AMDM 38th Annual Meeting

Software Specifications to Minimize Questions in Submissions and Inspections

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Objectives

- Understand FDA requirements for submissions and inspections
- Prepare specifications to reduce questions

Current Climate

- Since 1/2010 FDA reviewers have been asking more detailed questions
- FDA reviewers and inspectors have received additional “software” training
- Software related guidance documents and standards are increasing

Strategy

- Map required documents to inspection and submission checklists
- Focus on safety and essential performance
- Provide submission overviews and document summaries
- Provide traceability tables for test completeness

Sample Design Control Documents

	QSR Ref.	ISO Ref.	Design Control Element	Documents
1.	820.30(b)	7.3.1	Design and development planning	Design and Development Plan
2.	820.30(c)	7.3.2	Design input	System Requirements Specification Safety Risk Analysis
3.	820.30(d)	7.3.3	Design output	System Design Description Source code Drawings/Schematics
4.	820.30(e)	7.3.4	Design review	System review reports Design review reports
5.	820.30(f)	7.3.5	Design verification	Verification Test Procedures
6.	820.30(g)	7.3.6	Design validation	Validation Test Procedures Test Summary Report Requirements traceability matrix
7.	820.30(h)	NA	Design transfer	Design transfer procedure
8.	820.30(i)	7.3.7	Design changes	Change control procedures
9.	820.30(j)	4.2.3-4	Design history file	Document control procedures

