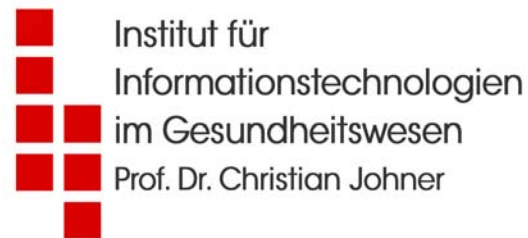


Processes for the Development of Healthcare Applications

Christian Johner

- Process/Life-Cycle Models: The true history
- Directives and Standards: Requirements with Respect to Processes
- Conclusion, Recommendations



Contact

- Institut für IT im Gesundheitswesen
c/o Calcucare GmbH
Kaiser-Joseph-Str. 274, D-79098 Freiburg
<http://www.johner-institut.de>
mail@johner-institut.de
- Private
Bodanstr. 16, D-78462 Konstanz
Tel.: +49 (700) 69712640
Fax.: +49 (700) 69712649

Activities

- Professor for software engineering and quality assurance
- Consultant for development and testing of healthcare applications
- Offering post-graduate on the job master study course

The poster features a yellow background. At the top left, the website www.donau-unl.ac.at/zpi is listed. The main headline reads "Gesundheitssysteme effizienter gestalten". Below this, there are two images: on the left, a computer monitor displaying a line graph with data points; on the right, a portrait of a woman in a white lab coat. At the bottom left, the text "Donau-Universität Krems" and "Zentrum für Praxisorientierte Informatik" is displayed. At the bottom right, the logo of Donau-Universität Krems is shown, followed by the program title "Professional MSc Informationstechnologien im Gesundheitswesen" and the details "Postgradueller Universitätslehrgang, Master of Science" and "4 Semester, berufsbegleitend".

www.donau-unl.ac.at/zpi

Gesundheitssysteme effizienter gestalten

Donau-Universität Krems
Zentrum für Praxisorientierte Informatik

Professional MSc
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Waterfall process

What?

