

Validation of Equipment and Computer Systems in Laboratories

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Agilent Technologies

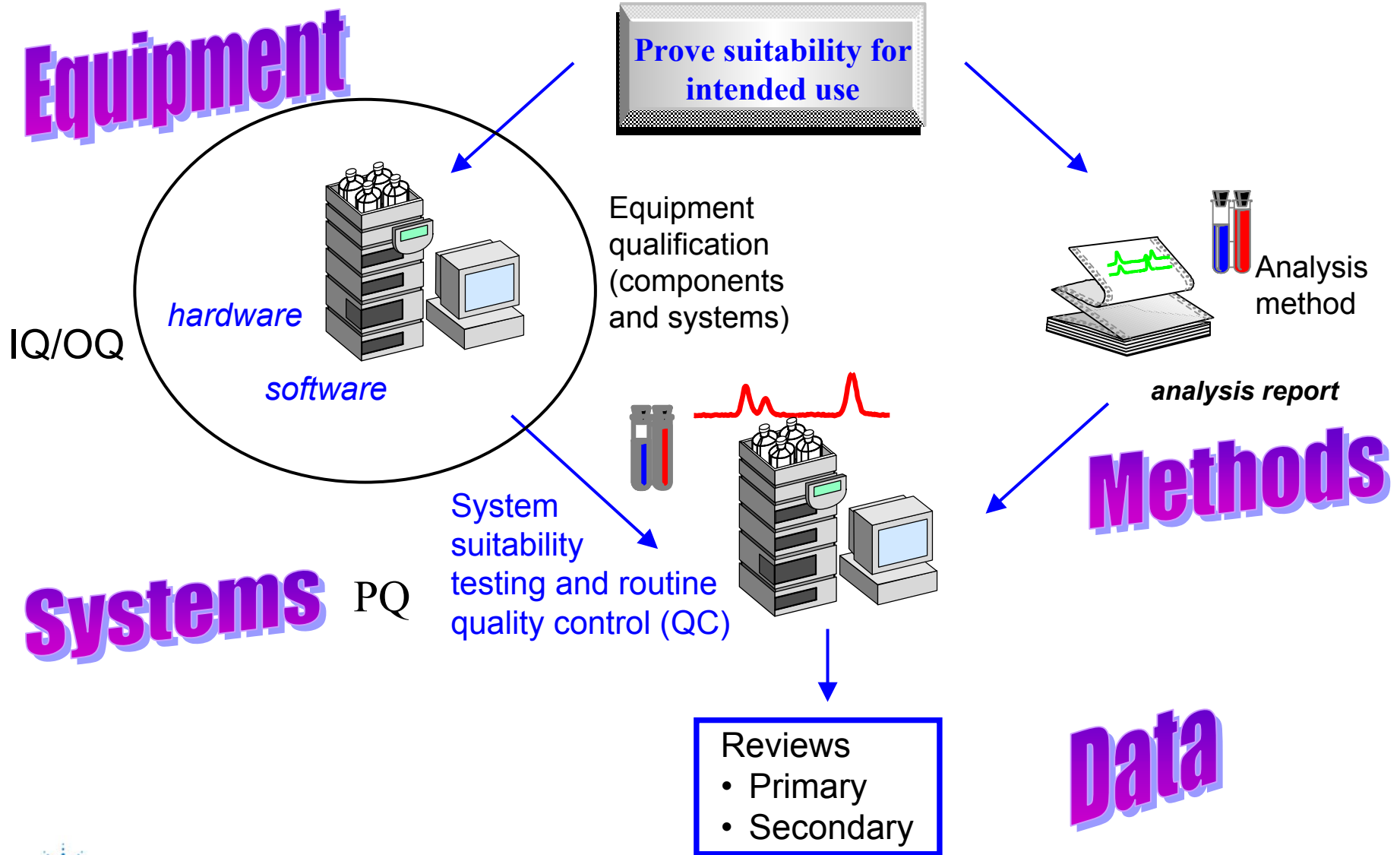
Content

- **Validation planning**
- **Qualification during installation and use**
- **Change control**
- **Legacy systems**
- **Macros and spreadsheets**
- **Network qualification**
- **Vendor contributions**

