Radiation Therapy Safety

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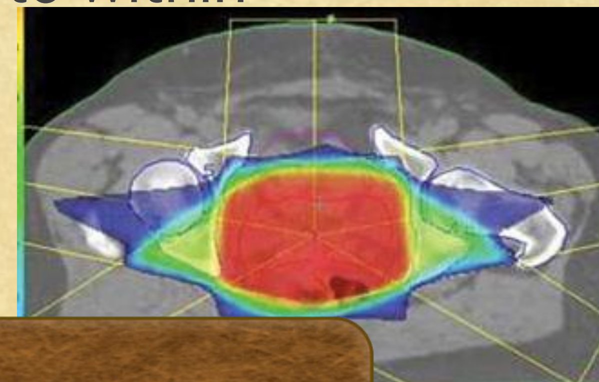
Thanks to Jeff Williamson, Mike Steinberg, James Purdy

Radiation Therapy

- 1.6M new cancer cases this year in US
- Approximately 60% of cancer patients receive radiation therapy during the course of their disease
- Half of them are for curative intent

Goals

- Deliver radiation prescription dose to within absolute 5% & 5mm

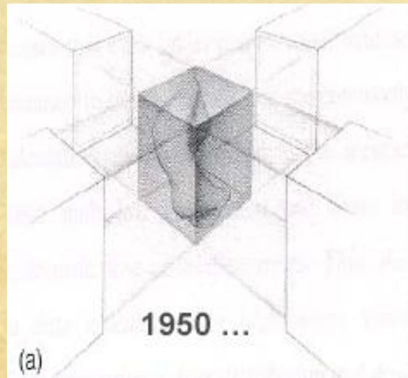


CT Simulation → Treatment Plan

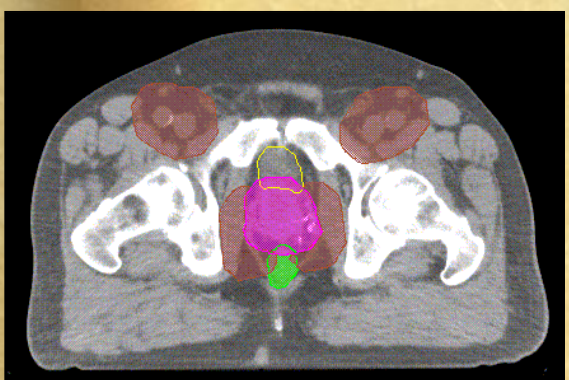
↓

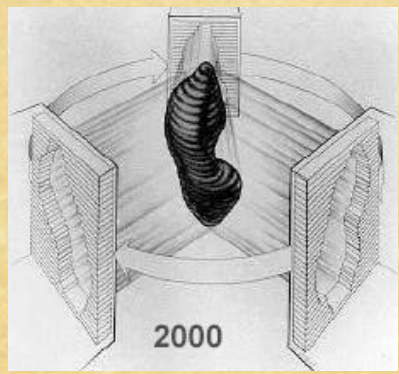
Treat Patient ← Position Patient

Why is the Present More Challenging than the Past?

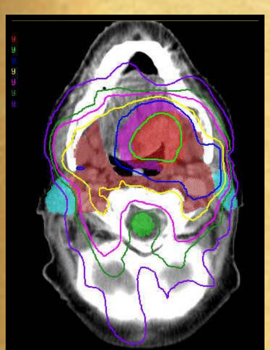


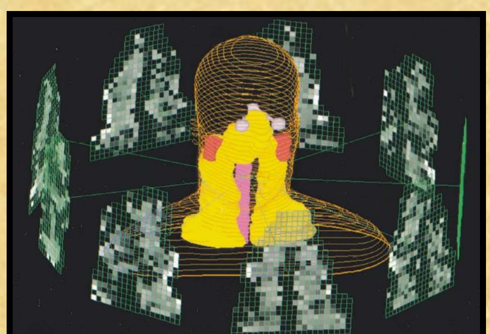
- 2D RT:1950-1985
  - 2D x-rays for planning RT



