

Introduction

The Capability Maturity Model Integration[®] (CMMI[®]) has been successfully applied for process improvement in various product development environments for almost 10 years, with its predecessor, the Software Capability Maturity Model (CMM-SW) used successfully in the 1990's. The Software Engineering Institute has provided reports on the successful use of the CMMI in aerospace, defense, government, financial, and insurance industry sectors. Little is known of adoption in medical device engineering.

This paper summarizes the comparison performed between the CMMI and the regulations and standards that drive software intensive medical device product development. The primary perspective is for medical device software engineering, where the most significant opportunity lies. This paper shows what is missed when medical device engineering teams chase ISO 13485 and IEC 62304 compliance without using CMMI to effectively manage processes.

The CMMI to IEC 62304 Mapping is provided at the end of this paper.

Definitions

First, a few definitions to set the context:

CMMI: Capability Maturity Model Integration

CMMI is a general reference model for process improvement in product development consisting of project management, engineering, support, and process management process requirements. Although applied across domains, the CMMI has most successfully been applied in software engineering.

IEC: International Electrotechnical Committee

IEC is a worldwide organization for standardization comprising national electrotechnical committees. IEC 62304 was prepared by a Joint Working Group of:

- Subcommittee (SC) 62A Common aspects of electrical equipment used in medical practice
- IEC Technical Committee (TC) 62, Electrical equipment in medical practice,
- ISO Technical Committee (TC) 210, Quality management and corresponding general aspects for medical devices
- Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and system engineering.

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

[®] CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

IEC 62304: Medical Device Software - Software Life Cycle Processes

IEC 62304 defines the life cycle requirements for medical device software. The set of processes, activities and tasks establish a common framework for medical device software life cycle processes. Since it clarifies expectations for medical device software, this global consensus standard has become widely adopted since its publication in 2006. It has been approved by the US FDA as a reference standard and will be required for CE Mark in the European Union by April 2010.

ISO: International Standards Organization

ISO is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard.

ISO 13485 Medical devices - Quality Management Systems - Requirements for Regulatory Purposes

Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

ISO 14971 Medical devices – Application of Risk Management to Medical Devices

Specifies a process to identify hazards associated with medical devices, estimate and evaluate the associated risks, control these risks, and monitor the effectiveness of the controls.

Approach

The approach taken to perform the mapping was to align the CMMI practices with requirements of IEC 62304, then, fill in with the requirements of ISO 13485 where possible. The mapping from ISO 13485 to CMMI is not provided since that could be indirectly accomplished from the existing ISO 9001 “Quality management systems – Requirements” to CMMI mapping and the comparison to ISO 9001 provided within ISO 13485. The FDA 21 CFR Part 820, Quality System Regulation, is not mapped since ISO 13485 covers most of the relevant sections and compliance to ISO 13485 is assumed. The mapping therefore is relevant to global medical device companies.

Observations from the Mapping

This section highlights the important similarities and differences between the CMMI, IEC 62304 and ISO 13485.

Project Management

PjM 1. Estimation

No estimation in IEC 62304.

PjM 2. Project Planning

No planning for budget, schedule, needed training, or stakeholder involvement in IEC 62304 or ISO 13485. There is no focus on reviewing plans with stakeholders, resolving resource levels, nor obtaining commitment before kick-off.

PjM 3. Project Monitoring and Control

No PMC in IEC 62304. 3485 incorporates systematic reviews of design and development, but no focus on commitments, planning parameters, identified project risks, etc. No resolving project issues (SG2).

PjM 4. Supplier Agreement Management

No SAM in IEC 62304. ISO 13485 lightly mentions selection of suppliers and evaluation of purchased product.

PjM 5. Integrated Project Management

The only alignment for IEC 62304 is in planning for standards, methods, and tools. ISO 13485 does require identification of processes specific to the product (not project), quality system improvement, and communication with customers, but falls well short of the tailoring, integrated planning, re-use, and collaboration with ALL stakeholders. Clearly, ISO 13485 is more focused on product than the projects that maintain products. The third goal in CMMI Integrated Project Management has requirements supporting IPPD (Integrated Product and Process Development) is not manifested in ISO 13485 or IEC 62304.

PjM 6. Risk Management

IEC 62304 does not address “project” risk management. ISO 13485 addresses risk management of nonconformance, but is weak in support of fundamental project risk management. Risk management in medical device engineering is all about product safety and NOT about risks to schedule, commitments, budget, and overall project objectives.

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

It is very important to note that the CMMI Risk Management process area addresses “project” risks and not safety risks. A good discussion on this topic occurred on the Yahoo CMMI Process Improvement Discussion Group (http://tech.groups.yahoo.com/group/cmmi_process_improvement/) early in 2009. The CMMI, including model and appraisal methods, does not require the application of the Risk Management process area to safety. The CMMI is clearly focused on project risk management. Notwithstanding, proper use of the model (for process improvement as a primary objective) would suggest that an organization engineering regulated medical devices would apply the practices of the Risk Management process area to safety, and a few lead appraisers would require it.

Although IEC 62304 does align very well with the CMMI Risk Management practices with respect to safety, there are a few omissions that are left up to the requirements of ISO 14971 Medical Devices – Application of Risk Management to Medical Devices.

PjM 7. Quantitative Project Management

In section 7.1.a, ISO 13485 provides the requirement to “Determine quality objectives and requirements for the product”. This is the only mention of setting and managing objectives and again addresses only product and not project.

CMMI elaborates significantly here by requiring the use of Quantitative Project Management practices to set and manage quantitative project objectives based on an understanding of process performance achieved through the Organizational Process Performance practices.

Engineering

ENG 1. Requirements Management

Good alignment in, but IEC 62304 is missing SP 1.5 where inconsistencies between project work and requirements are identified. This is a common problem and can happen when requirements are changing or project management process is not effective.

ENG 2. Requirements Development

Customer requirements are addressed in ISO 13485, product and product component requirements are addressed in IEC 62304. Although IEC 62304 is strong in requirements analysis, a few important omissions in IEC 62304 are:

- i. Establish operational concepts
- ii. Establish a definition of required functionality

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

- iii. Achieve balance
- iv. Validate. Again, IEC 62304 does not address validation.

ENG 3. Software Design

IEC 62304 is well aligned with CMMI in requirements for architecture, detailed designs, and interface designs. The following very important performance related requirements are missing:

- i. Develop and select alternative technical solutions
- ii. Establishment of a technical data package
- iii. Perform make/buy/reuse analysis
- iv. Develop product support documentation

The CMMI contains requirements for a formal decision analysis process that could help medical device designers to gather facts and data, analyze alternatives, make decisions, and record this decision data. Too often, engineers are quick to select a technical solution without weighing other alternatives. Without performing the make/buy/reuse analysis, the opportunity is lost to save money, shorten schedule, and reduce cycle time.

Medical device standards are not specific about certain types of engineering specifications that are necessary to support products. In the Technical Solution process area, the technical data package and product support documentation are described. Producing the necessary documentation is essential in efficiently maintain products and meeting customer expectations.

ENG 4. Product Integration

IEC 62304 is strong here. One weakness is the lack of planning for integration. It is very important to identify the integration sequence, environment, and success criteria early.

ENG 5. Verification

The word “verify” is used frequently in IEC 62304. The standard leaves it up to the manufacturer how to verify. The CMMI specifically calls out peer reviews and requires them. Naturally, a manufacturer would comply with IEC 62304 by selecting to perform peer reviews on certain work products. One very important performance related omission in IEC 62304 is the analysis of peer review data. The intent of this practice in the CMMI SP2.3 is to specifically look at the effort, pace, number of bugs found, etc, and make improvements based on what this data says.