Reference material:

www.labcompliance.com/agilent/computervalidation

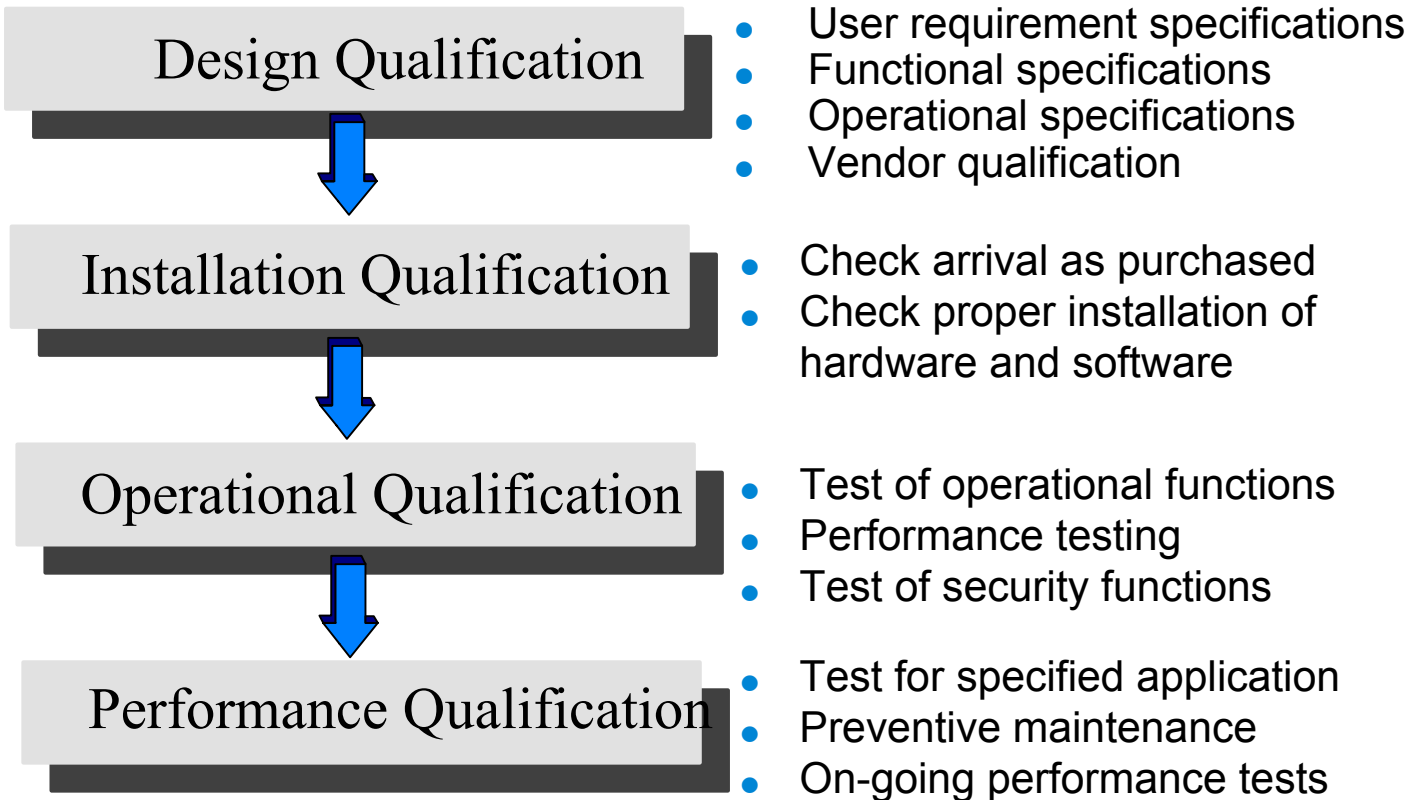
Validation in the Analytical Laboratory



Qualification/Validation Phases

4Q Model

Validation Plan



Validation Master Plan - Purpose

- Increases significantly efficiency and consistency of individual validation projects
- Answers the inspector's question:
“What is your company's approach towards validation?”
- Required EU GMP (Annex 15)
“Validation and Qualification”

For:

- corporate
- site
- department
- specific systems

Framework for individual validation projects

Validation Master Plan - Contents

- Scope, e.g., for all regulated an ISO7025 environments
- Glossary, e.g., validation, qualification
- Responsibilities, e.g., QA
- Steps/approaches for validation and testing, e.g., DQ, IQ, OQ, PQ
- Criteria and examples for risk assessment
- Release procedure, e.g., who has to approve
- Discontinuance
- Content of validation report
- Documentation and archiving

**Consistency
Efficiency
For audits**

Design Qualification - Purpose

- Helps in all later phases, e.g., OQ and PQ testing
- Answers the inspector's questions:
“What is the system doing and what are the system requirements and specifications?”
- Required by EU GMP (Annex 15)
“Qualification and Validation”

Does the system design meet our requirements?

