



Software in the World of In Vitro Diagnostics

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What Is Software

- Firmware
- Stand-alone software applications (incl. algorithms)
- Dedicated hardware/software for medical devices
- Software in accessories to medical devices
- Data management systems
- Web based applications



Review Of Software

Why?

- Software is integral to the operation and safety of medical devices.
- Software is part of medical devices, therefore regulated.

Where?

- PMAs, 510(k)s, HDEs



Regulated, Not Reviewed

- HIS
- LIS (Unless uses new algorithms)
- LAS (Unless takes over instrument functions like bar code reading)
- HIS and LIS Still subject to MDR reporting and recalls



Software Guidance

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (<http://www.fda.gov/cdrh/ode/guidance/337.html>)
- Level of concern – section 3.1
- Software Description - section 3.2
- Device Hazard Analysis - section 3.3
- Software Requirements Specification (SRS) - section 3.4
- Architecture Design Chart - section 3.5
- Design Specification - section 3.6
- Traceability Analysis - section 3.7
- Development - section 3.8
- Validation, Verification and Testing - section 3.9
- Revision Level History - section 3.10
- Unresolved Anomalies (Bugs) - section 3.11
- Release Version Number - section 3.12



Software Guidance

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	Required for all.		
Software Description	Required for all.		
Device Hazard Analysis	Required for all.		
Software Requirements Specification (SRS)	Summary SRS.	The complete SRS document.	
Architecture Design Chart	No documentation is necessary.	Detailed depiction of functional units and software modules.	
Software Design Specification (SDS)	No documentation is necessary.	Software design specification document.	



Software Guidance

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Traceability Analysis	Required for all.		
Software Development Environment Description	No documentation is necessary.	Summary Software Development Environment Description	Full Software Development Environment Description
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities with System level test protocols and results.	V&V activities with Unit and System level test protocols and results.
Revision Level History	Required for all.		
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary.	List of remaining software anomalies.	



Level Of Concern

- Level of concern defines documentation submitted, and does not indicate what is required by a quality system.
- Software guidance should be used to determine the device's level of concern.
- Most IVDs are moderate level of concern.



Documentation

- All functions of the device should have:
 - Requirements (SRS)
 - Design (SDS)
 - Hazard analysis identification/mitigation
 - Functionality verified
 - Its use in the device validated
- The traceability analysis should describe these relationships.

Requirement	Design	Hazard	Verification	Validation
Requirements Section V.V	Design Section W.W	Hazard Section X.X	Verification Section Y.Y	Validation Section Z.Z



Hazard Analysis

- Hazard analysis should include all potential hazards identified in standards, those unique to device use, AND address possible software errors/failures.

- Software failures
 - Systematic in nature
 - Probability of occurrence cannot be determined

Therefore, the software portion of the Hazard Analysis should focus on the SEVERITY of the harm that could result from the software failure.



Unresolved Anomalies (Bugs)

- List ALL unresolved software anomalies.
- For each anomaly, indicate the: problem, impact, plans for correction.
- Communicate unresolved bugs to customers.



Off The Shelf Software

- Off-The-Shelf Software Use in Medical Devices
(<http://www.fda.gov/cdrh/ode/guidance/585.html>)
- Examples
 - Networks
 - Microsoft operating systems
 - Databases, spreadsheets



Off The Shelf Software

Minor Level of Concern

Hazard Analysis

Basic Documentation

Moderate Level of Concern

Minor Level PLUS:

Hazard Mitigations

Describe and Justify Residual Risks

Major Level of Concern

Moderate Level PLUS:

Special Documentation (includes audit of OTS developer, V&V performed by developer and device manufacturer, continued maintenance plans should developer terminate support)



Wireless

- What if your software has wireless capability?
- This feature should still be documented like any other required feature of the device.
- Draft Guidance for Industry and FDA Staff - Radio-Frequency Wireless Technology in Medical Devices
(<http://www.fda.gov/cdrh/osel/guidance/1618.html>)



Should You Send Code?

- No.
- The review of software is based on the results (design, functionality, safety) of the software's code.



Guidance List

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
(<http://www.fda.gov/cdrh/ode/guidance/337.html>)
- Off-The-Shelf Software Use in Medical Devices
(<http://www.fda.gov/cdrh/ode/guidance/585.html>)
- Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
(<http://www.fda.gov/cdrh/comp/guidance/1553.html>)
- Draft Guidance for Industry and FDA Staff - Radio-Frequency Wireless Technology in Medical Devices
(<http://www.fda.gov/cdrh/osel/guidance/1618.html>)



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Questions?

- Ask away!