Validation of Equipment and Computer Systems in Laboratories

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Content

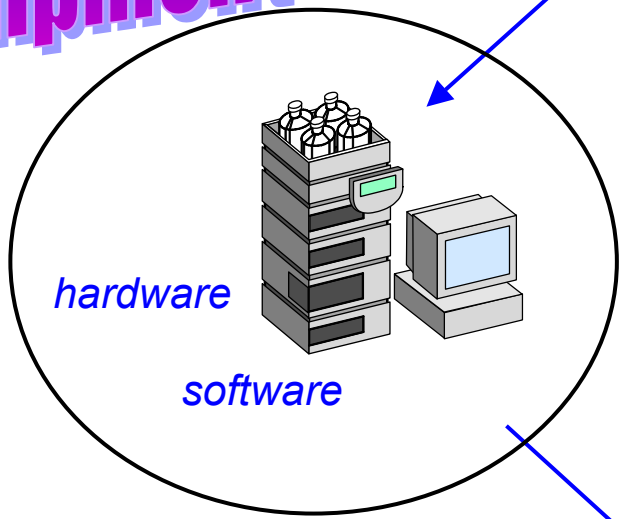
- Validation planning
- Qualification during installation and use
- Change control
- Legacy systems
- Macros and spreadsheets
- Network qualification
- Vendor contributions

Reference material:
www.labcompliance.com/agilent/computervalidation

Validation in the Analytical Laboratory

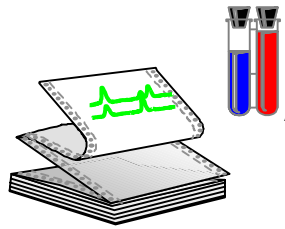
Equipment

Prove suitability for intended use



IQ/OQ

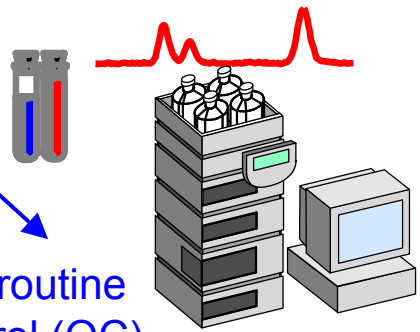
Equipment qualification (components and systems)



Analysis method

analysis report

Methods



System suitability testing and routine quality control (QC)

