

Quality Assurance Software (Expert Systems)

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Guidance Documents

- Guidance For Standards For Relationship Testing Laboratories, 7th Edition, American Association of Blood Banks, sec. 3.5
- <http://www.labcompliance.com/newsletter.htm>
- <http://www.fda.gov/cdrh/qsr/03desgn.html>
- 21CFRPart11
- NIST Guide: Risk Management For IT Systems

Presentation Objective

- Provide A Perspective On The Quality Assurance of Software Systems
- Discuss Laboratory Accreditation Requirements That Now Exist and Those Anticipated For Future
- Specific Discussion Of Expert Systems Evaluated Under The NEST Project

Role Of Expert Systems

- To Serve A Function Now Conducted By Qualified Analysts Who Meet Laboratory Standards For Primary and Secondary Data Review
- Laboratory Must Be Assured That The Software/Hardware System Meets These Standards
- Assurance Dependent On Software Developer, Vendor and User
- Must Satisfy The Scrutiny Of The Courts

AABB Document

- Specifically Oriented To A DNA Testing Laboratory
- Generated With ISO Standards In Mind
- Section 3.5 Focuses On Computer Systems: Risk Analysis, Training, Validation, Implementation And Evaluation Of Post-implementation Performance

Risk Analysis Of Software

- Know Or Anticipate The Laboratory Needs And The Expectations For An Expert System (ES)
- Single Source Samples v. Mixtures
- Current Or Future High Through-Put Status
- Assessment Of The Capability Of The Software Developer and Vendor To Modify The E.S.

Risk Analysis

- Having Access To IT Personnel/Software Experts Qualified To Assist In the Analysis Process
- The Structure Of The ES
- All Systems Require Data Collection Software As First Step, Feeds Raw Data Into Higher Level Software
- To GeneScan/Genotyper Or To GeneMapper ID Or TA2

Multilayer Software In FSS I³ And TA2

- FSS I³ Sits On Top Of GMID Or Other Software Capable Of Peak Size, Height and Area Determinations
- TA 2 Works In Conjunction Of Matlab®, A Technical Computing Software
- Does Risk Analysis Entail Analyzing Both ES and Underlying Foundational Software? Has The Interface Between Levels Of Software Been Analyzed And Are Documents Available To Verify Software Interactions?

Risk Analysis

- Are Developmental Validations of ES Available For Assessment?
- ES Are Still Being Refined In Part In Response To Requests From ES Users
- Version Changes May Be Minor Or Significant; Software Experts May Need To Evaluate ES Version Changes
- Concordance Studies With Version Change

Prioritization Of Risk

- Determine The Vulnerabilities Of The ES And Determine If They Impact Final Results, Correct Analysis of Data
- Prioritize Vulnerabilities, Which Ones Can Be Easily Remedied
- Do You Have To Purchase ES To Risk Analyze?
- Anticipate Possible Vulnerabilities, eg. Versions Of Data Collection Software Or GMID Change, Will These Changes Affect Overriding ES?

E.S. Optimization

- Periodic Optimization Of ES To Reach Peak Performance
- Optimization At A Distance TA2 Or In-House
- Assurance That Optimization Is Performed To Meet Laboratory Quality Standards
- Risk Analysis of Optimization Process

Additional Requirements

- Training For E.S. Users
- Validation (NDIS Appendix B),
- Implementation, Tested In A Live Environment
- Post-Implementation Performance, Produces Expected Results

Computer System Records

- Validation Of System Software, Hardware, Databases, Electronic Data Transfer and Receipt
- Fulfillment Of Life-Cycle Requirements For Internally Developed Software
- System Version Numerical Designation And Dates of Use
- Monitoring Data Integrity

Computer System Backup

- An Alternative System That Ensures Continuous Computer System (Expert System) Operation In The Event That Computer –Assisted Functions Fail
- Required Periodic Testing Of Alternative System

Management Of Computer System

- Manager Comply With Specified Requirements
- Documented Processes and Procedures To Support Management of Computer Systems
- Prevention of Unauthorized Access To Computers And Electronic Records Shall Be Established and Followed

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- Thank You
- Questions?