Design Qualification - Contents

- Description of the application and intended use of the equipment
- Description of the intended environment
- User requirement specifications
- Functional and performance specifications
- Qualification of the vendor

Use vendor specifications for help

Steps for Vendor Assessment

Laboratory
Computers

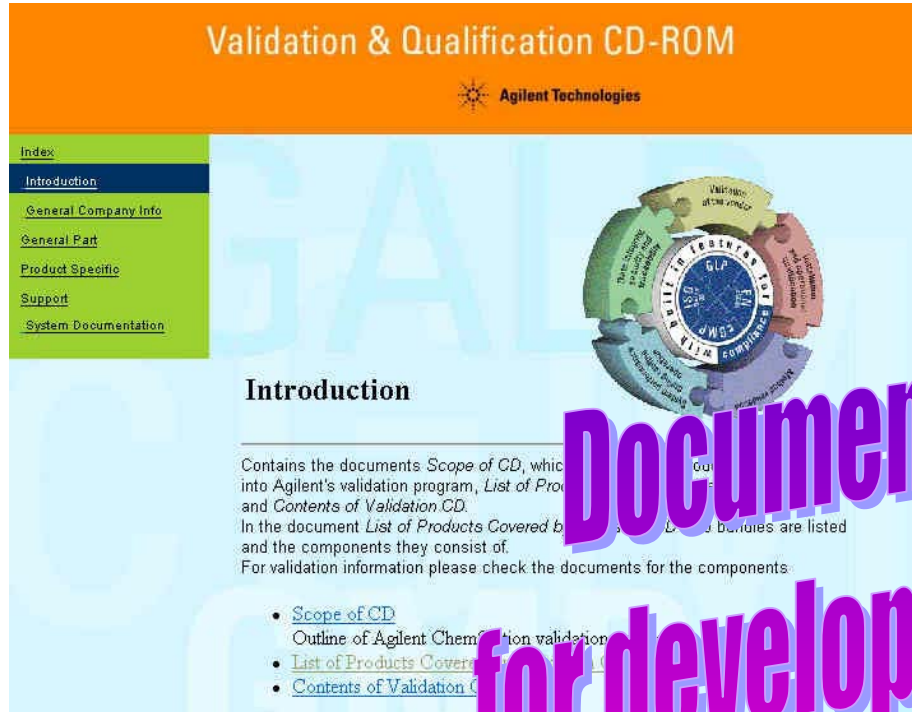
- Evaluation through references
- Evaluation through own experiences (in general, product specific)
- Mail audit (response to checklists)

-
- 3rd party audit
 - Audit through user's firm (general, project specific)

LIMS

FDA Validation Guidance: The evaluation (of a supplier' SW development activities) should preferably be derived from a reliable audit of the software developer, performed by the end user's organization or a trusted and competent third party.

Example - Agilent Validation CD



Validation & Qualification CD-ROM

Agilent Technologies

Index

Introduction

General Company Info

General Part

Product Specific

Support

System Documentation

Introduction

Contains the documents *Scope of CD*, which outlines the scope of the CD, and *List of Products Covered by Validation CD*, which lists the products covered by the CD, and *Contents of Validation CD*, which lists the documents included in the CD.

In the document *List of Products Covered by Validation CD*, the products and their components are listed and the components they consist of.

For validation information please check the documents for the components:

- [Scope of CD](#)
- [List of Products Covered by Validation CD](#)
- [Contents of Validation CD](#)



**Documented evidence
for development validation**

- Available to customers under confidentiality agreement
- Can minimize the need for on-site audits

Question and Answer Session

No. 1

Installation Qualification - Purpose

- Make sure everything is there as purchased
- Make sure software is 'properly' installed and systems are properly configured
- Required by regulations and standards

Have all information available for troubleshooting

Installation Qualification - Steps

- Compare equipment, as received, with purchase order
- Check documentation for completeness
- Install hardware (computer, printers, network cables)
- Install software and check correct installation
- Reboot and ensure that all modules power up and perform an electronic self-test
- Document all components with asset and serial numbers

**Assistance from Vendor
for IQ Services**

Example: Check Proper SW Software

| File name | File Description |
|--------------------------------|------------------|
| Missing files | |
| 1\instrmnt.ini | Initialization |
| repstyle\library.mac | Macro |
| 1\verify\default.val\integ.reg | Register |
| helpenu\hpsc6a00.hlp | Help |
| Changed files | |
| core\800\eevempt.ini | Initialization |
| core\800\eevtool.ini | Initialization |
| Identical files | |
| apg_top.exe | HP APG DataComn |
| apgdde.dll | HELP |

Part of Application Software and Agilent IQ Services

Example: IQ Documentation



Qualification Services for Agilent
Chemical Analysis Instruments

Agilent Technologies
Installation
Qualification (IQ)
For the Agilent
Technologies
ChemStation Plus

Protocol Revision Number: _____
Customer Name: _____



FIRST CLIENT or STANDALONE

Client Components

Client: _____
Instrument Description: _____

The Agilent ChemStation Plus is a Server/Client configuration of various modules. The clients are data acquisition and central data store. The client components are detailed in the Microsoft Diagnostic System Report.

Module Details

To fully document the installation, the details of all the instrument are given in the following tables. Details are given in the Microsoft Diagnostic System Report. The details are given in the Microsoft Diagnostic System Report.

