Reliability and Uptime in Proton Therapy Accelerator and Beam Delivery Systems; 
*The Need for a Fresh Medical Device Design Methodology.*

*Presented by: Niek Schreuder*

_Provision Center for Proton Therapy,
6450 Provision Cares Way, Knoxville,
TN 37909*_
Outline

• Current systems
• Fail Safe thinking – some misconceptions
• Lessons from the airline industry
• Case Studies
• Down-time Tracking + Management
• New Thinking
Disclaimers

• There is no compromise for

  a) Patient safety
  b) Personnel safety

• Nothing that I propose here should compromise safety

• There is no excuse for an improperly designed System.

• There is no excuse for an improperly tested / commissioned System
Misconceptions in Current Systems

• Incorrect Technical Approaches
  - Fail the system if anything goes wrong / out of tolerance.
  - Let the control systems make all the decisions.
  - Slowing things down improves safety.
  - Limiting functional capabilities improves safety.
  - Proton Therapy systems are more dangerous than X-Ray Systems.
  - The more checks, the more safe the system becomes.

• The safest system is one that does never treats a patient.
The Clinical Medical Physicist’s Perspective on Designing a Proton Therapy System
Misconceptions in Current Systems

• Incorrect Operational Approaches / Paradigms
  - The trained staff’s only objective is to harm the patients or damage the equipment.
  - More emphasis on protecting the equipment rather than finishing the treatment.
  - Proton Therapy systems are more dangerous than X-Ray Systems.
  - Untrained people are operating the systems.
  - Completing a treatment at the scheduled time is less important than fixing the system.
“Fail Safe” thinking

• Great idea but the focus should not be on “FAIL”

• Only “FAIL” the system after a treatment has been completed
  - Delivering a partial treatment is worse than delivering a treatment with a small uncertainty /risk

• Paradigm Shift
  - There are very few things in a radiation therapy system that can harm the patient

• Lets try to list those
  - Over dose – many ways to protect against this.
  - Too high beam current – operational parameters within certain windows.
  - Beam scanned to the wrong position – several redundancies can be implemented.

• Operational risks are much higher
  - wrong dose / # fractions delivered perfectly correct.
  - Treat wrong site / setup errors.
Learning From the Airline Industry

• Never Fail the plane in “Mid-Air”
  - “First land the plane” – get the passengers off – then take the plane to the hanger – fix it

• Preventative + Predictive maintenance

• Redundancies
  e.g. Manual / Pilot emergency landing at the nearest airport
  - the control systems did not prevent the pilot to land on the Hudson River

• Checklists rather than controls systems that are in full control

• Many more
The Radiation Therapy Reality

• Machines are operated by highly trained people

• Nobody wants to harm anybody

• It's very important (clinically and emotionally) to deliver treatments on time.

• Treatment deliveries must be delivered within certain tolerances
  - Systematics errors are bad
  - Random errors often cancel out

• Treatment plans are designed according to certain tolerances

• Fractionated treatments are more forgiving

• Operational risks are much higher
Challenge

• Design a traffic light

• The only way a traffic light can work is for the driver to obey the lights –
  - Red → STOP; Yellow → Clear the intersection; Green → Go

• What is required to drive a car
  - Learn to drive the car + 16 years old
  - Obtain Drivers license
  - Can be done in 3 months

• What is required to treat a patient
  - Rad Onc → 11 years of training + ABR
  - Medical Physicist → 7 years of training + ABR
  - RTT → 3 years of training + ASRT

 Much more that can go wrong
 Much more dangerous

 Systems Don’t allow any user autonomy –
 Safety systems are in control
Control systems are in Full control – Why not?

• Users stop thinking
  - The Computer must be correct (NY Accident)
  - Computers are always correct !!!
  - I cannot do anything anyhow – no user rights / permissions
  - Just going through the motions

• Allow overrides at the discretion of the trained user
  - Overrides expire automatically – time window depends on the risk
  - *This will allow to land the plane and take it to the hanger*
Limiting Capabilities improve safety

- **Allow only one motion at a time**
  - Current systems allow you to crash the systems –
    a) At slow speed
    b) One at a time

- **Multiple motions should be allowed**
  - Move as many things as the user can control
  - This will automatically attract undivided attention from the operator

- **IF the RTT Could move the Patient Positioner while the gantry is rotating this would not have happened**
- **Commercial linear Accelerators allow simultaneous motions**
- **Let the trained and responsible staff decide what is safe**
Slowing things down improve safety

• The user needs to multitask to get things done in time.

• Does other things instead of keeping an eye on the patient and equipment.

• Let the trained and responsible staff decide what is a safe speed of motion.

• **NOTE:** there is nothing wrong with sensible warnings and alerts, but disallowing things that are potentially safe and that will improve efficiencies is the problem
More Checks are More Safe?

- Checklists should not have more than 7 things to check.
- Rather focus on the 7 top and most important things than checking 25 less important things.
- Human nature states that “The more checks you have, the less important the initial checks / screening checks become.”
  - Someone will catch it at the bottom of the waterfall.
- The more unnecessary check there are, the more unnecessary failures can occur.
New Thinking

- FMEA must be done with the emphasis on completing a treatment
- Use a flagger – road works ahead
  - Something is not right
  - Take extra care
  - Cross check – not all the checks are in place
- Allow conditional overrides for all Interlocks that can be verified with at least one other method / tool
  - Visually / inspection
  - Mechanically
  - Optically
  - Audibly
New Thinking

• Modular Design Approaches
  - Faster / more efficient trouble shooting.

• Treatment rooms should be independent from each other
  - Software Upgrades are easier.

• Efficient Trouble shooting is as important as Reliability
  - Things will break – BUT - How quick can you recover
  - Efficient trouble shooting will reduce downtime
Use cases

• **X-Ray panels do not retract**
  • The protons never go through the patient
  • Shield the panel for flash beam

• **PPS goes unhealthy during a treatment**
  • Stop and verify that the patient is still in position
  • Appoint a flagger

• **Scan beam parameters are marginally out of tolerance**
  • Increase / override the tolerances to a next level
  • Tolerances reset automatically after the beam has beam delivered

• **Non Critical Inter system communication errors**
  • Verify that things are still good
  • Record data manually
  • Appoint a Flagger
Down-Time tracking / Management

- Technical Down-time vs Clinical Downtime
- A short technical down-time can easily lead to a large clinical downtime

  - Patient ready to treat → need to take patient off the table due to a problem
  - Fix the problem
  - Treatment start from scratch again → Large clinical down-time
The frequency of a problem is a bigger issue than the duration.
Ideal Definition → % of patients treated as scheduled.

Typical Definition → System is available as scheduled per the contractual agreements.

More than 98% uptime is desired

Less than 96% uptime – things become extremely painful

- Staff morale ↓
- Patient satisfaction ↓
- Clinical care is compromised
Conclusions

• Proton Therapy Systems are not more dangerous than X-Ray Therapy Systems.

• Proton Therapy Systems must be designed according to the same operational principles and safety guidelines as X-Ray Therapy Systems.

• Slowing things down and limiting functionalities does not improve safety.

• Completing a patient treatment must take priority over shutting the system down for repairs.

• Treating patients as scheduled is clinically and emotionally very important.