
## W9

Compliance
Wednesday, October 23rd, 2019 1:30 PM

# Safety-Critical Software the Quality Agilist's Way

**Presented by:**

## Roy Tuason

**Zap Surgical Systems**

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# Roy Tuason

Roy Tuason is director of SQA Engineering for Zap Surgical Systems and holds a degree in applied mathematics and computer science. He has over twenty years of medical device experience, including quality engineering and regulatory compliance in the cancer fields of stereotactic radiosurgery, chemotherapy administration, and oncology information systems. As a quality assurance manager and certified SPC (SAFe Scaled Agile Program Consultant) he guided international development organizations transitioning to the scaled agile framework. Prior to this he was a Gunnery Sergeant and Operations Chief for 155 artillery fire direction control in the Marine Corps.

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## Overview

1) Brain Cancer, Tumors, Treatment
2) Gamma Knife, CyberKnife, Zap-X
3) The Software Development Problem
4) The Solution: Process, and Regulatory Compliance
5) Audits and Inspections
6) Lessons Learned, and Keys to Success

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## Presenter: Roy Tuason – SW test engineering, medical devices

- US Marine Corps: ANGLICO/special ops, artillery FDC, platoon sergeant
- Lab technician, advanced composites, polymers, phenols/phenolics
- Motorcycle safety instructor
- Restaurant manager
- UPS truck loader (40-foot trailers)
- America's oldest newspaper, The Hartford Courant
- SW test engineering, system testing, medical device quality assurance (regulatory)
  - SW medical devices, oncology information systems, radiation treatment
  - Laboratory software, information systems (clinical and pathology labs)
  - Chemotherapy software, administration and charting
  - DNA software – SNP analysis; PCR instrumentation
  - Military hardware & software satellite orbital determination, orbital planning
- Certified Scaled Agile SPC; agile transformation, from waterfall model

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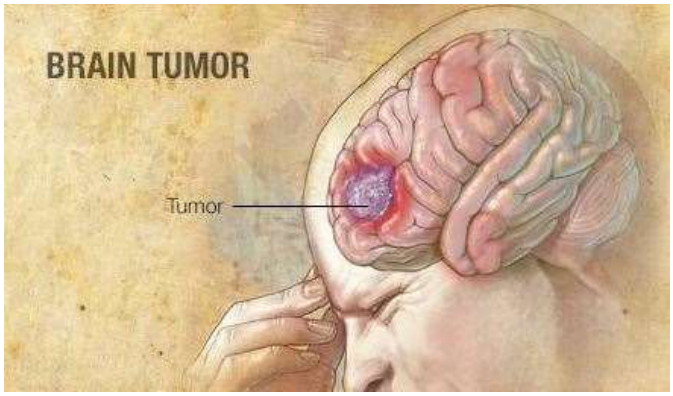
## Brain Cancer, Tumors, Treatments

An ugly disease

- ≥ 700,000 North Americans
- 70% benign
- 30% malignant
- 35% survive
- Glioblastoma, most common
- 30,000 children




2019:

- ≥ 85,000 primary dx
- ≥ 15,000 deaths

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## Brain Cancer, Tumors, Treatments

- 1879: first successful surgical removal of brain tumor
- 1898: Marie Curie discovers polonium, radium
- 1900-1950: different brain tumor types are discovered and characterized; continues
- 1940s: Medical linacs are developed
- 1958: Dexamethasone first synthesized
- 1950s, 1960s: Cobalt-60 ($^{60}$Co)
- 1968: 27 Jan, Stockholm, first tx Gamma Knife [mfr Elekta, Stockholm SWE]
- 1971: CT; planning and txs shift from 2-D to 3-D
- 1973: American Brain Tumor Association founded; national nonprofit
- 1978: first MRI of human brain
- 1988: CBTF

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## Brain Cancer, Tumors, Treatments

