



 **Lero** THE IRISH SOFTWARE
RESEARCH CENTRE

A Framework for taxonomy based testing using classification of defects in health software-SW91

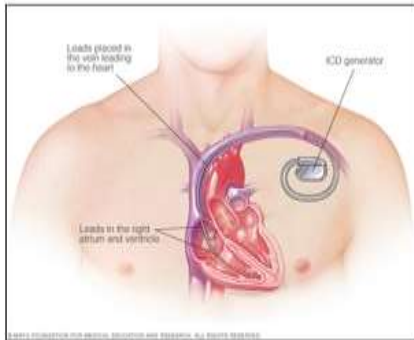
Overview

- Research problem
- Defect taxonomy and software testing
- SW91 and Taxonomy based testing
- Taxonomy based testing framework
- Integration of taxonomy based testing into standard test processes
- Future work and conclusion

The Problem

- **Malfunctioning medical devices can cause serious injury to or death of patients:**

Implantable defibrillator



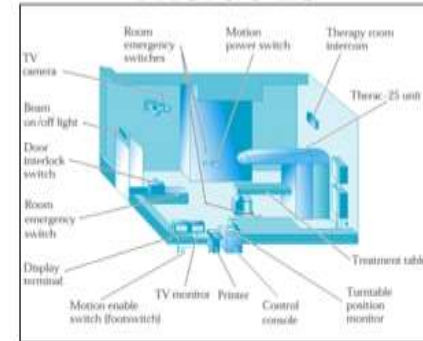
293 patients died

Physiological patient monitor



4 patients died

Therac 25



4 patients died
2 were permanently disfigured

- **FDA recalls**

Defect Taxonomies

- What is defect taxonomy?
- Examples of defect taxonomies
 - Orthogonal Defect Classification
 - IEEE standard classification for software anomalies
 - Hewlett-Packard defect categorization scheme
 - Taxonomy for software bugs

SW91 - Classification of defects in health software

- Developed by the Association for the Advancement of Medical Instrumentation (AAMI) in cooperation with the US Food and Drug Administration (FDA)
- SW91 was published on 22 of October 2018 and the US FDA has recognised SW91 as a consensus standard
- SW91 defect categories were validated and added into Annex D
 - Vulnerabilities from Common Weakness Enumeration(CWE) were mapped into SW91 defects

