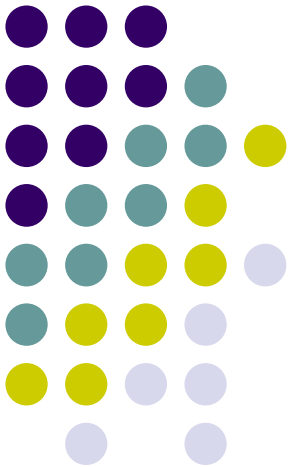
TSP Symposium – 2011

A Dedication To Excellence

Medical Device Software Development

Carl Wyrwa

September 22, 2011



Dr. Arnold O. Beckman

"There is no satisfactory substitute for excellence."

Today

- Share with you the world of Medical Device Software Development

- Show how the TSP establishes a framework for meeting the safety, quality, and regulatory compliance requirements on which we have to constantly stay focused

TSP

BECKMAN COULTER

Immunoassay

Chemistry

Hematology

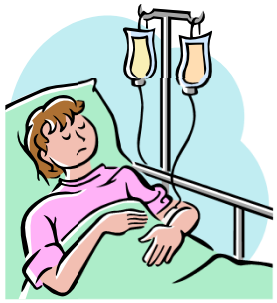
BECKMAN COULTER

Stand-Alone Automation

Connected Automation

December 24, 1978

Things That Keep Me Up At Night

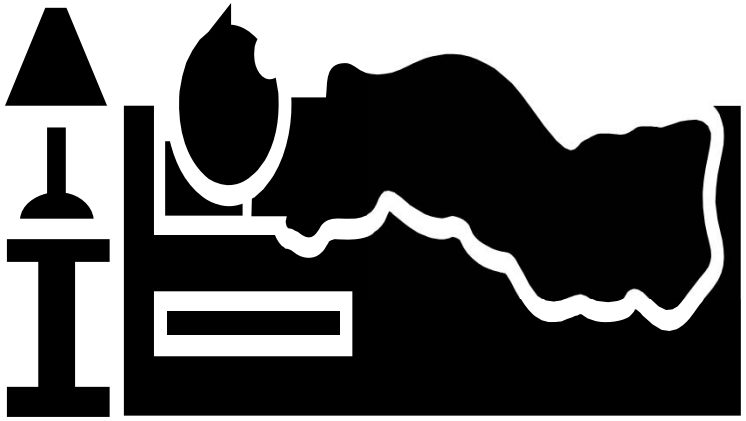


Patient Safety

Do No Harm

Worldwide Regulations

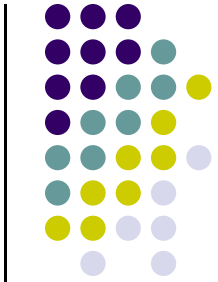
More Rigorous Process For Software Than Hardware



Software Safety, Quality & Compliance

Software Compliance

FDA
U.S Food and Drug Administration



FDA Overview

One of our nation's oldest consumer protection agencies

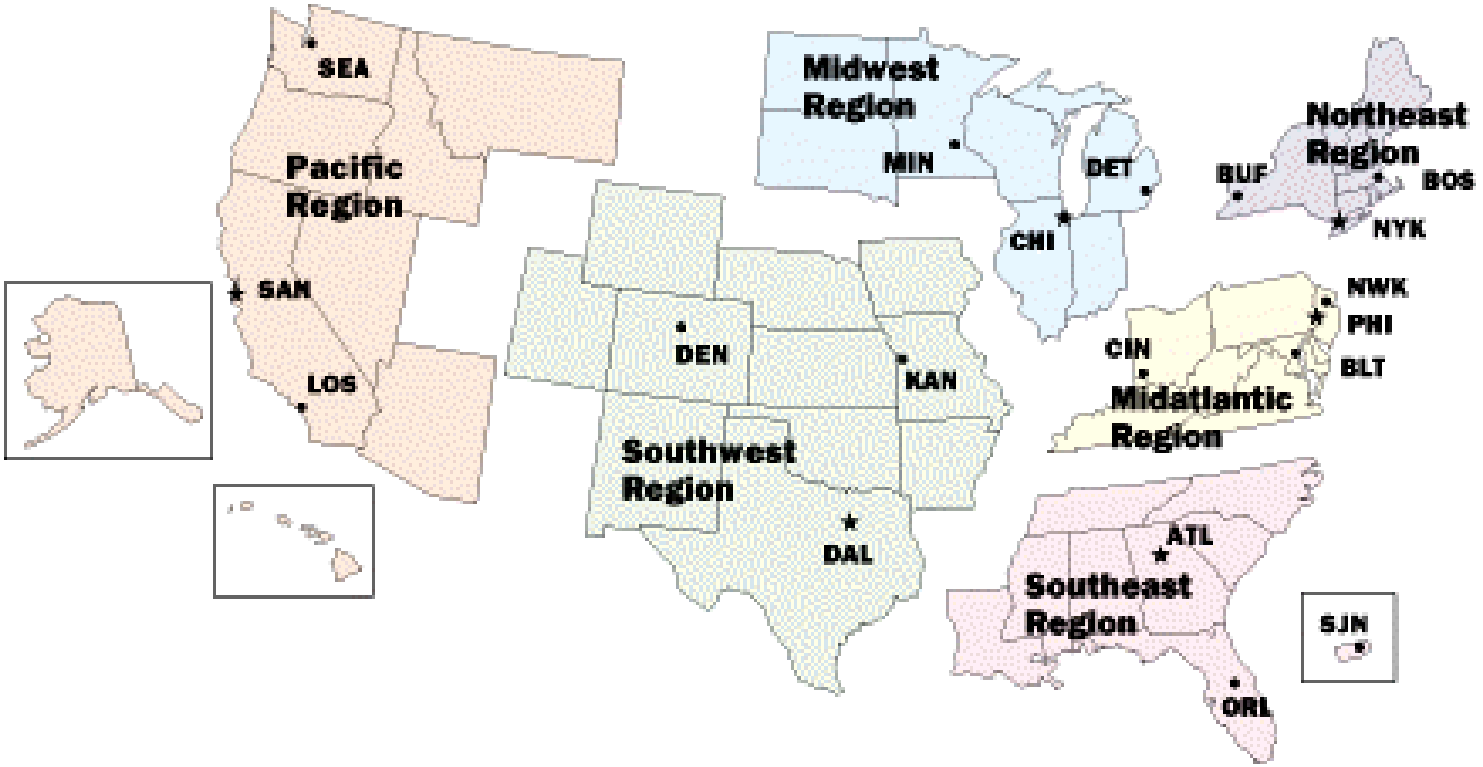
FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, **medical devices**, our nation’s food supply, cosmetics, and products that emit radiation (and recently tobacco)

