CMPUT 605

Ethics in the Software Development Life Cycle: A Case Study of Health Informatics Systems

Hamman Samuel
Dr. Osmar R. Zaïane
Dr. Dick Sobsey

February 4, 2010

Review of Last Meeting

- Look at FDA document
- Other literature found

Summary of FDA Document

- Purpose
  - Software defects and recalls/corrections
  - Minimize software errors/failures
  - Life cycle and risk management
- Outcomes
  - Less risk to patients and users
  - Reduced liability to manufacturers
  - Reduced costs
- Software validation
  - Requirements and specifications
  - Plans and procedures
  - Activities and tasks
- Objective supporting evidence
  - Independent validation versus self-evaluation

Life Cycle Activities

- Quality planning
- Requirements
- Design
- Coding
- Testing
- Installation
- Maintenance

Quality planning

- Plans and procedures for ensuring quality, acceptance criteria, risks and assumptions

Requirements

- Identify and document intended use, inputs, outputs, constraints, defaults
- Requirements are consistent, measurable, and verifiable

Design

“The software design needs to address human factors. User error caused by designs that are either overly complex or contrary to users' intuitive expectations for operation is one of the most persistent and critical problems encountered by FDA.”

Coding

- Coding guidelines, documentation
- Traceability analysis for design to code transformations

Testing

- Test plans and test cases

Installation

- Testing on-site
- User training, ease of use

Maintenance

- Corrective, perfective, adaptive
- Revision of all existing plans

Conclusion

- Ethical issues
  - Accuracy
  - Accessibility