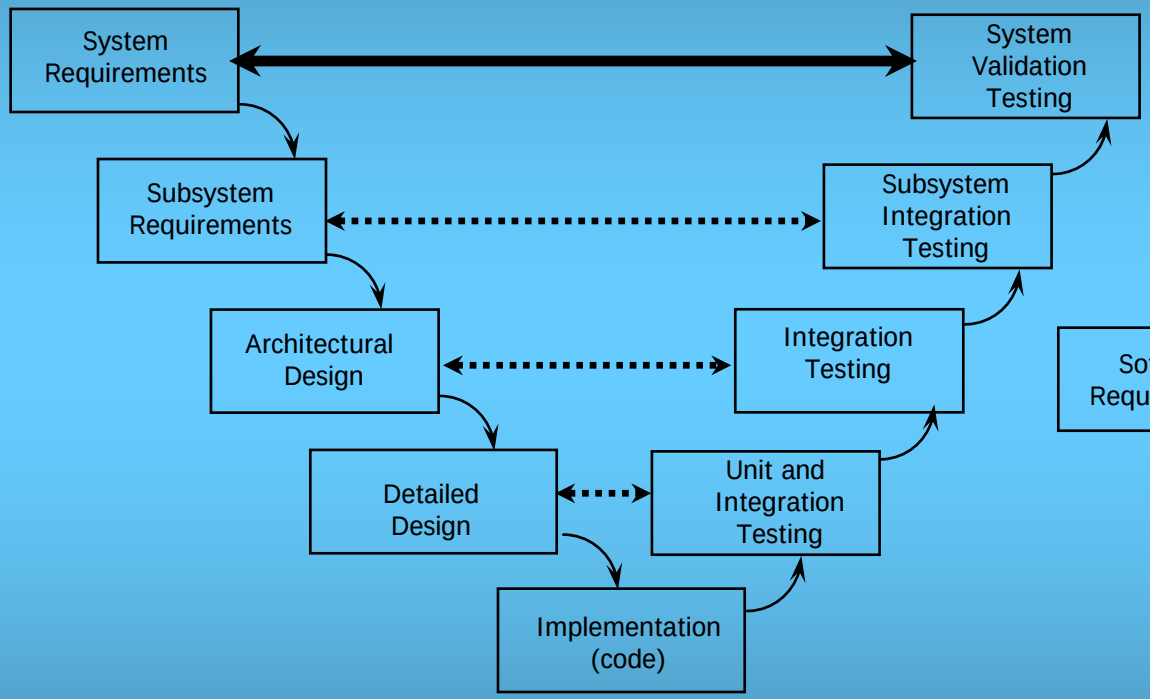
Sample Submission Documents

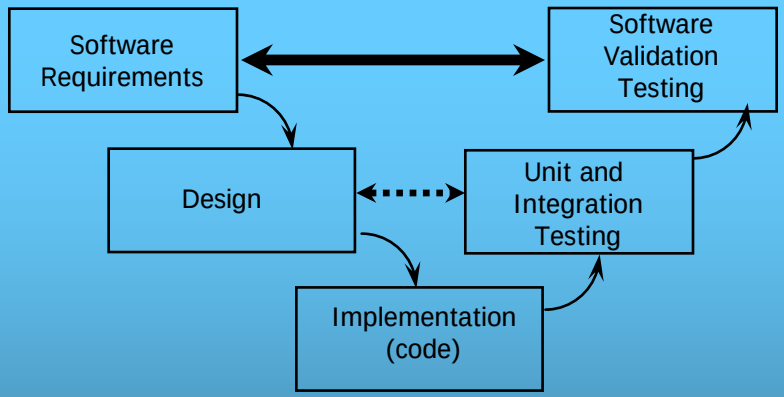
Num.	Requirement	Document
1.	Level of concern	Safety Risk Analysis
2.	Software Description	Design and Development Plan
3.	Device Hazard Analysis	Safety Risk Analysis
4.	Software Requirements Specifications (SRS)	System Requirements Specification
5.	Architecture Design Chart	System Design Description
6.	Software Design Specification	System Design Description
7.	Traceability Analysis	System and safety requirements traceability matrix
8.	Software Development Environment Description	Design and Development Plan
9.	Verification and Validation Documentation	Verification Test Procedures Validation Test Procedures Test Summary Report
10.	Revision Level History	Initial market release
11.	Unresolved anomalies	As per procedure, anomalies that affect safety or essential performance are not allowed in a release

Keep it Simple

- Help investigators/reviewers answer key questions (safety, performance, SE, …)
- Overviews simplify review for large documents
- Provide diagrams, tables, pictures where possible
- Highlight samples of safety testing
- Do not submit everything

Which would You Rather Review?





Traceability Matrix

Reqmt	Description	Safety	Design	Tests
3.1	Startup	N	2.1	2., 3., 4., 5., 6., 7., 8., 9.
3.1.1	Laser Controller Checks	Y	2.2	2., 3., 4., 5., 6., 7., 8.
3.1.2	Main Processor Checks	Y	2.3	2., 3., 9.
3.1.3	Operational Use Checks	N	2.4	1., 12.
3.2	Treatment Planning	N	3.1	11.
3.2.1	Patient Demographics	N	3.1	11.
3.2.2	Patient Treatment Data	Y	3.3	11.
3.3	Calibration	Y	4.1	12.
3.4.1	Pre-firing Checks	Y	4.2	13.
3.4.2	Firing Operations	Y	4.3	13.
3.5.1	Patient Summary Report	N	5.1	14.
3.5.2	Equipment Operations Rpt.	N	5.2	14.
3.5.3	Patient Graphical Report	N	5.3	14.
3.6	Shutdown	N	4.4	15.

One Size does not fit All

- Try to understand reviewer concerns
- What worked last time may not work this time
- You cannot win this argument
- Keep reviewer updated on response timelines

Typical Requests

- What is the level of concern?
- Show unit, integration, and system testing procedures
- How many unresolved anomalies?
- What is the change history?
- Do you have traceability to design?
- Do you have a Software Hazard Analysis?
- What OTS software do you use?

FDA Reviewer Guidance 2005

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.	Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.

Key Content for Key Documents

Safety risk analysis	Intended use, foreseeable “misuse”, labeling, software
Requirements specification	Testable, includes safety requirements
Design specification	Pictures, diagrams, traceable from Requirements
Test procedures	Executed results, objective evidence, can be selective
Test report	Minimal unresolved defects, safety requirements addressed

Summary

Lessons Learned

- Rules may change over time
- Simplify the job of the Reviewer
- Don’t provide everything for the initial submission
- Know when to challenge requests for more documentation