ENG 6. Validation

IEC 62304 section 1.2 says “This standard does not cover validation”. To some, this may hit like a train. But the FDA’s misuse of the term “validation” over the years has led to significant confusion. The GPSV (General Principles of Software Validation, 2002, FDA) is a good example of how the term “software validation” includes in scope planning, requirements definition, architecture, verification, testing, traceability, configuration management, and many other aspects of good software engineering.

The CMMI’s definition of validation: “Confirmation that the product, as provided (or as it will be provided), will fulfill its intended use”. This is similar to IEEE and Wikipedia. Validation is evaluating a product or work product against intended uses in the intended environment.

Although ISO 13485 does mention the requirement to perform validation, it does not mention the evaluation of validation results, a critical activity and potentially an accidental omission in the standard.

It’s important to note that in section 5.1.3.b of IEC 62304, the software development plan must include procedures for coordinating the software development and the design and development validation.

Support

SUP 1. Quality Assurance

Good alignment of IEC 62304. One weakness is the lack of focus on establishing QA records as in CMMI PPQA SP 2.2.

SUP 2. Measurement and Analysis

No MA in IEC 62304. ISO 13485 is weak in measurement. It does not provide the guidance necessary to implement and maintain an effective measurement process.

SUP 3. Configuration Management

There is impressive alignment of IEC 62304 with CMMI. One minor weakness is the lack of configuration audits as in CMMI CM SP 3.2. Note that ISO 13485 is not as strong in CM..... a hint that software requires more CM discipline.

SUP 4. Decision Analysis

IEC 62304 and ISO 13485 do not provide any guidance for formal decision analysis. Do we make important decisions in engineering medical devices? Employing a formal decision analysis process can have a significant positive impact on costs, schedule, and quality (including safety).

SUP 5. Causal Analysis and Resolution

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Although scattered somewhat, ISO 13485 contains impressive alignment with CMMI Causal Analysis and Resolution in requiring the statistical analysis of data to determine potential causes of nonconformities. Without the support of the OPP (Organizational Process Performance), QPM (Quantitative Project Management), and OID (Organizational Innovation and Deployment), the effectiveness of this analysis is questionable.

Process Management

There are no process management requirements in IEC 62304. It is left to the quality management system, ie ISO 13485, which does contain a few of the Organizational Process Focus, Organizational Process Definition, and Organizational Training process requirements.

PcM 1. Determine Process Needs

ISO 13485 does require the identification of needed processes but does not address appraisal of the organization's processes and the selection and prioritization necessary to achieve progress.

PcM 2. Process Action Planning

ISO 13485 has a few requirements for process sequence, criteria, and methods, but does not address the need for planning process improvements.

PcM 3. Process Deployment

ISO 13485 does not discuss deployment of processes and is missing the concept of "process assets".

PcM 4. Process Assets

This concept is missing in ISO 13485. The CMMI separates standard processes from process assets. Process assets are artifacts that relate to describing, implementing, and improving processes like policies, defined processes, checklists, lessons-learned documents, templates, standards, procedures, plans, and training materials.

PcM 5. Standard Processes with Tailoring Methods and Criteria

There is a hint of tailoring in ISO 13485 section 7.1.b, but in general, this standard does not provide guidance on defining the organizations set of standard processes, sub-processes, and tailoring guidelines. The tailoring guidelines adapt the standard process to meet objectives, constraints, and environment of the project.

PcM 6. Measurement Repository

This concept is not addressed in ISO 13485. Measurement is addressed, but the structure, organization, and archival of measurements to keep them readily available over time is not defined. In CMMI, the measurement repository is a critical resource providing a stable and reliable source of information to drive fact based decisions. It is the measurement repository that gathers the data necessary to move to higher process maturity levels (4 and 5).

PcM 7. Training

ISO 13485 does address the delivery, records management, and assessment of the training effectiveness, but does not specifically address training infrastructure (capability) and division of responsibilities for training.

PcM 8. IPPD

It is pleasing to see that ISO 13485 does have a CMMI IPPD (Integrated Product and Process Development, *an optional set of CMMI practices enabling timely collaboration of relevant stakeholders*) requirement to determine responsibilities and authorities for design and development and manage the interfaces between different groups in section 7.3.1.c.

PcM 9. Process Performance

ISO 13485 contains some light requirements in sections 5.1.c and 5.4.1 to ensure that quality objectives are established, but comes no where close to the rigor of the CMMI Organizational Process Performance process area that requires the use of historical data in the measurement repository to build performance baselines and models to help the organization be more predictable and successful in meeting quality and performance objectives.

Also not addressed in medical device standards is the CMMI Organizational Innovation and Deployment process area which enables the selection and deployment of improvements that can enhance an organization's ability to meet its quality and process performance objectives based on a quantitative understanding of the organization's current quality and process performance.

Generic Practices

The CMMI Generic Practices are vital to institutionalizing the processes. At maturity level two, there are 10 generic practices that set requirements for institutionalizing a managed process. These 10 generic practices apply to all process areas in institutionalizing the managed process (maturity level 2).

Note that IEC 62304 contains very little alignment with these generic practices. Unless specified, below, there are no requirements in IEC 62304 for these CMMI elements.

GP 2.1. Policy

ISO 13485 is well aligned.

GP 2.2. Plan The Process

Both IEC 62304 and ISO 13485 contain planning for only a few of the processes, but do not cover others as explicitly required in CMMI.

GP 2.3. Provide Resources

ISO 13485 requires resources necessary to support the operation and monitoring of the processes. This is intended to apply in general to the quality system.

GP 2.4. Assign Responsibility

ISO 13485 requires the determination of responsibilities in general.

GP 2.5. Train The People

The section on training in ISO 13485 is weak. Although it does address identification of training needs, training, and records, it does not address the importance of establishing a training capability with supporting infrastructure as is emphasized in the CMMI.

GP 2.6. Manage Configurations

IEC 62304 contains requirements for configuration management, but its application of these requirements specifically to process areas is sparse. ISO 13485 contains requirements to maintain configurations but does not apply specifically to each process.

GP 2.7. Identify And Involve Relevant Stakeholders

ISO 13485 requires adequate representation in reviews and ISO 14971 requires involvement of relevant parties in the risk management process, but these standards do not require the identification and planning for involvement of all relevant stakeholders in other critical activities as identified in the CMMI.

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

GP 2.8. Monitor And Control The Process

ISO 13485 requires actions necessary monitor, measure, and analyze processes to achieve planned results and maintain the effectiveness of these processes. This requirement is well aligned with the CMMI but does not specifically require evidence for each process area.

GP 2.9. Objectively Evaluate Adherence

ISO 13485 requires internal audits to maintain the quality system compliance.

GP 2.10. Review Status With Higher Level Management

ISO 13485 section 5.5.2 nails this requirement pretty good. But, again, evidence is not required specifically for each process as in the CMMI.

GP 3.x – 5.x

The only alignment of ISO 13485 in CMMI Generic Goal 3 is in section 8.5.1 “Identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system” which aligns with GP 3.2 “Collect Improvement Information”.

Medical device standards do not address any of the Generic Goals 4 and 5. ISO 13485 section 8.1 requires the use of statistical techniques as an applicable method for improving processes. This was not included in the mapping tables since it does not meet the intent of CMMI quantitative management and high maturity process management.

Reverse Mapping

Table 2 maps the IEC 62304 requirements to CMMI. Note that the CMMI performs well in providing a framework in which the various medical device software lifecycle requirements can fit. The mapping elements are mostly STRONG or MODERATE with CMMI lacking specific safety related requirements that have been derived over time though regulatory monitoring of software intensive medical devices.

Also note from Table 2 that IEC 62304 focuses on problem reports where the counterpart in CMMI is the change request (more general, but includes problem reports).

Conclusions

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

The CMMI-DEV significantly compliments medical device standards by focusing on process performance and closed loop improvement. There are placeholders for regulatory requirements such as design control and safety risk management.