Approximately 9,500 employees

Located in district and local offices in 157 cities across the country

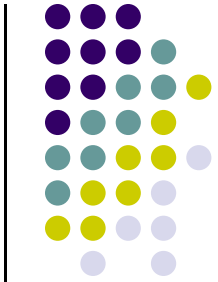
FDA Headquarters in Silver Spring, Maryland

FDA
U.S Food and Drug Administration



FDA Field Offices

FDA
U.S Food and Drug Administration



Field Offices

"the eyes and ears" of the FDA

inspectional operations

Approximately half of the FDA's 9,500 employees are assigned to field offices

FDA has some 1,100 investigators and inspectors (*see note)

Cover almost 95,000 FDA-related businesses

FDA's investigators and inspectors visit more than 15,000 facilities a year

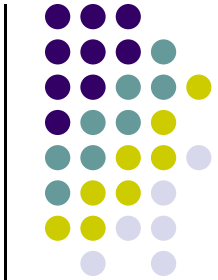
(*note: Early 2002 – 680 investigators, as of October 2002 about 1200 with 600 more to add)

FDA
U.S Food and Drug Administration

FDA Los Angeles District Office
Irvine, California

FDA

U.S Food and Drug Administration



Administrative Enforcement Powers

- Scheduled Inspections (Routine – every 2 years)
- Unannounced Inspections (For Cause – any time)
- Inspectional Observations - 483
- Warning Letters
- Adverse Publicity
- FDA-Initiated Recalls and Monitoring Company-Initiated Recalls
- Delay, Suspension, or Withdrawal of Product Approvals
- Preclusion of Government contracts
- Detention and Refusal of Entry into U.S. Commerce of Imported Products

Judicial Enforcement Powers

- Civil Enforcement Powers (Seizure)
- Criminal Enforcement Powers (Prosecution)

Software Safety, Quality & Compliance
Regulatory Requirements

The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply with are:

- **21 CFR 807** Establishment Registration
- **21 CFR 807** Medical Device Listing
- **21 CFR 807** Premarket Notification – 510(k)
- **21 CFR 814** Premarket Approval - PMA
- **21 CFR 820** Quality System Regulation
- **21 CFR 801** Labeling
- **21 CFR 803** Medical Device Reporting
- **21 CFR 11** Electronic Records & Signatures

Quality System Regulation (QSR)
Good Manufacturing Practices (GMP)

The quality system regulation includes requirements related to the methods used in and the facilities and controls used for: designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices.

Manufacturing facilities undergo FDA inspections to assure compliance with the QS requirements.

The quality system regulation includes design controls which must complied with during the design and development of the device.

FDA
U.S Food and Drug Administration

FDA Software Regulation Timeline

1987 - Technical Reference On Software Development Activities

1989 - FDA's policy for the Regulation of Computer Products

1991 - Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review

1992 - CDRH's "Application of the medical device GMP to computerized Devices..."

