Computer Controlled Treatment Delivery: History, Issues and Safety

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CEDARS-SINAI

LEADING THE QUEST

Acknowledgments

Jean Moran PhD	UM
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John Humm, PhD	MSKCC

Objectives

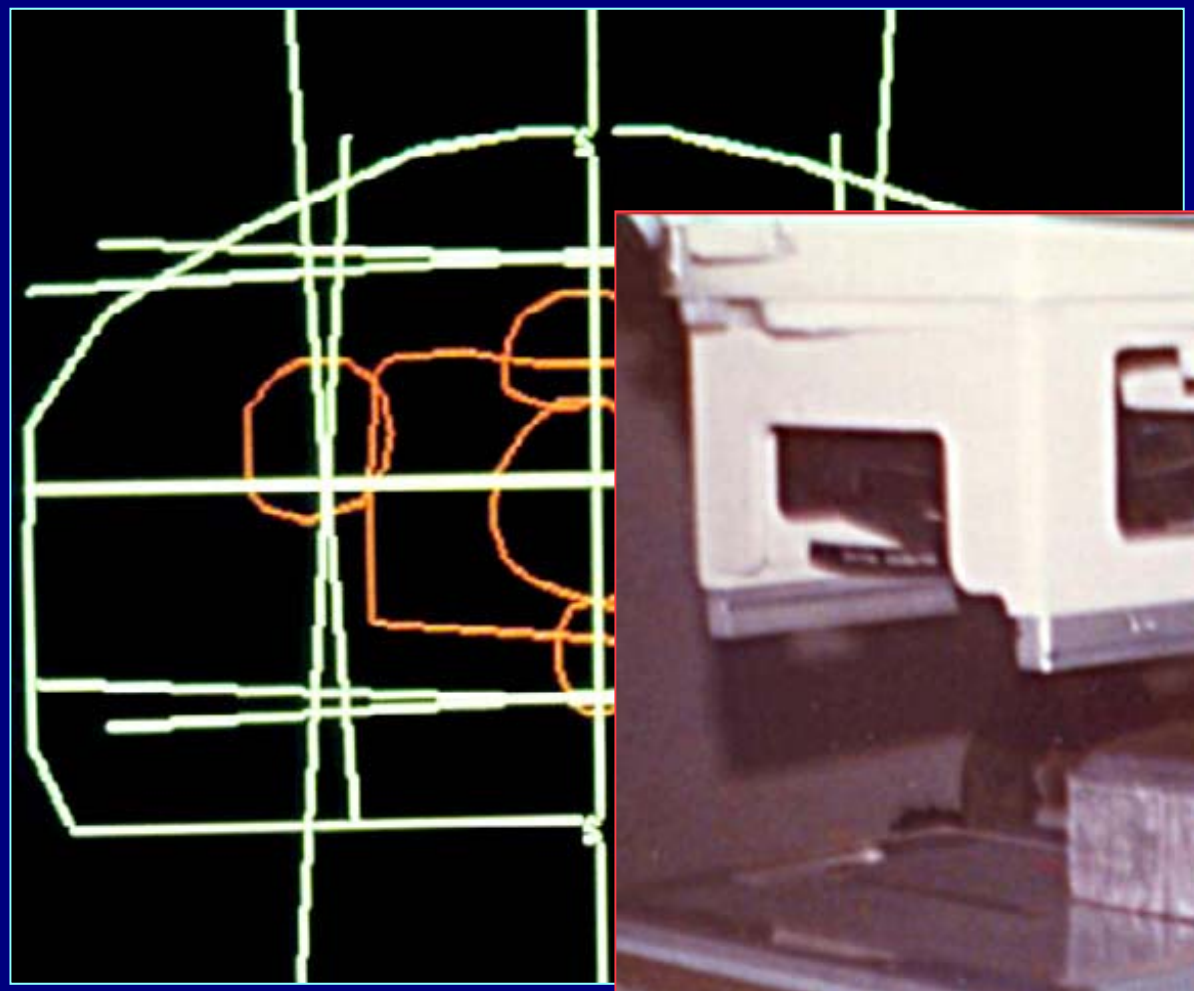
Describe

- **The progression from manual setup and treatment to routine use of computer-controlled treatment delivery (CCTxD) and intensity modulated radiation therapy (IMRT)**
- **Differences in treatment process using CCTxD compared to earlier manual setup techniques**
- **Safety and Quality Assurance issues associated with use of CCTxD and IMRT treatment techniques**
- **Some advantages of CCTxD and IMRT techniques**

