



# Equipment Qualification Plan

Enterprise Edition

Approval

Approver(s) of the EQP are approving:

- 1. This Agilent standard hardware OQ and its fixed selection of recommended tests, set points and limits.
- 2. The use of Agilent Compliance Engine (ACE) and delivery of qualification reports in pdf on CD disk.
- 3. The use of recommended delivery tools (digital thermometers, flow meters, analog-to-digital converters etc.) when valid calibration certificates are included in the qualification reports.
- 4. Delivery of Agilent standard hardware IQ and standard software IQ & OQ when purchased with this OQ. Separate EQP approval of the standard hardware IQ and software IQ & OQ is not required.

Review and approval signatures may be kept separately as paper records or electronic approval using Acrobat digital signature technology or electronic document management systems can be used.

Space is provided below for Acrobat digital signatures or 'hybrid' paper/electronic record signatures made directly onto a printed paper copy of this electronic document.

*Ink signatures will not appear in the original electronic record of this EQP.*

Name	Role	Hand-Written Signature	Date

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## OQ Test Design and Rationale for LC Systems

The OQ test design incorporates both 'modular' and 'holistic' testing which is a proven and regulatory acceptable approach.

Direct metrology is used to test pump flow rates and thermal controlled column compartment and auto sampler modules.

'Holistic' chemical testing is used for the evaluation of the following critical instrument characteristics: linearity; precision; signal-to-noise; carry-over.

Certified Reference standards and calibrated traceable thermometers & digital flow meters are used.

The test design for LC systems covers UV absorbance, Fluorescence and Refractive Index detectors, isocratic, binary, tertiary & quaternary pumps, most auto sampler models and fraction collector.

### Tests for LC Systems (non-MS Detector)

#### 1. Pump Flow Accuracy and Precision

Rationale: Accuracy of flow is important for comparability between systems and transferring methods. Flow precision is critical for repeatability of peak height and area.

Procedure: A calibrated digital flow meter is attached to the waste line of the system flowing pure water at representative back pressure provided by a small guard-column. Six readings are taken at each set point to determine the flow accuracy and precision. Flow accuracy is calculated as the absolute % difference of the mean of the six flow readings against the set point. The precision is calculated as the %RSD of the six flow readings. Two set points (0.5ml/min and 5.0 ml/min) are evaluated in the core test.

*Extra set points and flexible test range are only available in Customer-configured EQP's for flow, temperature and some other tests.*

#### 2. Column Temperature Accuracy and Stability

Rationale: The thermostat accuracy is important for comparability between systems and transferring methods. Column temperature stability is critical for repeatability of peak height and area.

Procedure: In this test, a calibrated digital temperature meter and a proprietary probe is used to measure the temperature of the flowing eluent. With the use of a T-union, the temperature probe is positioned to be in contact with the heated eluent. A typical column compartment temperature range of use is tested. At the high end of the range, after stabilization, the temperature accuracy is calculated as the absolute difference between what was measured and the set point.

After completing this measurement, at the low end of the range, six readings are taken every 4 minutes and temperature stability is calculated as the absolute difference between the highest and lowest measured temperature. The temperature accuracy is calculated as the average of the six readings compared to the set point. All readings are reported in Celsius.

### 3. Wavelength Accuracy

Rationale: Wavelength accuracy is critical for accuracy of quantitative and qualitative analysis. Wavelength Accuracy is also important for comparability between systems and transferring methods.

Procedure:

UV Absorbance detector (UV, VWD, DAD, PDA etc.): A traceable caffeine standard is used to determine the wavelength accuracy. In one procedure, for certain models, the caffeine is trapped in the flow cell and a programmable timetable is used to determine the wavelength maxima (205 and 273nm) and minimum (245nm).

For other models, for example DAD and PDA, a caffeine injection is made and a spectrum is acquired. The spectral maxima and minimum are determined directly from the scan or the table of scan results. The wavelength accuracy is determined as the absolute difference between the measured and certified wavelength values.

