nm	N/A	≤ 0.010 Abs	N/A
	120 mg/L	1.494 Abs at 235 nm 1.734 Abs at 257 nm 0.584 Abs at 313 nm 1.288 Abs at 350 nm	N/A	≤ 0.010 Abs	N/A
	600 mg/L	0.954 Abs at 430 nm	N/A	≤ 0.010 Abs	N/A
Photometric Linearity – NIST Glass Filters					
C 5.03 only for 8453 and 8454.					
All models	440 nm	N/A	Coeff. of det. (r²): ≥ 0.999	N/A	
	465 nm				
	546.1 nm				
	590 nm				
	635 nm				
Photometric Linearity – Potassium Dichromate					
All models	235 nm	N/A	Coeff. of det. (r²): ≥ 0.999	N/A	
	257 nm				
	313 nm				
	350 nm				
Photometric Noise					
8453	0 Abs at 500 nm	N/A	< 0.000200 Abs, rms	0.000200 – 0.00200	
8454	0 Abs at 500 nm	N/A	< 0.000200 Abs, rms	0.000200 – 0.00200	
Cary 50	0 Abs at 500 nm	N/A	< 0.000100 Abs, rms	0.000100 – 0.00100	
Cary 60	0 Abs at 500 nm	N/A	< 0.000100 Abs, rms	0.000100 – 0.00100	
Cary 100	0 Abs at 500 nm	N/A	< 0.0000850 Abs, rms	0.0000850 – 0.000850	
Cary 300	0 Abs at 500 nm	N/A	< 0.000060 Abs, rms	0.000060 – 0.00060	
Cary 4000	0 Abs at 500 nm	N/A	< 0.000030 Abs, rms	0.000030 – 0.00030	
Cary 5000	0 Abs at 500 nm	N/A	< 0.000030 Abs, rms	0.000030 – 0.00030	
	0 Abs at 1500 nm				

Configuration	Setpoint		Limits	
	Default	Allowable Range	Default	Allowable Range
Cary 6000i	0 Abs at 500 nm	N/A	< 0.000030 Abs, rms	0.000030 – 0.00030
	0 Abs at 1500 nm		< 0.000020 Abs, rms	0.000020 – 0.00020
Cary 7000	0 Abs at 500 nm	N/A	< 0.000030 Abs, rms	0.000030 – 0.00030
	0 Abs at 1500 nm			
Cary UMA	0 Abs at 500 nm	N/A	< 0.000100 Abs	0.000100 – 0.00100
	0 Abs at 1500 nm		< 0.000500 Abs	0.000500 – 0.00500
Generic	0 Abs at 500 nm	N/A	< 0.000100 Abs, rms	0.000100 – 0.00100
Photometric Reproducibility – NIST Glass Filters				
This test also calculates the accuracy based on the average of six measurements.				
For Abs setpoint values > 1.00, the accuracy limit changes to ≤ 0.80% Abs				
WL is wavelength.				
8453 (C 5.03) 8454 (C 5.03)	(Total of 15; each Abs at each WL) 1.0 Abs 0.7 Abs 0.5 Abs 440 nm 465 nm 546.1 nm 590 nm 635 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Ab	N/A
Cary 50	0.5 Abs at 546.1 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Abs	N/A
Cary 60 (W 5.0)	0.5 Abs at 546.1 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Abs	N/A
Cary 60 (W 5.1)	(Total of 15; each Abs at each WL) 1.0 Abs 0.7 Abs 0.5 Abs 440 nm 465 nm 546.1 nm 590 nm 635 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Ab	N/A
Cary 100	0.5 Abs at 546.1 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Abs	N/A
Cary 300	0.5 Abs at 546.1 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Abs	N/A
Cary 4000	0.5 Abs at 546.1 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Abs	N/A
Cary 5000	0.5 Abs at 546.1 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Abs	N/A
Cary 6000i	0.5 Abs at 546.1 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Abs	N/A
Cary 7000	0.5 Abs at 546.1 nm	N/A	Average acc: ≤ 0.008 Abs Std deviation: ≤ 0.005 Abs	N/A
Photometric Reproducibility – Potassium Dichromate				
This test also calculates the accuracy based on the average of six measurements.				
For Abs setpoint values > 1.00, the accuracy limit changes to ≤ 1.0% Abs.				
All	Std. Conc.			
	40 mg/L	235 nm	N/A	Average acc: ≤ 0.010 Abs
	60 mg/L	257 nm	N/A	Std deviation: ≤ 0.005 Abs