- 1989: gene therapy
- 1994: Stanford USA, CyberKnife tx, [mfr Accuray, Sunnyvale USA]
- 1994: first study at 3.0 T (1998, 8.0 T)
- 1997: first laser system to treat brain tumors
- 2000s: LITT
- 2005: Cancer Genome Atlas Project
- 2006: Astrocytoma
- 2010: 9 genes predict likelihood
- 2018: 25 Aug, Phoenix USA, Arizona Senator John McCain; glioblastoma
- 2019: 24 Jan, Phoenix USA, Zap-X tx [mfr Zap Surgical, San Carlos USA]
- 2019: 29 Aug, Phoenix USA, Zap-X tx [mfr Zap Surgical, San Carlos USA], pt #25

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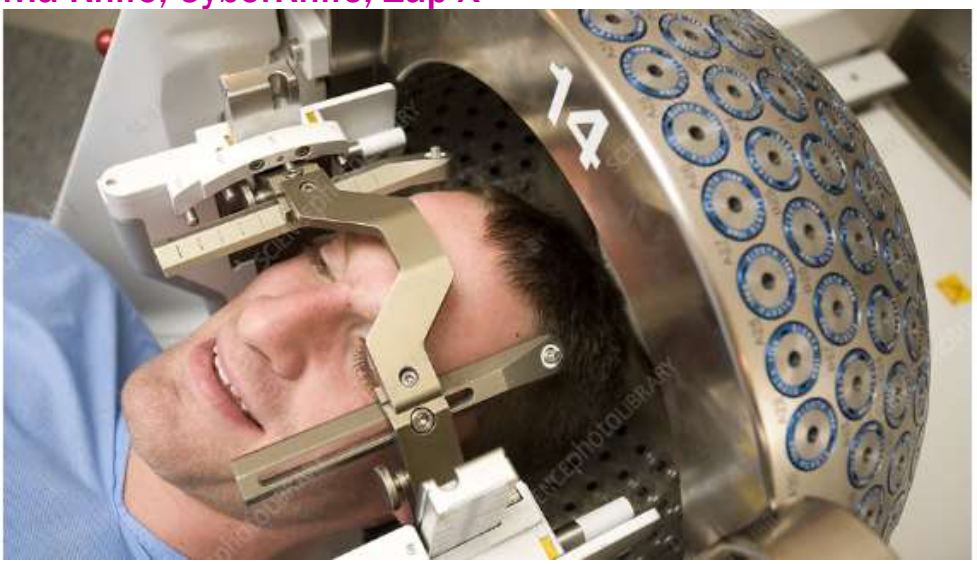
## Gamma Knife, CyberKnife, Zap-X



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## Gamma Knife, CyberKnife, Zap-X

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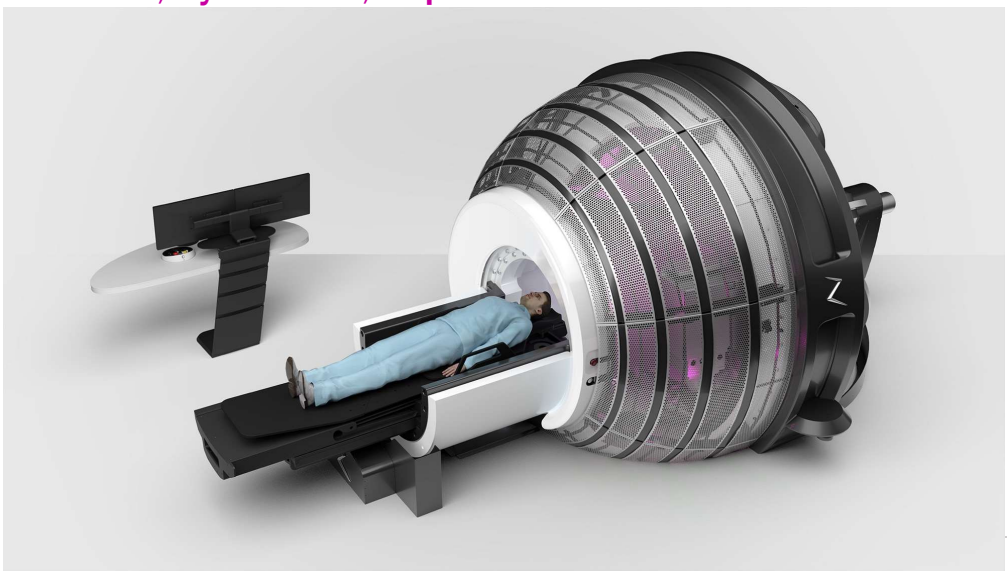
## Gamma Knife, CyberKnife, Zap-X