Fluorescence detector: The detector cell is filled with pure water. Using a programmable timetable, the excitation (350nm) and Raman Band emission (397nm) wavelengths are determined. The wavelength accuracy is determined as the absolute difference between the measured and theoretical peaks of Raman scattering (in nm).

### 4. Signal Noise and Drift

Rationale: This test gives an indication of detector sensitivity and stability.

Procedure:

UV Absorbance detector & Refractive Index detector: Pumping water at 1ml/min, the signal is monitored at a specified wavelength over a twenty minute period. The signal noise is calculated based on ASTM E685-93 as the average peak-to-peak noise in a number of signal segments. The drift is calculated as the slope of the linear regression for the signal.

### 5. Injection Precision

Rationale: System precision is critical for accuracy of quantitation. Auto sampler performance contributes to system precision.

Procedure: This test uses a short column to separate the evaluation standard from the void volume. Using a traceable standard, six injections from the same standard are made and the height, area, average height, average area, % RSD of height and %RSD of area are determined and calculated.

### 6. Injection Carry Over

Rationale: Low carry-over from a previous injection is critical for accuracy of quantitative and reliability of qualitative analysis. This test challenges the injector system in the LC system.

Procedure: Following the six injection precision test, a blank injection is made. The carry over result is calculated as a ratio of the area of any residual peak found in the blank injection to the average peak area of the previous six injections (expressed as a percentage).

## 7. Signal to Noise:

**Rationale:** Sensitivity is a critical performance feature in quantitative and qualitative analysis. A Signal-to-noise value of a representative compound at known concentration provides sensitivity statistics. This measurement is especially critical to establish level of detection.

**Procedure:**

**UV Absorbance detector & Refractive Index detector:** An evaluation standard is injected and the calculated height divided by the ASTM noise monitored over a specified range, provides the Signal to Noise result.

**Fluorescence detector:** Using pure water in the flow cell, the signal is monitored at the emission maximum wavelength of the Raman Band of water and then using a timetable, switched to a no emission wavelength where the noise is monitored. The Signal to Noise is calculated as the height of the Raman band peak divided by the monitored noise in a spectral region where no scattering is expected.

## 8. Response Linearity

**Rationale:** The linearity of a detector is a critical parameter to establish for reliable and accurate quantitative results and is important for comparability between systems and transferring methods.

**Procedure:** A series of five traceable standards which represent typical concentrations range are injected and evaluated. The response linearity is calculated by determining the coefficient of determination ( $r^2$ ) of the peak areas versus concentration. In addition, the %RSD of the response factors for all five peaks is calculated.

## 9. Gradient Composition

**Rationale:** Accuracy and stability of solvent mixing on-line is critical for consistent and accurate quantitative analysis. Gradient Composition is also important for comparability between systems and transferring methods

**Procedure:** This test uses an acetone tracer to determine the solvent gradient composition accuracy, stability and linearity. The test challenges the system by making compositional changes from 0% to 100% in 20% increments. In addition a linear ramp down from 100% to 0% is performed where the compositional accuracy is determined at 95, 75 and 25%. All compositional accuracies (20, 40, 60, 80, 95, 75 and 25%) are calculated as the absolute difference between the mean composition at each set point and the theoretical composition. Stability is the slope of the linear regression of all compositions versus time points in each composition step. Linearity is calculated from 95% to 5% in the linear portion of the gradient.

## 10. Sample Temperature Accuracy

**Rationale:** The thermostat accuracy is important for comparability between systems and transferring methods.

**Procedure:** In this test, four vials are filled with water and allowed to equilibrate to the temperature set point. Similar to the column compartment, the temperature of the water is measured using a traceable digital temperature meter and proprietary probe. Accuracy is determined as the difference between the measured temperature and the set point.

**11. Injection Linearity (optional extra test)**

Rationale: Injection Linearity of variable volume LC injector systems is normally *not* critical to quantitative or qualitative analysis. Most LC analytical methods use fixed and only nominal injection volumes and do not utilize variable volume injections within a single analysis. However, some users may wish to use variable volume injection if the linearity is demonstrated.