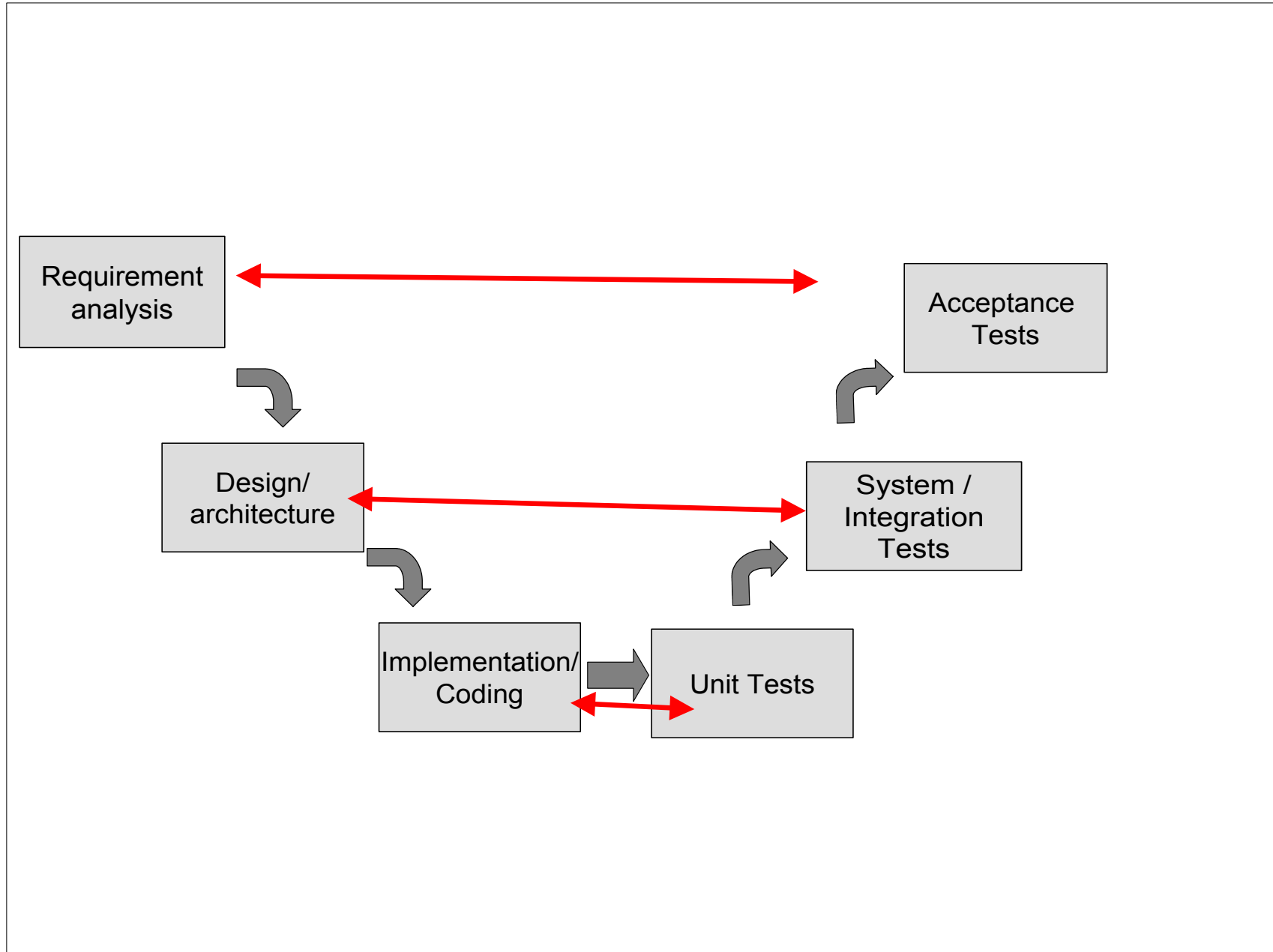
Requirement
analysis

How?

