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
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
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

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

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