Procedure: Five injections of increasing volumes of the same traceable caffeine standard are made. Injection linearity is calculated from the coefficient of determination ( $r^2$ ) of the peak areas versus injection volume. In addition, the %RSD of the response factor for all five peaks is calculated.

**12. Injection Response (optional extra test)**

Rationale: The accuracy of the injected volume is normally *not* critical to quantitative or qualitative analysis. Most LC analytical methods use fixed and only nominal injection volumes and results are not affected by even moderate inaccuracy in actual injected volume. However, it may be important for comparability between systems and transferring methods and is useful as a diagnostic for establishing the correct injection syringe/loop/device is installed.

Procedure: A known traceable caffeine standard is injected six times (in the precision tests) and the average response is calculated. The injection response is the mean of the average areas corrected for sample concentration, cell path length and attenuation and the response within an acceptance window indicates correct volume injected.

**13. Fraction Collection**

Rationale: It is important to demonstrate that a fraction collector is capable of collecting fractions either based on peak detection or time.

Procedure: In this test, two injections of a traceable standard are made and fractions are collected in either peak based or time based mode. This is a qualitative test in which the collected fractions are re-injected to demonstrate that they are fractions of the traceable standard.

## Test Specification Overview

In this section each available test type for LC systems in Agilent Compliance Engine (ACE) is listed. A number of the tests can be run on multiple detector configurations. In these cases the test acceptance limits can vary for different configurations. These are noted in the Configuration-Specific Limits section for each test description.

Those marked "Not run" are available as optional extra tests outside the standard OQ protocol.

After this annotated list is a copy of the real Test Specification document used in ACE. This allows a reviewer to see all the menu choices for each possible LC configuration.

### **Automated Selection of the Correct Tests for Different Pump & Detector Configurations**

All the main Agilent pumps and detectors are covered in Enterprise Edition with ACE release A.1.50 and the software automates the selection of the appropriate tests, set points & limits. The test specification is programmed according to the configuration details entered by the operator at time of delivery into the Instrument Details Section of the ACE software.

In a Standard Delivery the operator selects the precise configuration of the installed LC and the ACE software then schedules all the correct tests and set points and limits documented in this EQP. ACE ensures Agilent's recommended set points and limits are correctly applied to all possible configurations of the installed Agilent LC.

**In this way, customers can be assured that approval of this Global EQP is a single approval for all the LC configurations in scope of the EQP.**

**List of Tests and Limits Run in the Standard OQ for Analytical-Scale RRLC and HPLC Models**

**Pump Flow Accuracy and Precision**

This test uses a calibrated digital flowmeter to determine the accuracy and precision of solvent flow rate. Flow accuracy is calculated as the absolute % difference the mean of the six flow readings and the setpoint, and flow precision is calculated as the %RSD of the six flow readings.

	Pump 1	Pump 2	Pump 3	Pump 4
<b>Run the test?:</b>	Run	Run	Not run	Not run
<b>Customer Reference:</b>	Not specified			
<b>Flow Rate 1:</b>	0.500	ml/minute		
<b>Accuracy</b>				
(Limit 1:)		<=	5.00	%
(Limit 2:)		<=	5.00	%
<b>Precision</b>				
(Limit 1:)		<=	0.50	%RSD
(Limit 2:)		<=	0.50	%RSD
<b>Flow Rate 2:</b>	5.000	ml/minute		
<b>Accuracy</b>				
(Limit 1:)		<=	5.00	%
(Limit 2:)		<=	5.00	%
<b>Precision</b>				
(Limit 1:)		<=	0.50	%RSD
(Limit 2:)		<=	0.50	%RSD

**Configuration-Specific Limits**

None

**Notes:**

For Agilent 1200 series systems only Pump 1 Run (isocratic & quaternary) and Pumps 1 & 2 Run (Binary) are appropriate. For 1090 systems, Pumps 1, 2 and 3 are to be run. Some non-Agilent systems use four separate pumps in quaternary mode.