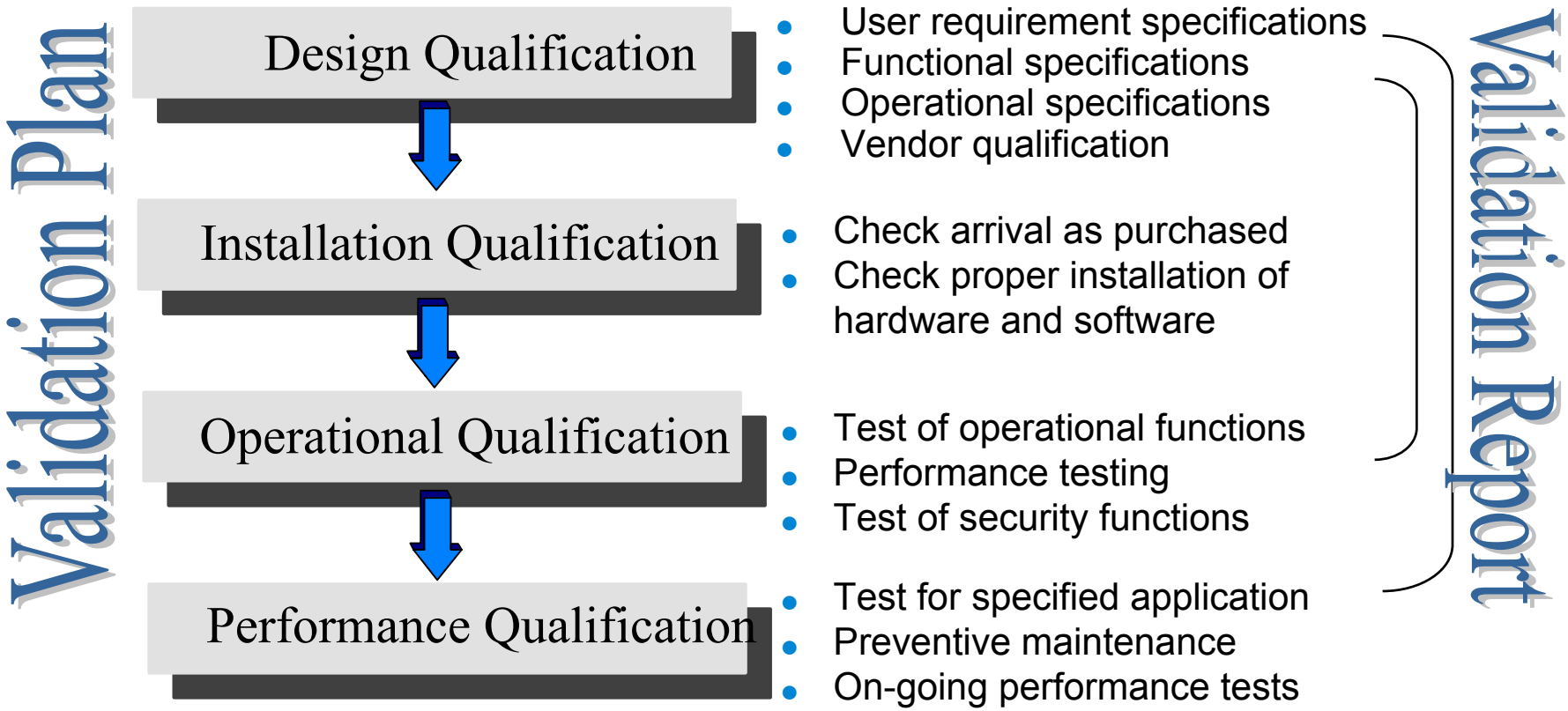
Systems

PQ

Reviews
- Primary
- Secondary

Data

Qualification/Validation Phases
4Q Model



