Safety in Radiation Therapy
Varian’s Perspective

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Varian Medical Systems, Inc.
All of us must work together to improve safety

Clinicians

Regulators

Manufacturers
Overview

- What does Varian do today for safety?
- The Radiotherapy process is complex, and is evolving
- How should the safety model evolve?
- What do we recommend?
What Varian does today

- Risk Analysis
- Current product feedback
- Clinician input
- Design control
- Pre-clinical checks
- Verification and Validation testing
- Regulatory clearance
- User training
- Post-market surveillance
Varian Design and Development Process

- Development Planning
- Design Input
- Design Review
- Design Output
- Design Verification and Validation
- Release
- Post-market Surveillance

510k clearance
Varian Design and Development Process

Significant Clinical Involvement – Closed Loop Process

- Development Planning
- Design Input
- Design Review
- Design Output
- Design Verification and Validation
- Release
- Post-market Surveillance

Advisory Boards
Clinical Councils Focus Groups
Clinical Councils
Customer Based Testing Clinical Consultants
User Groups Publications Improvement Requests Complaints

510k clearance
Design & Development Process is Extensive

**TrueBeam 510k**

- Design Description
  - 100 pages
- Risk Analysis
  - 400 pages
- V&V test records
  - 1,500 pages
Total for review
- 3,500 pages
Customer Inputs Prior to 510k Submission

RapidArc Council

- 11 sites
  - University of Alabama, Birmingham
  - University of Massachusetts
  - D3 Radiation Oncology Planning
  - Palo Alto Medical Foundation
  - MIMA, Melbourne, FL
  - British Columbia Cancer Authority
  - Rigshospitalet, Copenhagen
  - VUMC, Amsterdam
  - Oncology Institute of Southern Switzerland
  - Universität Zürich
  - Montpellier University Hospital

- 3 years and over 20 non-clinical versions
- > 500 feedback items in 41 reports
- > 20 publications on implementation, QA and cases
Current Education and Support Programs

Blended Learning Approach
- Classroom
- Remote
- On Site

Tools and Benefits
- Training Checklists
- CME Accredited Courses

Our People
- Medical Physicists
- Medical Dosimetrists
- Radiation Therapists

Post Training Support
- Clinical Helpdesk
- Remote Assistance
Active Post-market Surveillance Process

- Clinician interviews
- Advisory Board review
- Literature reviews
- Blog postings
- Medical meetings
- Customer Satisfaction Surveys
- Product Improvement Requests
- Complaints
- Help Desk trends
- Risk Management reports
- Product Quality records
The process is complex, but the objective is not:

**Goal**
- Increase patient survival
- Minimize side effects

**Solution**
- Deliver the *right dose*
- Deliver it to the *right site*
- To the *right patient*

**Constraints**
- Minimize impact on the patients’ lives
Modern Radiotherapy Process

- Diagnostic imaging
- Treatment prescription
- Target definition
- Treatment planning
- Plan review & approval
- Pre-treatment QA
- Setup verification
- Treatment delivery
Compounding trends in Radiotherapy

**IMRT**
- Complexity → Patient QA to validate plan
- Dose conformity → Position QA (IGRT)

**Hypofractionation**
- High doses → Low margin for error
- Small targets → Position QA (IGRT) essential

**Adaptive Radiotherapy**
- Frequent changes → Complicates Patient QA
- Needs Process QA

**Software and Automation**
- Separates operator from process
- May reduce margin for error
Why are there errors?

- Collaboratively developed treatment strategy
  - Multiple steps, multiple users, multiple devices
- Our equipment is used ~ 30M times annually
  - How can we reduce error below 1 : 1,000,000?
- Consider a process of 50 discrete steps:
  - \((99.9\% \text{ fidelity})^{50} \rightarrow 95\% \text{ correct treatments}\)
  - \((95.0\% \text{ fidelity})^{50} \rightarrow 8\% \text{ correct treatments}\)
- Must consider the entire RT Process
Safe and Effective Treatments

- Perfect treatment requires
  - Perfect Process
  - Perfect Execution
  - Perfect Products

- Relying on perfection is an imperfect strategy
  - QA each step
  - QA entire process
  - QA just before any new treatment
Modern Radiotherapy Process

Right PATIENT, Right SITE, Right DOSE …

QA process must address all three elements

Clinics must follow their QA process

Process QA is important
Process QA via a checklist

- Requires a change to current clinical practice
  - Other medical specialties have adopted “time-out” to resolve all concerns before beginning a procedure
  - E.g. The Universal Protocol
- Can be implemented manually initially
  - Simple pen and paper approach is workable
- Can be implemented within the devices eventually
  - Better compliance and auditing
  - Streamline checklist process
Checklist as a “time-out”

**User Configurable**
- Optional
- Content pre-defined far from the line of fire
- May be used at any point in the process
- Context specific

**Rules-Based**
- Checks may be manual or automatic
- Can enforce mandatory completion before process can advance to next stage
- Reinforces adherence to clinical best practice

**Risk-Adjusted**
- Sign-off levels commensurate with complexity or risk of procedure
- Different checklists for different techniques
- More details for more complex treatments
Checklist as a “Time-out” in Radiotherapy

- Complements existing QA methodologies
  - Should increase compliance with current practice
- Can be implemented at key points in the clinical process
  - More details for more complex or risky procedures
- Can be implemented within the RT software
  - Makes it more practical
Just before treatment:

Three elements needed for correct treatment

1. Right PATIENT
   - Verify Patient ID

2. Right SITE
   - Verify Patient Position

3. Right DOSE
   - Verify and Validate Dose
Suggested Additional Safety Improvements

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<td>• Tx Mode-specific “Sanity checks”</td>
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<td>• Time-out before 1st Tx</td>
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Safe and Effective Treatments

- Is a collective responsibility
- Together we must define the right strategies to cure more patients
  - Right Patient
  - Right Site
  - Right Dose

Clinicians
Regulators
Manufacturers