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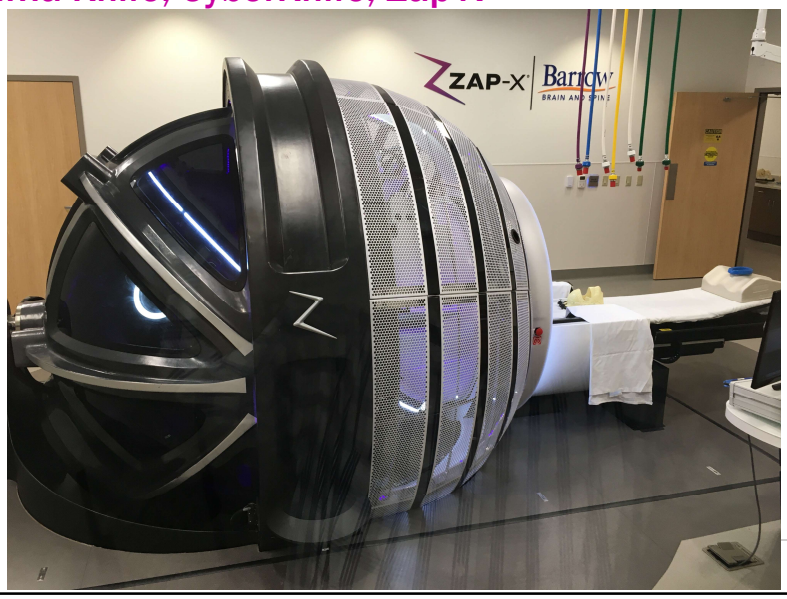
## Gamma Knife, CyberKnife, Zap-X

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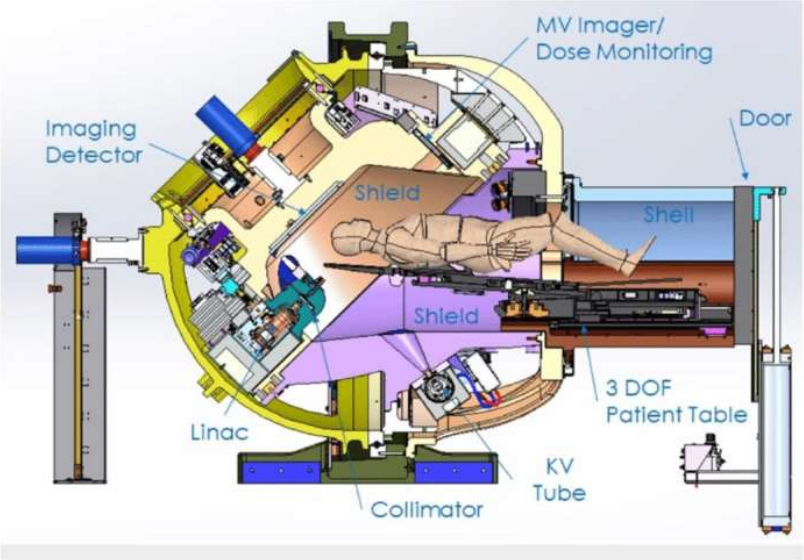
## Gamma Knife, CyberKnife, Zap-X



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## Gamma Knife, CyberKnife, Zap-X

- Zap-X differentiators
  - Self-shielded (compare – Gamma Knife, CyberKnife)
  - No Cobalt-60 ($^{60}$Co) (compare – Gamma Knife)
  - Brain surgery (compare – CyberKnife)
  - Smaller (compare – Gamma Knife, CyberKnife)
  - Significantly lower cost (compare – Gamma Knife, CyberKnife)
- Zap-X illustration (1:30 animation): https://tinyurl.com/e7t-zap01
  - Overview of self-shielding, and SRS (stereotactic radiosurgery)
- TV news, 1st-ever Zap-X patient treatment (2:30): https://tinyurl.com/e7t-zapNewsFPT
  - After 7 prior brain surgeries: “It almost seems too easy”, and, “A piece of cake.”