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

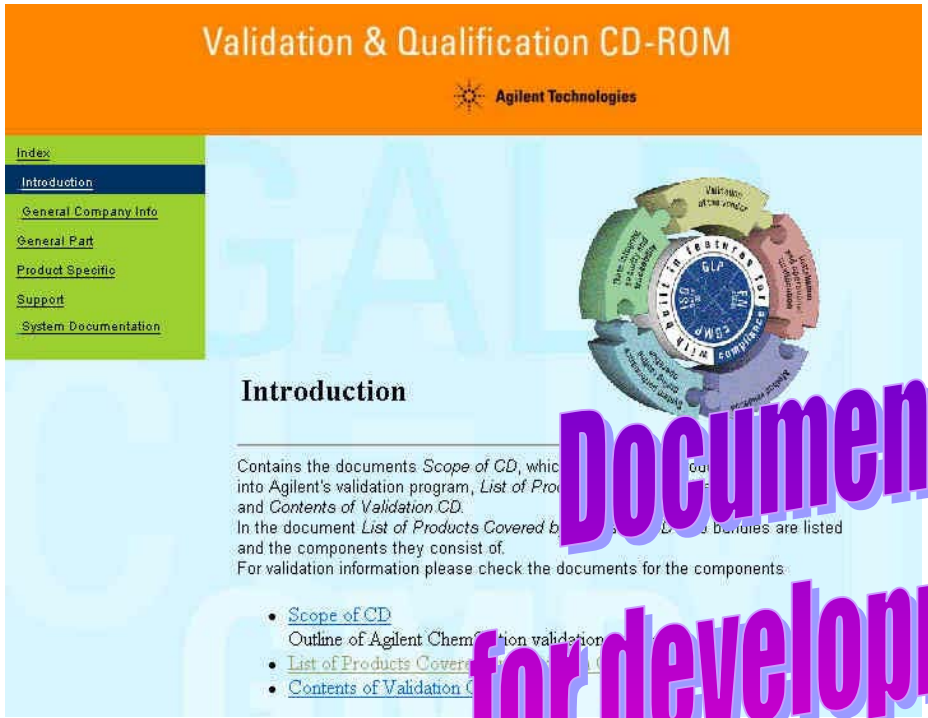
Steps for Vendor Assessment

- 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)