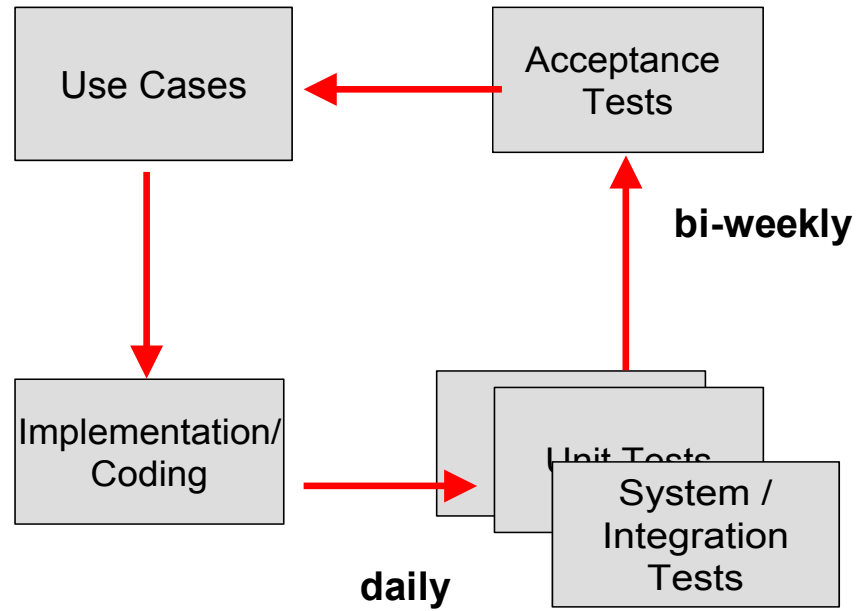
Design/
architecture

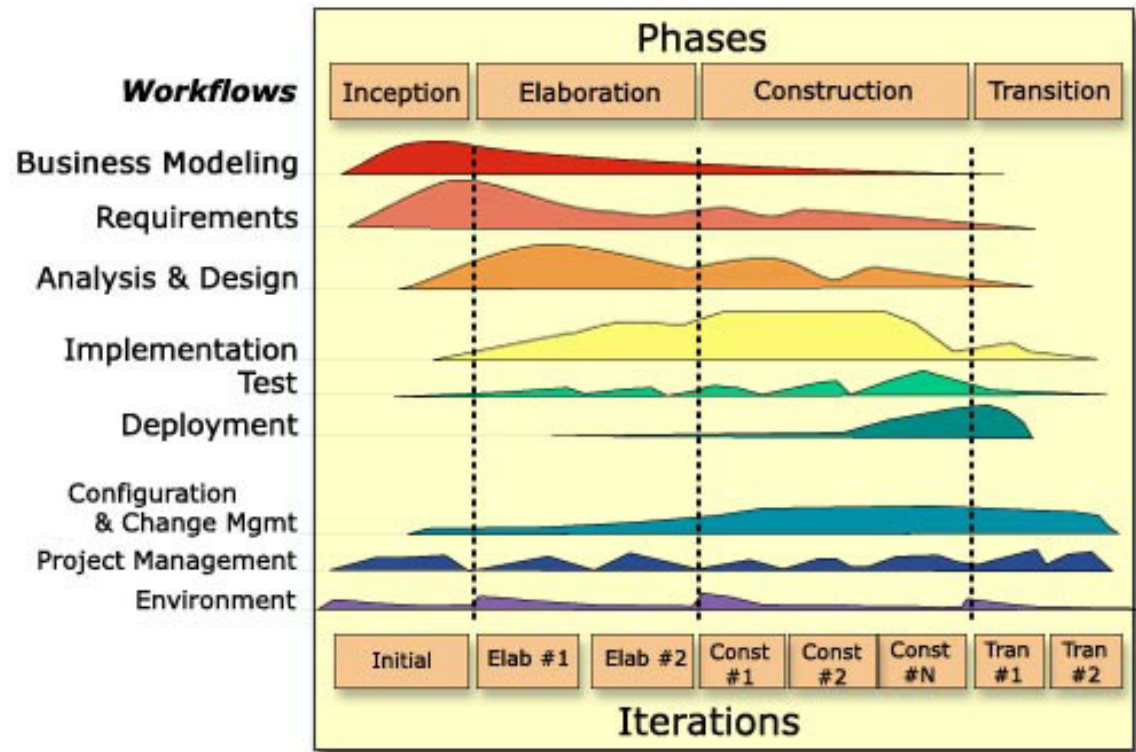
Implementation/
Coding

System
Integration
Acceptance
Tests



extreme Programming

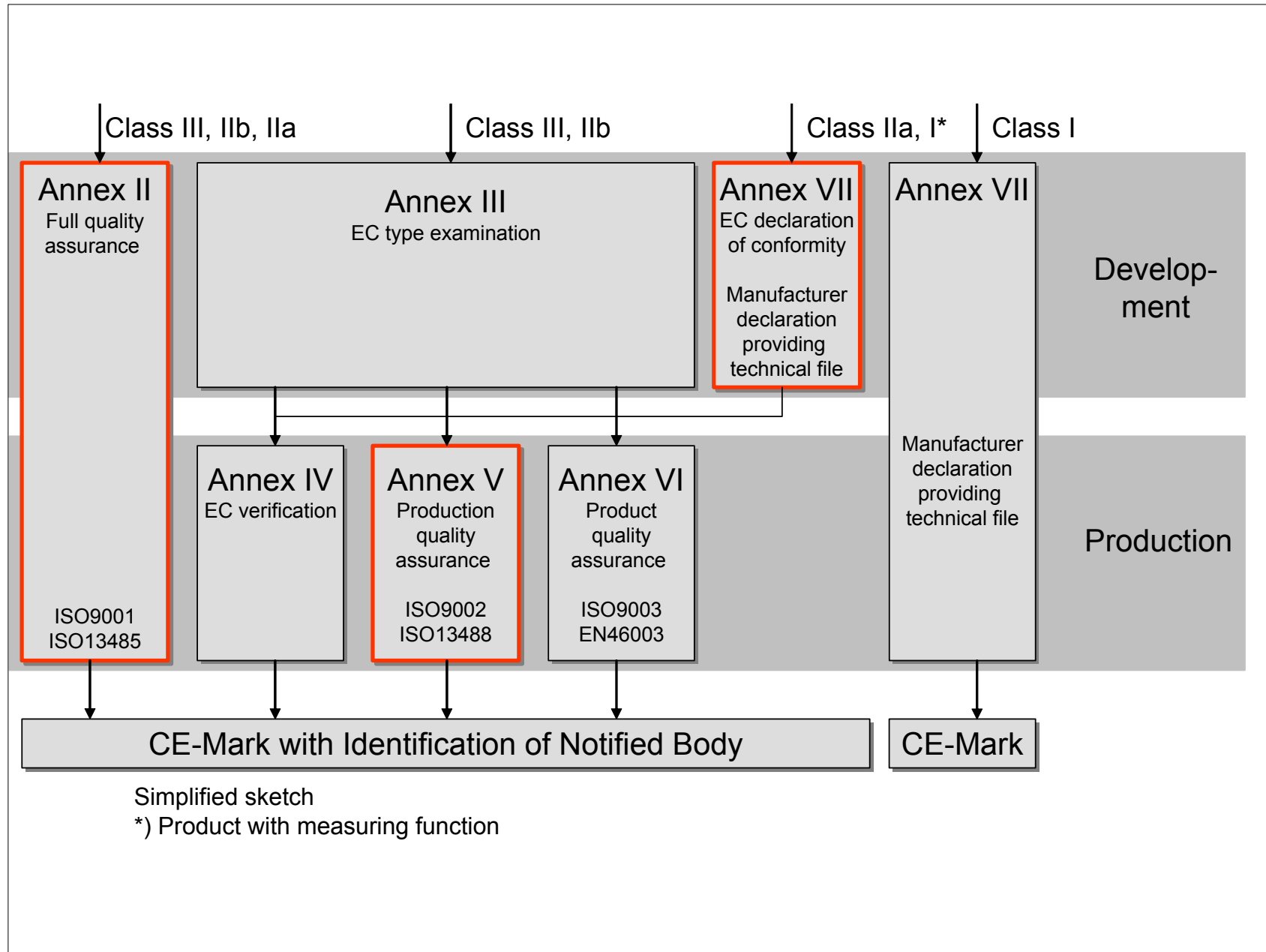




	V-Model	RUP	XP
Characteristics	Zuordnung Konstruktion und Test	Iterativ, inkrementell Architektur getrieben UML	iterativ, inkrementell Paarprogrammierung kurze Iterationszyklen Use casen driven test driven
Projects	nicht SW spezifisch staatliche Projekte	OO-SW	SW-Projekte
Project size	mittel - groß	mittel-groß	kleine - mittlere
Requirements	statische Anforderungen genug Zeit zum Testen	Ausbildungsstand Entwickler	Kundenverfügbarkeit

MDD 93/42/EEC

- Article §1: Definition Scope
- Article §3: Essential Requirements (Annex I)
- Article §9: Classification
- Article §11: Conformity Assessment Procedure
- Article §15: Clinical Investigation
- Article §16: Notified Bodies
- Article §17: CE mark
- Annex I: Essential Requirements
- Annex II: Full quality management system
- Annex III: EG type examination