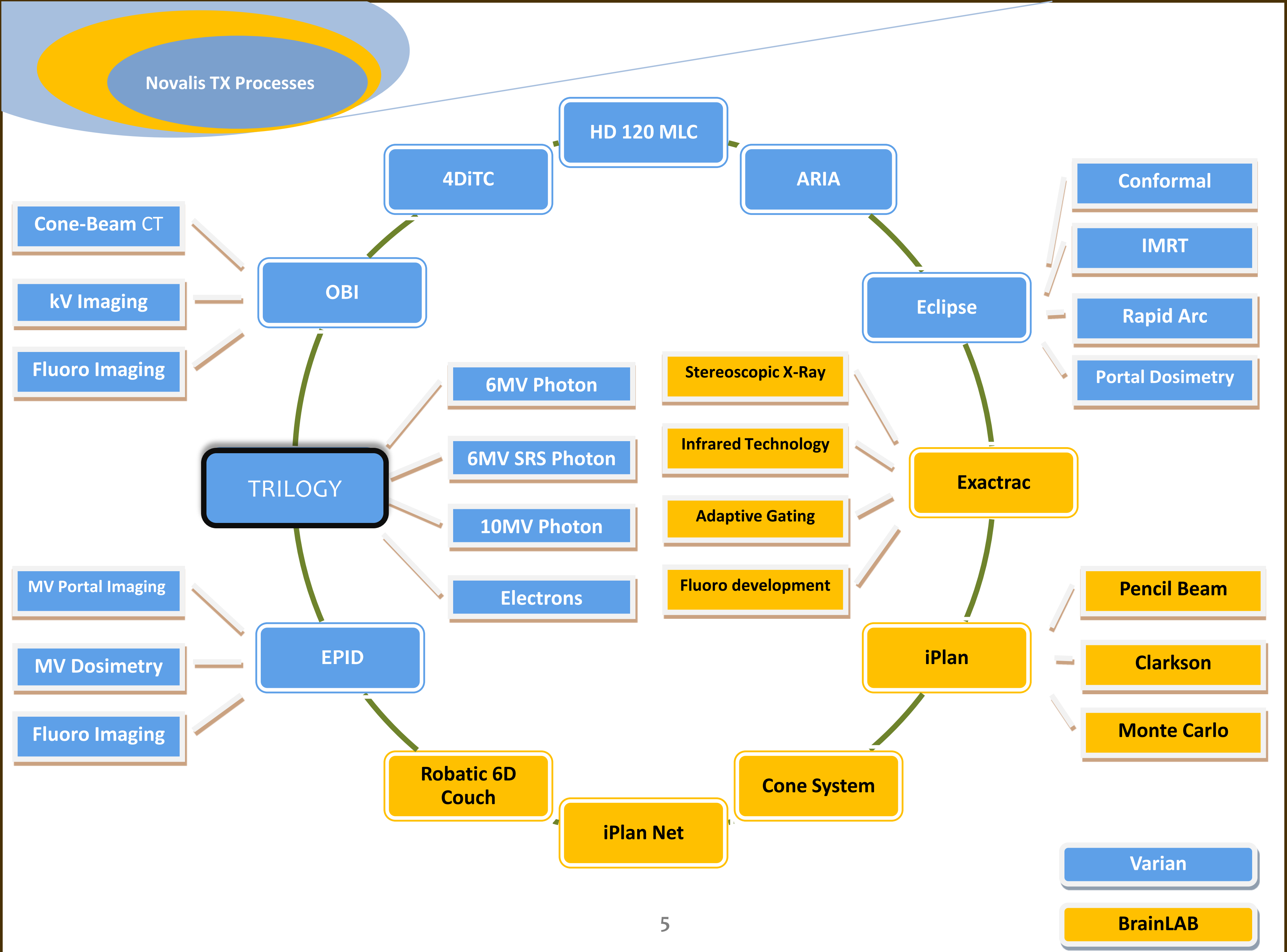


- 3D CRT: 1985-2000
  - Image-based planning on 3D anatomical model





- IMRT: 2000-present
  - Intensity modulation
  - Inverse planning

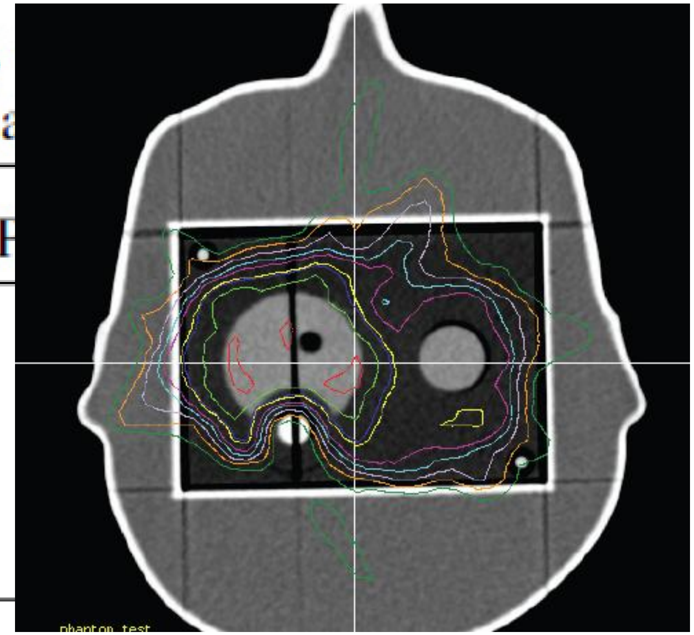

Novalis TX Processes
HD 120 MLC
4DiTC
ARIA
Cone-Beam CT
kV Imaging
Fluoro Imaging
OBI
Conformal
IMRT
Rapid Arc
Portal Dosimetry
Eclipse
6MV Photon
6MV SRS Photon
10MV Photon
Electrons
TRILOGY
Stereoscopic X-Ray
Infrared Technology
Adaptive Gating
Fluoro development
Exactrac
MV Portal Imaging
MV Dosimetry
Fluoro Imaging
EPID
Pencil Beam
Clarkson
Monte Carlo
iPlan
Robatic 6D Couch
iPlan Net
Cone System
Varian
BrainLAB

Advanced Technology Clinical Trials

Credentialing - "ATC/RPC Phantom" Test

Table 1. Institution passing rates
Physics Center pha

Phantom	Head and neck	F
Irradiations	250	
Pass	179	
Fail	71	
Year introduced	2001	



"…roughly 30% of institutions failed to deliver a dose distribution to the head-and-neck IMRT phantom that agrees with their own treatment plan to within 7% or 4 mm."

Ibbott, G. S, et al. Challenges in credentialing institutions and participants in advanced technology multi-institutional clinical trials. *Int J Radiat Oncol Biol Phys* 71:S71–S75, 2008.

Recent Articles Revealed Inadequacies in System

The New York Times

The New York Times

Health

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with
and throat, nauseated,
be studied and talked a
live his nightmare.

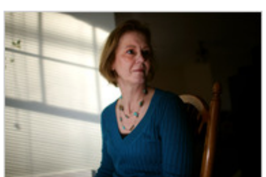
The New York Times

THE RADIATION BOOM

As Technology Surges, Radiation Safeguards Lag

By WALT BOGDANICH
