## Therac 25

#### Who is accountable for software failures?

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## <u>Outline</u>

What is the Therac-25 ?Consequences of software failure

- Aftermath and accountability
- Stakeholders and key ethical issues
- Comparison to classical engineering field
- Going forward

#### What is the Therac-25?

- Medical linear accelerator used to treat cancer
- Developed by Atomic Energy Commission Limited (AECL)
- Released in 1983
- More computer control
- Safety checks moved from HW to SW

#### What is the Therac-25?



#### What Happened

Possible for computer to lag behind operator orders

Resulted in improper setting

 Focused electrons at full power to a small spot on body

#### **Consequences of Software Failure**

June 1985 to January 1987

- 6 patients received radiation overdose
- 3 died soon after overdose

## Factors Leading to the Failure

- Poor implementation of software engineering principles
  - One programmer lack of review, testing
  - No formal test plan
  - Lack of Human-Computer Interface design principles
  - Fundamental programming errors
  - Reuse of code without verification

#### Factors Leading to the Failure

- Inadequate responses by AECL
- "Pre-market equivalence" approval by FDA
- AECL's use of Fault Tree Analysis

#### Aftermath and Accountability

- FDA / CRPB require Therac-25 units to shutdown until AECL makes satisfactory modifications
  - Software fixes
  - Independent mechanical safety interlocks
- No individuals held accountable
- Legal cases settled out of court

## Steps Taken to Alleviate Future Occurrences

FDA adjusts policies to address

- Communication with medical centres
- Product approval

 1990 – health-care facilities required by law to report incidents to manufacturer and FDA

#### **Stakeholders**

- Atomic Energy Commission Limited
- Programmer
- FDA (public)
- Machine operators
- Patients
- (Software) engineering profession

## Key Ethical Issues

Engineer's responsibility to the company vs. the consumer (public)

- Engineers shall be honest
- Engineers shall expose risks openly to supervisors
- Engineers shall hold paramount the safety, health, and welfare of the public in the performance of professional duties

Accountability with respect to computing

# <u>Comparison to Classical</u> <u>Engineering Field</u>

Registered professional engineer would have risked losing license due to

- Inappropriate action to ensure public welfare and safety
- Ethical principles
  - Engineers shall expose risks openly to supervisors
  - Engineers shall participate in a lifelong learning process regarding the practice of their profession
- More difficult for accountability
  - Many parties involved in development
  - General acceptance of errors in software

## Going Forward

Safety-critical software requires rigorous testing and failure analyses

- Education and recognition of software engineers
- Society will require us to take responsibility for what we build

#### <u>References</u>

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## **Questions / Comments ?**