Like ISO and other standards and industry guidance, the regulations do not provide adequate guidance on process institutionalization. CMMI emphasizes the importance of institutionalization through the application of the generic practices that must be accomplished for each process area. This observation alone suggests a profound opportunity for organizational process performance.

Regulations do not require project management practices. This is a massive gap in enabling performance, and potentially, a shortcoming in enabling safety management. It is when projects are not adequately managed that firefighting begins, overtime starts, burnout begins, shortcuts are taken, and safety mitigation falls apart. The CMMI requires project management discipline at the start with maturity level 2. CMMI project management practices become more standardized at maturity level 3, and more sophisticated at maturity level 4.

Regulations and standards do not require process focus, quantitative methods, or innovation and deployment. No guidance on the mechanics of improvement. ISO 13485 provides some essence of statistical measurement, but falls well short of the sophistication of the CMMI quantitative management and optimization process areas.

Although the CMMI Risk Management process area most often addresses project risk, it is well positioned to include safety risk management practices which follow very similar methodology.

Although alignment of the regulations with corporate operating procedures is assumed, project tailoring is not discussed in the regulations or standards. IEC 62304 introduces three safety classifications that vary the rigor of development practices. But the focus is on safety only, and fall well short of CMMI's Organizational Process Definition and Integrated Project Management.

The conclusion from this research is that medical device R&D organizations are a good fit with the CMMI model. The model provides a comprehensive framework on which medical device realization processes can thrive. The opportunity for performance improvement is profound. Medical device manufacturers are encouraged to see training in the CMMI-DEV and gain experience improving processes performance.

David Walker has worked with SEI models for over 15 years, teaches CMMI classes, coaches software development teams across all industries, and has led software teams to CMMI Maturity Level 2 and 3. He has 25 years of experience in software engineering, software quality assurance, and continuous improvement. David has a Master Of Science Degree in Computer Science from Northwestern University, holds the ASQ CSQE, a 20 year ASQ member, and immediate past Chair of the Software Division. Since 2005, he has served on the AAMI Software Standards Committee and participated in the US review of IEC 62304 and IEC 80002.

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

This white paper has been created by David W. Walker using the Technical Report "CMMI® for Development, Version 1.2", CMU/SEI-2006-TR-008, ESC-TR-2006-008 (c) 2006 Carnegie Mellon University, with special permission from its Software Engineering Institute.

ANY MATERIAL OF CARNEGIE MELLON UNIVERSITY AND/OR ITS SOFTWARE ENGINEERING INSTITUTE CONTAINED HEREIN IS FURNISHED ON AN "AS-IS" BASIS. CARNEGIE MELLON UNIVERSITY MAKES NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, AS TO ANY MATTER INCLUDING, BUT NOT LIMITED TO, WARRANTY OF FITNESS FOR PURPOSE OR MERCHANTABILITY, EXCLUSIVITY, OR RESULTS OBTAINED FROM USE OF THE MATERIAL. CARNEGIE MELLON UNIVERSITY DOES NOT MAKE ANY WARRANTY OF ANY KIND WITH RESPECT TO FREEDOM FROM PATENT, TRADEMARK, OR COPYRIGHT INFRINGEMENT.

This white paper is not endorsed by Carnegie Mellon University or its Software Engineering Institute.

Capability Maturity Model and CMMI are registered trademarks of Carnegie Mellon University.

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Copyright © 2009 David Walker SPCS, LLC

Summary

Table 1 presents the mapping from CMMI-DEV to IEC 62304. In this table, since compliance to ISO 13485 is assumed for medical device manufacturers that market globally, mapping from CMMI to ISO 13485 is shown where the IEC 62304 is absent or weak.

Table 2 presents the mapping from IEC 62304 to CMMI-DEV. It is important to review both mappings to understand the scope, strengths, and weaknesses of both standards.

Alignment Strength

Primary Model: Model component listed on the left side of the table.

Secondary Model: Model component listed on the right side of the table.

STRONG: Secondary model fully satisfies the requirements of the primary model.

MODERATE: The secondary model minimally addresses the requirement of the primary model.

WEAK: Topic is minimally covered by the secondary model, but not required.

General Notes

- **CMMI has 356 practices at Maturity Level 3. IEC 62304 has 95 class C requirements, 89 class B requirements, and 43 class A requirements.**
- **Alignment is done for IEC 62304 Class C Requirements (or all requirements).**
- **IEC 62304 Table C.1 shows alignment of 13485 with IEC 62304, Table C.2 shows alignment of 14971 with 62304, and see section B.4.1 regarding the potential use of CMMI based quality system.**
- **IEC 62304 does NOT address validation. It is left to the system level and quality management system, ie ISO 13485.**
- **ISO 13485 mappings are marked in **Green**.**

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Copyright © 2009 David Walker SPCS, LLC

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
	Level 2				
	Requirements Management				
SG 1	Manage Requirements				
SP 1.1	Obtain an Understanding of Requirements	5.2.3	Software requirements content	STRONG	
SP 1.2	Obtain Commitment to Requirements				
SP 1.3	Manage Requirements Changes	8.2.1	Approve CHANGE SPECIFICATIONS	STRONG	
SP 1.4	Maintain Bidirectional Traceability of Requirements	5.2.3	Include RISK CONTROL measures in software requirements	MODERATE	
		5.2.5	Update SYSTEM requirements	MODERATE	
		5.7.1	Establish tests for software requirements	MODERATE	
		7.3.3	Document TRACEABILITY	STRONG	But not bidirectional
SP 1.5	Identify Inconsistencies Between Project Work and Requirements				
	Project Planning				
SG1	Establish Estimates				
SP 1.1	Estimate the Scope of the Project				
SP 1.2	Establish Estimates of Work Product and Task Attributes				
SP 1.3	Define Project Lifecycle				
SP 1.4	Determine Estimates of Effort and Cost				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SG2	Develop a Project Plan				
SP 2.1	Establish the Budget and Schedule				
SP 2.2	Identify Project Risks				
SP 2.3	Plan for Data Management	5.1.8	Software configuration management planning	STRONG	
SP 2.4	Plan for Project Resources	5.1.4	Software development standards methods and tools planning	MODERATE	
SP 2.5	Plan for Needed Knowledge and Skills				
SP 2.6	Plan Stakeholder Involvement				
SP 2.7	Establish the Project Plan	5.1.1	Software development plan	MODERATE	
		6.1	Establish software maintenance plan	MODERATE	
SG 3	Obtain Commitment to the Plan				
SP 3.1	Review Plans That Affect the Project				
SP 3.2	Reconcile Work and Resource Levels	7.2.2.c	The organization has the ability to meet the defined requirements.	MODERATE	Ability to meet requirements. Does not imply the ability to reconcile.
SP 3.3	Obtain Plan Commitment				
	Project Monitoring & Control				
SG 1	Monitor Project Against Plan				
SP 1.1	Monitor Project Planning Parameters				
SP 1.2	Monitor Commitments				
SP 1.3	Monitor Project Risks				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.4	Monitor Data Management				
SP 1.5	Monitor Stakeholder Involvement				
SP 1.6	Conduct Progress Reviews	7.3.4	At suitable stages, systematic reviews of design and development shall be performed	MODERATE	Fits better in SP 1.7
SP 1.7	Conduct Milestone Reviews	5.8.6	Ensure activities and tasks are complete	WEAK	Weak. Only at release.
		7.3.4	At suitable stages, systematic reviews of design and development shall be performed	STRONG	
SG 2	Manage Corrective Action to Closure				No Project CA, only product.
SP 2.1	Analyze Issues				
SP 2.2	Take Corrective Action				
SP 2.3	Manage Corrective Action				
	Supplier Agreement Management				
SG 1	Establish Supplier Agreements				No SAM
SP 1.1	Determine Acquisition Type				
SP 1.2	Select Suppliers	7.4.1	Purchasing Process	MODERATE	
SP 1.3	Establish Supplier Agreements				
SG 2	Satisfy Supplier Agreements				
SP 2.1	Execute the Supplier Agreement				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 2.2	Monitor Selected Supplier Processes				
SP 2.3	Evaluate Selected Supplier Work Products	7.4.3	Verification of Purchased Product		
SP 2.4	Accept the Acquired Product				
SP 2.5	Transition Products				
	Process & Product Quality Assurance				
SG 1	Objectively Evaluate Processes and Work Products				
SP 1.1	Objectively Evaluate Processes	8.2.2	The organization shall conduct internal audits at planned intervals	STRONG	Only addresses processes
SP 1.2	Objectively Evaluate Work Products and Services				
SG 2	Provide Objective Insight				
SP 2.1	Communicate and Ensure Resolution of Noncompliance Issues	8.2.2.b	The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes	MODERATE	Missing "Communicate".
SP 2.2	Establish Records				
	Measurement & Analysis				
SG 1	Align Measurement and Analysis Activities	8.4	Analysis of data	WEAK	CMMI provides much more guidance and scope.