***Diagnostic System Report Printed and Attached**

Verified by: _____ Date: _____

Computer

Component _____

Manufacturer: _____
Name/Model Number: _____
Serial Number: _____
Other Identifying Number: _____
Processor: _____
Memory (RAM): _____
Graphics Adapter: _____
Video Memory: _____
Pointing Device: _____

Verified by: _____ Date: _____

(1) Information displayed on Computer Start-Up.
(2) My Computer -> Control Panel -> Display -> Settings -> Display Type
(3) My Computer -> Control Panel -> Mouse -> General

Deviation: Yes _____ No _____ Verified by: (Customer) _____
Comments: _____
Rev 07/00 Date Printed: 21-Jul-00 12:45:11 Page 21 of 43

Hard Disk Configuration

| Hard-Disk Type | Partitions | Partition Size |
|----------------|------------|----------------|
| | | |
| | | |
| | | |
| | | |
| | | |

Verified by: _____ Date: _____

* My Computer -> (Drive letters) -> Properties (Example Local Disc: NTFS)

Operating System

Description: _____
Manufacturer: Microsoft

Version and Service Pack: * _____
Directory/Path: _____
Verified by: _____
* Found on host. Version also available by: Star

Virtual memory

| Pagefile Drive* | Minimum Size (Mb) | Maximum Size (Mb) |
|-----------------|-------------------|-------------------|
| | | |
| | | |
| | | |



Components

INSTALLATION QUALIFICATION UTILITY

To qualify the complete and correct installation of the Agilent ChemStation software the Installation Qualification utility is used. Instructions for executing the utility are detailed in the Installing Your ChemStation manual.

Details from the Installation Verification report:

| | |
|-----------------------|--|
| Verification Result: | |
| Reference Files: | |
| Ambiguous References: | |
| Missing Files: | |
| Changed Files: | |

Report printed and attached to this protocol:

Verified by: _____ Date: _____

Declaration of System Validity

A declaration of System Validation is required for Plus software. The documents are attached to this protocol.

Accepted: _____
Declaration Attached? _____

Print copies of the following log files:

| File Name | Location | Description |
|------------------|----------------------------|--------------------------|
| CsClient.log | X:\Hpchem\ChemStor\Install | ChemStation Installation |
| CsClient.lst.log | X:\Hpchem\ChemStor\Install | ChemStation Installation |
| HpAccess | X:\Hpchem\ChemStor\Install | ChemStation Installation |

Verified by: _____ Date: _____

The ChemStation Plus software was installed (without errors).

Note: Clearly associate each print-out with information that will identify the system (the print-out).
Note: The CsClient.log will have as its last line a statement indicating that the installation was successful. If an error occurred on installation it will state that the install had errors associated with it.

Verified by: _____ Date: _____

Inspection ready

- Documentation of all hardware and system software
- Performed by vendor or customer with training and certification

Operational Qualification - Purpose

- Check suitability of equipment hardware/software in the user's environment
- Required by regulations and standards

Check with User Specifications

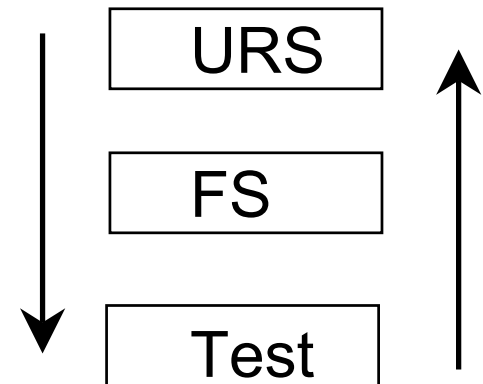
Operational Qualification - Steps

- Define critical functions for the computer system as defined in DQ
- Develop test cases for the functions and define acceptance criteria
- Perform the tests
- Evaluate results and compare with acceptance criteria
- Document results

**Assistance from Vendor
for OQ services
Hardware and software**

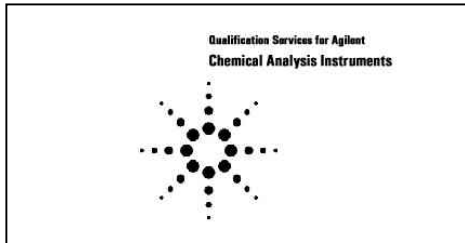
Key Points for OQ Tests

- Tests should be linked to user requirement and functional specifications (test traceability matrix)
- Test cases should include normal and stress conditions
- Tests should be quantifiable
- Test cases should be designed for reuse



FDA Validation Guidance: Test conditions: test conditions should include not only "normal" or "expected" values, but also stress conditions (such as a high number of users accessing a network at the same time).

Example: OQ Documentation



Operational Qualification/ Performance Verification for the Agilent Technologies ChemStation Plus

| | |
|--------------------------|-------------|
| Protocol Revision Number | Rev. A.08.0 |
| Customer Name | |



PROTOCOL APPROVAL

Protocol Acceptance/Approval by Customer

Agilent Technologies recommends that operation of the ChemStation use reportable data and in the further qualification of attached hardware, qualified state. This procedure provided the Operational Qualification (OQ) overall qualification process. It is also recommended that the ChemStation appropriate change control.