Configuration	Setpoint		Limits	
	Default	Allowable Range	Default	Allowable Range
	313 nm			
	350 nm			
	120 mg/L	235 nm	N/A	Average acc: ≤ 0.010 Abs Std deviation: ≤ 0.007 Abs
		257 nm	N/A	Average acc: ≤ 0.010 Abs Std deviation: ≤ 0.009 Abs
		313 nm	N/A	Average acc: ≤ 0.010 Abs Std deviation: ≤ 0.005 Abs
		350 nm	N/A	Average acc: ≤ 0.010 Abs Std deviation: ≤ 0.006 Abs
Photometric Stability				
8453 8454	0 Abs at 340 nm	N/A	> -0.00100 and < 0.00100 Abs/hr	-0.01000 – -0.00100 and 0.00100 – 0.01000
Cary 50 Cary 60	0 Abs at 500 nm		> -0.00040 and < 0.00040 Abs/hr	-0.0040 – -0.0004 and 0.0004 – 0.0040
Cary 100 Cary 300	0 Abs at 500 nm		> -0.00030 and < 0.00030 Abs/hr	-0.0030 – -0.0003 and 0.0003 – 0.0030
Cary 4000 Cary 5000 Cary 6000i Cary 7000	0 Abs at 500 nm		> -0.000180 and < 0.000180 Abs/hr	-0.00180 – -0.00018 and 0.00018 – 0.00180
Stray Light – Acetone				
8453 (C 5.02) 8454 (C 5.02)	300 nm	250 – 320 nm	< 1.0%T	N/A
8453 (C 5.03) 8454 (C 5.03)	320 nm	250 – 320 nm	< 1.0%T	N/A
Cary 50	320 nm	250 – 320 nm	< 1.0%T	N/A
Cary 60 (W 5.1.2)	320 nm	250 – 320 nm	< 1.0%T	N/A
Cary 60 (W 5.1.3)	300 nm	250 – 320 nm	< 1.0%T	N/A
Cary 100	320 nm	250 – 320 nm	< 1.0%T	N/A
Cary 300	320 nm	250 – 320 nm	< 1.0%T	N/A
Cary 4000	320 nm	250 – 320 nm	< 1.0%T	N/A
Cary 5000	320 nm	250 – 320 nm	< 1.0%T	N/A
Cary 6000i	320 nm	250 – 320 nm	< 1.0%T	N/A
Cary 7000	320 nm	250 – 320 nm	< 1.0%T	N/A
Generic	300 nm	250 – 320 nm	< 1.0%T	N/A
Stray Light – Potassium Chloride				
All models	198 nm	190 – 200 nm	< 1.0%T	N/A
Stray Light – Sodium Iodide				
8453	220 nm	200 – 230 nm	< 0.050 %T	0.050 – 0.1
8454	220 nm	200 – 230 nm	< 0.050 %T	0.050 – 0.1
Cary 50	220 nm	200 – 230 nm	< 0.050 %T	0.050 – 0.1
Cary 60	220 nm	200 – 230 nm	< 0.050 %T	0.050 – 0.1
Cary 100	220 nm	200 – 230 nm	< 0.020 %T	0.020 – 0.1
Cary 300	220 nm	200 – 230 nm	< 0.00050 %T	0.00050 – 0.1
Cary 4000	220 nm	200 – 230 nm	< 0.000070 %T	0.000070 – 0.1
Cary 5000	220 nm	200 – 230 nm	< 0.000070 %T	0.000070 – 0.1
Cary 6000i	220 nm	200 – 230 nm	< 0.000070 %T	0.000070 – 0.1
Cary 7000	220 nm	200 – 230 nm	< 0.000070 %T	0.000070 – 0.1