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



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

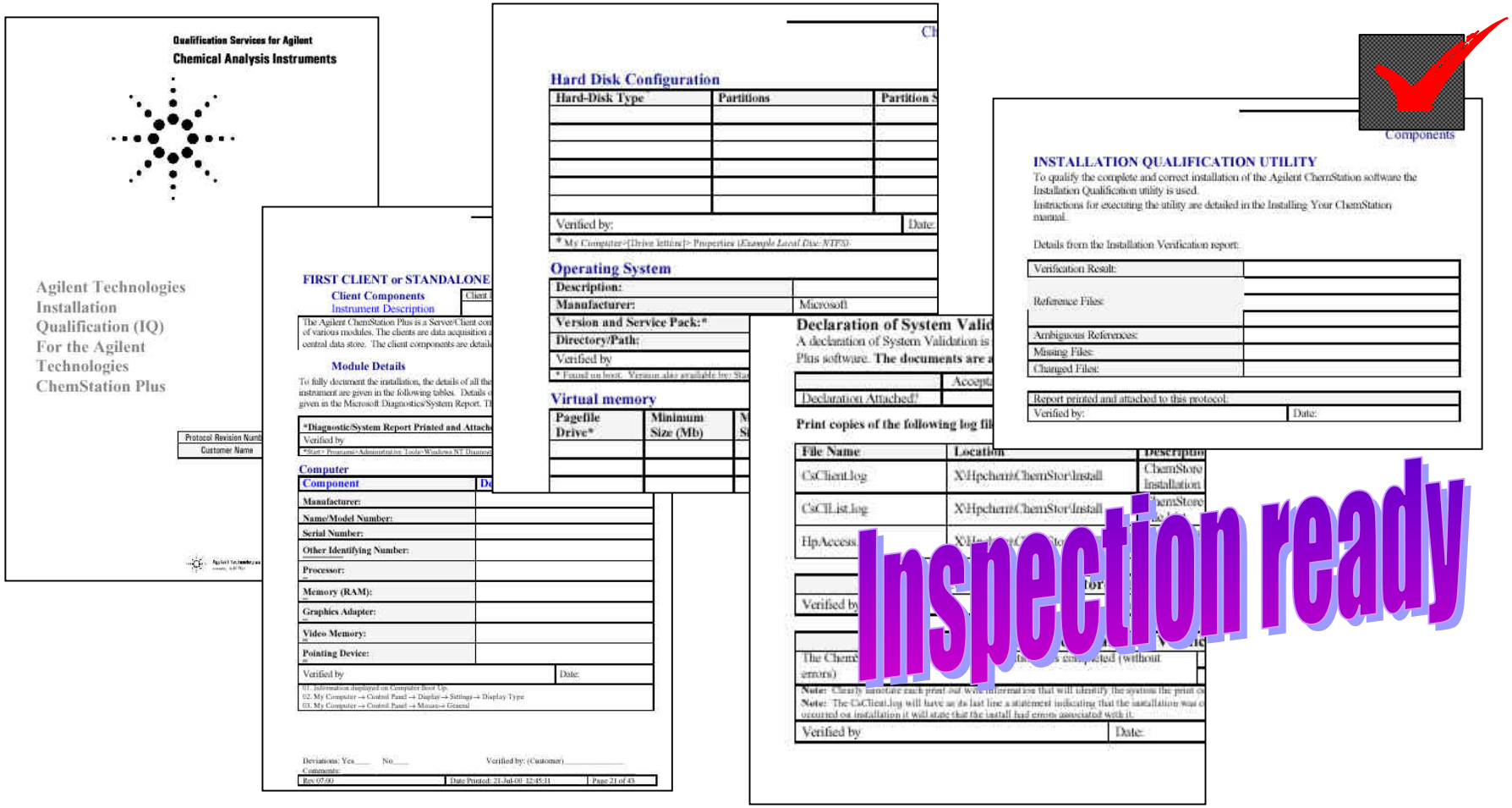
Assistance from Vendor for IQ Services

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



- 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

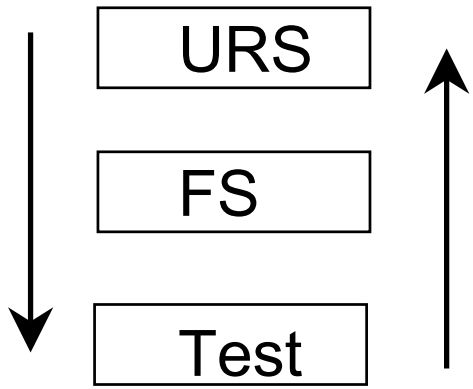
Operational Qualification - Steps

- 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

- 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 are you sure that the application works as intended day-by-day?"
- Helps to prevent errors

Performance Qualification - Steps

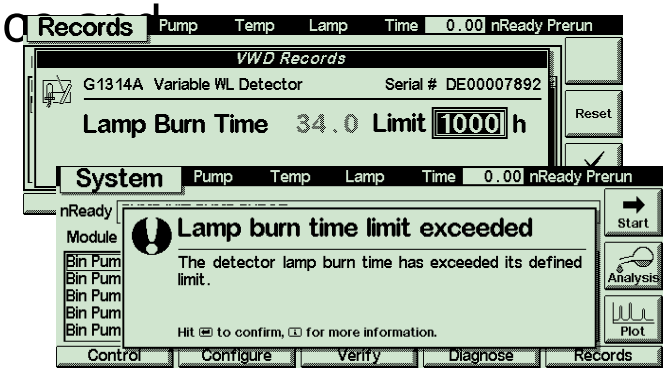
Develop and implement procedures for:

- 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

Ongoing Performance Qualification

Agilent Tools&Services

- Early maintenance feedback to prevent errors
- Preventive maintenance for hardware to ensure on-going 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