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## The Software Development Problem

- Zap Surgical software products: Tx Planning and Delivery (TPS, TDS)
- Agile cadence: staggered 2-week sprints with releasable increments (PSIs)
- Quality System history: consultants, “canned” modified; purchased
  - Comprehensive Quality System, comprehensive SOPs
- Separation from QS consultant
  - Zap Surgical hires VP RA/QA, creates department
  - “Learning to Crawl”
- Monolithic SW Release Process
  - Extensive, comprehensive documentation requirements
  - Release Authorization form has 67 deliverable items

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## The Software Development Problem

Stage I – Planning
Change Purpose
Market Release
Design Control Release
Change Category
SW
HW
Manufacturing Process
Change Identification
SW Items, Change Descriptions, Reasons
HW Items, Change Descriptions, Reasons
Change-related References
Activities
Revised controlled documents
SRSs
PRs (Test Protocols)
Test Protocol, Validation
Risk Management
Change Verification: choose from
Design Review
Code Review
Verification Tests
Standard Compliance Tests
Validation Tests
Usability Tests
SW/HW Traceability Matrix
Other(s)
Initial Risk Assessment
Applicable Hazard IDs
SW Test Plan
Substantive Change Assessment
Stage I Approvals
Stage I Initiator
Quality Assurance
Regulatory Affairs
Engineering
Clinical
Program Management
SQA Engineering
Stage II – Implementation, Test, Release
Activities Performed
Documents Modified by this Change
SW Revision History
TPS Open Anomalies List
TDS Open Anomalies List
Customer Release Note
SW Forms to identify the SW Modules
TPS
TDS
TDCS
DB Broker
Verification Activities
Updated and approved PRs
Test reports for same
Final Risk Assessment
Regulatory Submission Assessment
Attach the assessment flowchart with conclusion
Stage II Approvals
Stage II Initiator
Quality Assurance
Regulatory Affairs
Engineering
Clinical
Program Management
SQA Engineering

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## The Solution: Process, and Regulatory Compliance

- Identify objectives
  - Fast SW releases enabling rapid customer responses as needed
  - Safe, effective, clinical applications
  - Not released to manufacturing

- Create SOP: improvise, adapt, overcome
  - "Minor" change: no new specifications, or changes to risk file or labeling
  - A new 'delta doc' to capture changes to SRS, test PRs, risk, trace (DMR, DHF)
    - Identifies changes, planned testing, initial risk assessment
    - Two Design Reviews: Planning, and Release
    - Becomes the report for testing and final risk assessment
  - Harmonize with Quality System
  - Success!

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## Audits and Inspections

- Implementation before plan approval
- Test protocols not approved before testing
- Test methodology, sample sizes not identified
- Risk Management File not updated
- SOPs inconsistent, not harmonized
- Test Summary statement with Conclusion not provided
- No SOP describing how to perform verification testing



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# Lessons Learned, and Keys to Success

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October 2019

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## Lessons Learned, and Keys to Success

- Clear objectives
- Own the process
- SOPs are living entities
- Close, positive, regular collaboration between Dev and SQA
- Collaborate assertively with Quality (RA/QA)
- Know your stakeholders
- Divide and Conquer
- Inspect and adapt
- Focus on accuracy and correctness before speed
  - The speed will come