**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?:**

**Customer Reference:**

**Temperature 1:**  °C

**Accuracy**

(Limit 1:)   °C

(Limit 2:)   °C

**Temperature 2:**  °C

**Accuracy**

(Limit 1:)   °C

(Limit 2:)   °C

**Stability**

(Limit 1:)   °C

(Limit 2:)   °C

**Configuration-Specific Limits**

Notes:

No configuration specific limits but for all Column Compartments:  
 If the higher temperature set point is below 50.0°C, Accuracy can be set to ≤ 2.0°C.  
 The Stability limit does not change.

**Wavelength Accuracy**

This test uses a traceable standard or water to determine the wavelength accuracy. Wavelength accuracy is determined as the absolute difference between the measured and defined wavelengths.

<b>Run the test?:</b>	Run		
<b>Customer Reference:</b>	Not specified		
<b>Detector:</b>	UV or UV-Vis		
<b>Wavelength 1:</b>	205	nm	Maximum
<b>Accuracy</b>			
<b>(Limit 1:)</b>	<=	2	nm
<b>(Limit 2:)</b>	<=	2	nm
<b>Wavelength 2:</b>	245	nm	Minimum
<b>Accuracy</b>			
<b>(Limit 1:)</b>	<=	2	nm
<b>(Limit 2:)</b>	<=	2	nm
<b>Wavelength 3:</b>	273	nm	Maximum
<b>Accuracy</b>			
<b>(Limit 1:)</b>	<=	2	nm
<b>(Limit 2:)</b>	<=	2	nm
<b>Wavelength 4:</b>	Not applicable	nm	(Select an item)
<b>Accuracy</b>			
<b>(Limit 1:)</b>	<=	2	nm
<b>(Limit 2:)</b>	<=	2	nm

**Configuration-Specific Limits**

For Agilent 1090,1050, 1100 & 1200:  
 Accuracy: ≤ 2nm (At Maximum 205 and 273nm and Minimum 245nm)

For Waters Alliance:  
 Accuracy: ≤ 2nm (At Maximum 205 and 273nm and Minimum 245nm)

All Fluorescence Detectors:  
 Accuracy: ≤ 3nm (At Maximum 350 and 397nm) Raman band determination.

All other non-Agilent UV-UVVIS Detectors:  
 Accuracy: ≤ 3nm (At Maximum 205 and 273nm)  
 No determination of the caffeine minimum at 245nm is performed.

Signal Noise and Drift

This test determines signal noise and drift. Signal noise is calculated as the average peak-to-peak noise in a number of signal segments, and signal drift is calculated as the slope of the linear regression for the signal.

**Run the test?:**

**Customer Reference:**

**Wavelength:**  nm

**Noise**

(Limit 1:)	<=	0.100	units*	* mAU, uV, or nRIU
(Limit 2:)	<=	0.100	units*	

**Drift**

(Limit 1:)	<=	10.000	units*/hour
(Limit 2:)	<=	10.000	units*/hour

**Configuration-Specific Limits**

UV-UVVIS Detectors:

Noise: ≤ 0.100 (or 100.000 if the customer data station is EZChrom)  
 Drift: ≤ 10.000 (or 10000.000 if the customer data station is EZChrom)

Refractive Index Detectors:

Noise: ≤ 10.000 (or 10000.000 if the customer data station is EZChrom)  
 Drift: ≤ 400.000 (or 400000.000 if the customer data station is EZChrom)

**Injection Precision**

This test uses a traceable standard to determine injection precision.

Run the test?:

Customer Reference:

Injection Volume On Column:

 ul

**Height RSD**

(Limit 1:)

<=	2.00	%
----	------	---

(Limit 2:)

<=	2.00	%
----	------	---

**Area RSD**

(Limit 1:)

<=	1.00	%
----	------	---

(Limit 2:)

<=	1.00	%
----	------	---

**Configuration-Specific Limits**

For Agilent 1090,1050, 1100 & 1200:

Height RSD: ≤ 2.00

Area RSD: ≤ 1.00

For Waters Alliance:

Height RSD: ≤ 2.00

Area RSD: ≤ 1.00

The Injection Precision test can be performed only on systems with UV-UVIS and refractive index detectors. This test is not yet offered for systems with fluorescence detectors.