Configuration	Setpoint		Limits	
	Default	Allowable Range	Default	Allowable Range
Generic	220 nm	200 – 230 nm	< 0.050 %T	0.050 – 0.1
Stray Light – Sodium Nitrite				
8453	340 nm	300 – 390 nm	< 0.030 %T	0.030 – 0.1
8454	340 nm	300 – 390 nm	< 0.030 %T	0.030 – 0.1
Cary 50	370 nm	300 – 390 nm	< 0.050 %T	0.050 – 0.1
Cary 60 (W 5.1.2)	370 nm	300 – 390 nm	< 0.050 %T	0.050 – 0.1
Cary 60 (W 5.1.3)	340 nm	300 – 390 nm	< 0.050 %T	0.050 – 0.1
Cary 100	370 nm	300 – 390 nm	< 0.0050 %T	0.0050 – 0.1
Cary 300	370 nm	300 – 390 nm	< 0.00020 %T	0.00020 – 0.1
Cary 4000	370 nm	300 – 390 nm	< 0.000070 %T	0.000070 – 0.1
Cary 5000	370 nm	300 – 390 nm	< 0.000070 %T	0.000070 – 0.1
Cary 6000i	370 nm	300 – 390 nm	< 0.000070 %T	0.000070 – 0.1
Cary 7000	370 nm	300 – 390 nm	< 0.000070 %T	0.000070 – 0.1
Generic	340 nm	300 – 390 nm	< 0.050 %T	0.050 – 0.1
Stray Light Ratio – Potassium Chloride, Acetone, Sodium Iodide, Sodium Nitrite				
All models	N/A	N/A	Absorbance ≥ 0.7 Abs Stray Light ≤ 0.01	N/A
Toluene/Hexane Resolution				
All models	N/A	N/A	≥ 1.6	N/A
Wavelength Accuracy – Didymium				
8453 (C 5.02)	731.6 nm 740.0 nm 794.1 nm 800.0 nm 864.4 nm	N/A	Accuracy ≤ 2 nm	N/A
8454 (C 5.02)				
8453 (C 5.03)	731.6 nm 740.0 nm 794.1 nm 800.0 nm 864.4 nm	N/A	Accuracy ≤ 2 nm Std Deviation ≤ 0.5 nm	N/A
8454 (C 5.03)				
Cary 50	731.6 nm 740.0 nm 794.1 nm 800.0 nm 864.4 nm	N/A	Accuracy ≤ 2 nm	N/A
Cary 60 (W 5.0)				
Cary 60 (W 5.1)	731.6 nm 740.0 nm 794.1 nm 800.0 nm 864.4 nm	N/A	Accuracy ≤ 2 nm Std Deviation ≤ 0.5 nm	N/A
Cary 100	731.6 nm 740.0 nm 794.1 nm 800.0 nm 864.4 nm	N/A	Accuracy ≤ 2 nm	N/A
Cary 300				
Cary 4000				
Cary 5000				
Cary 6000i				
Cary 7000				
Generic				
Wavelength Accuracy – Holmium Oxide in Perchloric Acid				
8453	241.13 nm	N/A	Accuracy ≤ 0.6 nm	N/A
8454	249.98 nm			

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Configuration	Setpoint		Limits	
	Default	Allowable Range	Default	Allowable Range
Cary 50 (X)	541.92 nm	N/A	≤ 0.50 nm	N/A
Cary 60 (X)				
Cary 100 (D)	Zero order	N/A	≤ 0.70 nm	N/A
Cary 300 (D)	486.0 nm 656.1 nm		≤ 0.20 nm	
Cary 4000 (D)	Zero order 486.0 nm 656.1 nm	N/A	≤ 0.08 nm	N/A
Cary 5000 (D)	Zero order 486.0 nm 656.1 nm	N/A	≤ 0.08 nm	N/A
Cary 6000i (D)			≤ 0.40 nm	N/A
Cary 7000 (D)	1312.2 nm 1968.3 nm* (* N/A for 6000i)	N/A		
Generic (D)	486.0 nm 656.1 nm	N/A	≤ 2 nm	N/A
Generic (X)	541.92 nm	N/A	≤ 2 nm	N/A
Wavelength Reproducibility				
8453 (D)	486.00 nm	N/A	≥ -0.02 – ≤ 0.02 nm	-0.04 – 0.04
8454 (D)	656.10 nm			
8453 (H)	241.13 nm 249.98 nm 278.11 nm 287.40 nm 333.49 nm 345.38 nm 361.18 nm 385.70 nm 416.42 nm 451.33 nm 467.86 nm 485.26 nm 536.71 nm 640.62 nm	N/A	≥ -0.02 – ≤ 0.02 nm	-0.04 – 0.04
8454 (H)				
Cary 50 (H)	536.50 nm	N/A	> -0.10 – < 0.10 nm	-0.20 – 0.20
Cary 60 (H)				
Cary 100 (D)	656.10 nm	N/A	> -0.080 – < 0.080 nm	-0.160 – 0.160
Cary 300 (D)				
Cary 4000 (D)	656.10 nm	N/A	> -0.0250 – < 0.0250 nm	-0.0500 – 0.0500
Cary 5000 (D)				
Cary 6000i (D)				
Cary 7000 (D)				
Generic (D)	656.10 nm	N/A	> -0.080 – < 0.080 nm	-0.160 – 0.160
Generic (X)	541.92 nm	N/A	> -0.50 – < 0.50 nm	-1.0 – 1.0
Wavelength Accuracy and Reproducibility – Cerium Sulfate				
All models	201.1 nm 211.4 nm 222.6 nm 240.4 nm 253.7 nm	N/A	Accuracy ≤ 1 nm Reproducibility ≤ 0.5 nm	N/A