Computer Controlled Tx Delivery: History, Issues and Safety

- Manual Treatment Delivery
- Modern Computer-Controlled Treatment Delivery (CCTxD)
- IMRT, IGRT, VMAT, 4-D:more complex!
- Safety/QA Issues for CCTxD, IMRT
- Conclusions

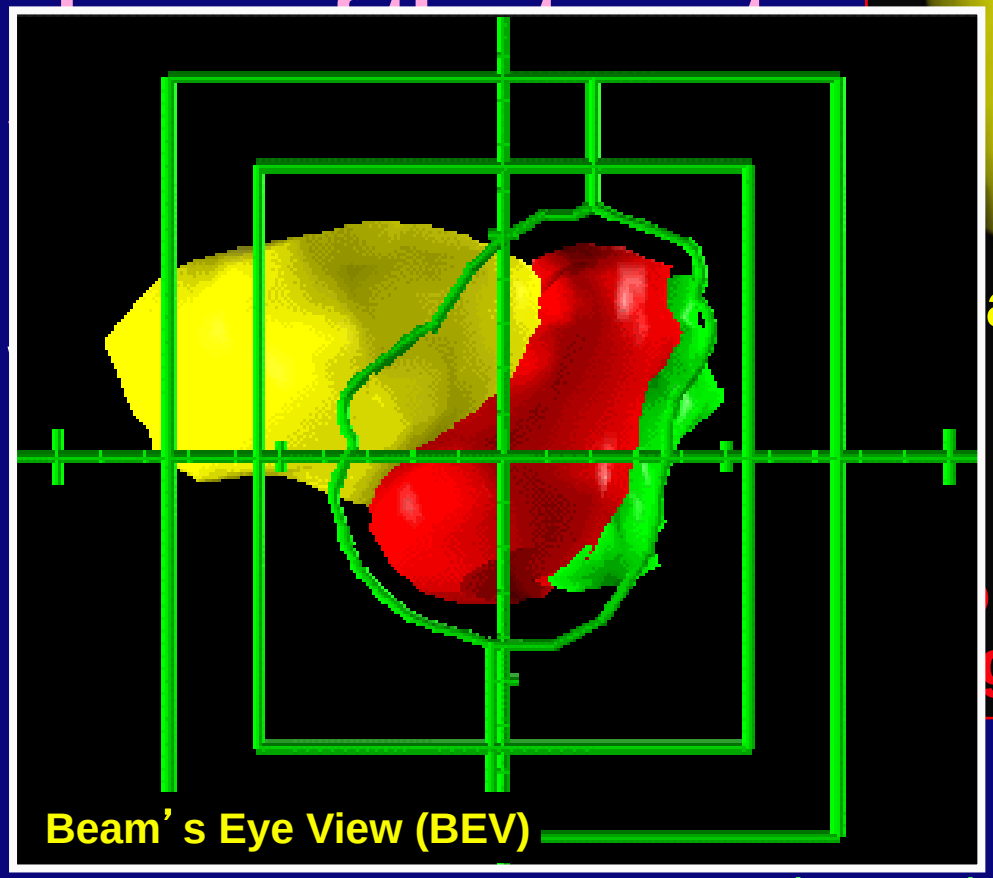
1950s-80s: 2-D Radiotherapy

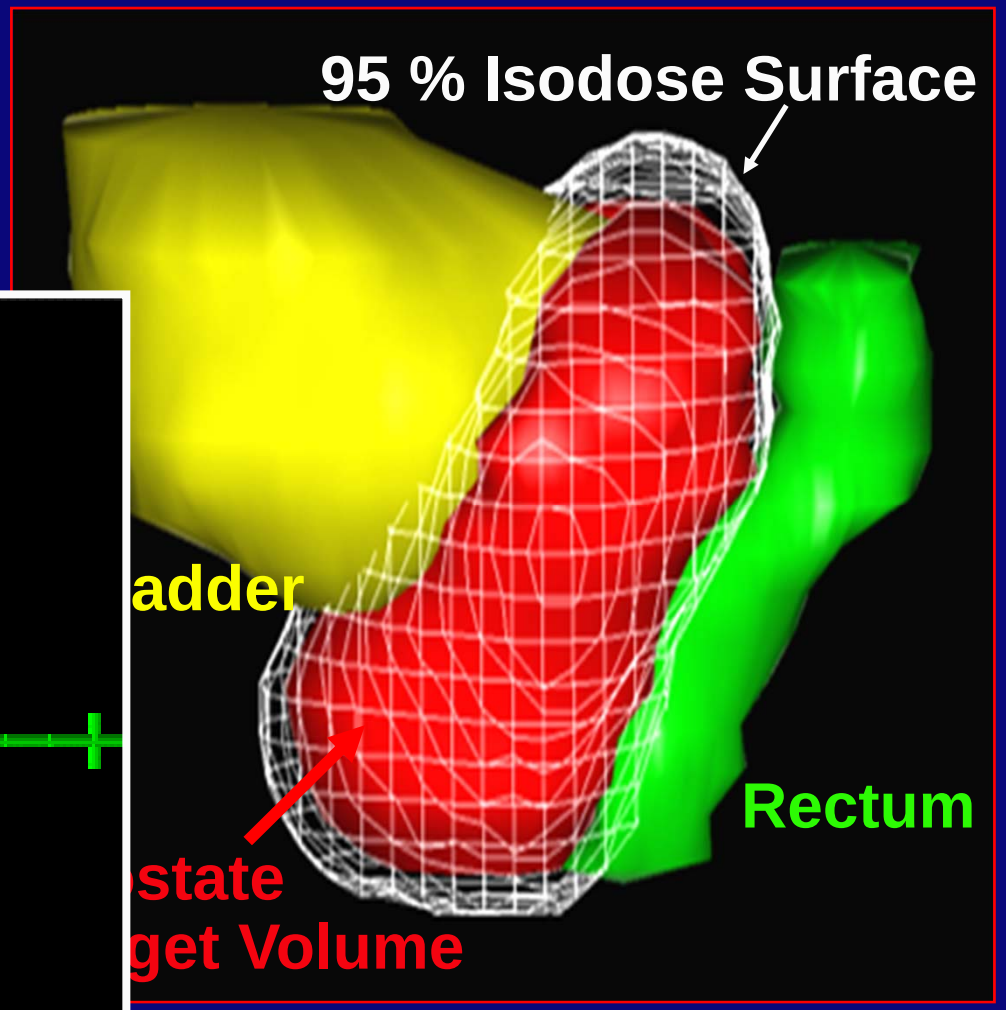


1980s: CT-Based Planning

1986 – 1990s: Conformal Therapy

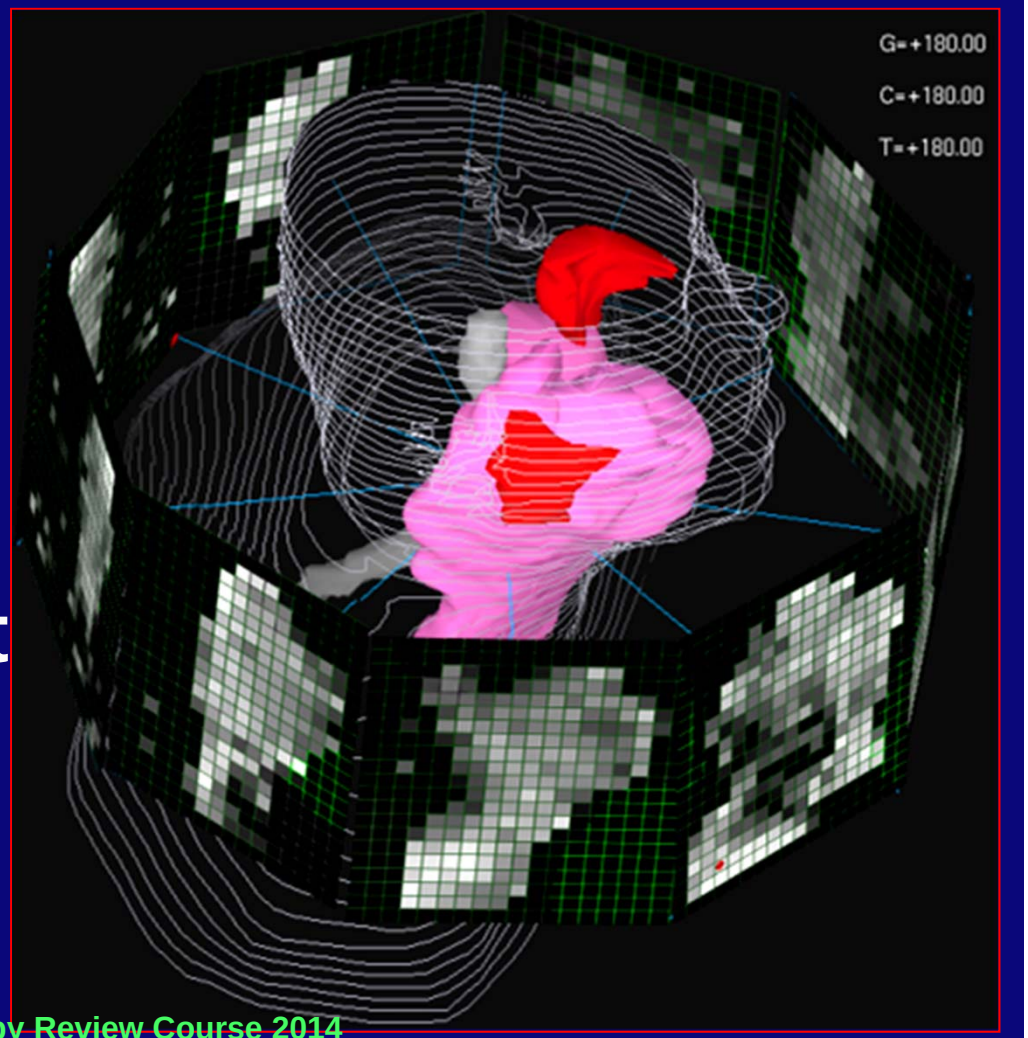
A dose distribution that conforms to the