1995 - ORA Glossary Of Computerized System And Software Development Terminology

1996 - Do It By Design: An Introduction To Human Factors In Medical Devices

FDA
U.S Food and Drug Administration

FDA Software Regulation Timeline

1997 – Pre-Production Design Controls

1997 - Reviewer Guidance For A Premarket Notification Submission For Blood Establishment Computer Software

1997 - General Principles of Software Validation, Version 1.1

1997 - 21 CFR Part 11 Electronic Records; Electronic Signatures

1998 - Guidance for the Content of Premarket Submissions for Software Contained In Medical Devices

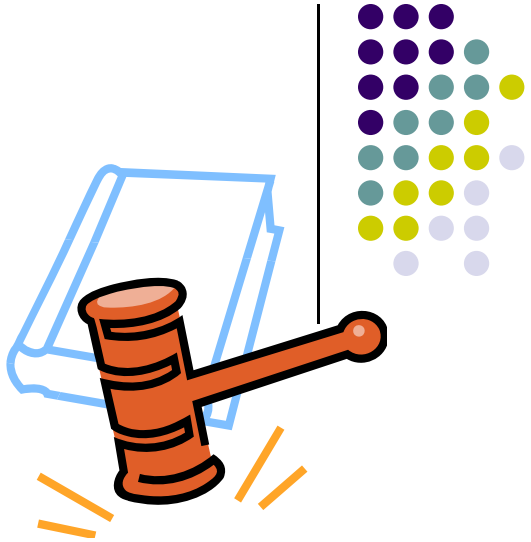
1998 - FDA Standards Recognition Statement for ISO/IEC 12207 Information Technology – Software Lifecycle Processes

1999 - Guidance on Off-the-Shelf Software Use in Medical Devices

2000 - Medical Device Use--Safety: Incorporating Human Factors Engineering into Risk Management

2001 - FDA Standard Recognition Statement for ISO 14971:2000, Medical devices – Application of risk management to medical devices

FDA
U.S Food and Drug Administration



FDA Software Regulation Timeline

2002 - Final General Principles of Software Validation Guidance

2002 - FDA Standards Recognition Statement AAMI SW68 Medical Device Software Life Cycle Processes

2005 - AAMI TIR32: 2004 Medical Device Software Risk Management

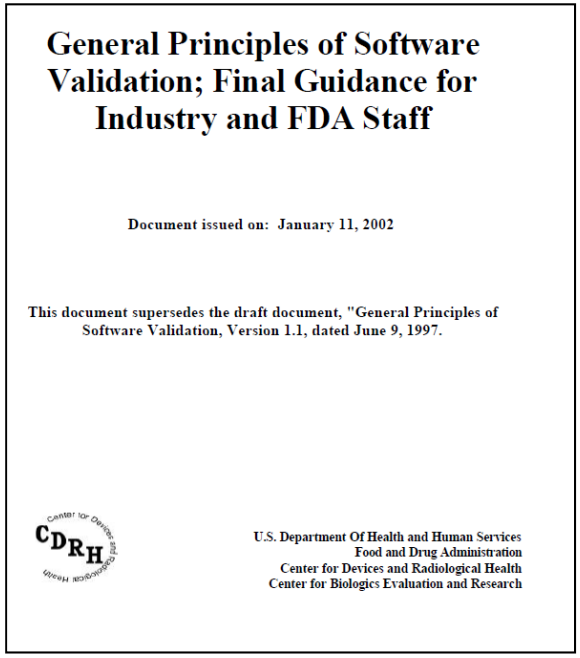
2005 - FDA CDRH/CBER Guidance for Content of Premarket Submissions for Software Contained in Medical Devices

2006 – ANSI/AAMI/ICE 62304 – Medical Device Software – Software Life Cycle Processes

FDA
U.S Food and Drug Administration

3.3 Software Is Different From Hardware

"……. for these and other reasons, software engineering needs an even greater level of managerial scrutiny and control than does hardware engineering"


General Principles of Software Validation; Final Guidance for Industry and FDA Staff

Document issued on: January 11, 2002

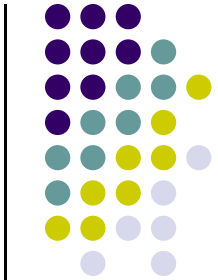
This document supersedes the draft document, "General Principles of Software Validation, Version 1.1, dated June 9, 1997.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

TSP

FDA – General Principles of Software Validation;
Final Guidance for Industry and FDA Staff
January 11, 2002

FDA
U.S Food and Drug Administration



Software Life Cycle Model

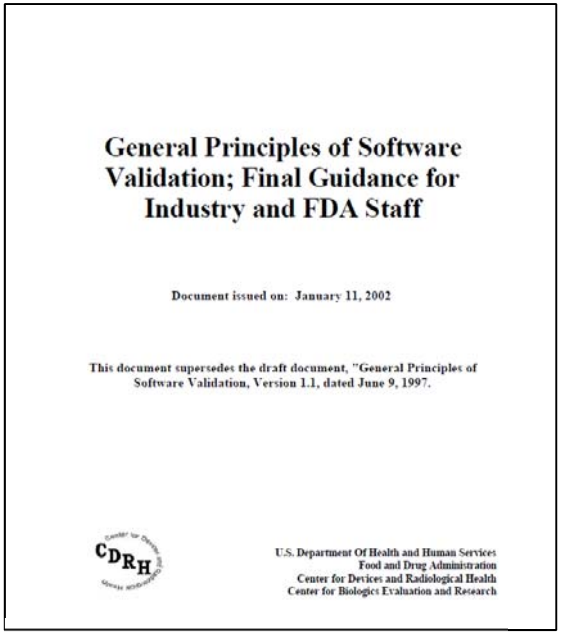
TSP

Software developers should establish a software life cycle model that is appropriate for their product and organization