For all other non-Agilent Injectors:

Height RSD: ≤ 2.00

Area RSD: ≤ 2.00

**Injection Carry Over**

This test uses a traceable standard to determine injection carry over.

**Run the test?:**

Run

**Customer Reference:**

Not specified

**Injection Volume On Column:**

20 ul

**Height Carry Over**

(Limit 1:)

<=	0.40	%
----	------	---

(Limit 2:)

<=	0.40	%
----	------	---

**Area Carry Over**

(Limit 1:)

<=	0.20	%
----	------	---

(Limit 2:)

<=	0.20	%
----	------	---

**Configuration-Specific Limits**

For Agilent 1100 & 1200:

Height %: ≤ 0.40

Area %: ≤ 0.20

For Waters Alliance:

Height %: ≤ 0.40

Area %: ≤ 0.20

The Carry Over test can be performed only on systems with UV-UVVIS and refractive index detectors. This test is not yet offered for systems with fluorescence detectors.

For all other non-Agilent Injectors:

Height %: ≤ 1.00

Area %: ≤ 1.00

**Signal to Noise**

This test uses a traceable standard or water to determine signal to noise.

**Run the test?:**

Run

**Customer Reference:**

Not specified

**Detector:**

UV or UV-Vis

**Signal to Noise**

(Limit 1:)

>=	3,000
----	-------

(Limit 2:)

>=	3,000
----	-------

**Configuration-Specific Limits**

All UV-UVVIS Detectors:

S/N:  $\geq 3000$

All Fluorescence Detectors:

S/N:  $\geq 400$

All Refractive Index Detectors:

S/N:  $\geq 2000$

**Response Linearity**

This test uses a traceable standard to determine response linearity. Response linearity is calculated by determining the coefficient determination ( $r^2$ ) of the peak areas versus concentration. In addition, the %RSD of response factors for all five peaks is calculated.

**Run the test?:**

**Customer Reference:**

**Detector:**

**Coefficient of Determination ( $r^2$ )**

(Limit 1:)	>=	0.99900
(Limit 2:)	>=	0.99900

**R/F Precision**

(Limit 1:)	<=	5.00	%RSD
(Limit 2:)	<=	5.00	%RSD

**Configuration-Specific Limits**

All UV-UVVIS Detectors:  
 Coefficient of Determination ( $r^2$ ):  $\geq 0.99900$   
 R/F Precision:  $\leq 5.00$

All Refractive Index Detectors:  
 Coefficient of Determination ( $r^2$ ):  $\geq 0.99500$   
 R/F Precision:  $\leq 10.00$

**Gradient Composition**

This test uses an acetone tracer to determine solvent gradient composition accuracy, stability and linearity. Accuracy is calculated as the absolute difference between the mean composition and each set composition. Stability is the slope of the linear regression of all composition versus time points in each composition step. Linearity is the coefficient of determination (r2) of the composition values versus time measured in three sections from 95% to 5% in the linear portion of the gradient.