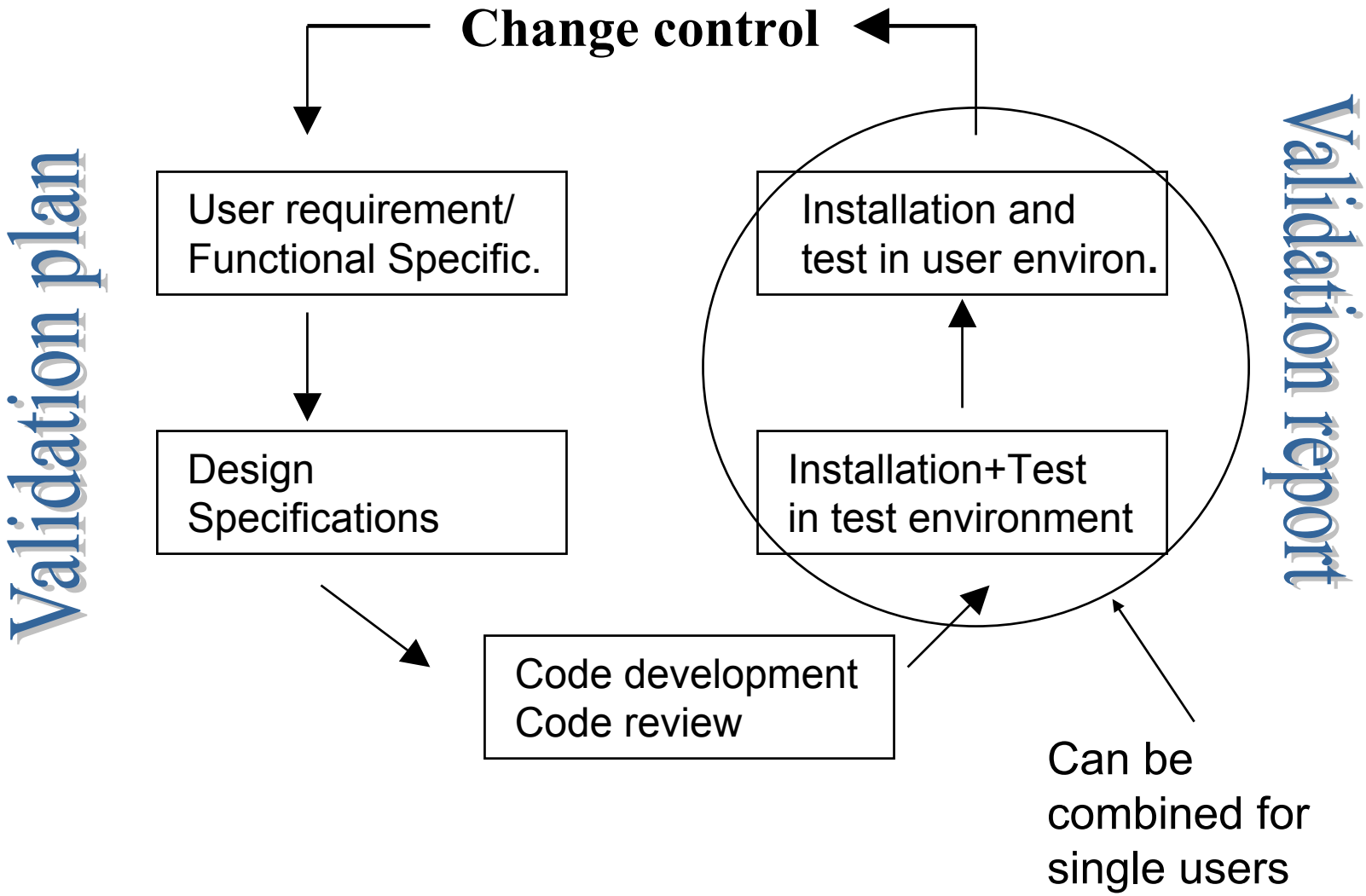
What ?