A sign-off area has been provided on each page for those situations where a review requires review and acceptance of every page of the delivered document. It is considered to be complete when the Certification of System Qualification is signed by the responsible parties.

Per-page sign-off in this protocol:
(Required/Not Required):

I have reviewed this document and agree that it provides appropriate Operational Qualification of the equipment for which it has been configured.

Customer Name (Print) _____ Signature _____

Customer Assigned Reviewer if required _____

Print Reviewer's Name/Title (Print) _____ Signature _____

Protocol Acceptance/Approval by Agilent

I agree that the OQ / PV procedures in this document, assembled by Validation Services, are appropriate for the equipment defined within an Agilent qualification procedure.

Executing Engineer's Name (Print) _____ Signature _____ Date _____

FIRST CLIENT or STANDALONE CHEMSTATION

First Instrument

Security Pack

Security Pack imposes a compliant configuration on the ChemStation as well as a secure database environment for raw data as well as metadata storage. The following scripts will verify the configuration compliance as well as test the critical data security functions. These tests require that the ChemStation and the ChemStore components be previously qualified or are being qualified as part of a complete system qualification.

Note: For the first tests the user logged on to the NT system must NOT be part of the Administrator group.

Logon Test

Logon security (Logon/Locking and Access Rights Control) is tested as part of ChemStation functionality tests. As the following tests are performed you will be logged on to the system at different times. We will use these opportunities to evaluate Pack Specific features.

ChemStation Configuration Control

Security Packs configuration compliance will be performed directly through the tests and indirectly as the functionality tests are performed.

1. Start the offline version of the ChemStation being evaluated using an appropriate Operator name and password.

Note: Verify that you are in Method and Run Control View

2. Verify that there is no alternative to logging on to the default database (i.e. you are unable to open the database without logging on to the database).

A password must be entered to open ChemStation

Pass/Fail / Verified by

Logon is mandatory for ChemStation

3. Verify that the ChemStore Locking feature is available in the ChemStation View->Lock ChemStation-(Privately, Non-privately, Time Based Lock)

4. Verify that Change Access Level is disabled (applies to all views): View->Access Level

5. Verify that only the Printer Setup, Print and Exit menus are available under menu.

Deviations: Yes _____ No _____ Verified _____

Comments: _____

_____ Name (Print Name) _____ Signature _____ Date _____

_____ Executing Engineer (Print Name) _____ Signature _____ Date _____

Certification of System Qualification

CERTIFICATION OF SYSTEM QUALIFICATION

OQ / PV Certification

| Certification Type | Initial (At time of installation) | Requalification (Reoccurring) |
|--------------------|-----------------------------------|-------------------------------|
| | | |

The analytical system as identified in the Instrument Module: General Procedures Section has yielded the following results:

| Summary of Results | |
|--|-----------------------|
| All qualification tests and measurements were successfully completed | Pass |
| Some of the qualification tests or measurements required correction in order to successfully complete* | Pass after correction |
| Some of the qualification tests or measurements were not successfully completed* | Fail |

*A Deviation Report must be attached showing the corrective action taken. The Deviation Reports associated with this document are listed below. If a deviation is due to a process change (Product Support Bulletin, Service Note etc.) then a copy of the change notification must be attached. It is recommended that the system be removed from service until suitable repairs can be made.

Deviation Record/Cross-Reference

| Deviation # | Page # | Brief Problem Description | Repeat Attached Yes/No* | Resolution Date* |
|-------------|--------|---------------------------|-------------------------|------------------|
| | | | | |
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Inspection ready

- Protocol review and approval by customer and Agilent
- System Challenges and documentation of results
- Final Sign off with deviations and necessary supporting documents

OQ - Computerized Systems

- Install all hardware and software
- Verify complete software installation
- Qualify equipment hardware and complete system
- Make additional tests for the software part, e.g., limited access and electronic audit trail

Tests should be traceable to specifications

Performance Qualification - Purpose

- Ensures that the system and application work as intended day in day out
- Answers the inspector's question: "How are you sure that the application works as intended day-by-day?"
- Helps to prevent errors

**Performed
by User**

Performance Qualification - Steps

Develop and implement procedures for:

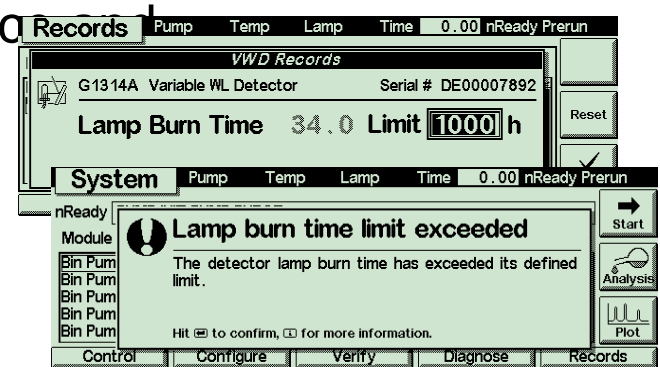
- Preventive maintenance of hardware
- Recalibration of equipment
- Back-up and disc maintenance, removal of temp files and virus checks
- Regular system performance tests, for example system suitability testing

**Performed
by User**

Ongoing Performance Qualification

Agilent Tools & Services

- Early maintenance feedback to prevent errors
- Preventive maintenance for hardware to ensure ongoing function and performance
- Re-qualification for hardware after updates and repair
- Software for automated system suitability testing and analysis of quality control samples (chemical performance tests)
- On-line monitoring tools of network performance and connectivity



System Suitability Testing

Why ?