**Run the test?:**

**Customer Reference:**

**Step 1:**  %

**Accuracy**

(Limit 1:)   %

(Limit 2:)   %

**Composition Noise**

(Limit 1:)   %

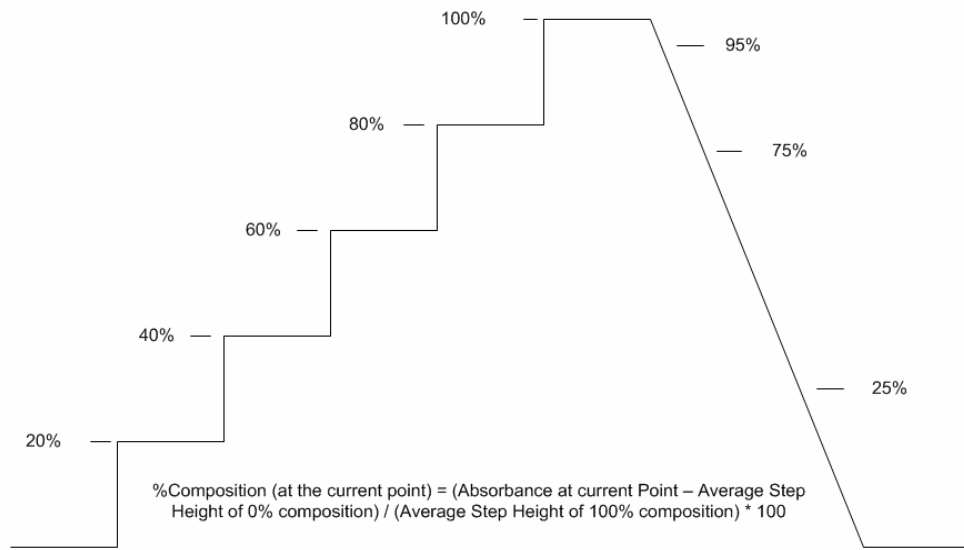
(Limit 2:)   %

**Composition Drift**

(Limit 1:)   %

(Limit 2:)   %

Same limits for step 2 [40%], step 3 [60%] and step 4 [80%].  
 These composition steps 20%, 40%, 60%, and 80% are fixed by the test design and cannot be custom-configured to alternative steps.



## Linearity of gradient slope at high end, middle and low end of slope

High Correlation Start:	95.00	%		
Coefficient of Determination (r2)				
(Limit 1:)			>=	0.99900
(Limit 2:)			>=	0.99900
Mid Correlation Start:	75.00	%		
Coefficient of Determination (r2)				
(Limit 1:)			>=	0.99900
(Limit 2:)			>=	0.99900
Low Correlation Start:	25.00	%		
Coefficient of Determination (r2)				
(Limit 1:)			>=	0.99900
(Limit 2:)			>=	0.99900

After the step compositions are made a linear gradient back down from 100% to 0% is made. The linearity of the curve from 95% to 75% is evaluated. Similarly the middle section (75% to 25%) and the low section (25% to 5%) are evaluated for linearity using best-fit line of regression.

## Configuration-Specific Limits

None

Notes:

Gradient testing can only be performed on systems with a UV detector because this is the only type of detector capable of accurately detecting the acetone tracer profile generated by the gradient composition program.

Systems such as LCMS with no UV detector or systems with only FLD or RID detectors cannot have the gradient test performed.

**Sample Temperature Accuracy**

This test uses a traceable digital thermometer to determine sample temperature accuracy. Accuracy is determined as the difference between the measured temperature and the setpoint.

<b>Run the test?:</b>	Run		
<b>Customer Reference:</b>	Not specified		
<b>Temperature:</b>	4.0	°C	
<b>(Limit 1:)</b>	>=	-2.0	°C
<b>(Limit 2:)</b>	>=	-2.0	°C
<b>(Limit 1:)</b>	<=	5.0	°C
<b>(Limit 2:)</b>	<=	5.0	°C

**Configuration-Specific Limits**

For all Injector Thermostats:  
 For Temperatures < 10°C, limit is -2.0 to +5.0  
 For Temperatures > 10°C, limit is -3.0 to +3.0

**Injection Linearity (Additional Test)**

This test uses a traceable caffeine standard to determine injection linearity. Injection linearity is calculated by determining the coefficient of determination (r2) of the peak areas versus injection volume. In addition, the %RSD of response factors for all five peaks is calculated.

Run the test?:

Customer Reference:

Standard Concentration:  ug/ml

**Coefficient of Determination (r2):**

(Limit 1:)	>=	0.99900
(Limit 2:)	>=	0.99900

**R/F Precision:**

(Limit 1:)	<=	5.00	%RSD
(Limit 2:)	<=	5.00	%RSD

**Configuration-Specific Limits**

None

Notes:

Test is only offered for systems with UV-UVVIS detectors. The standard concentration and/or injection volume is selected such that the linear dynamic range of the detector is not exceeded.