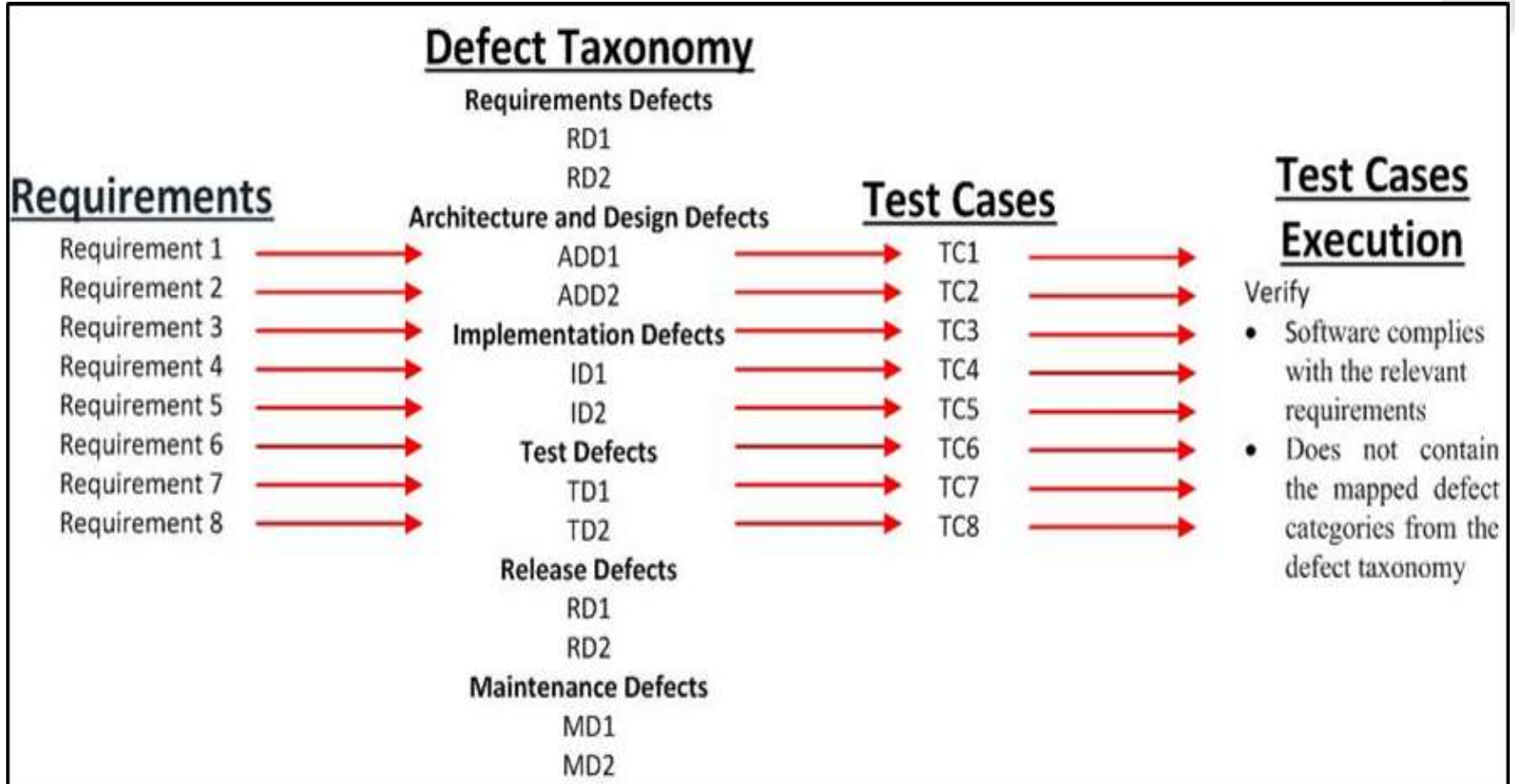
SW91 - Classification of defects in health software

Parent level defects	Number of defects
Planning (1)	2
Requirements (2)	15
Architecture and Design (3)	28
Implementation (4)	106
Test (5)	18
Release Defects (6)	4
Maintenance (7)	13