Test Design and Rationale

Overview

NOTE: In the test descriptions, **CRM** is certified reference material.

Many GMP/GLP enforcement agency inspectors now ask firms to provide a risk assessment of their equipment and computer systems plus a science-based rationale for subsequent validation and qualification testing.

GENERAL RISK STATEMENT: Any laboratory chemical system used for raw material testing or final drug product / medical device testing in GMP or used in formal GLP studies will likely fall into a HIGH RISK category. This risk assessment will imply the need for IQ & OQ & on-going qualification. ANY USER SPECIFIC RISK ANALYSIS SUPERCEDES THIS GENERAL RISK STATEMENT.

The rest of this section outlines the science-based rationale for each test in the Agilent hardware OQ plus a brief test design and procedure description.

The recommended set of hardware OQ tests described in this EQP derives from Agilent's interpretation of FDA, USP, Ph. Eur., and GAMP guidelines and other authoritative expert literature. OQ test design incorporates both modular and holistic testing, which is a proven and regulatory acceptable approach. When applicable, direct metrology is used to test pump flow rates and thermal-controlled column compartments, for example. Holistic chemical testing is used to evaluate critical instrument characteristics. When applicable, certified reference standards and calibrated equipment are used.

Considering the number of setpoints, parameters, and conditions of each recommended OQ test, the proven concepts of worst case, range, and representative have been applied. If a property or characteristic is known to have its worst performance at one end of a range of use, this is the setpoint that should be tested and other setpoints are not required. If a property or characteristic has no known worst case, testing at the high and low points of the range of use is required. If there are too many possible use cases and conditions to realistically test (and none is a worst case), a representative sample for test is the best approach.

CDS Logon Verification

Description: To satisfy the attributable requirement of ALCOA+, evidence of the logon used to collect data must be provided.

Procedure: The test uses a screen capture to document who is logged on to the software that controls the instrument being qualified. The capture is automatically included with this test in the EQR.

Baseline Flatness

Description: This test measures the system's ability to compensate for inherent optical and electronic noise across the entire wavelength range. A baseline correction and test scan are performed across the entire wavelength range of the system. The corrected signal is evaluated for peak-to-peak fluctuations. The test passes if the measured baseline stability is within test limits. This test's limits conform to manufacturer requirements.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Verify there are no samples in the cell holders. Using the spectrophotometer's controlling data software (CDS), setup the Baseline Flatness test. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Maximum Resolution

Description: This test determines maximum resolution (often called the limiting resolution) by calculating the width of the 656.1 nm peak at half height that the instrument can achieve. The test passes if the calculated maximum resolution is less than or equal to the test limit.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Verify there are no samples in the cell holders. Using the spectrophotometer's controlling data software (CDS), setup the Maximum Resolution. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Photometric Accuracy—NIST Glass Filters, Potassium Dichromate

Description: This test uses standards to determine the accuracy. The test passes if the measured absorbance value is within the test limit of the expected absorbance value.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Using the spectrophotometer's controlling data software (CDS), setup the Photometric Accuracy test using the standard. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Photometric Linearity—NIST Glass Filters, Potassium Dichromate

Description: This test uses the resulting measured absorbance averages of the CRM from the photometric tests. These measured averaged absorbances are calculated against the respective certified absorbance values to determine the correlation of determination (r^2). The test passes if the calculated r^2 is greater than the expected r^2 value.