**Injection Response (Additional Test)**

This test uses a traceable standard to determine response based on injection volume.

Run the test?:

Not run

Customer Reference:

Not specified

Injection Volume On Column:

20 ul

**Average Area**

(Limit 1:)

>=	1,200,000	counts
----	-----------	--------

(Limit 2:)

>=	1,200,000	counts
----	-----------	--------

(Limit 1:)

<=	1,800,000	counts
----	-----------	--------

(Limit 2:)

<=	1,800,000	counts
----	-----------	--------

**Configuration-Specific Limits**

None

Notes:

This test is only offered for systems with a UV-UVVIS detectors. If the injection volume is changed from the default of 20ul, adjust the limits accordingly. For example, if the requested injection volume is 10ul, then limit 1 will be 600,000 and limit 2 will be 900,000.

**Fraction Collection (Additional Test 1)**

This test uses a traceable standard to evaluate the correct operation of a fraction collector used with the first detector.

**Run the test?:**

Not run

**Customer Reference:**

Not specified

**Fraction Collector:**

1

**Collection Mode:**

Peak Based

**Configuration-Specific Limits**

No limits. The test verifies collection is functional.

Form Showing All Selectable Settings.  
Not for Fixed OQ Use

For Review Purposes Only

Form Showing All Selectable Settings.  
Not for Fixed OQ Use

For Review Purposes Only

Form Showing All Selectable Settings.  
Not for Fixed OQ Use

For Review Purposes Only

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## Section 2: Report Definition

Document Revision A.01.50

Software Release A.01.50

Report Definition Name:

Std Full Report Definition

Creation Date:

April 2007

Report Definition Comments:

No comment

### Purpose

This section allows you to define the required format of a Qualification Report. You can specify the level of company details, test script details, and appendices to include, and you can also specify names for test limits and statuses. Specifying names is optional: it allows you to tailor our default names to match company glossaries and usage.

This information will be applied to all Qualification Reports with the same Report Definition Name in this EQP.

### Limit Names

The pass/fail status for each test is based on a one- or two-limit model for evaluating limits. You can specify the number of limits as well as their values.

However, Agilent recommends that you use a one-limit model based on Agilent recommended limits. For other models, individual test results will indicate if a pass/fail was caused by a user-specified limit that was more/less stringent than the Agilent recommended limit. If a test fails a more stringent limit, Agilent reserves the right to refuse entitled repairs. If a test passes a less stringent limit, those results may not be meaningful.

#### Default Names and Descriptions

Limit 1: This name describes the Limit 1 selectable value. If a two-limit evaluation model is used, this limit should be the more stringent requirement.

Limit 2: This name describes the Limit 2 selectable value. If a two-limit evaluation model is used, this limit should be the less stringent requirement.

#### User-Specified Limit Names

User Limit

Manufacturer Limit

## Status Names

### Default Names and Descriptions

Pass: If test result meets applicable limit(s), report test status as:

PASS

Pass Recommended Limit Only: If test result meets less (but not more) stringent user limit, report test status as:

PASS recommended limit only

Fail: If test result does not meet applicable limit(s), report test status as:

FAIL

### User-Specified Status Names

## Report Format

**Cover**

Include in report

**Report Details**

Include in report

**Concise Revision History**

Include in report

**Detailed Revision History**

Do not include in report

**Scope and Purpose**

Include in report

**Glossary**

Include in report

**Qualification Details**

Include in report

**Instrument Details**

Include in report

**Protocol, Materials, and Calibrated Tool Details**

Include in report

**General Procedure**

Include in report

**Calculation Formulas**

Include in report

**Test Summary**

Include in report

**Declaration of Change Control**

Include in report

**Regulatory Disclaimer**

Include in report

**Tests**

Include in report

**Attachments**

Include in report