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.1	Establish Measurement Objectives				
SP 1.2	Specify Measures				
SP 1.3	Specify Data Collection and Storage Procedures				
SP 1.4	Specify Analysis Procedures				
SG 2	Provide Measurement Results	8.2.3	Monitoring and measurement of processes	MODERATE	Does not provide the guidance and scope that CMMI does.
		8.2.4.1	The organization shall monitor and measure the characteristics of the product		
SP 2.1	Collect Measurement Data				
SP 2.2	Analyze Measurement Data	9.6	Analyze problems for trends	WEAK	There may not be any data, just the reports.
SP 2.3	Store Data and Results				
SP 2.4	Communicate Results				
	Configuration Management				
SG 1	Establish Baselines				
SP 1.1	Identify Configuration Items	8.1.1	Establish means to identify CONFIGURATION ITEMS	STRONG	
		8.1.2	Identify SOUP		
		9.8	Test documentation contents		
SP 1.2	Establish a Configuration Management System	8.2.4	Provide means for TRACEABILITY of change	STRONG	

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.3	Create or Release Baselines	5.1.11	Software CONFIGURATION ITEM control before VERIFICATION		
		5.8.4	Document released VERSIONS		
		5.8.5	Document how released software was created		
		5.8.7	Archive software		
		6.3.2	Re-release modified SOFTWARE SYSTEM		
		8.1.3	Identify SYSTEM configuration documentation		
		4.2.3.c	Ensure that changes and the current revision status of documents are identified	MODERATE	
SG 2	Track and Control Changes	7.3.7	Control of design and development changes	MODERATE	
SP 2.1	Track Change Requests	5.6.8	Use software problem resolution PROCESS	STRONG	
		5.7.2	Use software problem resolution PROCESS		
		5.8.2	Document known residual ANOMALIES		

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		6.2.1.1	Monitor feedback		
		6.2.2	Use software problem resolution PROCESS		
		8.2.2	Implement changes		
		8.2.3	Verify changes		
		8.2.4	Provide means for TRACEABILITY of change		
		4.2.3.a	Review and approve documents for adequacy prior to issue	MODERATE	
SP 2.2	Control Configuration Items	6.2.3	Analyze CHANGE REQUESTS	STRONG	
		6.2.4	CHANGE REQUEST approval		
		7.4.1	Analyze changes to MEDICAL DEVICE SOFTWARE with respect to SAFETY		
		7.4.2	Analyze impact of software changes on existing RISK CONTROL measures		
		7.4.3	Perform RISK MANAGEMENT ACTIVITIES based on analyses		

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Copyright © 2009 David Walker SPCS, LLC

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		8.2.1	Approve CHANGE REQUESTS		
		9.4	Use change control process		
SG 3	Establish Integrity				
SP 3.1	Establish Configuration Management Records	5.8.4	Document released VERSIONS	STRONG	
		5.8.5	Document how released software was created		
		5.8.7	Archive software		
		8.3	Configuration status accounting		
		9.5	Maintain records		
		4.2.3.e	Ensure that documents remain legible and readily identifiable	MODERATE	
SP 3.2	Perform Configuration Audits	5.8.8	Assure repeatability of software release	Moderate	Only part of configuration audit
	Level 3				
	Requirements Development				
SG 1	Develop Customer Requirements				
SP 1.1	Elicit Needs				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.2	Develop the Customer Requirements	7.2.1.a	Determine requirements specified by the customer, including the requirements for delivery and post-delivery activities	STRONG	
		7.2.1.c	Determine statutory and regulatory requirements related to the product		
		7.2.1.d	Determine any additional requirements determined by the organization		
SG 2	Develop Product Requirements				
SP 2.1	Establish Product and Product Component Requirements	5.3.4	Specify SYSTEM hardware and software required by SOUP item	WEAK	CMMI clarifies the decomposition of customer requirements, product requirements, and product component requirements.
		5.2.1	Define and document software requirements from SYSTEM requirements	STRONG	
		7.2.1.b	Determine requirements not stated by the customer but necessary for specified or intended use, where known	MODERATE	
		7.2.2.a	Ensure that product requirements are defined and documented		
		7.3.2	Design and development inputs		
SP 2.2	Allocate Product Component Requirements	5.3.3	Specify functional and performance requirements of SOUP item	STRONG	

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		5.2.1	Define and document software requirements from SYSTEM requirements		
		5.4.1	Refine SOFTWARE ARCHITECTURE into SOFTWARE UNITS		
SP 2.3	Identify Interface Requirements	5.3.2	Develop an ARCHITECTURE for the interfaces of SOFTWARE ITEMS	STRONG	
		5.3.5	Identify segregation necessary for RISK CONTROL	MODERATE	Addresses only the safety aspect of the intent of this practice
SG 3	Analyze and Validate Requirements				
SP 3.1	Establish Operational Concepts and Scenarios				
SP 3.2	Establish a Definition of Required Functionality				
SP 3.3	Analyze Requirements	5.2.6	Verify software requirements	STRONG	Good criteria included
SP 3.4	Analyze Requirements to Achieve Balance				
SP 3.5	Validate Requirements				
	Technical Solution				
SG 1	Select Product Component Solutions				
SP 1.1	Develop Alternative Solutions and Selection Criteria				
SP 1.2	Select Product Component Solutions				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SG 2	Develop the Design	7.3.3	Design and development outputs	MODERATE	CMMI provides much more guidance.
SP 2.1	Design the Product or Product Component	5.4.2	Develop detailed design for each SOFTWARE UNIT	STRONG	
		5.3.1	Transform software requirements into an ARCHITECTURE		
SP 2.2	Establish a Technical Data Package				
SP 2.3	Design Interfaces Using Criteria	5.4.3	Develop detailed design for interfaces	MODERATE	Does not include criteria
		5.3.2	Develop an ARCHITECTURE for the interfaces of SOFTWARE ITEMS		
SP 2.4	Perform Make, Buy, or Reuse Analyses				
SG 3	Implement the Product Design				
SP 3.1	Implement the Design	5.5.1	Implement each SOFTWARE UNIT	STRONG	
SP 3.2	Develop Product Support Documentation	6.1	Establish software maintenance plan	WEAK	
	Product Integration				
SG 1	Prepare for Product Integration	5.1.5	Software integration and integration testing planning	WEAK	Weak, not specific.