Published: January 26, 2010

In New Jersey, 36 cancer patients at a veterans hospital in East Orange were overradiated — and 20 more received substandard treatment — by a medical team that lacked experience in using a machine that generated high-powered beams of radiation. The mistakes, which have not been publicly reported, continued for months because the hospital had no system in place to catch the errors.



Chang W. Lee/The New York Times

Lorraine Raymond, a radiation therapist, raised concerns about overradiation in the treatment of Frederick Stein at a Veterans Affairs hospital in New Jersey in 2006. More

In Louisiana, Landreaux A. Donaldson received 38 straight overdoses of radiation, each nearly twice the prescribed amount, while undergoing treatment for prostate cancer. He was treated w
machine so new that the hospital made a misca
even with training instructors still on site.

In Texas, George Garst now wears two externa
one for urine and one for fecal matter — becaus
radiation injuries he suffered after a medical ph

The New York Times

Health

At V.A. Hospital, a Rogue Cancer Unit

The New York Times

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POLITICS EDUCATION BAY AREA CHICAGO TEXAS

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ
Published: February 24, 2010

A hospital in Missouri said Wednesday that it had overradiated 76 patients, the vast majority with brain cancer, during a five-year period because powerful new radiation equipment had been set up incorrectly even with a representative of the manufacturer watching as it was done.