2000s: Conformal Therapy with Intensity Modulated Radiation Therapy (IMRT)

IMRT: Rather than uniform intensity beams, optimize the intensities of "**beamlets**" to allow further improvement of the dose distribution



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2010s: IGRT and VMAT

IGRT:
Image Guided RT

Daily setup using kV imaging or Cone Beam CT

2010s: IGRT and VMAT

VMAT: Volumetric Modulated Arc Therapy

Rotational gantry delivery combined with dynamic MLC motion

Rather than simulators + manual contours we have CT-Simulators and 4D CT

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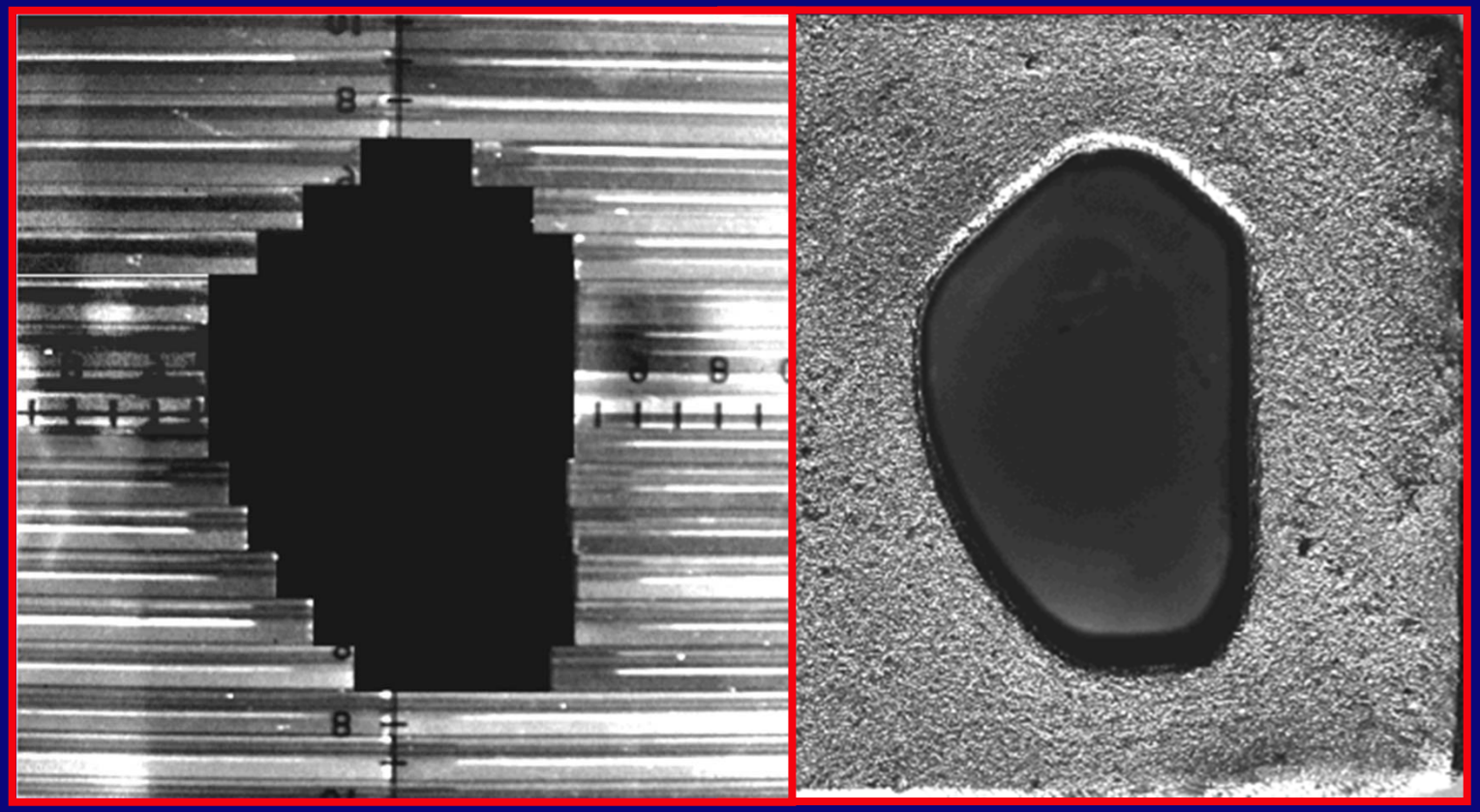
Rather than focused blocks