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.1	Determine Integration Sequence				
SP 1.2	Establish the Product Integration Environment				
SP 1.3	Establish Product Integration Procedures and Criteria				
SG 2	Ensure Interface Compatibility				
SP 2.1	Review Interface Descriptions for Completeness	5.3.6	Verify software ARCHITECTURE	STRONG	
SP 2.2	Manage Interfaces				
SG 3	Assemble Product Components and Deliver the Product				
SP 3.1	Confirm Readiness of Product Components for Integration	5.3.6	Verify software ARCHITECTURE	MODERATE	Readiness implies defined criteria
		5.4.4	Verify detailed design		
		5.5.3	SOFTWARE UNIT acceptance criteria		
SP 3.2	Assemble Product Components	5.6.1	Integrate SOFTWARE UNITS	STRONG	
SP 3.3	Evaluate Assembled Product Components	5.6.2	Verify software integration	STRONG	
		5.6.3	Test integrated software		

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		5.6.6	Conduct regression tests		
		5.6.7	Integration test record contents		
		5.7.3	Retest after changes		
		5.7.5	SOFTWARE SYSTEM test record contents		
		7.1.d	Determine records needed to provide evidence that the realization processes and resulting product meet requirements	MODERATE	
SP 3.4	Package and Deliver the Product or Product Component	5.8.4	Document released VERSIONS	MODERATE	Does not address actual delivery
	Verification				
SG 1	Prepare for Verification				
SP 1.1	Select Work Products for Verification	5.2.6	Verify software requirements		
		5.7.1	Establish tests for software requirements		
		5.3.6	Verify software ARCHITECTURE	STRONG	Although it does not address selection, the primary work products are listed.
		5.4.4	Verify detailed design		
		5.5.5	SOFTWARE UNIT VERIFICATION		

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		5.6.5	Verify integration test procedures		
		5.7.4	Verify SOFTWARE SYSTEM testing		
		7.3.1	Verify RISK CONTROL measures		
		8.2.3	Verify changes		
SP 1.2	Establish the Verification Environment	5.1.4	Software development standards	MODERATE	Close, but it lists specific things and seems to leave out test equipment and lab environment.
		5.6.7	Integration test record contents		
		5.7.5	SOFTWARE SYSTEM test record contents		
SP 1.3	Establish Verification Procedures and Criteria	5.1.6	Software VERIFICATION planning	STRONG	
		9.8	Test documentation contents		
		5.6.4	Integration testing content		
		5.5.2	Establish SOFTWARE UNIT VERIFICATION PROCESS		
		5.5.3	SOFTWARE UNIT acceptance criteria		
		5.5.4	Additional SOFTWARE UNIT acceptance criteria		
SG 2	Perform Peer Reviews	7.3.5	Design and development verification	WEAK	Very little guidance in 13485
SP 2.1	Prepare for Peer Reviews	5.1.6	Software VERIFICATION planning	MODERATE	Not specific to peer reviews

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 2.2	Conduct Peer Reviews	5.2.6	Verify software requirements		
		5.3.6	Verify software ARCHITECTURE		
		5.4.4	Verify detailed design		
		5.5.5	SOFTWARE UNIT VERIFICATION		
		5.6.5	Verify integration test procedures		
		5.7.4	Verify SOFTWARE SYSTEM testing		
		7.3.1	Verify RISK CONTROL measures		
		8.2.3	Verify changes		
SP 2.3	Analyze Peer Review Data	5.8.1	Ensure software VERIFICATION is complete	MODERATE	The CMMI practice is addressing the data regarding performance of peer reviews.
		5.8.2	Document known residual ANOMALIES		
		5.8.3	EVALUATE known residual ANOMALIES		
SG 3	Verify Selected Work Products				
SP 3.1	Perform Verification	5.7.3	Retest after changes	STRONG	
		5.6.6	Conduct regression tests		
		5.3.6	Verify software ARCHITECTURE		

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		5.4.4	Verify detailed design		
		5.5.5	SOFTWARE UNIT VERIFICATION		
		7.3.1	Verify RISK CONTROL measures		
		5.6.7	Integration test record contents		
		5.7.5	SOFTWARE SYSTEM test record contents		
		5.6.3	Test integrated software		
		9.7	Verify software problem resolution		
SP 3.2	Analyze Verification Results	5.8.1	Ensure software VERIFICATION is complete	STRONG	
		5.8.2	Document known residual ANOMALIES		
		5.8.3	EVALUATE known residual ANOMALIES		
		7.1.d	Determine records needed to provide evidence that the realization processes and resulting product meet requirements	MODERATE	Scope is more narrow.
	Validation				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SG 1	Prepare for Validation	5.1.3	Software development plan reference to SYSTEM design and development	WEAK	IEC 62304 does not address Validation, only requires a reference to validation performed at a system level, addressed at the ISO 13486 QMS Level.
SP 1.1	Select Products for Validation				
SP 1.2	Establish the Validation Environment				
SP 1.3	Establish Validation Procedures and Criteria				
SG 2	Validate Product or Product Components				
SP 2.1	Perform Validation	7.3.6	Design and development validation	STRONG	
SP 2.2	Analyze Validation Results				
	Organizational Process Focus				Not Addressed in 62304
SG 1	Determine Process Improvement Opportunities				
SP 1.1	Establish Organizational Process Needs	4.1.a	Identify the processes needed for the quality management system and their application throughout the organization	STRONG	
SP 1.2	Appraise the Organization's Processes				
SP 1.3	Identify the Organization's Process Improvements				
SG 2	Plan and Implement Process Improvements				
SP 2.1	Establish Process Action Plans				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 2.2	Implement Process Action Plans	4.1.b	Determine the sequence and interaction of these processes	MODERATE	Doesn't really address the planning and acting on the plan.
		4.1.c	Determine criteria and methods needed to ensure that both the operation and control of these processes are effective		
SG 3	Deploy Organizational Process Assets and Incorporate Lessons Learned				
SP 3.1	Deploy Organizational Process Assets				
SP 3.2	Deploy Standard Processes				
SP 3.3	Monitor Implementation	8.5.1	Ensure and maintain the continued suitability and effectiveness of the quality management	STRONG	
SP 3.4	Incorporate Process-Related Experiences into the Organizational Process Assets	8.5.1	Identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system	MODERATE	CMMI requires more than just process improvements. Lessons learned, examples of good and bad process artifacts, metrics, etc are expected to be collected.
	Organizational Process Definition				Not Addressed
SG 1	Establish Organizational Process Assets				
SP 1.1	Establish Standard Processes	4.2.1.c	Documented procedures required by this International Standard.	MODERATE	Standard processes can be outside of the 13485 scope.

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.2	Establish Lifecycle Model Descriptions	4.2.1.d	Documents needed by the organization to ensure the effective planning, operation, and control of its processes.	MODERATE	
SP 1.3	Establish Tailoring Criteria and Guidelines	7.1.b	Determine the need to establish processes, documents, and provide resources specific to the product	MODERATE	Project, not product.
SP 1.4	Establish the Organization's Measurement Repository				
SP 1.5	Establish the Organization's Process Asset Library				
SP 1.6	Establish Work Environment Standards	6.4	Work environment	STRONG	
	IPPD Addition				
SG 2	Enable IPPD Management				
SP 2.1	Establish Empowerment Mechanisms				
SP 2.2	Establish Rules and Guidelines for Integrated Teams				
SP 2.3	Balance Team and Home Organization Responsibilities	7.3.1.c	Determine the responsibilities and authorities for design and development & "...manage the interfaces between different groups..."	STRONG	
	Organizational Training				Not Addressed in 62304
SG 1	Establish an Organizational Training Capability				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.1	Establish the Strategic Training Needs	6.2.2.a	Determine the necessary competence for personnel performing work affecting product quality	MODERATE	More than product quality, CMMI addresses also process capability
SP 1.2	Determine Which Training Needs Are the Responsibility of the Organization				
SP 1.3	Establish an Organizational Training Tactical Plan				
SP 1.4	Establish Training Capability				
SG 2	Provide Necessary Training				
SP 2.1	Deliver Training	6.2.2.b	Provide training or take other actions to satisfy these needs	STRONG	
SP 2.2	Establish Training Records	6.2.2.e	Maintain appropriate records of education, training, skills, and experience	STRONG	
SP 2.3	Assess Training Effectiveness	6.2.2.c	Evaluate the effectiveness of the actions taken	STRONG	
	Decision Analysis & Resolution				Not Addressed
SG 1	Evaluate Alternatives				
SP 1.1	Establish Guidelines for Decision Analysis				
SP 1.2	Establish Evaluation Criteria				
SP 1.3	Identify Alternative Solutions				
SP 1.4	Select Evaluation Methods				
SP 1.5	Evaluate Alternatives				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

© CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.6	Select Solutions				
	Integrated Project Management				Not Addressed
SG 1	Use the Project's Defined Process				
SP 1.1	Establish the Project's Defined Process	7.1.b	Determine the need to establish processes, documents, and provide resources specific to the product	MODERATE	Product, not project as in CMMI, and defined process provides more guidance.
SP 1.2	Use Organizational Process Assets for Planning Project Activities	5.1.4	Software development standards, methods and tools planning	WEAK	SP 1.2 is much more
		7.1.b	Determine the need to establish processes, documents, and provide resources specific to the product	MODERATE	Product, not project as in CMMI
SP 1.3	Establish the Project's Work Environment	6.4	Work environment	MODERATE	Product, not project as in CMMI
SP 1.4	Integrate Plans				
SP 1.5	Manage the Project Using the Integrated Plans				
SP 1.6	Contribute to the Organizational Process Assets	8.5.1	Identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system	MODERATE	It fits, but only part of the picture.
SG 2	Coordinate and Collaborate with Relevant Stakeholders	7.2.3	Determine and implement effective arrangements for communicating with customers	WEAK	Weak.... Doesn't include all stakeholders
SP 2.1	Manage Stakeholder Involvement				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 2.2	Manage Dependencies				
SP 2.3	Resolve Coordination Issues				
	IPPD Addition				
SG 3	Apply IPPD Principles				
SP 3.1	Establish the Project's Shared Vision				
SP 3.2	Establish the Integrated Team Structure				
SP 3.3	Allocate Requirements to Integrated Teams				
SP 3.4	Establish Integrated Teams				
SP 3.5	Ensure Collaboration among Interfacing Teams				
	Risk Management				
SG 1	Prepare for Risk Management	8.5.3	Preventive action	MODERATE	
SP 1.1	Determine Risk Sources and Categories	7.1.2 7.1.3 7.1.4	Identify potential causes of contribution to a hazardous situation EVALUATE published SOUP ANOMALY lists Document potential causes	STRONG	
SP 1.2	Define Risk Parameters				Left to 14971
SP 1.3	Establish a Risk Management Strategy				Left to 14971

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SG 2	Identify and Analyze Risks	5.8.3 6.2.1.3 7.1.4 7.1.5 7.3.2 7.1.1	EVALUATE known residual ANOMALIES Evaluate PROBLEM REPORT'S affects on SAFETY Document potential causes Document sequences of events Document any new sequences of events Identify SOFTWARE ITEMS that could contribute to a hazardous situation	STRONG	See also ISO 14971.
SP 2.1	Identify Risks	7.2.2	RISK CONTROL measures implemented in software	STRONG	
SP 2.2	Evaluate, Categorize, and Prioritize Risks	8.5.3.b	Evaluating the need for action to prevent occurrence of nonconformities	WEAK	A very small piece of risk management.
SG 3	Mitigate Risks	5.2.3	Include RISK CONTROL measures in software requirements		
SP 3.1	Develop Risk Mitigation Plans	7.2.1	Define RISK CONTROL measures	STRONG	
SP 3.2	Implement Risk Mitigation Plans	5.2.4	Re-EVALUATE MEDICAL DEVICE RISK ANALYSIS	MODERATE	Implies follow up on mitigation plans.
		8.5.3.e	Reviewing preventive action taken and its effectiveness	MODERATE	
	Level 4				
	Quantitative Project Management				
SG 1	Quantitatively Manage the Project				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.1	Establish the Project's Objectives	7.1.a	Determine quality objectives and requirements for the product	WEAK	Product, but not project
SP 1.2	Compose the Defined Process				
SP 1.3	Select the Subprocesses that Will Be Statistically Managed				
SP 1.4	Manage Project Performance				
SG 2	Statistically Manage Subprocess Performance				
SP 2.1	Select Measures and Analytic Techniques				
SP 2.2	Apply Statistical Methods to Understand Variation				
SP 2.3	Monitor Performance of the Selected Subprocesses				
SP 2.4	Record Statistical Management Data				
	Organizational Process Performance				
SG 1	Establish Performance Baselines and Models				
SP 1.1	Select Processes				
SP 1.2	Establish Process-Performance Measures				
SP 1.3	Establish Quality and Process-Performance Objectives	5.1.c	Ensuring that quality objectives are established	MODERATE	Does not imply quantitative management.
		5.4.1	Quality objectives		
SP 1.4	Establish Process-Performance Baselines				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
SP 1.5	Establish Process-Performance Models				
	Level 5				
	Organizational Innovation & Deployment				
SG 1	Select Improvements				
SP 1.1	Collect and Analyze Improvement Proposals				
SP 1.2	Identify and Analyze Innovations				
SP 1.3	Pilot Improvements				
SP 1.4	Select Improvements for Deployment				
SG 2	Deploy Improvements				
SP 2.1	Plan the Deployment				
SP 2.2	Manage the Deployment				
SP 2.3	Measure Improvement Effects				
	Causal Analysis & Resolution				
SG 1	Determine Causes of Defects				
SP 1.1	Select Defect Data for Analysis	8.4	Analysis of data	STRONG	
		8.1	This shall include determination of applicable methods, including statistical techniques, and the extent of their use	STRONG	

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Copyright © 2009 David Walker SPCS, LLC

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		8.5.2.a	Reviewing nonconformities	MODERATE	Does not imply quantitative management.
SP 1.2	Analyze Causes	8.4	Analysis of data	MODERATE	Does not imply quantitative management.
		8.1	This shall include determination of applicable methods, including statistical techniques, and the extent of their use	STRONG	
		8.5.2.b	Determining the causes of nonconformities	STRONG	
SG 2	Address Causes of Defects				
SP 2.1	Implement the Action Proposals	8.5.2.d	Determining and implementing action needed	MODERATE	Does not imply quantitative management.
SP 2.2	Evaluate the Effect of Changes	8.5.2.f	Reviewing corrective action taken and its effectiveness	MODERATE	Does not imply quantitative management.
SP 2.3	Record Data	8.5.2.e	Recording of the results of any investigation and of action taken	MODERATE	Does not imply quantitative management.
	Generic Goals				
GG 1	Achieve Specific Goals				
	GP 1.1 Perform Specific Practices				
GG 2	Institutionalize a Managed Process				
GP 2.1	Establish an Organizational Policy	4.2.1.a	Documented statements of a quality policy and quality objectives	STRONG	
		5.1.b	Establishing the quality policy		

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		5.3	Quality policy		
GP 2.2	Plan the Process	5.1.5 5.1.6 5.1.7 5.1.9 6.3.1	Software integration and integration testing planning Software VERIFICATION planning Software RISK MANAGEMENT planning Software configuration management planning Use established PROCESS to implement modification	WEAK	Does not cover other process areas
		5.4.2	Quality management system planning		VER, VAL, PMC, PPQA
		7.1.c	Required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance	WEAK	ENG process areas
		7.3.1	Design and development planning		Does not cover other process areas
GP 2.3	Provide Resources	4.1.d	ensure the availability of resources and information necessary to support the operation and monitoring of these processes	STRONG	
		5.1.e	Ensuring the availability of resources		