The hospital, CoxHealth in Springfield, said half of all patients undergoing a particular type of treatment — stereotactic radiation therapy — were overdosed by about 50 percent after an unidentified

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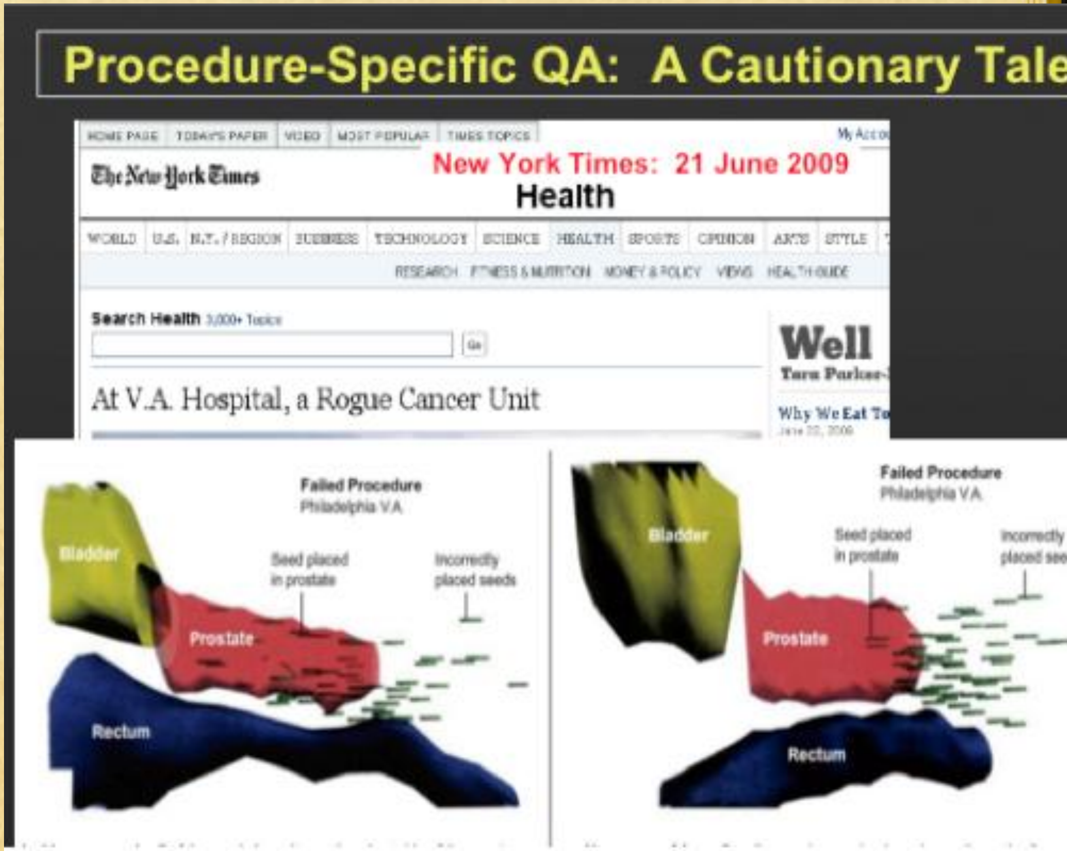
Device versus Process Errors

- Large catastrophic errors
  - Majority are human or process related errors although poor device design often contributes

- 97 of 116 implants were medical events, many were wrong site

- Failures of process rather than devices

- QA is a team effort: focus on key physician as well as technical steps



Current QA Paradigm Focus

- Approach developed in the 2D RT era
  - Most extant guidance is limited to 2D RT
- Tends to focus on **devices**
  - planning systems, LINACs, imaging systems
  - Acceptance testing, commissioning, periodic QA
  - Process QA: limited to quantitative verification of device outputs, e.g., plan review and chart checks