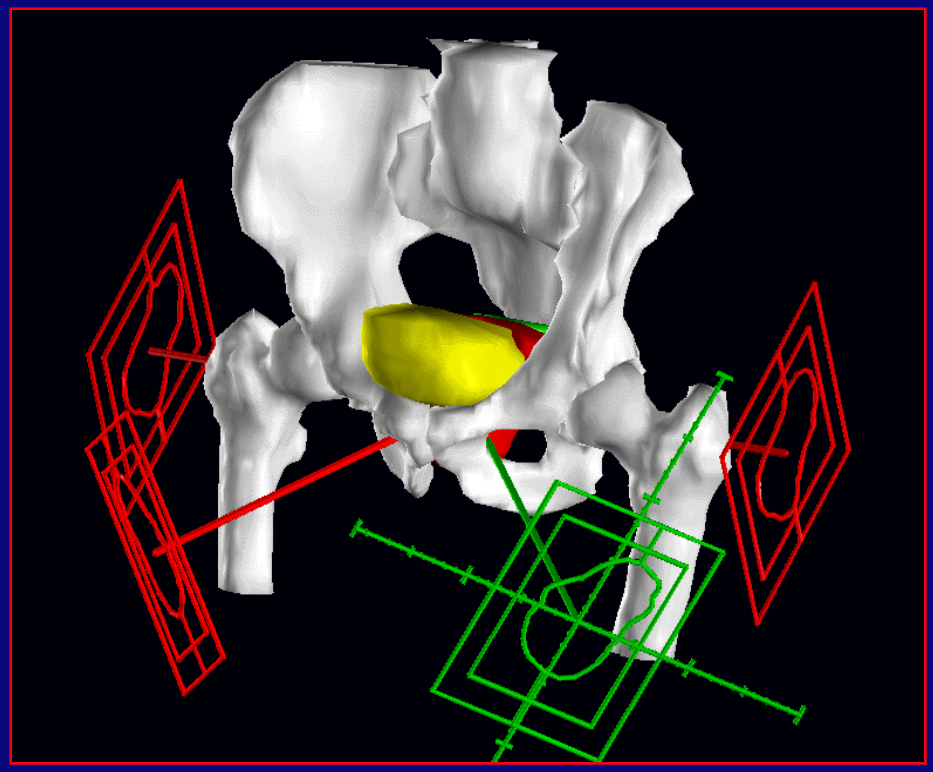
we have MLCs

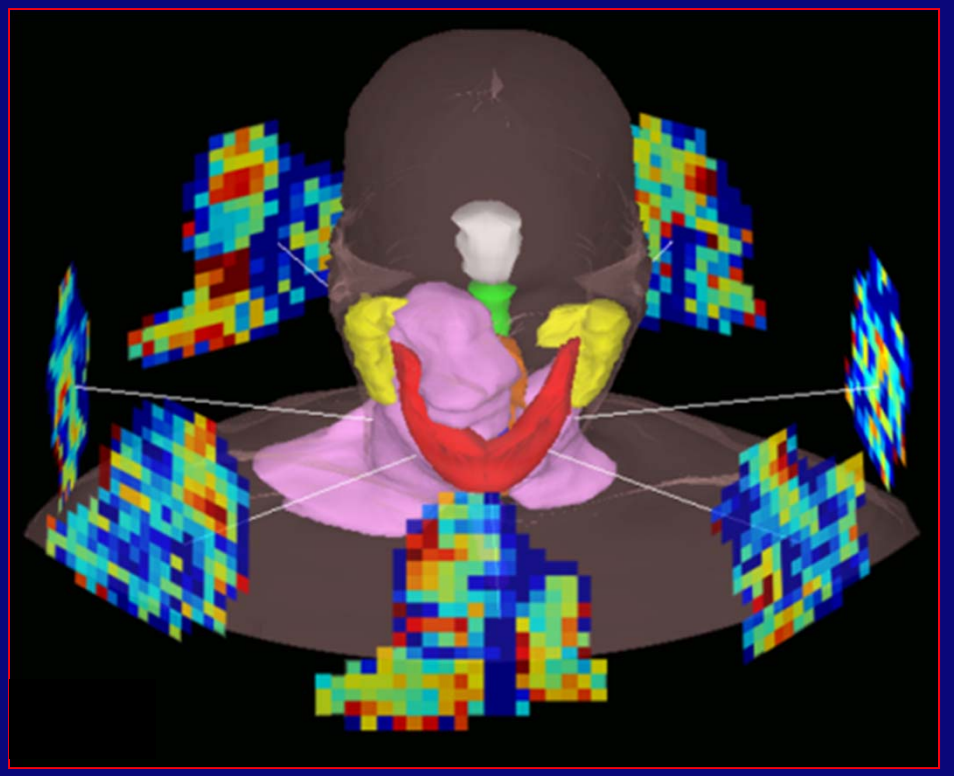


Multileaf Collimator **Focused Blocks**

Rather than static shaped fields