Activities in a typical software life cycle model include the following:

- Quality Planning TSP
- System Requirements Definition
- Detailed Software Requirements Specification
- Software Design Specification
- Construction or Coding
- Testing

Key FDA Guidances
Industry Standard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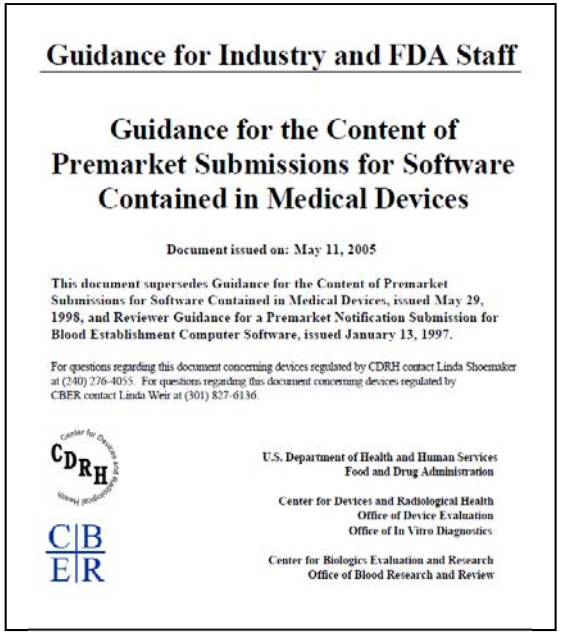

Guidance for Industry and FDA Staff

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Document issued on: May 11, 2005

This document supersedes Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 29, 1998, and Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software, issued January 13, 1997.

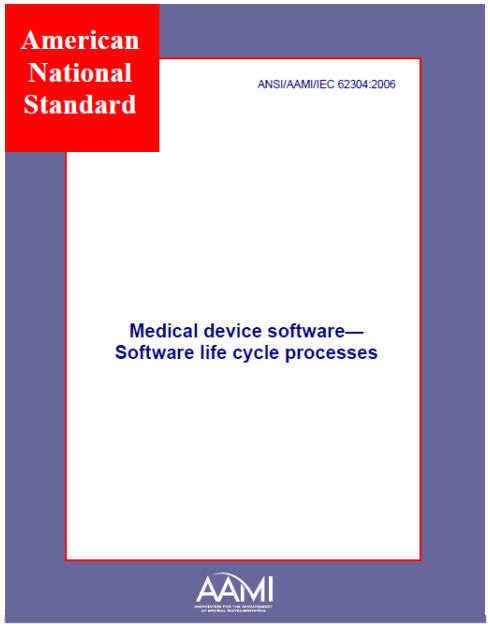
For questions regarding this document concerning devices regulated by CDRH contact Linda Shoemaker at (240) 276-4055. For questions regarding this document concerning devices regulated by CBER contact Linda Weir at (301) 827-6136.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostics

Center for Biologics Evaluation and Research
Office of Blood Research and Review

TSP



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FDA
U.S Food and Drug Administration

Effectiveness Of The Quality System

SUBCHAPTER H--MEDICAL DEVICESPART 820 -- QUALITY SYSTEM REGULATION Subpart B--Quality System Requirements

