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Acceptance test of medical devices

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Acceptance test

- Customer's acceptance of the product
  - fullfilling the specification
  - by verification and validation of the product
- Medical devices
  - Medical authorities are the customer's advocate
    - minimising risk of harm
    - based on standards
- Key requirements
  - Basic safety for the customer
    - the patient, the operator
  - Essential performance
    - Works as specified on key features

Medical devices standards

- Key standard

IEC 60601

- defining RPF – Risk Priority Factor
  - probability versus impact
- approx. 400 pages
- referring to approx. 60 other standards
  - many of these specify test methods

Functional safety devices standards

- Key standard

IEC 61508

- defining SIL – Safety Integration Level
  - probability of dangerous failure
- approx. 100 pages
- referring to approx. 20 other standards
  - some of these specify test methods

Where to begin … where to end?

- Pinpoint relevant standards
  - Safety
    - Basic safety and essential performance
  - Quality management
    - Quality assurance during development and production
  - Design
    - Methods and management of development and **test**
  - Interface and accessories
    - Communication with other medical devices
    - Accessories to follow same standards

Safety related

- General safety

NEW	IEC 60601-1	2005	Medical electrical equipment Part 1: General requirements for **basic safety and essential performance** (3rd Edition)
	IEC 60601-1-1	2005	Medical electrical equipment Part 1-1: Safety Requirements for Medical Electrical Systems (3rd Edition)
	IEC 60601-1-2	2007	Medical electrical equipment Part 1-2: Electromagnetic compatibility requirements and tests
	IEC 60601-1-4	1999	Medical Electrical Equipment Part 1-4: Programmable electrical medical systems
NEW	IEC 60601-1-6	2010	Medical Electrical Equipment Part 1-6: Usability
	IEC 60601-1-8	2007	Medical electrical equipment Part 1-8: Alarm systems in medical electrical equipment and medical electrical systems
NEW	IEC 60601-1-11	2011	Medical electrical equipment Part 1-11: Medical electrical systems used in the home healthcare environment
	IEC 60529	2001	Degrees of protection provided by enclosures (IP Code)
	ISO 10993	2009	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process Part 5: Tests for in vitro cytotoxicity Part 10: Tests for irritation and skin sensitization
	ISO 15223	2012	Symbols to be used with medical device labels, labeling and information to be supplied

Safety related

- Specific device safety
  - Example: anesthetic system

IEC 60601-2-13	2009	Medical electrical equipment Part 2-13: Safety and essential performance of anesthetic systems
ISO 21647	2009	Medical electrical equipment. Basic safety and essential performance of respiratory gas monitors
ISO 15001	2011	Anesthetic and respiratory equipment Compatibility with oxygen Note: Conformity not demonstrated, not compliant as off this revision

  - Example: insulin pump

IEC 60601-2-24	1998	Medical electrical equipment Part 2-24: Safety and essential performance of infusion pumps and controllers
ISO 17665	2006	Sterilization of health care products - Moist heat

