Application of Industry best Practices to the Acceptance and Commissioning of Linear Accelerators

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Learning Objectives

- Lessons from industry best practices as they relate to acceptance and commissioning
- Concepts behind risk management at the design and systems integration levels
  - New directions in risk assessment
  - Examples of when things go wrong
  - Lessons to be learned

What are Industry best Practices?

- Cross industry boundaries
  - Tracking – FEDEX
  - Customization – Restaurant
  - Individual care - Hotels
- Not all best practices are appropriate
  - Construction
    - Structural vs. Radiation safety
  - IT priorities
    - Access, Privacy, Integrity (Highest to Lowest)

So you have a new accelerator…

Project Management

Physicist?

- Construction — *Vendor*
- Installation — *Vendor*
- Acceptance — *Physicist*
- Commissioning — *Physicist*
- Design / Integration — *Vendor*

Should physicists be project managers?

- Pros
  - Expertise in the technical aspects of the project
  - Risk adverse and pro safety
  - Maximum control
- Cons
  - Time consuming / Opportunity cost
  - Expensive
  - Minimal opportunity to gain experience
  - Lack project management skills

Construction / Installation

- Normally vendor managed
- Hard to correct after the fact
- Trust no one!
  - Eg. Missing walls, garbage, wrong density etc

Project Management

- Recommendations from Civil Engineering:
  - Role for medical physicists as consultants specializing in installations
  - Various certifications / training available – PMI

Acceptance

- Comprehensiveness?

  "Software is allowing us to build systems with such a high level of interactive complexity that potential interactions among components cannot be thoroughly planned, anticipated, tested or guarded against."

  Nancy Leveson

- Source?
  - Vendor or user
  - Eg. All Therac 25s passed acceptance
- Final responsibility?
  - Vendor or user
  - Eg. MLC driver

Therac 25

- Description:
  - June 85 – Jan 87, 6 patients massively overdosed
  - First linac to be totally computer controlled
    - Mechanical interlocks replaced
    - Indpt. protective circuits removed
  - Turntable position was not always confirmed
- Failure:
  - Design failure, adaptation (wrt design and use)

MLC Driver

- Description:
  - During an upgrade to the 4DTC the MLC driver was not upgraded.
  - Unit passed acceptance.
  - MLC driver would not recognize MLC shapes associated with gantry angles <0
  - No interlocks were triggered
  - 16 SRS patients were mistreated
- Failure:
  - Design failure, failure to comply with upgrade procedure (adaptation)

Acceptance

- Comprehensiveness?

  "Software is allowing us to build systems with such a high level of interactive complexity that potential interactions among components cannot be thoroughly planned, anticipated, tested or guarded against."

  Nancy Leveson

- Source?
  - **BOTH Vendor and User**
  - Eg. All Therac 25s passed acceptance
- Final responsibility?
  - **BOTH Vendor and User**
  - Eg. MLC driver

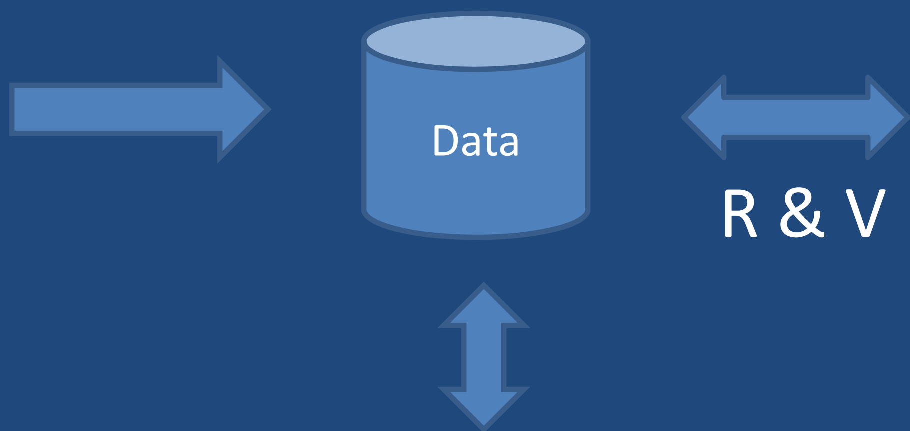
Commissioning

- Recommendations from Industry
  - Don’t do it – standardize instead
  - Eg. Containerization, guns
- Benefits – LINAC Outputs
  - Able to transfer patients
  - Faster installation to treat time
  - Differences between units become obvious