Procedure: Record the respective certified absorbance of the CRM in the ACE tasklist. Once the photometric tests are completed, record the resulting measured absorbance averages of the CRM into the ACE Data Manager. ACE will determine if the test passes.

Photometric Noise

Description: This test measures short-term fluctuations in the detector signal caused by inherent optical and electronic noise in the system. The amount of photometric noise will define the precision and minimum detection limit of the system. The test passes if the measured photometric noise is within the test limits. This test's limits conform to manufacturer requirements.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Verify there are no samples in the cell holders. Using the spectrophotometer's controlling data software (CDS), setup the Photometric Noise test. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Photometric Reproducibility—NIST Glass Filters, Potassium Dichromate

Description: This test uses CRMs to find the accuracy and reproducibility of the photometric absorbance. The accuracy is determined by using the average of six measurements to meet specific USP 'Control of Absorbance' requirements.

For each CRM, six measurements are taken at each respective wavelength, and the average and standard deviation are then calculated. Accuracy is calculated as, depending on absorbance values, (1) the absolute difference between the average of the six measurements and Certificate of Analysis (CoA) absorbance values or (2) the absolute percentage difference between the average of the six measurements and Certificate of Analysis (CoA) absorbance values. The standard deviation is used to determine the reproducibility (or precision). The test passes if the reported results of both accuracy and reproducibility are within the respective test limits.

NOTE: For 8453 and 8454 models with ChemStation B.05.03 and later software, the results are calculated by the instrument control software (vs. ACE) and entered directly into the ACE tasklist.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Using the spectrophotometer's controlling data software (CDS), setup the Photometric Accuracy test for the CRM of interest. Follow the software prompts to complete the test. Perform the test six times to obtain values for reproducibility at each wavelength. Upon completion, record the values to the test record.

Photometric Stability

Description: This test measures the photometric drift of the spectrophotometer when monitoring the Zero Absorbance signal at a single wavelength for an hour. Photometric Stability is an indicator of how stable photometric results will be over an extended period of time. The test passes if the measured drift of the photometric stability is within test limits. This test's limits conform to manufacturer requirements.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Verify there are no samples in the cell holders. Using the spectrophotometer's controlling data software (CDS), setup the Photometric Stability test. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Stray Light—Acetone, Potassium Chloride, Sodium Iodide, Sodium Nitrite

Description: This test measures the presence of light outside the bandwidth of a selected wavelength that reaches the detector. The presence of stray light can decrease the photometric selectivity, increase the photometric response, and create non-linear response of the instrument causing problems with quantitative analysis. The CRM does not allow light to pass through it below a cut-off wavelength. The test will pass if the Percent Transmittance at the setpoint wavelength is within test limits.

Standard	Cut-off Wavelength
Acetone	326 nm
Potassium Chloride	201 nm
Sodium Iodide	260 nm
Sodium Nitrite	391 nm

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present, disable the cell changer for testing. Using the spectrophotometer's controlling data software (CDS), setup the Stray Light test using the CRM. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Stray Light Ratio – Acetone, Potassium Chloride, Sodium Iodide, Sodium Nitrite

Description: As with the stray light test, this test also measures the presence of light, outside the bandwidth of the selected wavelength that reaches the detector. This test, however, uses a matched pair of CRMs, one in a 10 mm sealed cuvette and one in a 5 mm sealed cuvette, with the 5 mm cuvette as reference. The measured Absorbance at the wavelength maximum must be greater or equal to the Absorbance limit. The measured Absorbance is also used to calculate the Stray Light Value. The result must be less than or equal to the Stray Light Value limit. Both criteria must be met to pass this test.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present, disable the cell changer for testing. Using the spectrophotometer's controlling data software (CDS), setup the Stray Light Ratio test using CRMs. Perform the test using the 5 mm cuvette as the reference and the 10 mm cuvette as the sample. Follow the software prompts. Upon completion, record the values to the test record.