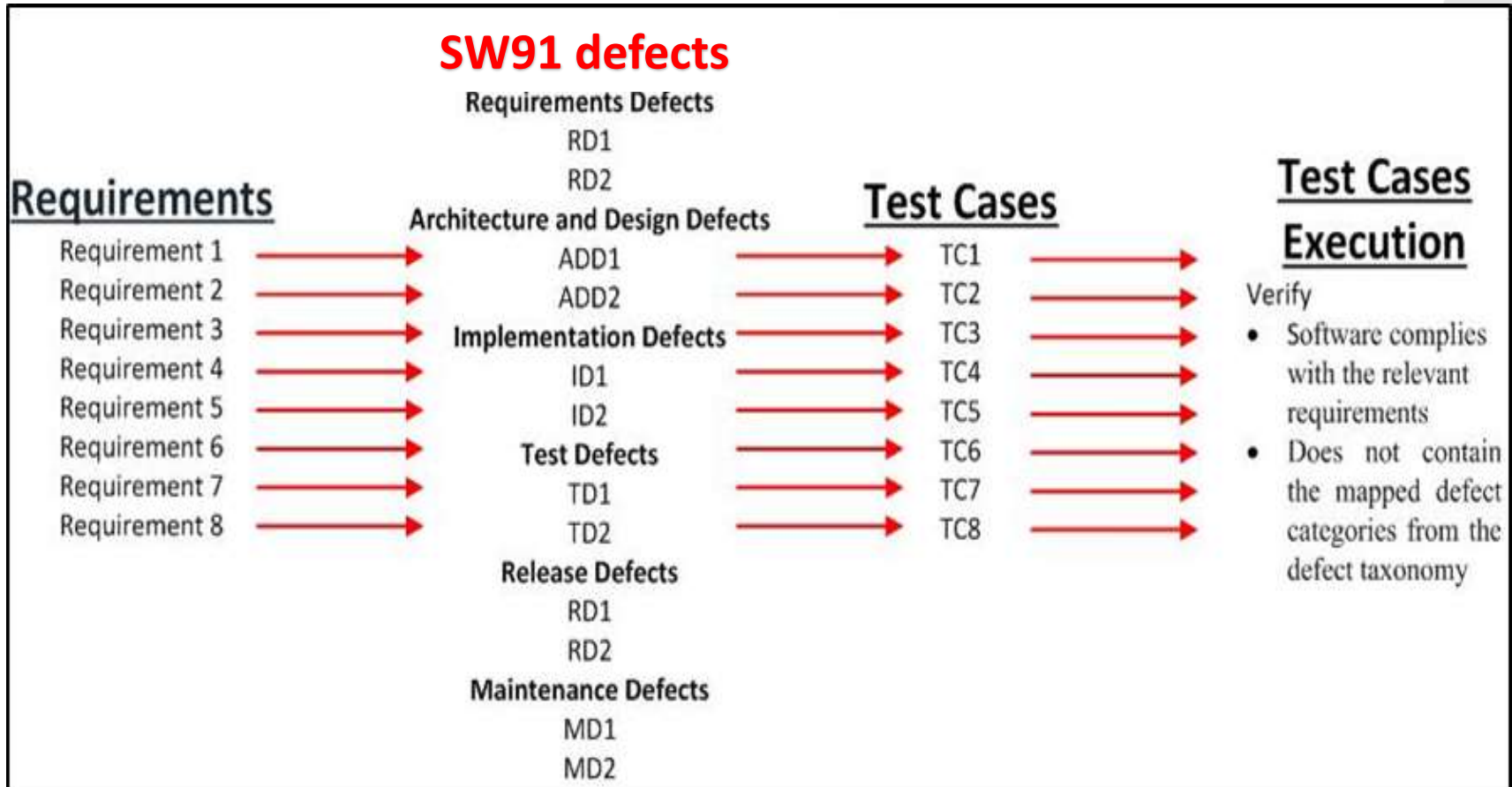
Defect taxonomies in software testing

- Prof. Dr. Michael Felderer
- Benefits of defect taxonomies in testing
 - Early detection of defects
 - Taxonomies can help to brainstorm the test ideas
 - Easy to train the new testers regarding important areas of testing
 - Maximize the test coverage with small number of goal oriented test cases
 - Cost-Benefit and help explain the testing process to management