QA Formulation

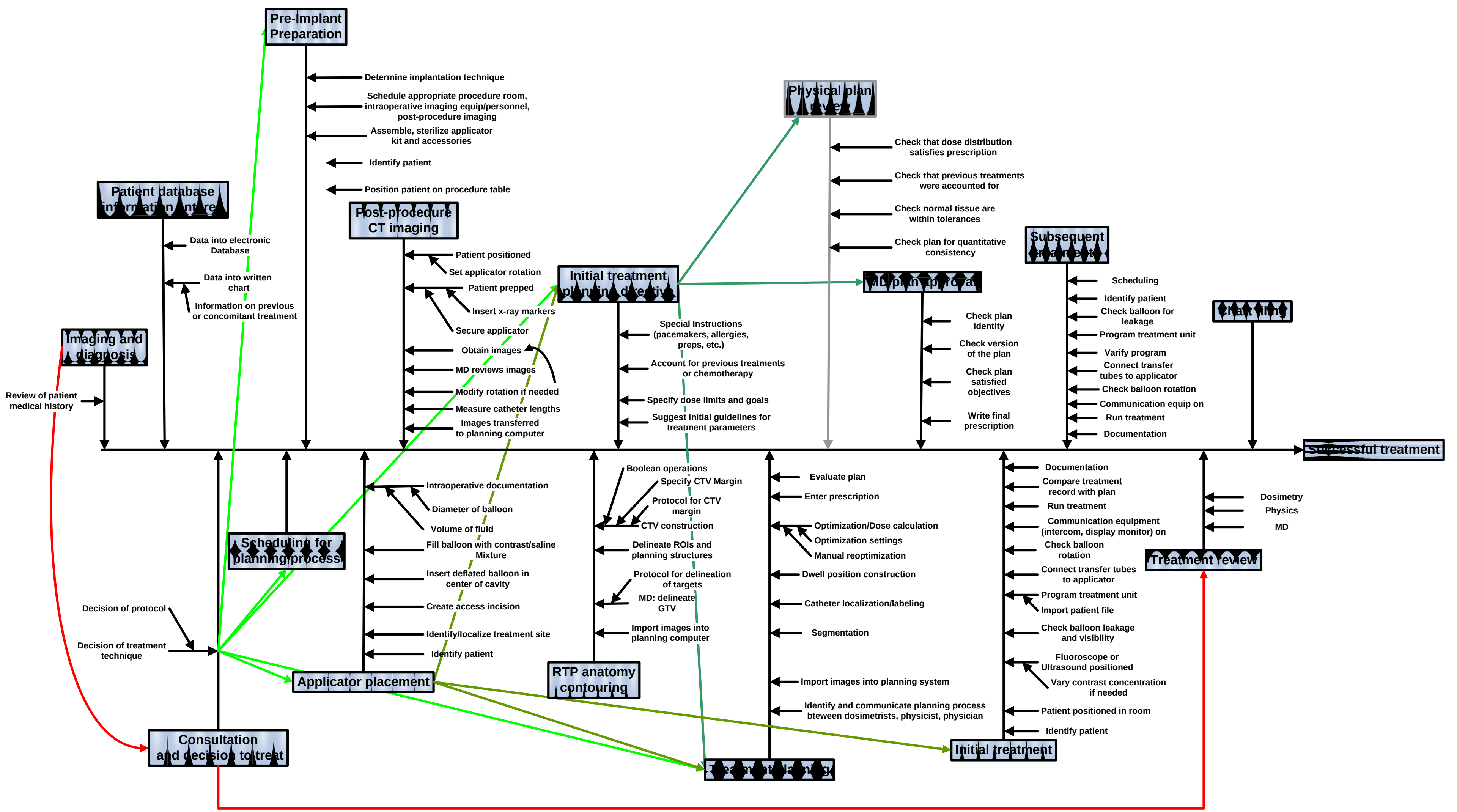
- Current QA Protocol formulation methodology
  - Consensus opinion of small group of experts
  - Periodically check all device functions/outputs that could compromise overall delivery accuracy
  - Fixed test frequencies **not** driven by actual device reliability or risk estimates
  - "One size fits all" menu of tests
- Tolerance levels:
  - Limit dose delivery uncertainty to 5% & 5 mm
  - Errors in anatomic modeling, dose computation, dose delivery, and calibration add quadratically
  - Assume variations about target values are well behaved random variables with **no catastrophic outliers**

Process-Based QA

- AAPM TG-100 proposal (S. Huq, Chair)
  - Failure modes and effects analysis (FMEA)
  - Fault-tree Analysis (FTA)

"Method for Evaluating QA Needs in Radiation Therapy"

Breast Brachytherapy Process Map



What to Do?