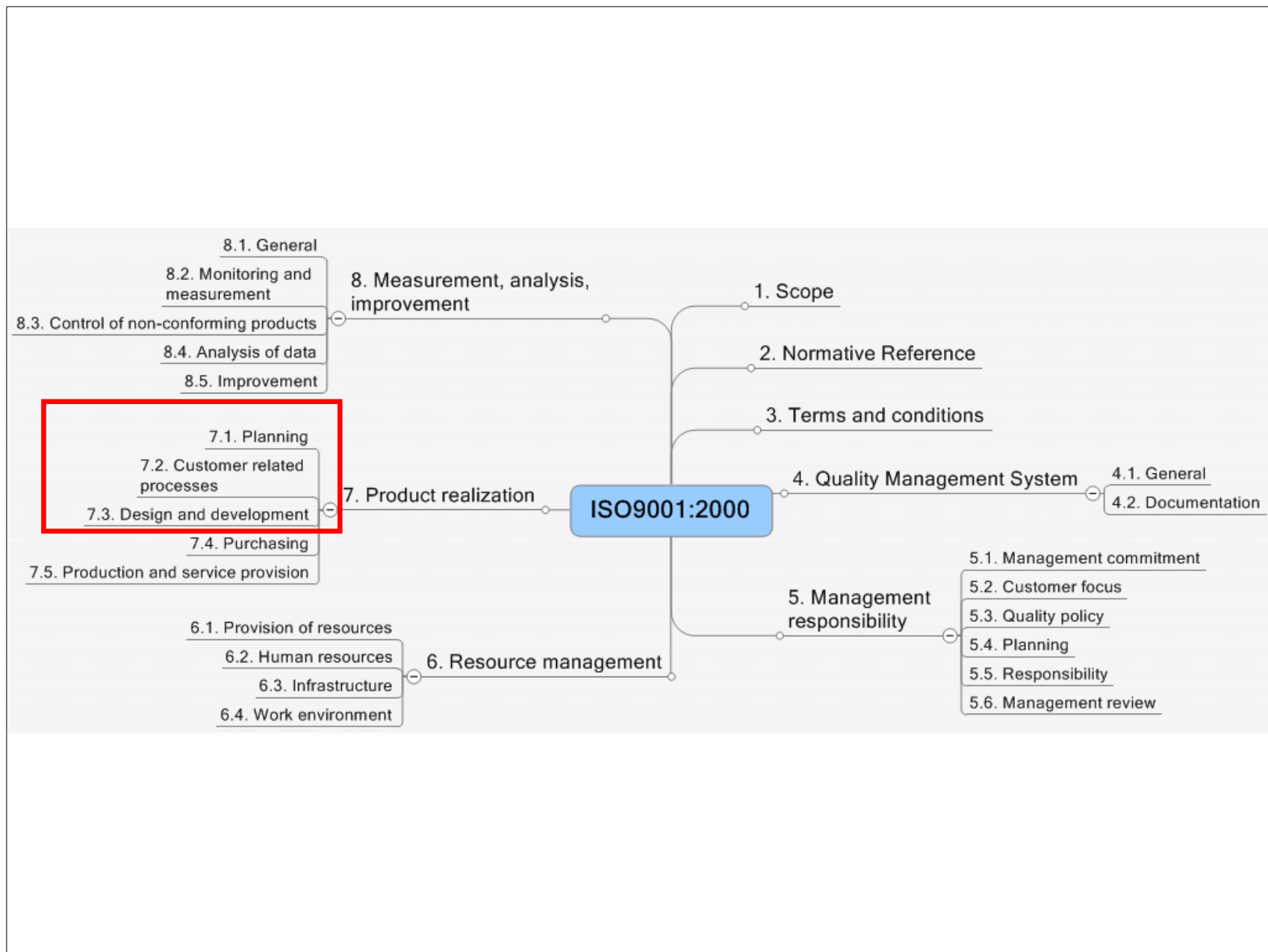


Annex II: Full Quality Assurance System

3.2: “It shall include in particular an adequate description of [...] the procedures for monitoring and verifying the design of the products and in particular [...] the design specifications, [...] the results of the risk analysis [...] the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed [...]”

Annex III: EC Type Examination

3. “The documentation must allow an understanding of the design [...] and must contain [...] design drawings [...] and diagrams of components, sub-assemblies, [...] the results of the design calculations, risk analysis, [...] technical tests [...]”



Chapter 7.1

- “The organization shall plan and develop the **processes** needed for product realization. [...] The organization shall determine [...] **verification, validation**, monitoring, inspection and test activities specific to the product and the criteria for **product acceptance**;”
- 13485:2003 additionally: “The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained.”