Integrated System

IT / Admin

Imaging



R & V

Delivery, Imaging

Planning

Vendors

Users

System Issues

- Year 2000
- Time Synchronization
- Computer Viruses
- Network offline, DNS offline
- IS policies / procedures
  - New password policies
  - Real-time virus scanning
  - OS patches
  - Encryption etc
- Change management
  - Firewalls

Design

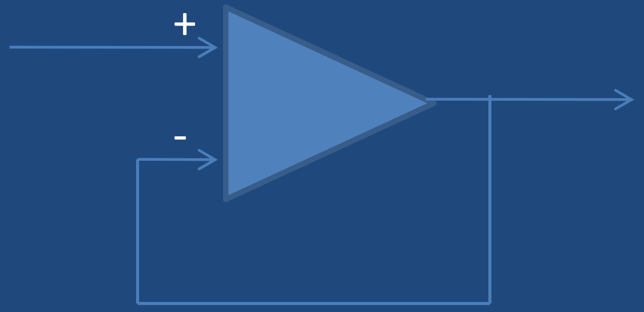
- No room for complacency
- Improved partnership needed between vendors/users
- Need for independent design reviews
  - Identify single points of failure
  - Identify conceptual design flaws

Single points of failure

- Currently single points of failure exist that can:
  - x3 max runaway gantry rotation
  - x3 max runaway couch vertical
  - >15% electron asymmetry
  - Unknown positioning of:
    - X jaw
    - Colliminator angle
    - Couch angle, vert. lat. and long.

Conceptual design flaws

- Interlocks monitor servos not output
  - Eg 3 Mile Island
- Interlocks differ between service/physics and clinical modes
- Rate of technology development >> measurement of clinical outcomes



Control system
-ve feedback

Current Risk Modeling

- Based on event flow diagrams
- Assume independence of failures
- The Swiss-cheese model
  – holes randomly align

- Appropriate to electro-mechanical systems

New Risk Models

- Need to deal with ‘adaptation’
  - Systems and processes are continually changing towards faster, cheaper, easier…
  - Systematic and conscious optimization process – not random
- Many events have systemic results
  - Power fluctuations
  - Network failures
  - Lack of training/ resources
  - Inappropriate policies
- The Guinness model
  - Bubbles rise to the top

Union Carbide

- Description:
  - Bhopal 1984, history of minor incidents leading to a single major incident, deaths estimated 1,750 – 10,000
  - Cutbacks in staff numbers, training and maintenance
  - Multiple levels of failure: Vent gas scrubber, flare tower, water curtain, sirens, communication
- Failure:
  - System wide adaptation due to cost cutting

DC-10 Cargo Door

- Description:
  - 1974, multiple instances
  - The cargo door appeared to be closed and locked, but would explosively open at altitude.
  - A sizeable section of floor and corresponding control systems failed.
- Failure:
  - Design flaw and inappropriate risk evaluation

3 Mile Island

- Description:
  - 1979, single instance
  - During an increase in reactor coolant pressure a relief value opened but did not close. Indicators showed it had closed. Incorrect decisions were made on the basis of this information.
- Failure:
  - Design flaw – indirect measurement of output

Conclusion

1. Project Management of Linac installation is a specialty
2. Standardization – where appropriate
   – Linacs / Data formats /Treatment protocols
3. Acceptance documents need to be a joint effort between vendors and users, open and transparent.
4. Greater focus on risks associated with integrated systems.
5. Learn from accidents in other industries

References

- “Safeware”
- “System Safety Engineering: Back to the Future”

Nancy Leveson, MIT