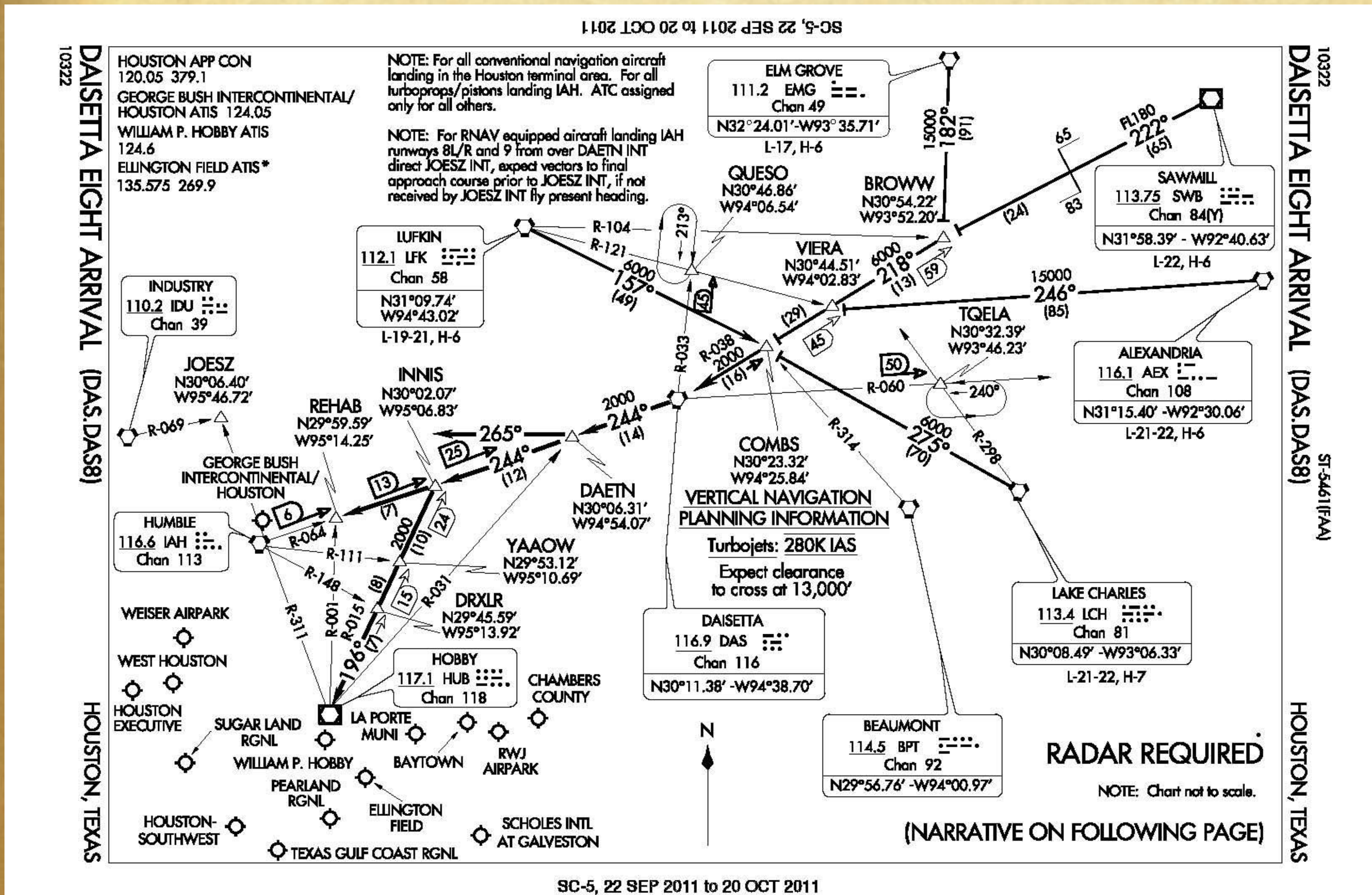
- FMEA/FTA is doable (UCSD and Brachytherapy)
  - What about multiple small clinics without full time physics, what do they do?
- FMEA/FTA does not consider process interactions
- STAMP?
- How do we translate work from academic/large centers to everyone and make the processes safer?
- Answer: Standardize!

Standardize?

- "Thus, first-time users of this technology should ascertain which of these aims are desirable for their own clinics and tailor their commissioning and QA programs accordingly."
- "Clinics should have the option to customize these standards to their own specifications, or to select from various national/international guidelines."

Standardize

Standardization



Standardize and Rationalize

- Standardized procedures
  - Allows the development of FMEA, FTA, STAMP to be developed by national organizations
- Standardized QC/QA
- Risk-based QA
- Treatment Directives

M. Workman, 2009