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		6.1	Provision of resources		
GP 2.4	Assign Responsibility	5.5.1	Responsibility and authority	MODERATE	Not specific to each process area
		7.3.1.c	Determine the responsibilities and authorities for design and development		
GP 2.5	Train People	6.2.2	Competence, awareness, and training	WEAK	Not specific to each process area
GP 2.6	Manage Configurations	5.1.2 5.1.8 5.1.9 5.1.10 8.1	Keep software development plan updated Software configuration management planning Documentation planning Supporting items to be controlled Configuration Identification	MODERATE	62304 is much more narrow in scope here.
		5.4.2.b	Integrity of the quality management system is maintained when changes to the quality management system are planned and implemented	MODERATE	Not specific to each process area
GP 2.7	Identify and Involve Relevant Stakeholders	7.3.4	Design and development review	WEAK	Only addresses stakeholder involvement in reviews.
		9.3	Advise relevant parties	WEAK	Only notifies relevant stakeholders of safety issues.
GP 2.8	Monitor and Control the Process	5.1.2	Keep software development plan updated	MODERATE	Only PP, Not specific to each process area
		4.1.f	Implement actions necessary to achieve planned results and maintain the effectiveness of these processes	MODERATE	Not specific to each process area

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 1 - Mapping CMMI to IEC 62304

CMMI	Description	62304	Description	Alignment Strength	Observations
		4.1.e	Monitor, measure, and analyze these processes		
		8.2	Monitoring and measurement	MODERATE	Not specific to each process area
GP 2.9	Objectively Evaluate Adherence	8.2.2	Internal audit	WEAK	Not specific to each process area
GP 2.10	Review Status with Higher Level Management	5.1.d	Conducting management reviews	WEAK	Not specific to each process area
		5.5.2	Management representative	STRONG	
		5.6.2	Review input		
GG 3	Institutionalize a Defined Process				
GP 3.1	Establish a Defined Process				
GP 3.2	Collect Improvement Information	8.5.1	Identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system	STRONG	
GG 4	Institutionalize a Quantitatively Managed Process				
GP 4.1	Establish Quantitative Objectives for the Process				
GP 4.2	Stabilize Subprocess Performance				
GG 5	Institutionalize an Optimizing Process				
GP 5.1	Ensure Continuous Process Improvement				
GP 5.2	Correct Root Causes of Problems				

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 2 - Mapping IEC 62304 to CMMI

IEC 62304 Section	Description	CMMI Component	Alignment Strength	Observations
4	General requirements			
4.1	Quality management system	ALL	MODERATE	CMMI is the QMS, without a safety focus
4.2	RISK MANAGEMENT	RSKM	STRONG	
4.3	Software safety classification	RM RD	MODERATE MODERATE	CMMI does not address safety specifically
5	Software development PROCESS			
5.1	Software development planning			
5.1.1	Software development plan	PP SG2	STRONG	
5.1.2	Keep software development plan updated	PP GP 2.6 PP GP 2,8	STRONG MODERATE	
5.1.3	Software development plan reference to SYSTEM design and development	IPM SP 1.4	WEAK	SP 1.4 is much more, but references to other plans is a start
5.1.4	Software development standards, methods and tools planning	IPM SP 1.2	STRONG	But with no OPD, we're not sure how good these assets are
5.1.5	Software integration and integration testing planning	PI SG 1 PI GP 2.2	STRONG	
5.1.6	Software VERIFICATION planning	VER SG 1 VER GP 2.2	STRONG	
5.1.7	Software RISK MANAGEMENT planning	RSKM	STRONG	
5.1.8	Documentation planning	CM PP GP 2.6	STRONG	
5.1.9	Software configuration management planning	CM PP SP 2.3 PP GP 2.6	STRONG	
5.1.10	Supporting items to be controlled	CM PP GP 2.6	MODERATE	Not specifically addressed
5.1.11	Software CONFIGURATION ITEM control before VERIFICATION	CM SP 1.3	MODERATE	Timing is not specifically addressed in CMMI

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

© CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 2 - Mapping IEC 62304 to CMMI

IEC 62304 Section	Description	CMMI Component	Alignment Strength	Observations
5.2	Software requirements analysis			
5.2.1	Define and document software requirements from SYSTEM requirements	RD SG 2	STRONG	
5.2.2	Software requirements content	RD	MODERATE	Elements a-l not all addressed in CMMI
5.2.3	Include RISK CONTROL measures in software requirements	RSKM SG 3 RM SP 1.4	WEAK	Not specifically addressed in CMMI
5.2.4	Re-EVALUATE MEDICAL DEVICE RISK ANALYSIS	RSKM SP 3.2	STRONG	But Cohesion between mitigation activities and requirements not emphasized in CMMI
5.2.5	Update SYSTEM requirements	RM SP 1.4 CM SG 2 RD GP 2.8	STRONG	
5.2.6	Verify software requirements	RD SG 3 VER SG 2	STRONG	Specific criteria not defined in CMMI
5.3	Software ARCHITECTURAL design			
5.3.1	Transform software requirements into an ARCHITECTURE	TS SP 2.1	STRONG	
5.3.2	Develop an ARCHITECTURE for the interfaces of SOFTWARE ITEMS	TS SP 2.3	STRONG	
5.3.3	Specify functional and performance requirements of SOUP item	RD TS	MODERATE	SOUP not singled out in CMMI in this way
5.3.4	Specify SYSTEM hardware and software required by SOUP item	RD TS	MODERATE	SOUP not singled out in CMMI in this way
5.3.5	Identify segregation necessary for RISK CONTROL	RD	WEAK	Could be implemented in RD, but not specifically addressed in CMMI
5.3.6	Verify software ARCHITECTURE	VER SG 2,3 PI SP 2.1, 3.1	STRONG MODERATE	CMMI does not specifically call out SOUP
5.4	Software detailed design			
5.4.1	Refine SOFTWARE ARCHITECTURE into SOFTWARE UNITS	RD SG 2	STRONG	
5.4.2	Develop detailed design for each SOFTWARE UNIT	TS SG 2	STRONG	

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 2 - Mapping IEC 62304 to CMMI

IEC 62304 Section	Description	CMMI Component	Alignment Strength	Observations
5.4.3	Develop detailed design for interfaces	TS	STRONG	
5.4.4	Verify detailed design	PI SP 3.1 VER	STRONG	
5.5	SOFTWARE UNIT implementation and verification			
5.5.1	Implement each SOFTWARE UNIT	TS SP 3.1	STRONG	
5.5.2	Establish SOFTWARE UNIT VERIFICATION PROCESS	VER SG 1, 2	MODERATE	CMMI applies VER selectively. Verification of test procedures is done selectively in CMMI.
5.5.3	SOFTWARE UNIT acceptance criteria	PI SP 3.1 VER SP 1.3	STRONG	
5.5.4	Additional SOFTWARE UNIT acceptance criteria	VER SG 1,2	MODERATE	Criteria applies selectively in CMMI
5.5.5	SOFTWARE UNIT VERIFICATION	VER SG 3	STRONG	
5.6	Software integration and integration testing			
5.6.1	Integrate SOFTWARE UNITS	PI SP 3.2	STRONG	
5.6.2	Verify software integration	PI SP 3.3	MODERATE	CMMI does not address support for manual operations
5.6.3	Test integrated software	PI SP 3.3 VER SG 3	STRONG	
5.6.4	Integration testing content	VER SP 3.2	STRONG	
5.6.5	Verify integration test procedures	VER SG 2,3	MODERATE	Only selectively applied in CMMI
5.6.6	Conduct regression tests	PI SP 3.3 VER SG 2,3	MODERATE	Not specifically called out in CMMI, but inferred
5.6.7	Integration test record contents	PI SP 3.3 VER SG 3	MODERATE	Specific requirements not addressed in CMMI
5.6.8	Use software problem resolution PROCESS	CM SP 2.1	MODERATE	CMMI does not address problem resolution specifically
5.7	SOFTWARE SYSTEM testing			