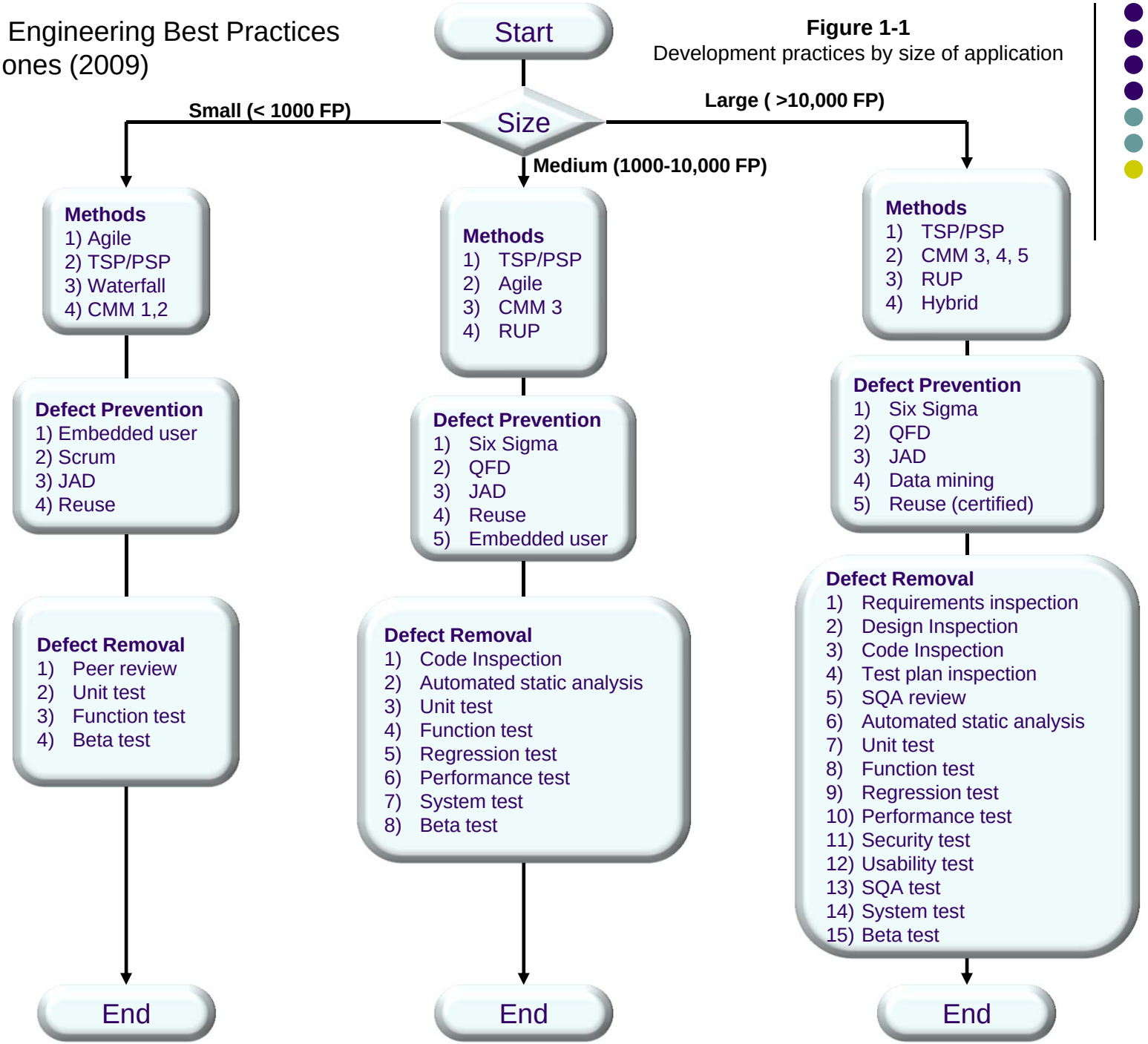
Sec. 820.22 Quality audit.

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the **effectiveness** of the quality system.

TSP

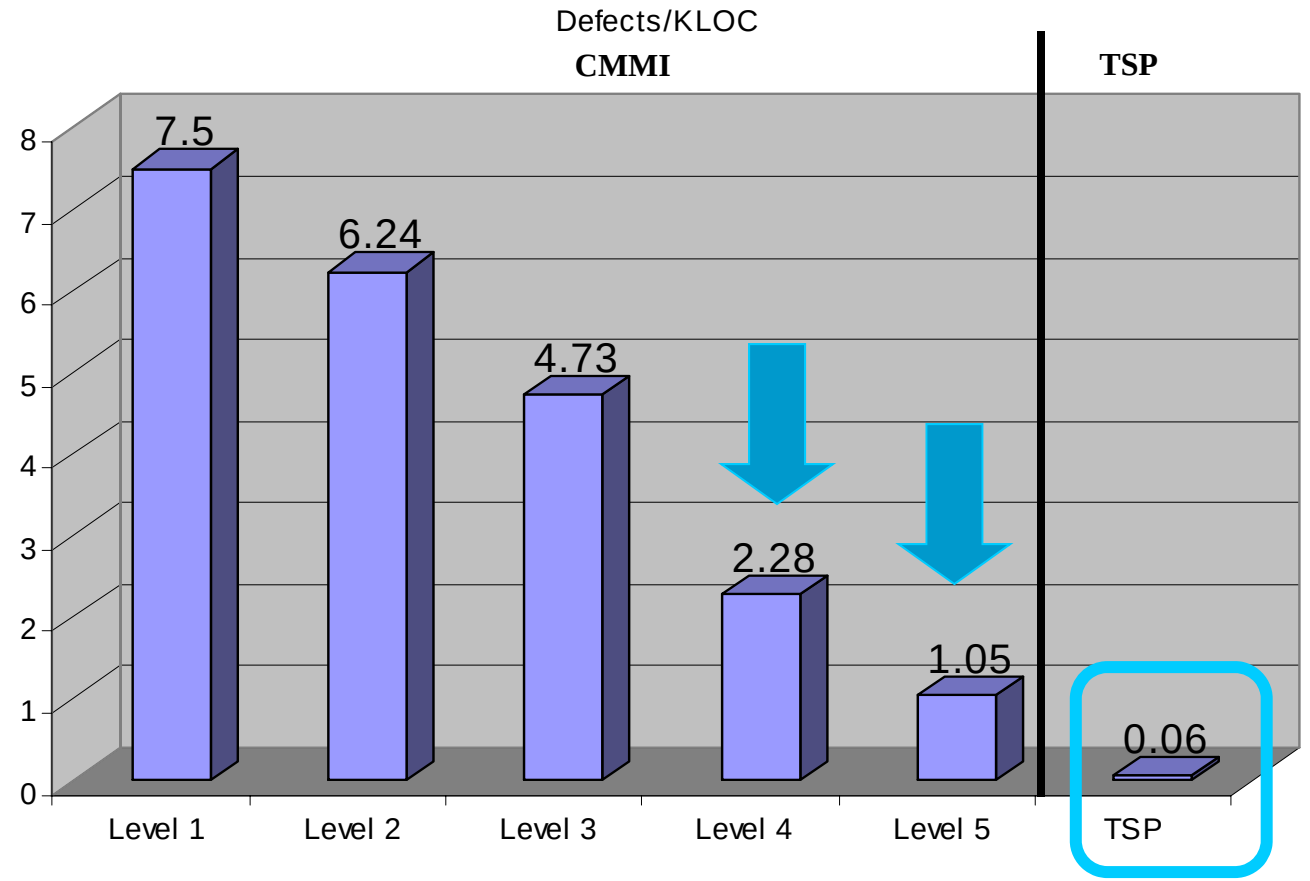
Software Engineering Best Practices
Capers Jones (2009)