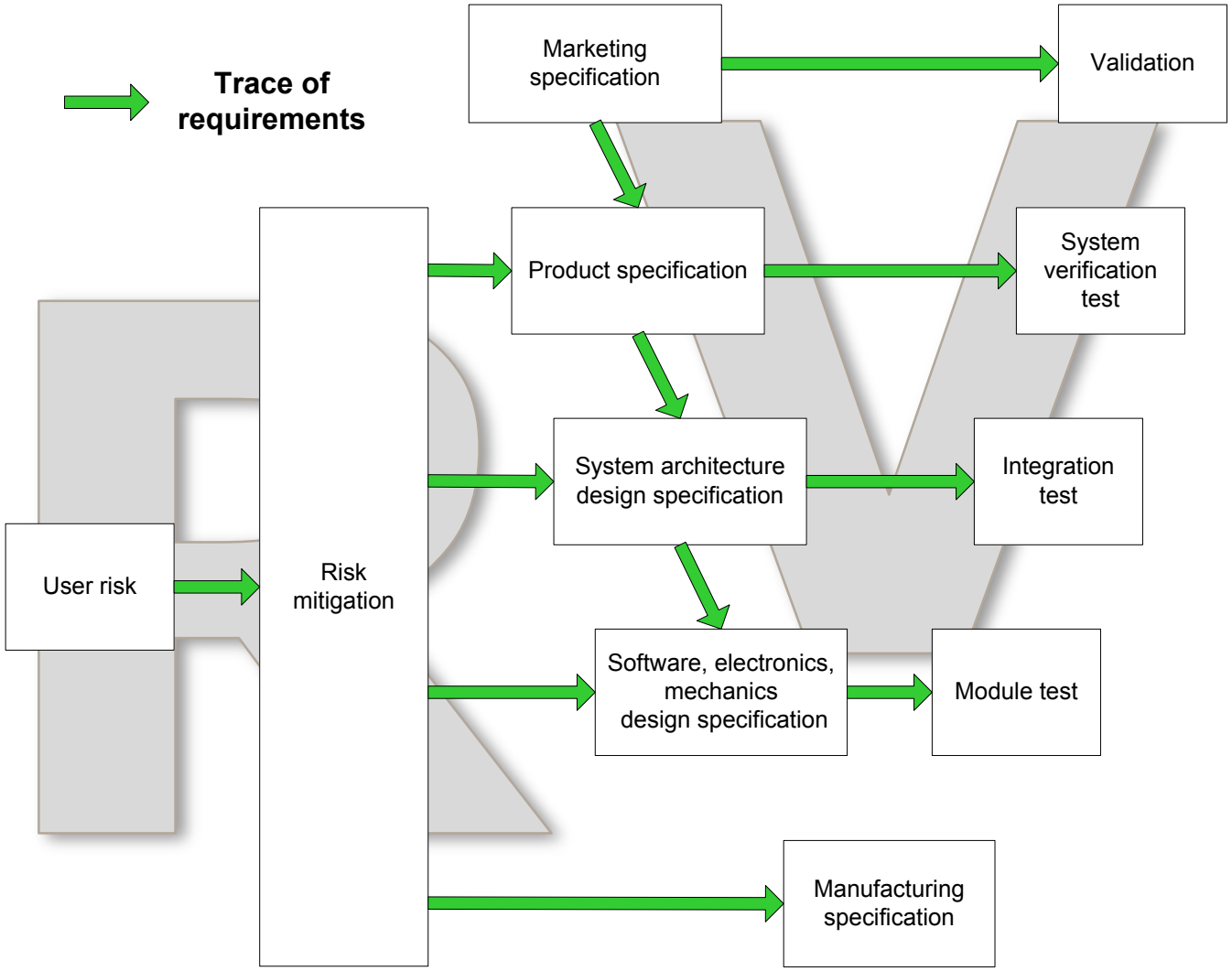
Quality management

- During design and development

ISO 13485	2003	Medical devices Quality management systems - Requirements for **regulatory** purposes
ISO 14971	2009	Medical devices Application of **risk management** to medical devices
ISO 62304	2006	Medical device software Software life-cycle processes
ISO 1041	2008	Information supplied by the manufacturer of medical devices

- What is risk management ?
  - A crucial part of development
  - Focus on probability versus impact

Quality management (Risk V-model)



New kid in town: Usability

- Focus points on specification
  - intended use
  - intended patient population
  - intended part of body
  - intended operator profile

- In real-life operation
  - Markings and user manuals
  - Push-buttons, screen outlay
  - Audio and visual informative signals
  - **Alarm signals**