we have IMRT and VMAT

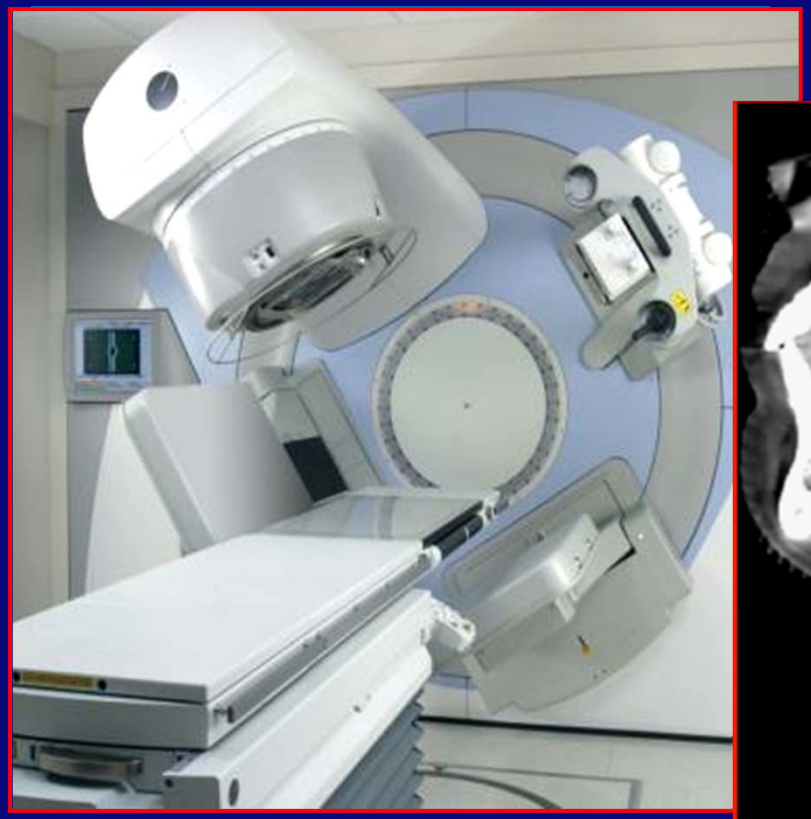




3-D Conformal

IMRT

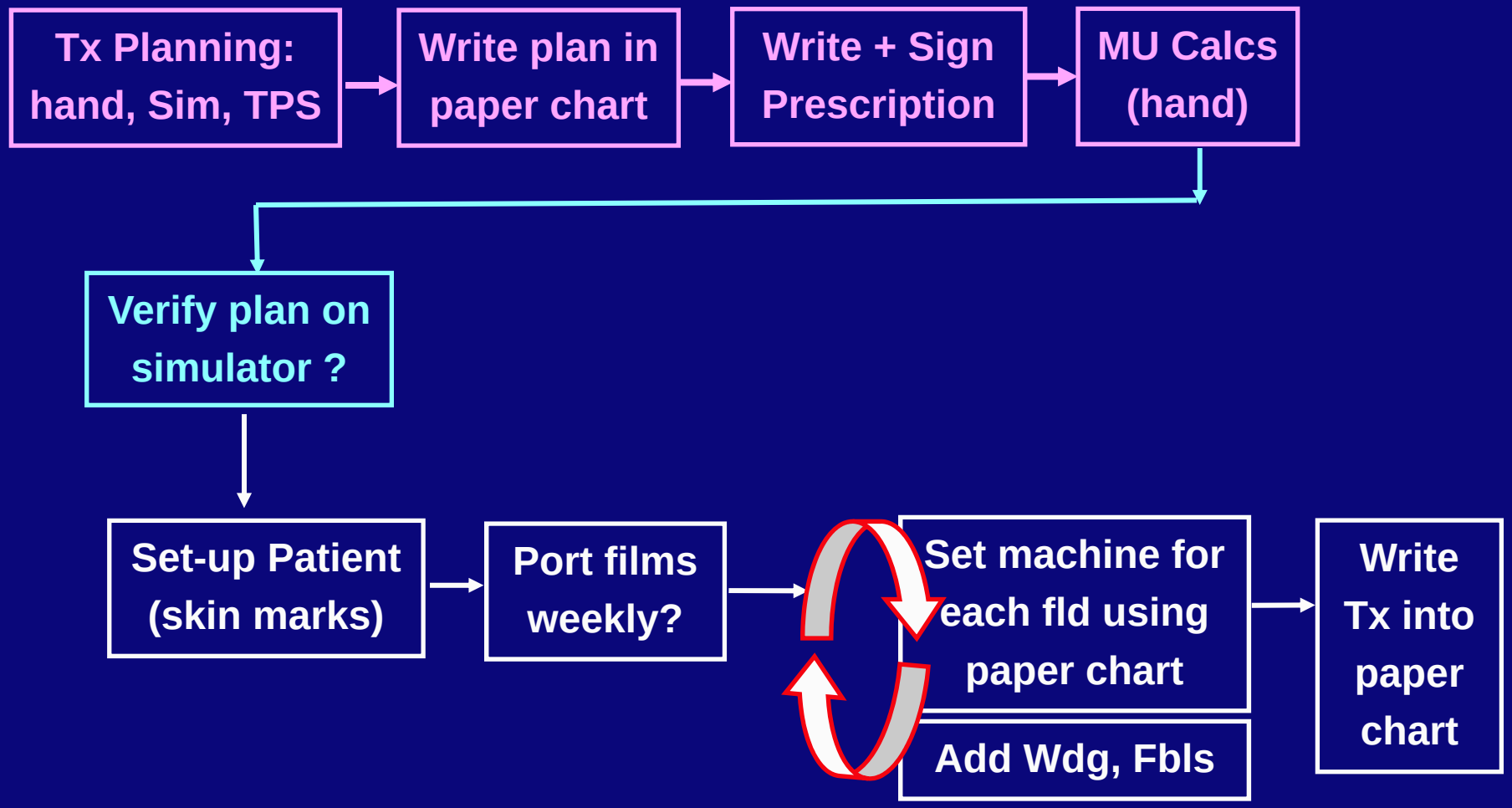
Rather than lasers and weekly port films we have Image-Guided RT with ConeBeam CT



Has the Planning/Delivery Process Changed?

Have we changed our quality assurance to take into account these changes?