- Makes sure that systems and applications work on day-by-day basis

When

- Before, during and maybe after routine sample analysis
- Daily

What ?

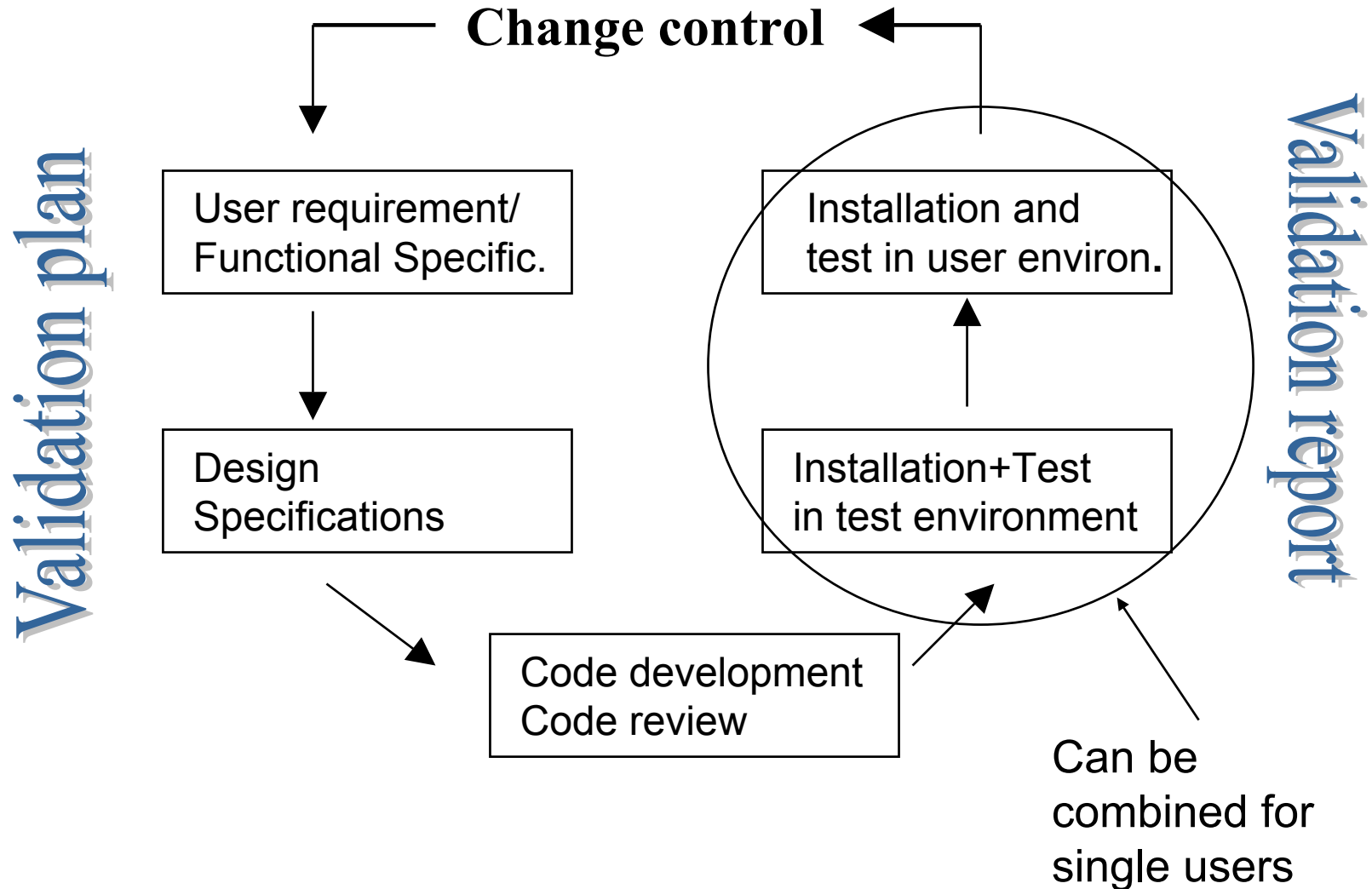
- Any critical parameter which may be for HPLC
- Precision of retention times, peak areas
- Resolution between two peaks
- Tailing factor (in chromatography)
- *Other parameters optional*