Chapter 7.2

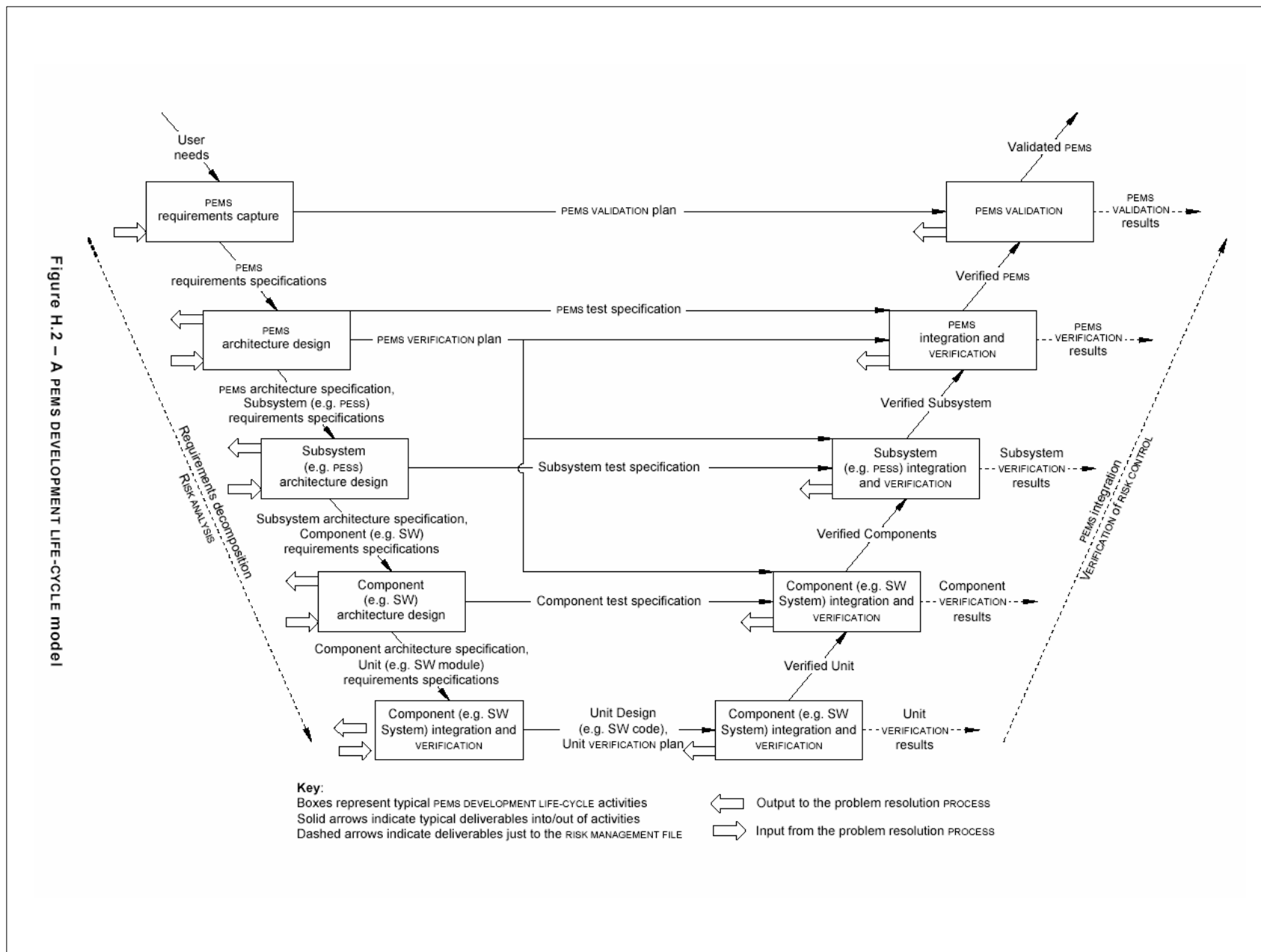
- “The organization shall determine [...] requirements specified by the customer, [...] requirements not stated by the customer but necessary for specified or intended use. [...]”
- “The organization shall review the requirements related to the product[...] and shall ensure that product requirements are defined, [ISO13485] and documented [...].”
- “The organization shall determine and implement effective arrangements for communicating with customers in relation to [...] customer feedback, including customer complaints.”

Chapter 7.3

- “The organization shall establish documented procedures for design and development [...], shall determine the design and development stages, the review, verification, validation and design transfer activities [...]”
- “Inputs relating to product requirements [...] shall include functional, performance and safety requirements, [...] output(s) of risk management. [.. and] shall be reviewed”
- “The outputs of design and development shall [...] enable verification against the design and development input [...], contain or reference product acceptance criteria”
- “Verification shall [...] ensure that the design and development outputs have met the design and development input requirements.”
- “Design and development validation shall ensure that the resulting product is capable of meeting the requirements”

ISO 60601-1

- A PEMS development life-cycle shall be documented [...] and shall include a set of defined milestones. At each milestone, the activities to be completed and the verification methods to be applied to those activities shall be defined. Each activity shall be defined including its inputs and outputs. Each milestone shall identify the risk management activities that must be completed before that
- Compliance [...] does not require that any particular PEMS development life-cycle is used [...]



ISO62304

- Applies to the development and maintenance of medical device software
- May be used when software is itself a medical device or when software is an embedded or integral part of the final medical device.
- (Does not cover validation and final release)
- Does not prescribe a specific life-cycle model
- Requires verification for each life-cycle activity
- Defines three (risk) classes
- Addresses risk management, QMS
- Addresses change, version, configuration mgmt.