Figure 1-1
Development practices by size of application



Software Quality

TSP Performance: Quality



Where I Learned About Quality Workmanship

"always do your work in a way that you would be proud to put your name to it"
Eugene Wyrwa - 1974

I Started Using TSP In the ‘70s

This is where I learned about rework!

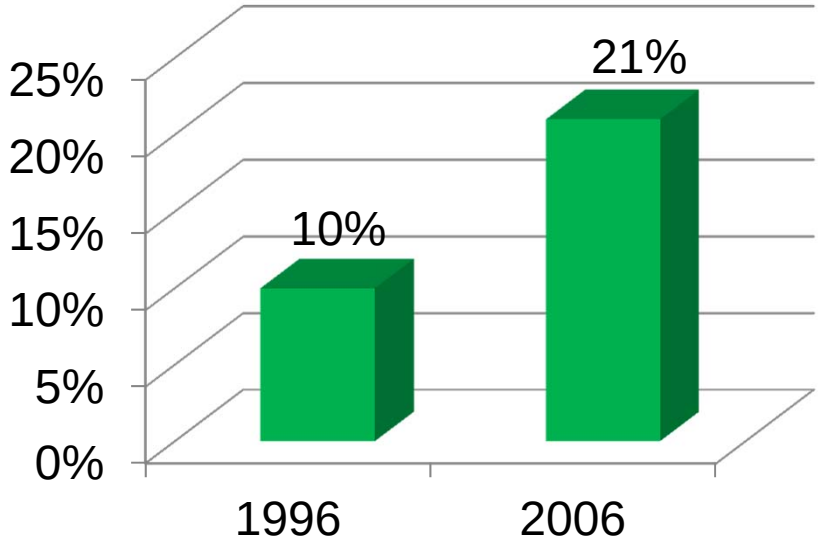
Software Safety

FDA

U.S Food and Drug Administration

In 1996 10% of medical devices recalls were caused by software-related issues

In June of 2006, software errors in medical devices made up 21% of recalls

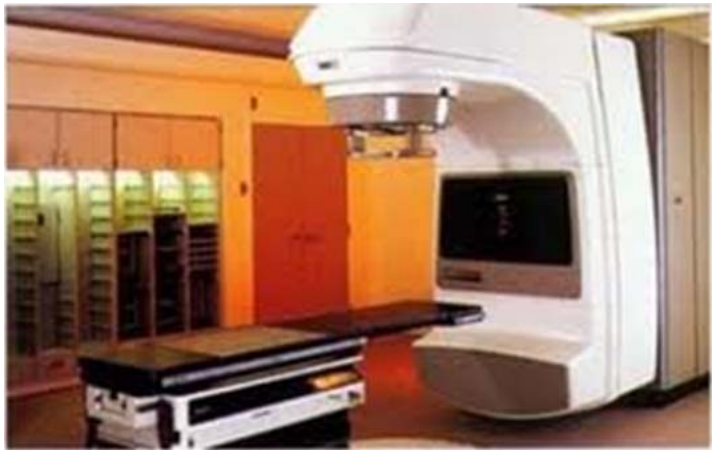


Therac 25

1985 - 1987

The Therac 25 was a radiation therapy device

- It malfunctioned and delivered lethal radiation doses at several medical facilities
- At least 5 people died and many were seriously injured
- The Therac 25 was to be an improved replacement product for the Therac 20
- The Therac 20 had hardware safety interlocks, the Therac 25 used software control which was believed to be more reliable