- 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*

Question and Answer Session

No. 2

Lifecycle Model for Spreadsheets&Macros

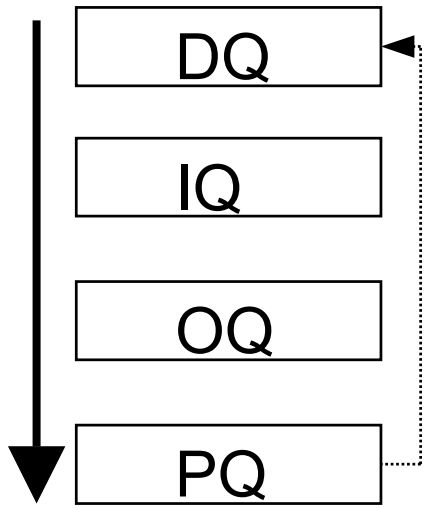


Change Control

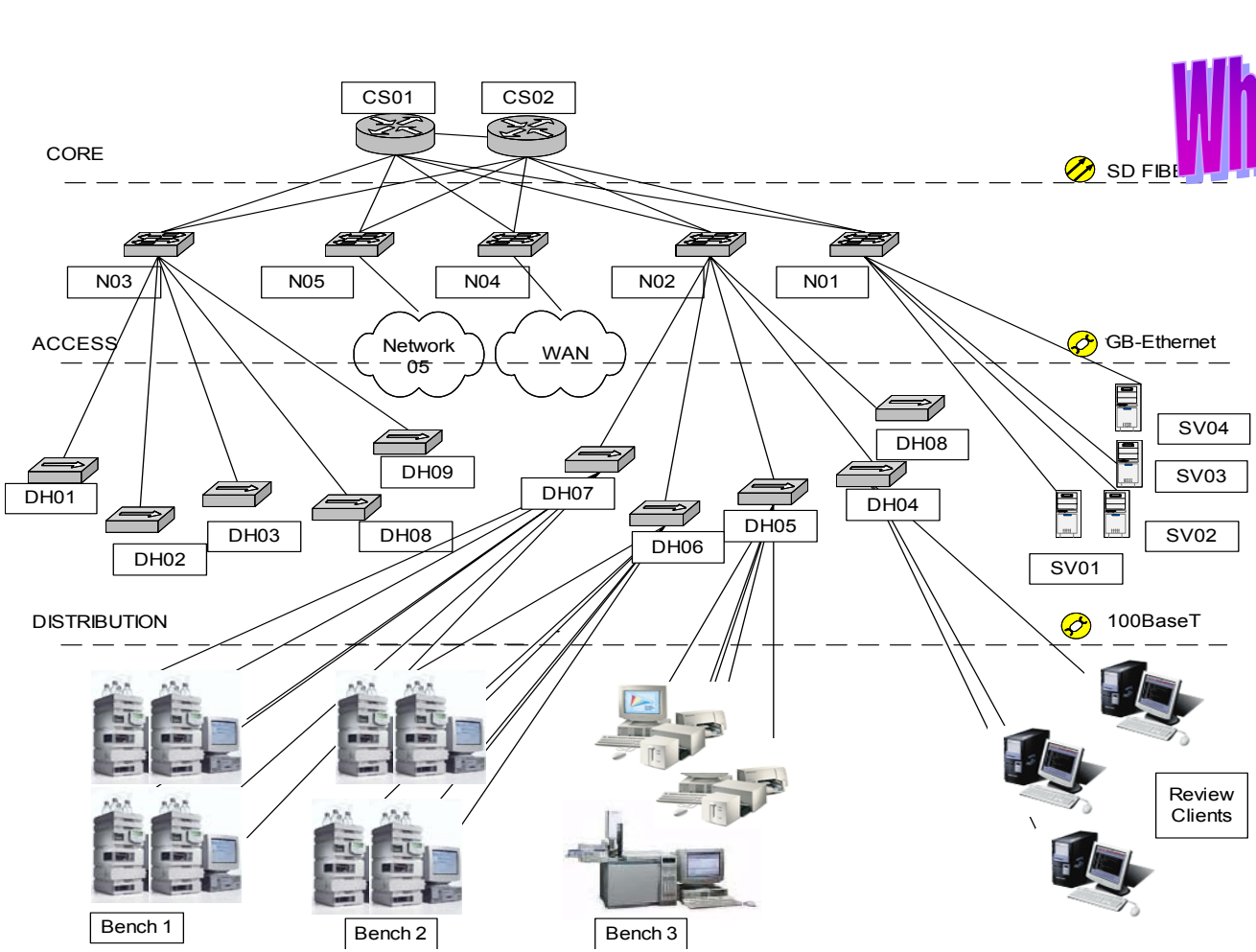
- Main reasons for changes: hardware maintenance and repair and software upgrades
- Changes must follow a documented change procedure
- Procedure should require risk analysis and evaluation if the change may affect the computerized system's validation status
- Document changes; what, why, who, how tested?