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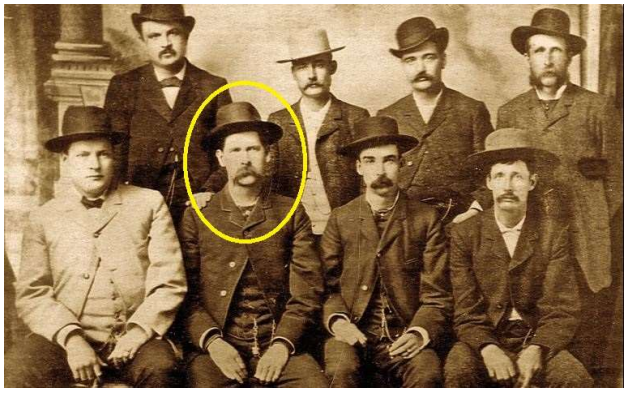
## Lessons Learned, and Keys to Success



1883 – The Dodge City Kansas Peace Commission

Wyatt Earp circa 1887

"Fast is fine, but accuracy is final." – Wyatt Earp (1848 – 1929, Monmouth IL – aged 80, Los Angeles; Dodge City KS, Nome AK)

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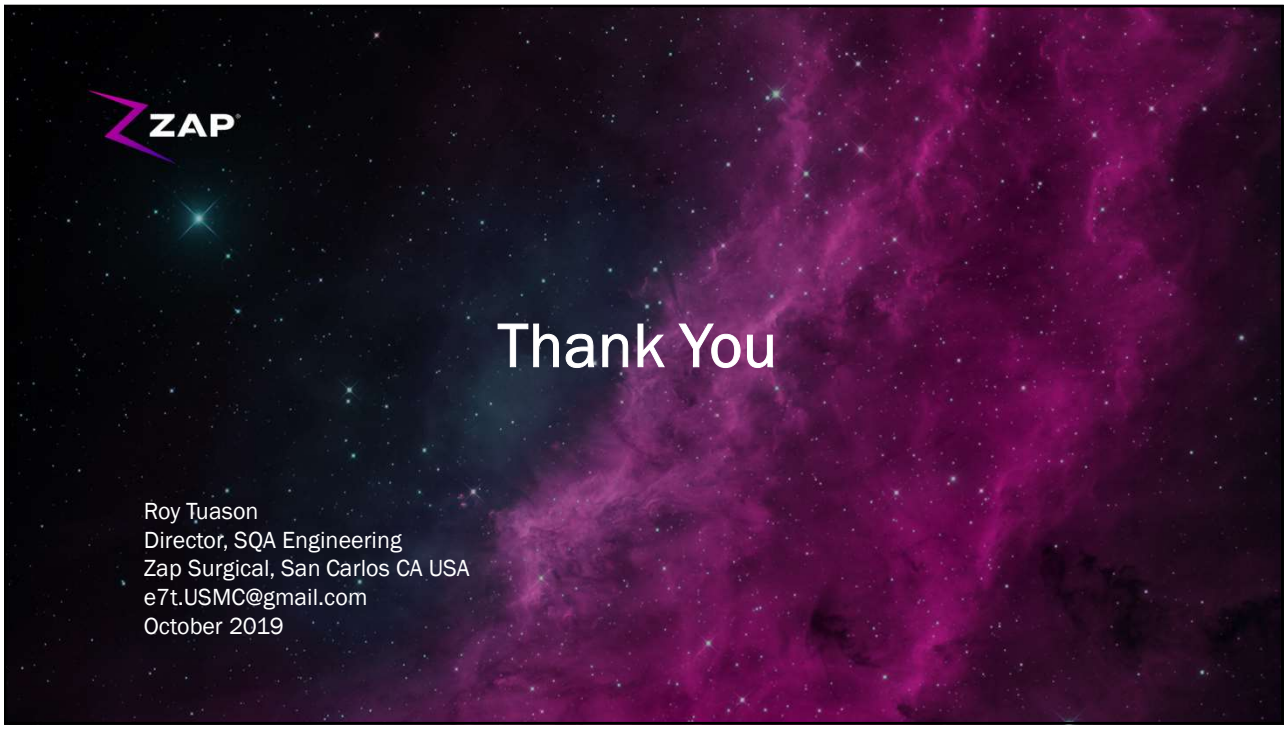
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Thank You
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