Garfinkel, Simson (2005) *History's Worst Software Bugs*

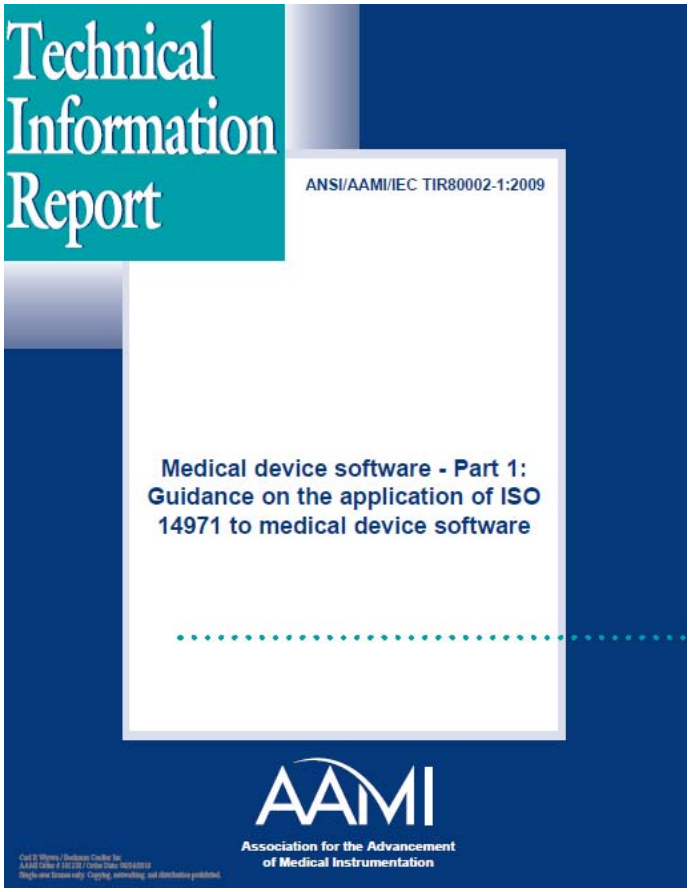
National Cancer Institute

Panama City - 2000

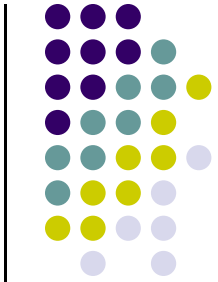
- Radiation therapy planning software miscalculates the proper dosage of radiation
- At least 8 patients died, another 20 received overdoses likely to cause significant health problems

Garfinkel, Simson (2005) *History's Worst Software Bugs*

ANSI/AAMI/ISO 14971:2010
ANSI/AAMI/IEC TIR 80002-1:2009



Human Factors – Use Errors



Contains Nonbinding Recommendations
Draft - Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

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Applying Human Factors and Usability Engineering to Optimize Medical Device Design

DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.
Document issued on: June 22, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Ron Kaye at ron.kaye@fda.hhs.gov or (301) 796-6289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-1456.

When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

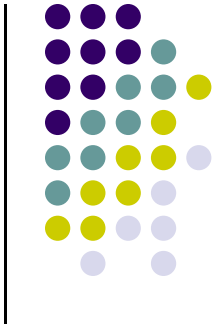
Risk (Safety) Management

TSP

To systematically identify and, when necessary, Reduce these risks, the risk management process is integrated into the design process.

In this way, Unacceptable risks can be identified and managed earlier in the design process when changes are easier to make and less costly.

Risk Management
Integrated Into The Design Process



Planning	SWPLAN	0	None
Requirements	SWREQ	1	Requirements
Requirements-Review	SWREQR	2	RequirementsReview
Requirements-Inspection 1 (Owner)	SWREQINSP	3	RequirementsInspection
Requirements-Inspection 2	SWREQINSP	4	RequirementsInspection
Requirements-Inspection 3	SWREQINSP	5	RequirementsInspection
Requirements-Inspection 4 (ST)	SWREQINSP	7	RequirementsInspection
Requirements-FMEA 1	SWREQINSP	8	RequirementsInspection
Requirements-FMEA 2	SWREQINSP	9	RequirementsInspection
Detailed-Design	SWDLD	10	Design
Detailed-Design-Review	SWDLDR	11	DesignReview
Detailed-Design-Inspection 1 (Owner)	SWDLDINSP	12	DesignInspection
Detailed-Design-Inspection 2	SWDLDINSP	13	DesignInspection
Detailed-Design-Inspection 3	SWDLDINSP	14	DesignInspection
Detailed-Design-FMEA 1	SWDLDINSP	15	DesignInspection
Detailed-Design-FMEA 2	SWDLDINSP	16	DesignInspection
Code	SWCODE	17	Code
Code-Review	SWCR	18	CodeReview
Code-Inspection 1 (Owner)	SWCODEINSP	19	CodeInspection
Code-Inspection 2	SWCODEINSP	20	CodeInspection
Code-Inspection 3	SWCODEINSP	21	CodeInspection
Code-FMEA 1	SWCODEINSP	22	CodeInspection
Code-FMEA 2	SWCODEINSP	23	CodeInspection
Unit-Test	SWUT	24	Test
Build and Integration-Test	SWIT	25	Test
Post-Mortem	SWPM	26	None