Toluene/Hexane Resolution

Description: Decreased spectral resolution can impact the photometric sensitivity and selectivity. This test determines resolution by calculating the peak-to-trough ratio between the reported absorbance maximum and minimum from a scan of 0.02% v/v Toluene in Hexane. The absorbance maximum should occur at approximately 269 and the minimum at approximately 266 nm. The test passes if the calculated spectral resolution ratio is greater than or equal to the test limit.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present, disable the cell changer for testing. Using the spectrophotometer's controlling data software (CDS), set up the Toluene/Hexane Resolution test. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Wavelength Accuracy—Didymium

Description: This test determines accuracy by comparing the reported wavelength values against the expected wavelength values of a CRM. The test passes if the reported wavelength values do not differ from the expected values by more than the accuracy limit. The average and standard deviation of six measured wavelength values of the CRM are calculated by ACE.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Using the spectrophotometer's controlling data software (CDS), setup a Wavelength Accuracy test for the CRM. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Wavelength Accuracy—Holmium Oxide in Perchloric Acid

Description: This test determines accuracy by comparing the reported average (of 10 measured wavelengths for 8453, 8454 models; of six for all other models) and expected wavelength values of a holmium oxide in perchloric acid—holmium perchlorate—test solution. For models other than the 8453 and 8454, the standard deviation of the six measured wavelengths is also calculated.

NOTE: For Cary 60 models with CaryWinUV 5.1 and later software, results are calculated by Cary WinUV (vs. ACE) and entered directly into the ACE tasklist.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Using the spectrophotometer's controlling data software (CDS), setup the Wavelength Accuracy test for the Holmium Oxide in Perchloric Acid (Holmium Perchlorate). Perform the test by following the software prompts. Upon completion, record the values to the test record.

Wavelength Accuracy—Mercury Line

Description: This test verifies the mercury lamp performance. The mercury lamp produces photometric peak maxima at various wavelengths. In this test, Wavelength Accuracy is verified by scanning a wavelength range for the mercury lamp. The test passes if the reported wavelength maxima do not differ from the expected values by more than the accuracy limit.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Verify there are no samples in the reference and sample cell holders. Using the spectrophotometer's controlling data software (CDS), setup the Wavelength Accuracy test for the Mercury Lamp. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Wavelength Accuracy—Source Line

Description: This test verifies performance of the installed source lamp (either Xenon or Deuterium). The source lamp produces peak maxima at various wavelengths. In this test, Wavelength Accuracy is verified by scanning a spectrum number of nanometers above and below the theoretical maxima for the installed source lamp. The test passes if the reported wavelength maxima do not differ from the expected values by more than the accuracy limit.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present, disable the cell changer for testing. Verify there are no samples in the reference and sample cell holders. Using the spectrophotometer's controlling data software (CDS), setup the Wavelength Accuracy test for the Source Lamp Emission Line. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Wavelength Reproducibility

Description: This test measures the instrument's reproducibility when making repeated readings of the same wavelength. The reproducibility is defined as the deviation of 10 consecutive wavelength maximum readings taken using the peak(s) of the reference (holmium oxide in perchloric acid/holmium perchlorate or the deuterium lamp). The test passes if the maximum deviation of the 10 wavelength maxima values is less than the test limit. For the 8453 and 8454 models, this test is completed with the Wavelength Accuracy tests.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present disable the cell changer for testing. Using the spectrophotometer's controlling data software (CDS), setup the Wavelength Reproducibility test using the reference. Perform the test by following the software prompts. Upon completion, record the values to the test record.

Wavelength Accuracy and Reproducibility – Cerium Sulfate

Description: This test calculates accuracy by comparing the reported wavelength values against the expected wavelength values of a CRM. The test passes if the reported wavelength values do not differ from the expected values by more than the accuracy limit. The average and standard deviation of six measured wavelength values of the CRM are calculated by ACE.

Procedure: Power on and warm up the spectrophotometer for the appropriate time prior to testing. If a cell changer is present, disable it for testing. Using the spectrophotometer's controlling data software (CDS), setup a Wavelength Accuracy test for the CRM. Perform the test by following the software prompts. Upon completion, record the values to the test record.

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V@ÁāoÁ^[[, Ág&~ā^•Á]ā}•Á^|&c^āÁ!Ág&~•ā}ÁÁ@ÁÖÜÛËÓÁ^~æ|dÁ^] ^æ^āÁ~}Á[*•ÁgāÁg}•æā}Á[*•Ág^Ág, æ•
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Üæ•KÖÜÚÁÁ[ā[&^ā
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