USP/EP

Question and Answer Session

No. 2

Lifecycle Model for Spreadsheets&Macros

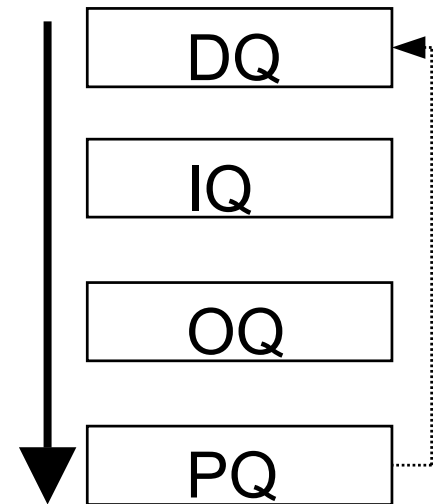


Change Control

- Main reasons for changes: hardware maintenance and repair and software upgrades
- Changes must follow a documented change procedure
- Procedure should require risk analysis and evaluation if the change may affect the computerized system's validation status
- Document changes; what, why, who, how tested?

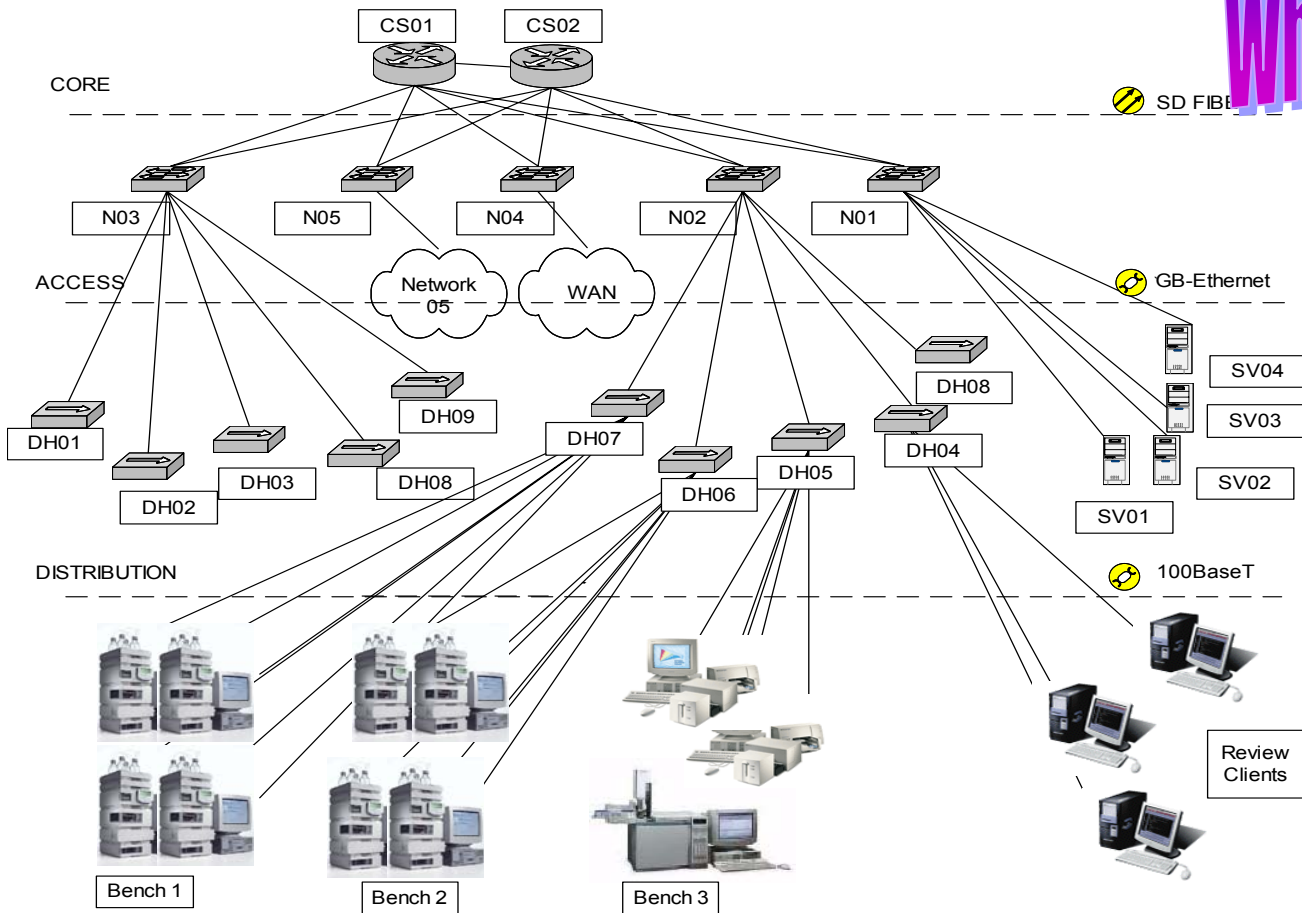
Legacy/ Existing Systems

- Follow computer validation/qualification practices
- Follow lifecycle approach (4Q model)
- May not have info from vendor, but lot's of experience
- Describe what the system is doing, how it is being used, and what functions it has
- Document installation
- Document past tests or develop new ones
- Declare the system as validated



Networks - Know Everything at Any Time

What do we want?