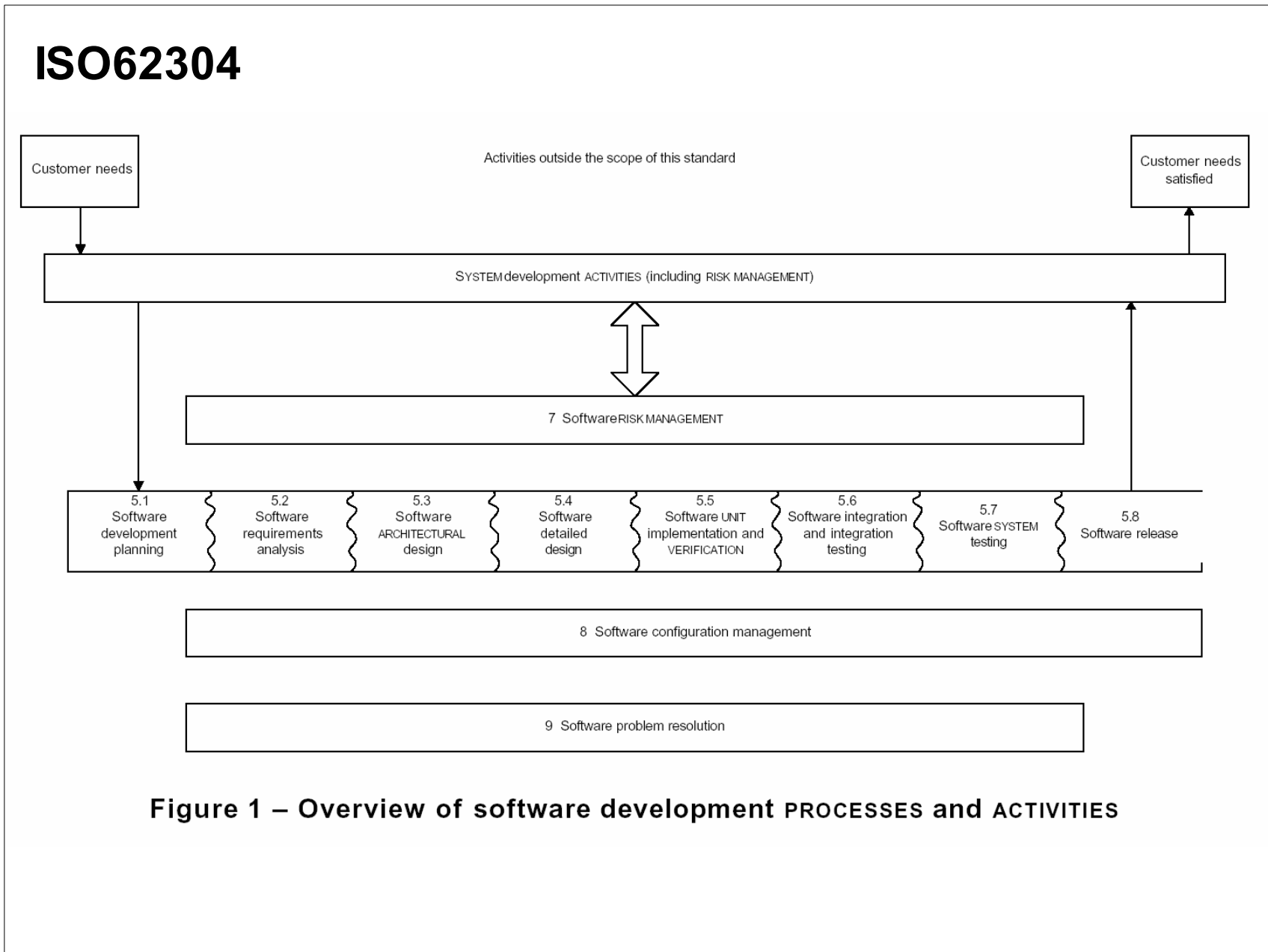
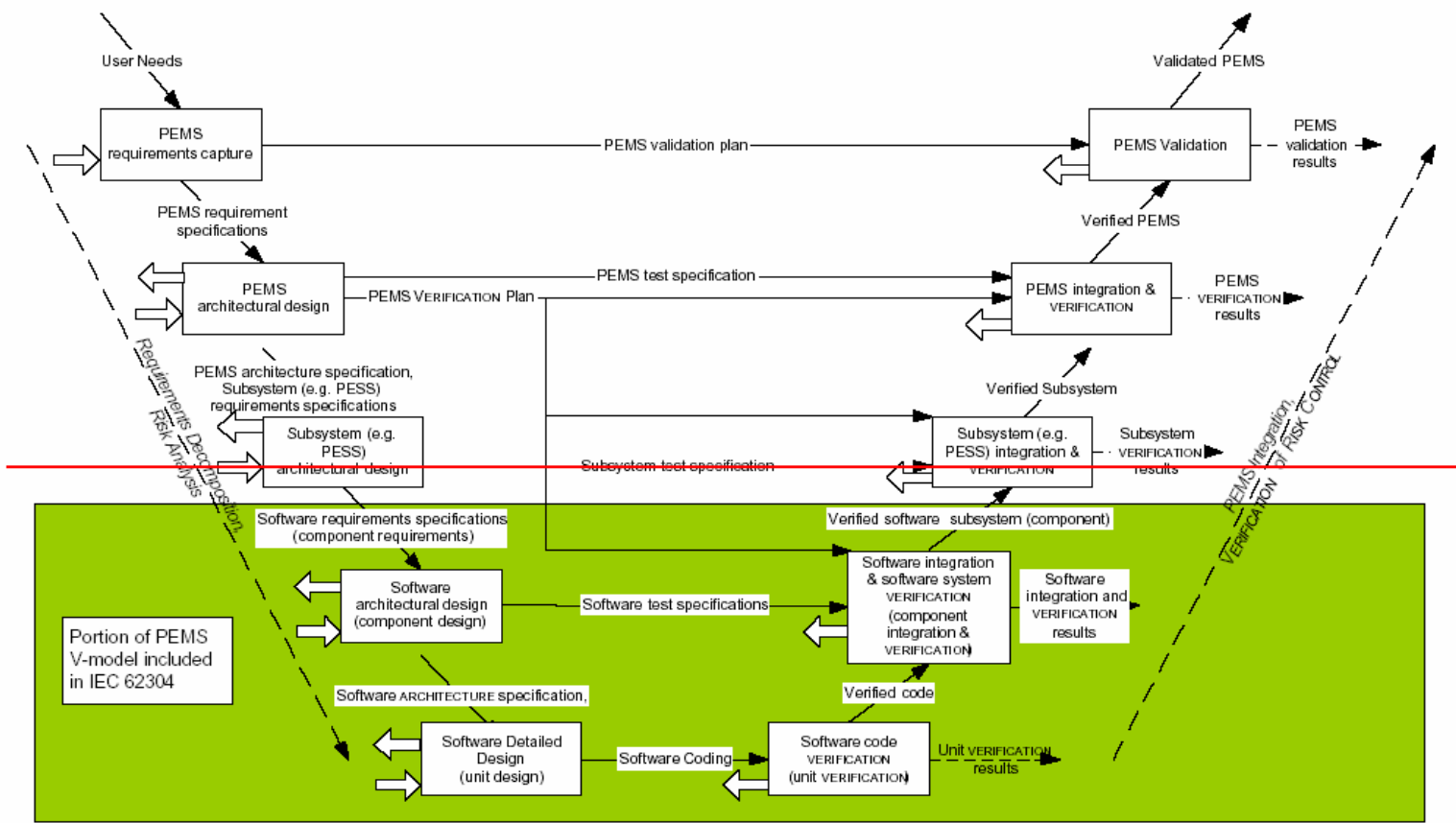


Figure 1 – Overview of software development PROCESSES and ACTIVITIES

ISO62304



Key:
Boxes represent typical development lifecycle activities
Solid Arrows indicate typical deliverables transferred into/out of activities
Dotted arrows indicate deliverables just to the Risk Management File

⇒ Outputs from problem resolution process
⇐ Inputs to problem resolution process

Summary

- Standards are getting more specific to medical software: 13485 → 60601-1 → 62304
- Process orientation is mandatory, no particular life-cycle is prescribed, however V-model seems to be favoured (reflects mind-set of auditors)
- Risk management is mandatory (→ ISO 14971)
- ISO 62304 closely guides / determines development of medical software

Recommendations

- Use V-Model as core process model
 - Risk based
 - Process management tool (automated, paper-less)
- Adopt best practices from other models
 - Architecture centric, vertical prototypes (RUP)
 - Iterative and incremental design, development (RUP)
 - Frequent peer reviews (XP)
 - Short iteration cycles with frequent customer feedback (XP)
 - Daily builds, complete regression testing (XP)