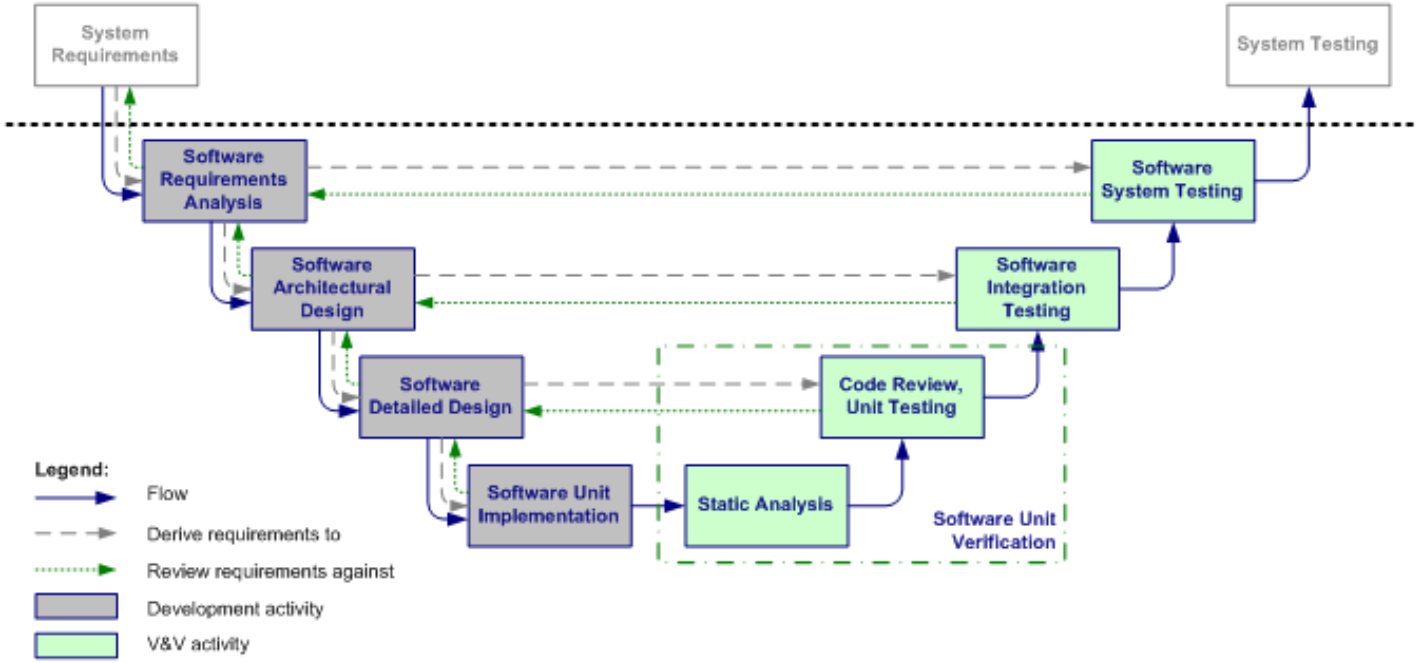
- What about usability testing?
  - Hmmm … you are still on your own

New kid in town: software development

- Functionality very complexed
- Authorities have no previous experience
- -> so strict, tradional and burdensome rules
  - Only handling the tradional waterfall and V-model
  - **Not** handling
    - Agile development
    - Model-based development
    - …
- What about
  - Exploratory testing?
  - Usability testing?
  - Smoke testing?
- Software living in its own world
  - No interface to electronics and mechanics

New kid in town: software development

- The tradional waterfall and V-model



- What about software testing?
  - Hmmm … you are still on your own

Verification and validation

- Testing standards and methods
  - Referenced in all standards
  - Mostly environmental

IEC 60601-1-1	Medical electrical equipment Part 1-1: Safety Requirements for Medical Electrical Systems (3rd Edition)	Type test Electrical safety test 60068-2-xxx: Mech. test
IEC 60601-1-2	Medical electrical equipment Part 1-2: Electromagnetic compatibility requirements and tests	61000-3: Emission, Immunity
IEC 60601-1-4	Medical Electrical Equipment Part 1-4: Programmable electrical medical systems	Verification Validation
IEC 60601-1-6	Medical Electrical Equipment Part 1-6: Usability	60601-1-8: Alarm test
IEC 60601-1-8	Medical electrical equipment Part 1-8: Alarm systems in medical electrical equipment and medical electrical systems	Alarm signal test 60651: sound test
IEC 60601-1-11	Medical electrical equipment Part 1-11: Medical electrical systems used in the home healthcare environment	Safety test Environmental test
IEC 60529	Degrees of protection provided by enclosures (IP Code)	Ingress test (water, dust)
ISO 10993	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process Part 5: Tests for in vitro cytotoxicity Part 10: Tests for irritation and skin sensitization	Biological hazard test
ISO 15223	Symbols to be used with medical device labels, labeling and information to be supplied	Unified symbols test

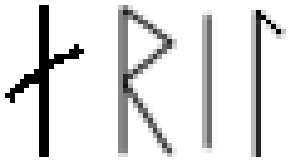
Ups – what did we forget?

- RoHS and REACH
  - RoHS (EU directive 2011/65/EU): compliance of materials to the material composition limits of the restricted substances (approx. 0.1%)
    - Lead, Cadmium, Mercury, Chromium, Bromides
  - REACH (EU directive 2006): compliance of materials to the Substances of Very High Concern (SVHC list)
    - Current list of **138** substances
    - Example: phthalate, chromate, benzene, toluene

Future of medical devices acceptance

- No shortcuts possible

  - ”Nissen flytter med”
    - Problems hunt you down
      if you try to run away instead of finding the real cause
  - “Siden Arilds tid”
    - Standards valid ten years ago have changed



  - “Grib fremtiden”

Believing in changing future
is the only way to success