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

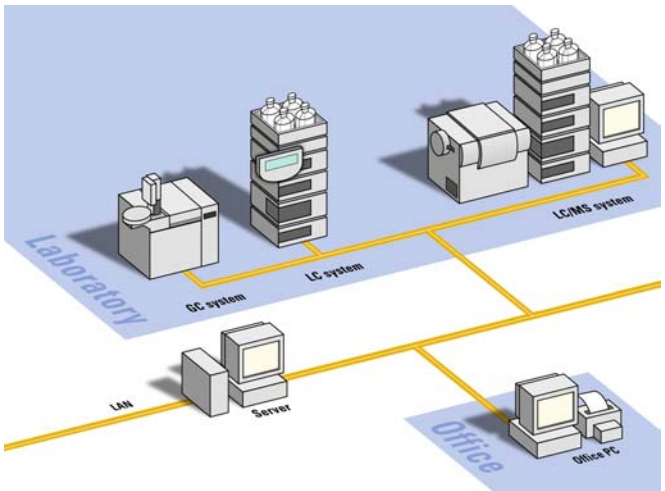


Security
Data integrity
Uptime

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



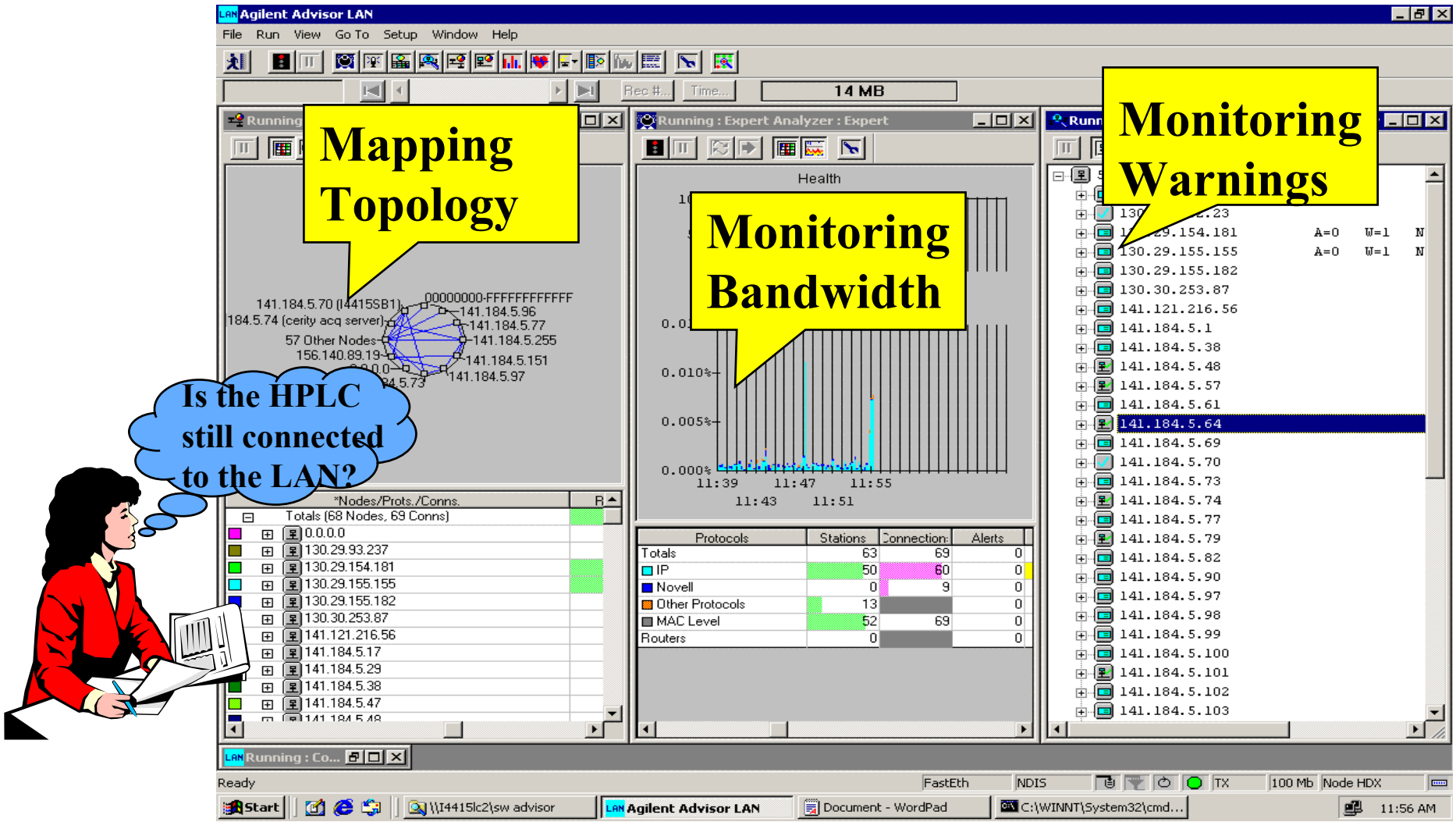
Agilent Technologies Provides for Networked Systems

- 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



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 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.