Requirements Verification and Validation on a Global Project

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GE Healthcare IT
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Would you tell me please, which way I ought to go from here?
That depends a good deal on where you want to get to, said the cat.
I don't much care where, said Alice.
Then it doesn't matter which way you go, said the cat.

Lewis Carroll, *Alice in Wonderland*, Chapter 6.
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Presentation Objectives

- Requirement types and how to use them
- Techniques for test case coverage of requirements
- Recommendations for success

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Agenda

Definitions

Project Overview

Requirement Types

Coverage

Keys to Success

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Definitions (CSQA CBOK)

- ✓ Verification
  - Verification ensures that the system (software, hardware, documentation, and personnel) complies with an **organization's standards and processes**, relying on review of **non-executable methods**
- ✓ Validation
  - Validation physically ensures that the system operates **according to plan** by executing the system functions through a **series of tests** that can be **observed** and **evaluated**

Definitions (CSQA CBOK)

- ✓ Verification
  - **All QC activities throughout the life cycle** that assure that **interim** product **deliverables** process their inputs in accordance with **specifications** and **standards**.
- ✓ Validation
  - **Any activity** that helps assure that the **end product** (e.g., system) under defined operating conditions **meets** its currently approved **requirements** and **expectations**.

Definitions (CMMI and Six Sigma)

- ✓ Verification
  - Verification answers the question, **“Was the product built right?”**
- ✓ Validation
  - Validation answers the question, “**Was the right product built?”**

Definitions (FDA)

- ✓ Verification
  - Verification means **confirmation** by **examination** and provision of **objective evidence** that specified **requirements** have been fulfilled
- ✓ Validation
  - Validation means **confirmation** by **examination** and provision of **objective evidence** that the particular **requirements** for a specific **intended use** can be **consistently** fulfilled

Definitions

Which definition to follow?

"In theory there is no difference between theory and practice. In practice there is."
Yogi Berra

Focus on the needs.
Be consistent with your organization.

Project Overview

- ✓ PACS: Picture Archiving and Communication System
  - In medical imaging, picture archiving and communication systems (PACS) are computers or networks dedicated to the storage, retrieval, distribution and presentation of images…including ultrasound, magnetic resonance, PET, computed tomography, endoscopy, mammograms, DR/CR etc.
- ✓ Headline: GE wins £110m PACS contract for South of England

http://www.e-health-insider.com/News/940/ge_wins_%C2%A3110m_pacs_contract_for_south_of_england

  - "GE Healthcare has signed with Fujitsu Services Ltd to provide Picture Archiving and Communications System (PACS) across the whole of the Southern region of the English National Health Service under the National Programme for IT (NPfIT)…"
  - "…GE Healthcare should install PACS in the 72 hospitals run by 42 NHS hospital trusts across the South of England…"

Project Overview

- ✓ International Project
- ✓ Government Regulations
- ✓ Sub-Contract
- ✓ Certification Required
- ✓ Test Witnessing
- ✓ New Processes
- ✓ Significant Penalty Potential

Requirement Types

Process

User/System

Features

Use Cases

Contractual

Test Areas

Unit Test Areas

- Data and data input handling
- Data display formatting
- Screen layout
- Max/Min values
- Context data through screen navigation
- Error handling and reporting
- Database content and locking
- Data Integrity at the data commit point

System Test Areas

- End to end cross system data and process flows
- Data integrity across the system
- Continuity of processing across the system
- Systematic prevention of potentially damaging processes
- Max/Min value handling across the system
- Business process exception handling
- Use of simulated live data
- Interface testing
- Volume testing
- Security
- Installation and configuration
- Usability testing

Coverage

Process/Contractual Requirements:

- Documentation
- Test Phases
- Defect Tracking
- Results Reporting

Proof of Coverage:

- Document Reviews
- Official Testing Announcements
- Defect Reviews
- Test Witnesses

Coverage

User/System Requirements:

- Requirements/Design Documentation
- Typically includes Features and Use Cases

Proof of Coverage:

- Traceability Matrix

	Requirement 1	Requirement 2	Requirement 3
Test 1	X		
Test 2		X	
Test 3		X	
Test 4			X

Coverage

Test Areas:

- Can be used with or without defined functional requirements
- Cover at the requirement or feature level

Proof of Coverage:

- Traceability Matrix

	Feature		Test Areas		
	New UI	Undo	Screen Layout	Security	Data Integrity
Test 1	X		X		
Test 2	X			X	
Test 3		X		X	
Test 4		X			X

Challenges

- Vague requirements
- New processes
- Late involvement
- Initial pessimism

Keys to Success

- Plan a strategy for execution
- Do **your** part correctly
- Communicate
- Management support

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