Taxonomy based testing



Taxonomy based testing using SW91

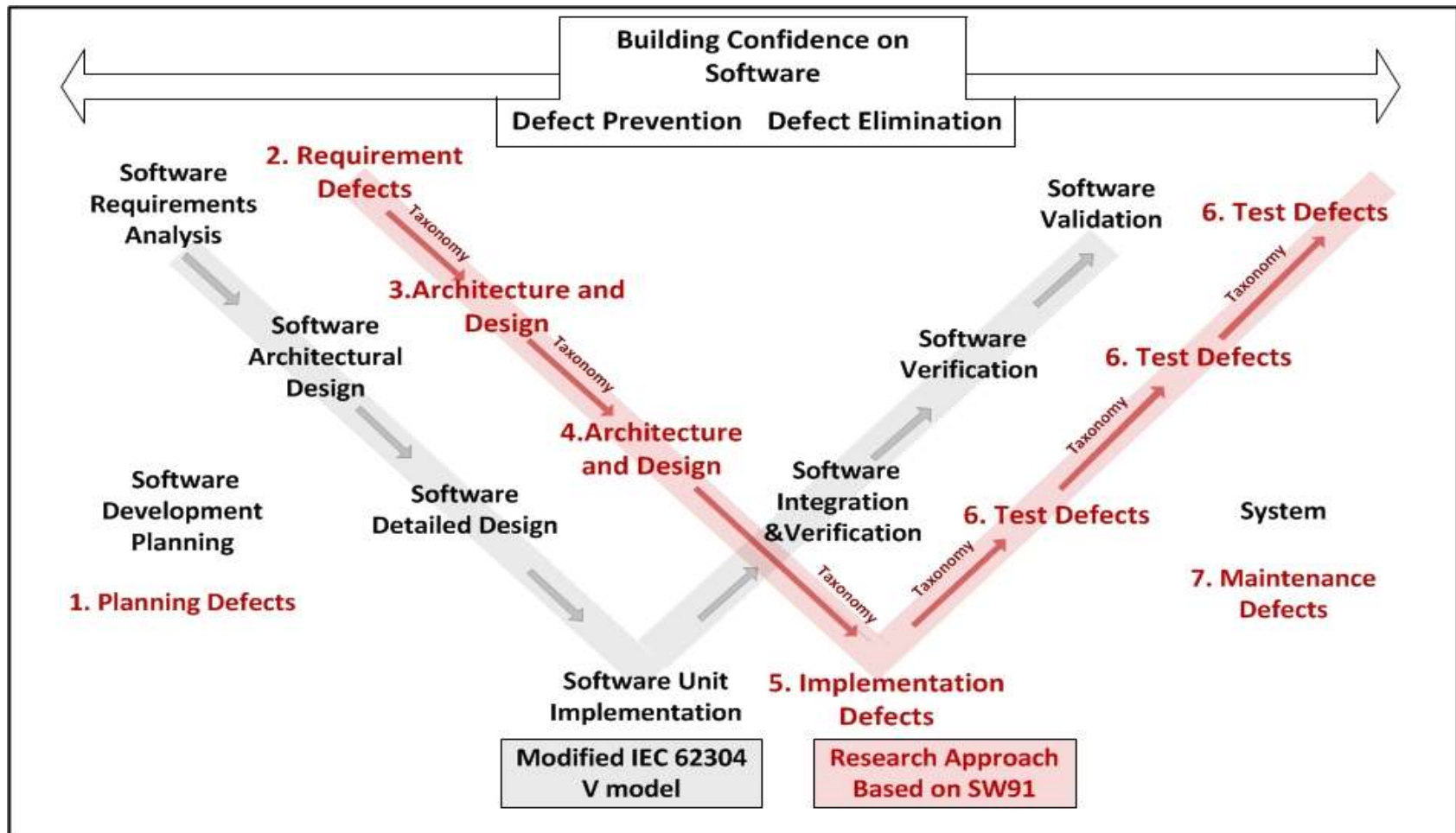


Taxonomy based testing using SW91 and IEC 62304:2006+A1:2015



IEC 62304 Medical device software lifecycle processes	SW91, Classification of Defects in Health Software
Software development planning	Planning (1)
Software requirements analysis	Requirements (2)
Software architectural design	Architecture and Design (3)
Software detailed design	Architecture and Design (3)
Software unit implementation	Implementation (4)
Software integration and integration testing	Implementation (4), Test (5)
Software system testing	Test (5)
Software release for utilisation at a system level	Release Defects (6)
Software maintenance process	Maintenance (7)

Taxonomy based testing using SW91 and IEC 62304:2006+A1:2015



Retrospective study of taxonomy based testing

- An empirical retrospective study of taxonomy based testing was conducted using data from a medical device software development organization, company A
- This study has helped to assess the applicability and the benefits of taxonomy based testing
- Following benefits were observed during the retrospective study of taxonomy based testing :
 - Improved defect reporting at the testing phase
 - Defect minimisation
 - Risk minimisation
 - Root cause analysis

Taxonomy based testing framework development

- Another medical device software development organization , company B from Ireland which provides products and services for connected health was contacted to implement taxonomy based testing
- Company B did not agree to share their data due to concerns about data confidentiality
- Alpha version of the taxonomy based testing framework was written feedback was received
- Feedback on the α -taxonomy based testing framework indicated that, while the approach was recognized to be beneficial, implementation of the α taxonomy based testing framework would require a lot of resources