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 2 - Mapping IEC 62304 to CMMI

IEC 62304 Section	Description	CMMI Component	Alignment Strength	Observations
5.7.1	Establish tests for software requirements	RM SP 1.4 VER SP 1.3	MODERATE	CMMI does not specifically require that ALL requirements are tested
5.7.2	Use software problem resolution PROCESS	CM SP 2.1	MODERATE	CMMI does not address problem resolution specifically
5.7.3	Retest after changes	PI SP 3.3 CM SG 2 VER SG 2,3	MODERATE	Not specifically called out in CMMI, but inferred
5.7.4	Verify SOFTWARE SYSTEM testing	VER	MODERATE	Specific requirements not stressed in CMMI
5.7.5	SOFTWARE SYSTEM test record contents	PI SP 3.3 VER SG 3	MODERATE	Specific requirements not addressed in CMMI
5.8	Software release			
5.8.1	Ensure software VERIFICATION is complete	VER SP 2.3 VER SP 3.2	STRONG	
5.8.2	Document known residual ANOMALIES	CM SP 2.1 VER SP 3.2	MODERATE	Not specifically addressed in CMMI
5.8.3	EVALUATE known residual ANOMALIES	RSKM SG 2 VER SP 3.2	MODERATE	Not specifically addressed in CMMI
5.8.4	Document released VERSIONS	PI SP 3.4 CM SP 1.3 CM SP 3.1	STRONG	
5.8.5	Document how released software was created	PI SG 1 CM SP 1.3 CM SP 3.1	STRONG	
5.8.6	Ensure activities and tasks are complete	PMC SP 1.7	STRONG	
5.8.7	Archive software	CM SP 1.3 CM SP 3.1	MODERATE	Specific archival requirements not addressed in CMMI
5.8.8	Assure repeatability of software release	CM SP 3.2 PPQA SG 1	STRONG	
6	Software maintenance PROCESS			
6.1	Establish software maintenance plan	PP SG 2	MODERATE	Maintenance is not specifically discussed in CMMI, but

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 2 - Mapping IEC 62304 to CMMI

IEC 62304 Section	Description	CMMI Component	Alignment Strength	Observations
		TS 2.2 TS 3.2		inferred
6.2	Problem and modification analysis			
6.2.1	Document and EVALUATE feedback			
6.2.1.1	Monitor feedback	CM SP 2.1	MODERATE	Not specifically addressed in CMMI
6.2.1.2	Document and EVALUATE feedback	CM SG 2	MODERATE	Not specifically addressed in CMMI
6.2.1.3	Evaluate PROBLEM REPORT'S affects on SAFETY	CM SG 2 RSKM SG 2	MODERATE	Not specifically addressed in CMMI
6.2.2	Use software problem resolution PROCESS	CM SP 2.1	MODERATE	Not specifically addressed in CMMI
6.2.3	Analyze CHANGE REQUESTS	CM SP 2.2	STRONG	
6.2.4	CHANGE REQUEST approval	CM SP 2.2	STRONG	
6.2.5	Communicate to users and regulators	CM SP 1.2	MODERATE	Specific reporting requirements not stressed in CMMI
6.3	Modification implementation			
6.3.1	Use established PROCESS to implement modification	CM GP 2.2	MODERATE	
6.3.2	Re-release modified SOFTWARE SYSTEM	PI SG 3 CM SP 1.3	MODERATE	Some elements of 5.8 are MODERATE
7	Software RISK MANAGEMENT PROCESS			
7.1	Analysis of software contributing to hazardous situations			
7.1.1	Identify SOFTWARE ITEMS that could contribute to a hazardous situation	RSKM SG2	MODERATE	Safety risk analysis not specifically required by CMMI
7.1.2	Identify potential causes of contribution to a hazardous situation	RSKM SP 1.1 RSKM SG 2	MODERATE	Safety risk analysis not specifically required by CMMI
7.1.3	EVALUATE published SOUP ANOMALY lists	RSKM SP 1.1	MODERATE	Not specifically required by CMMI
7.1.4	Document potential causes	RSKM SP 1.1 RSKM SG 2	MODERATE	Safety risk analysis not specifically required by CMMI

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 2 - Mapping IEC 62304 to CMMI

IEC 62304 Section	Description	CMMI Component	Alignment Strength	Observations
7.1.5	Document sequences of events	RSKM SG 1 RSKM SG 2	MODERATE	Not specifically required by CMMI
7.2	RISK CONTROL measures			
7.2.1	Define RISK CONTROL measures	RSKM SP 3.1	STRONG	
7.2.2	RISK CONTROL measures implemented in software	RSKM SP 2.1 RD SG 1, 2	MODERATE	Not specifically required by CMMI
7.3	VERIFICATION of RISK CONTROL measures			
7.3.1	Verify RISK CONTROL measures	VER SG 2,3	MODERATE	CMMI applies VER selectively
7.3.2	Document any new sequences of events	RSKM SG 2	MODERATE	Not specifically required by CMMI
7.3.3	Document TRACEABILITY	RM SP 1.4	MODERATE	Risk traceability not specifically required by CMMI
7.4	RISK MANAGEMENT of software changes			
7.4.1	Analyze changes to MEDICAL DEVICE SOFTWARE with respect to SAFETY	CM SP 2.2	MODERATE	Not specifically required by CMMI
7.4.2	Analyze impact of software changes on existing RISK CONTROL measures	CM SP 2.2	MODERATE	Not specifically required by CMMI
7.4.3	Perform RISK MANAGEMENT ACTIVITIES based on analyses	CM SP 2.2	MODERATE	Not specifically required by CMMI
8	Software configuration management PROCESS			
8.1	Configuration identification			
8.1.1	Establish means to identify CONFIGURATION ITEMS	CM SP 1.1	STRONG	
8.1.2	Identify SOUP	CM SP 1.1		
8.1.3	Identify SYSTEM configuration documentation	CM SP 1.3	STRONG	
8.2	Change control			
8.2.1	Approve CHANGE REQUESTS	CM SP 1.2	STRONG	

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.

Table 2 - Mapping IEC 62304 to CMMI

IEC 62304 Section	Description	CMMI Component	Alignment Strength	Observations
		CM SP 2.2	STRONG	
8.2.2	Implement changes	CM SP 2.1 RSKM	STRONG STRONG	
8.2.3	Verify changes	CM SP 2.1 VER	MODERATE	Not specifically required by CMMI
8.2.4	Provide means for TRACEABILITY of change	CM SP 1.2 CM SP 2.1	STRONG STRONG	
8.3	Configuration status accounting	CM SP 3.1	STRONG	
9	Software problem resolution PROCESS			
9.1	Prepare PROBLEM REPORTS	CM SP 2.1	WEAK	
9.2	Investigate the problem	CM SP 1.1	WEAK	CR may be created in response to a PR
9.3	Advise relevant parties	CM SP 3.1	WEAK	
9.4	Use change control process	CM SP 1.2 CM SP 2.2	STRONG STRONG	
9.5	Maintain records	CM SP 3.1	STRONG	But addresses CRs not PRs
9.6	Analyze problems for trends	CM GP 2.8 CAR	WEAK	Only lightly addressed. CAR would imply quantitative management and a stable process.
9.7	Verify software problem resolution	CM SP1.1 VER SG 3	STRONG	
9.8	Test documentation contents	CM SP 1.1 VER SG 3	MODERATE	Not specifically required by CMMI

Permission granted to the American Society for Quality (ASQ) and Carnegie Mellon University and its Software Engineering Institute (SEI) for publication and duplication.

® CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University.