Requirements	SWREQ	1	Requirements
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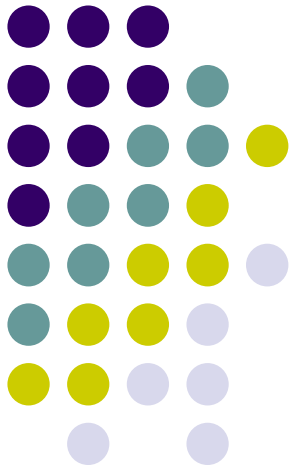
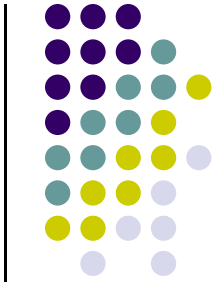
TSP

The Beckman Coulter Story



Beckman Coulter



2008 - TSP/PSP introduced to Beckman Coulter, 2 pilot projects selected

Today

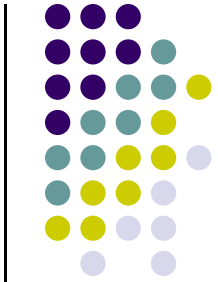
- Medical Device Projects – 7
- IT Projects - 1
- Sites - Brea, Chaska, Miami, Indianapolis, Munich
- Coaches – 6

Every business is a software business, and every business can profit from improved software processes

LEADERSHIP, TEAMWORK, AND TRUST

Building a Competitive Software Capability

WATTS S. HUMPHREY & JAMES W. OVER



Golfer's Advice

Advice From Watts Humphrey and Jim Over

“why don’t you try two TSP pilot projects?”

Acknowledgements

Watts Humphrey – SEI

Austin Montgomery - SEI

Jim Over – SEI

Alan Willett – SEI

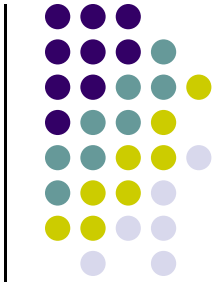
Gene Miluk, Dan Burton, Bill Nichols, Tim Chick, Bill Reier, Kim Campbell – SEI

Noopur Davis – Davis Systems

Our Corporate Sponsors – Scott Atkin, Clair O'Donovan

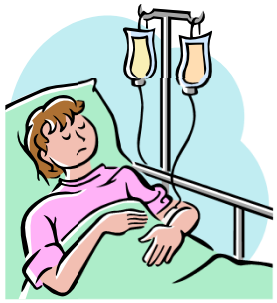
My Partner Implementation Champion – Rick Marshall

Our Coaches – Larry Whitford, John Hetzler, Brian Rogers, Doug Warren, Lourdes Villanueva



Questions?

1978 - 2008



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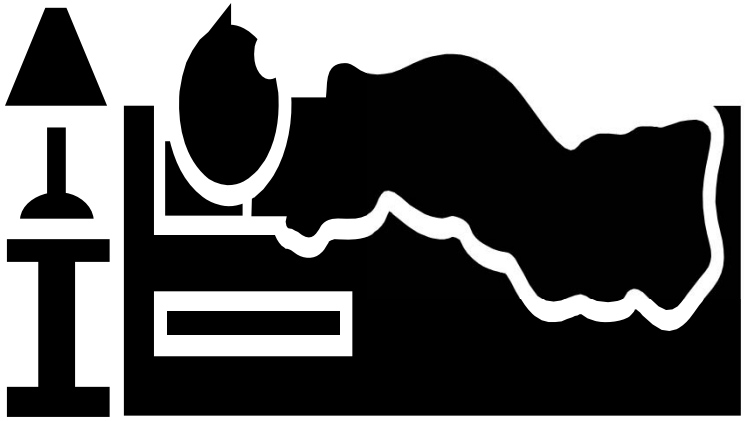
More Rigorous Process For Software Than Hardware



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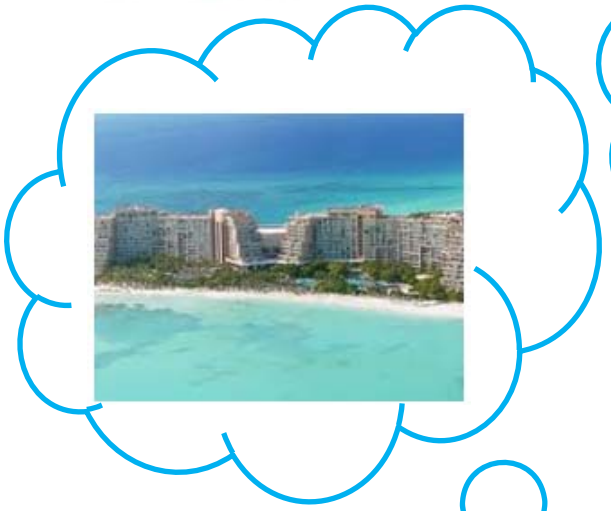

Thanks!!!

Carl Wyrwa
Director – Quality

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