



Center for Devices and
Radiological Health

Software Standards Update

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Where I begin this story

- ◆ FDA Modernization Act
 - November 1997
- ◆ The Magee Tripp Text
 - Guide to Software Engineering Standards and Specifications
- ◆ The Moore Text
 - Software Engineering Standards



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What did we discover?

- ◆ There is a well established set of software standards
- ◆ There are some 300 plus standards
- ◆ There are many standards that may be necessary
- ◆ There are few that are sufficient for our purpose

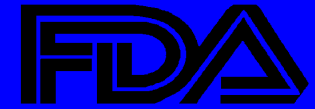


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What did we discover?

- ◆ These standards do cover all major areas of software engineering
- ◆ The majority of software standards are written to address all business sectors
- ◆ The granularity of these standards needs refinement to cover our concerns
- ◆ The majority of these standards have limited conformance assessment criteria

Long Term Goal



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- ◆ Create a regulatory environment that eliminates the need for the pre-market submission of software
- ◆ Global Harmonization
- ◆ Eliminate repackaging and restructuring

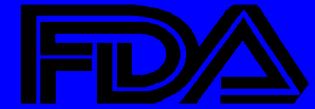


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Achieving the Goal

- ◆ Develop Standards that benefit the Public Health, the Regulator, and the Industry
- ◆ Develop standards that address the safety and effectiveness of software

Focus on the Fundamentals



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- ◆ Safe Software requires sound “safety” system engineering
- ◆ Agreement on what affects software safety and effectiveness
- ◆ Common framework and language
- ◆ A working partnership



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Adding Structure

- ◆ To help understand the landscape I ask that you consider the following 4 level structure
- ◆ Its purpose is to show the relationship of the various levels of standards related to software



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The Four Levels

- ◆ 1 - General Process - ISO 9001 and the Quality System
- ◆ 2 - Software General Process ISO/IEC 12207 and AAMI SE
- ◆ 3 - Software Specific - IEEE Standards
- ◆ 4 - Software Product Specific - For future use



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Concurrent Activities

- ◆ Recognition of ISO/IEC 12207
- ◆ AAMI Software Engineering Standard
- ◆ HIMA Software Quality Audits
- ◆ CDRH/IEEE CRADA
- ◆ AAMI Software Hazard Management TIR
- ◆ IEC SC62A WG15/WG22