Steps for taxonomy based testing

Step 1: Review SW91 defect categories



Step 2: Requirements analysis and test phase selection



Step 3: Requirements mapping



Step 4: Writing test cases



Step 5: Test execution



Step 6: Results analysis

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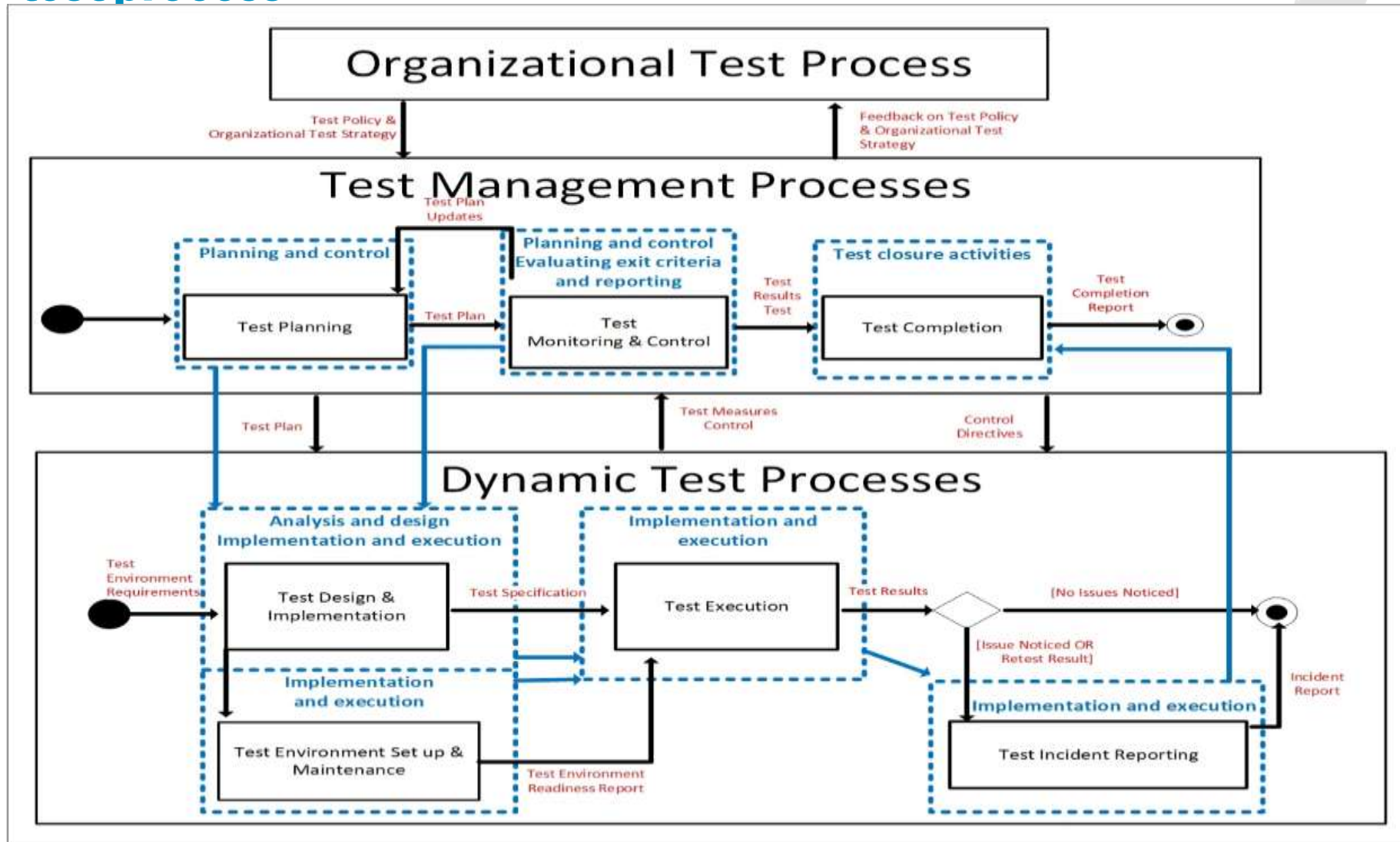
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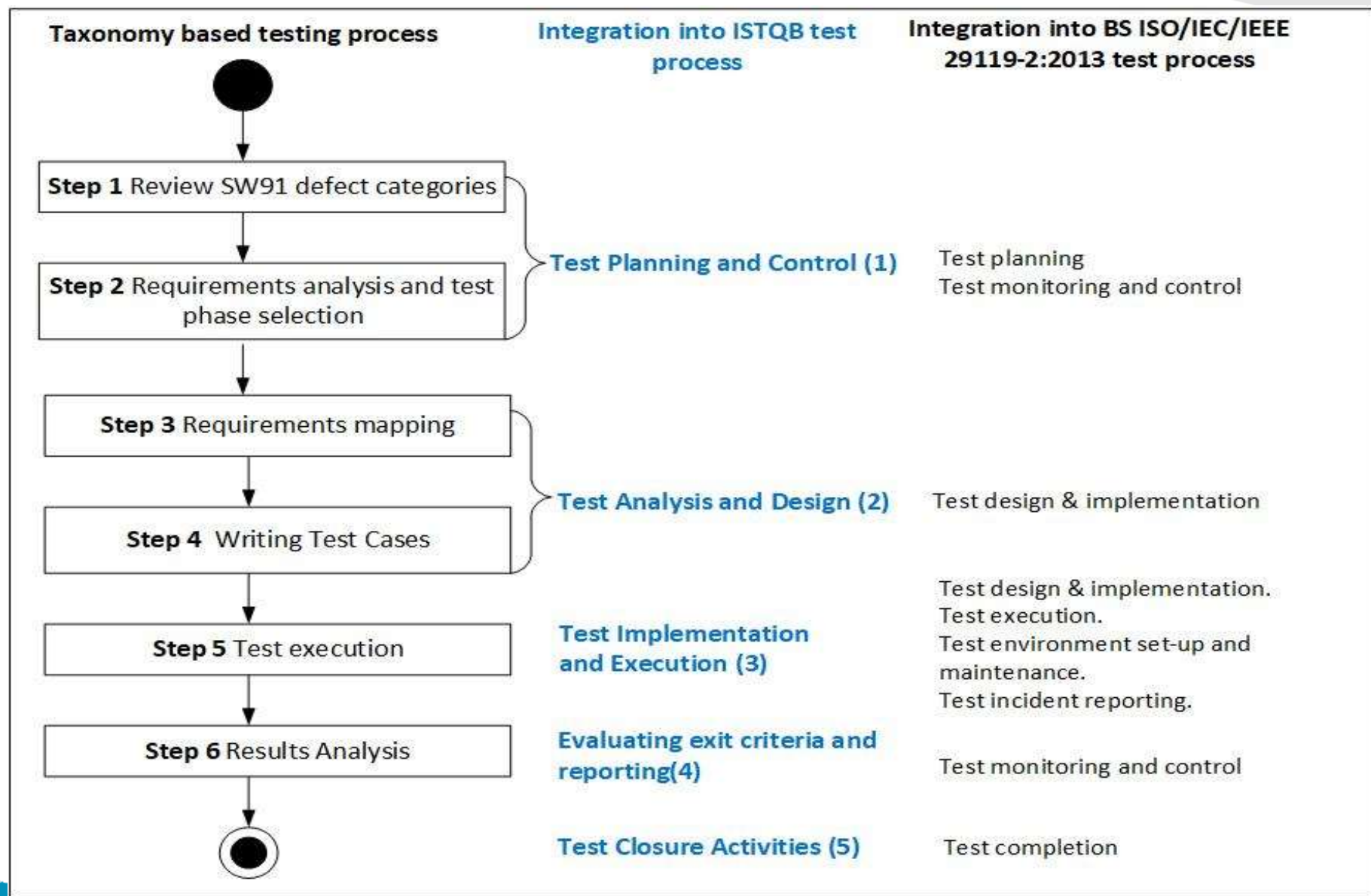
Step 5: Test execution

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Integration of taxonomy based testing into the standard test processes, ISTQB test process and BS ISO/IEC/IEEE 29119-2 test process



Integration of taxonomy based testing using SW91 into the standard test processes



Future work

- Testing techniques and SW91 defects
- Academic experts review
- Industry experts review from two different medical device software companies
- Implementation of taxonomy based testing at two different medical device software companies

Conclusion

- Medical device software defects have resulted in increasing FDA recalls and they have potentially increased the risk of patient injuries including threats to life
- Defect taxonomies are successfully used in software testing
- Taxonomy based testing and retrospective study
- Taxonomy based testing framework
- Integration of taxonomy based testing into standard test processes
- Future work



Thank you

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