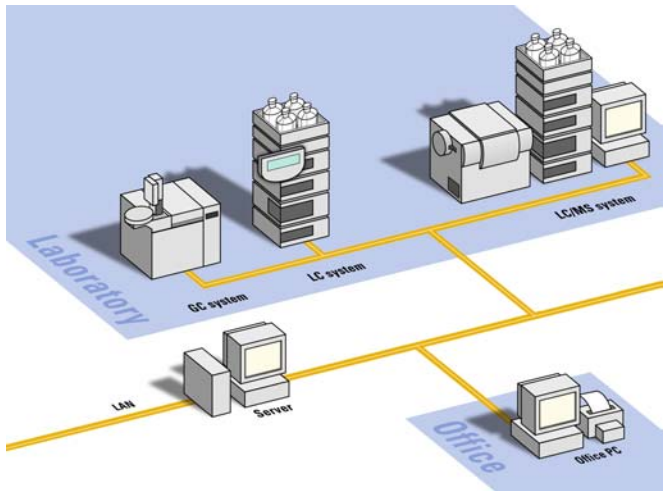


Security
Data integrity
Uptime

The Approach for Networks

- Qualify Network Infrastructure
 - document baseline
 - check connectivity and bandwidth
- Validate Networked Systems/Applications
- Develop and implement rigorous configuration management and change control procedures
- Monitor network connections and traffic using a network health monitoring software for this.

Example: Agilent Networked Data Systems



Agilent Technologies Provides for Networked Systems

- IQ/OQ of networked system (C/S Chromatographic data system)
- Guidance & Documentation to support retrospective DQ and IQ
- Mapping network topology
- Determination of network bandwidth & utilization
- Continuous Monitoring of network health

Scaleable LAN based Client/Server Chromatographic Data System

To find out more about Agilent's compliance program please visit the website www.agilent.com/chem/compliance.

Agilent Advisor - Monitoring Tool

The screenshot shows the Agilent Advisor LAN interface with several key components:

- Mapping Topology:** A network diagram showing nodes and connections. A yellow callout bubble points to it with the text "Mapping Topology".
- Monitoring Bandwidth:** A bar chart showing bandwidth usage over time. A yellow callout bubble points to it with the text "Monitoring Bandwidth".
- Monitoring Warnings:** A list of IP addresses with associated status information. A yellow callout bubble points to it with the text "Monitoring Warnings".
- Thought Bubble:** A blue thought bubble from a woman character asks, "Is the HPLC still connected to the LAN?".
- Tables:** Two tables are visible: one for "Totals (68 Nodes, 69 Conns)" and another for "Protocols".

| *Nodes/Prots./Conns. | | | |
|-----------------------------|--|--|--|
| Totals (68 Nodes, 69 Conns) | | | |
| 0.0.0.0 | | | |
| 130.29.93.237 | | | |
| 130.29.154.181 | | | |
| 130.29.155.155 | | | |
| 130.29.155.182 | | | |
| 130.30.253.87 | | | |
| 141.121.216.56 | | | |
| 141.184.5.17 | | | |
| 141.184.5.29 | | | |
| 141.184.5.38 | | | |
| 141.184.5.47 | | | |
| 141.184.5.48 | | | |

| Protocols | Stations | Connection | Alerts |
|-----------------|----------|------------|--------|
| Totals | 63 | 69 | 0 |
| IP | 50 | 60 | 0 |
| Novell | 0 | 9 | 0 |
| Other Protocols | 13 | | 0 |
| MAC Level | 52 | 69 | 0 |
| Routers | 0 | | 0 |

<http://onenetworks.com>

LAN Analyzer

Qualification/Validation Report

- Response to validation plan
- Qualification/validation approach
- Describes application, use and environment of system
- Summarizes test plan/acceptance criteria/results
- Authorizes use of system

Validation plan and validation report are most important

Final

Question and Answer Session

Agilent Technologies Offerings for Validation of Software and Computer Systems

- Help with design qualification, e.g., provide specifications
- Provide CD with development validation documents
- Offer and assist users during vendor audits
- Provide services for installation qualification and operational qualification of equipment hardware and computer systems
- Automated OQ testing reduces system downtime
- Provide tools and services for network infrastructure qualification
- Services offered worldwide and for instruments from multiple vendors

References with successful FDA inspections

Further Information

To attend the Agilent e-seminar series, please visit our WEBSITE:

<http://www.agilent.com/chem/eseminars-compliance>

For further information on our products and services please contact your local Agilent Office.