Traditional Planning/Delivery Process



Tra ocess

Tx Planr
hand, Sim

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Verify
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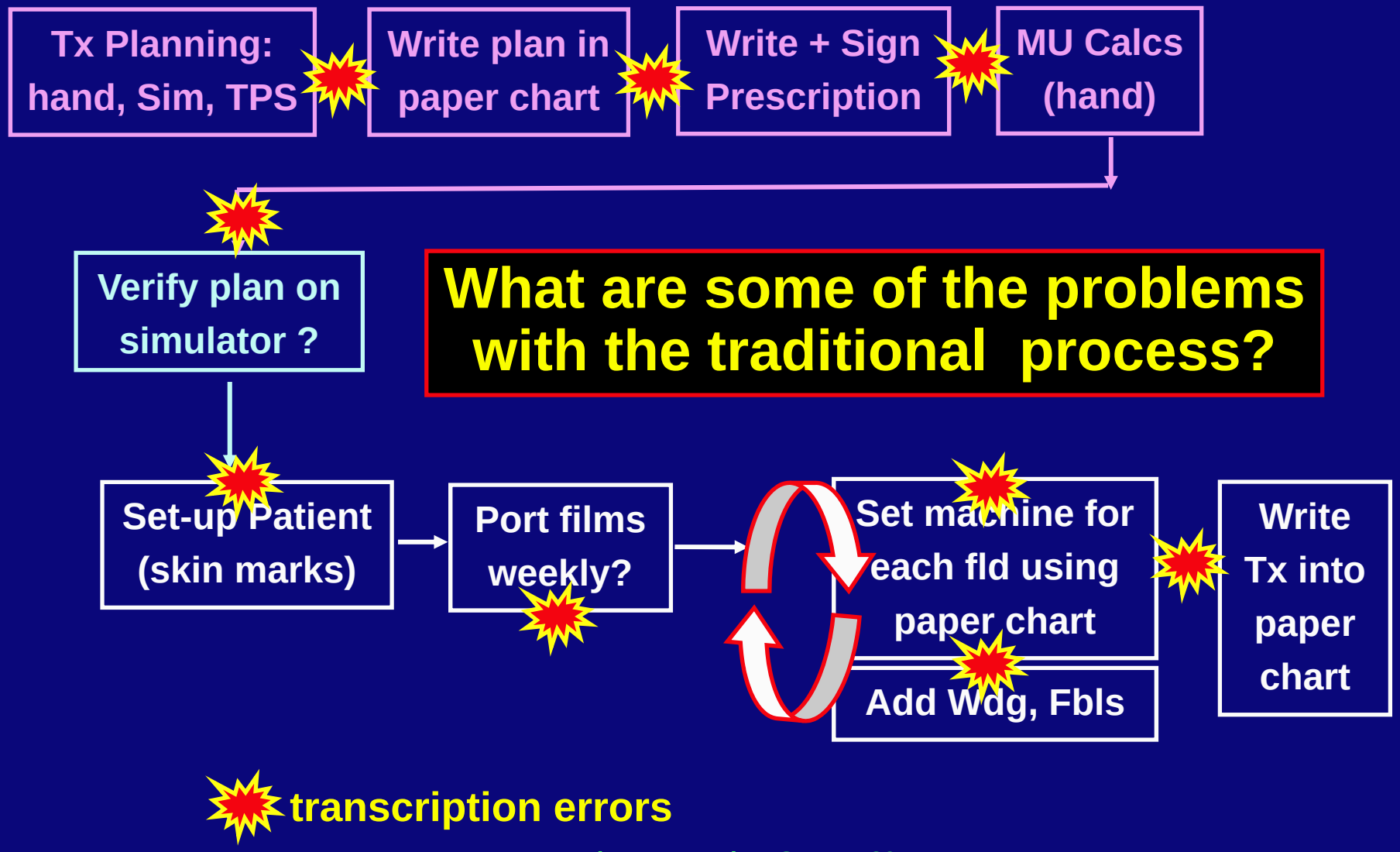
s

Write Tx into paper chart

Treatment Parameters							
Plan #							
Field/Segment #							
Field/Segment Name							
Field/Segment Type							
Machine/Energy	———	———	———	———	———	———	———
Technique							
SSD							
Gantry Angle (Arc Start/Stop)							
Collimator Angle							
Table Angle							
Field Width (Total)							
Jaw X1-Left							
Jaw X2-Right							
Field Length (Total)							
Jaw Y1-Down							
Jaw Y2-Up							
Field Shaping							
Wedge Angle/Code	/	/	/	/	/	/	/
Bolus							
Compensators							
M.U.							
Backup Time							
Daily Dose (Gy)							
cGy/MU							
Dosimetrist/Date							
M.U.							

Traditional Planning/Delivery Process



Manual Planning/Delivery Process

- Information is transferred by hand from place to place, or written by hand into paper chart
- Since each step is manual, random transcription + look-up errors occur routinely

Why is this such a big deal?

- Much routine QA has been aimed at these transcription issues
- Is this what we still need to be doing ?

Record/Verify (R/V) Systems

R/V systems were the solution to the many transcription errors:
"Use a computer to check the parameters set on the machine!"

A programmable calculator to acquire, verify and record radiation treatment parameters from a linear accelerator. H Perry, IJROBP 1: 1976

Can R/V Cause Errors?

Yes, if you put the wrong info in,
or select the wrong patient or plan,
or…

Errors "due to" R/V

Error Rate	Author
15.3 %	Macklis, 1998
23.7 %	Patton, 2003
15.6 %	Huang, 2005

R/V-Related Errors

- **The solution: integrate the R/V system into the planning/delivery system, to avoid errors entering info into R/V, or picking the wrong patient/plan.**
- **However, these changes remove the independence of the R/V system, and it becomes part of the integrated computer-controlled treatment delivery system**

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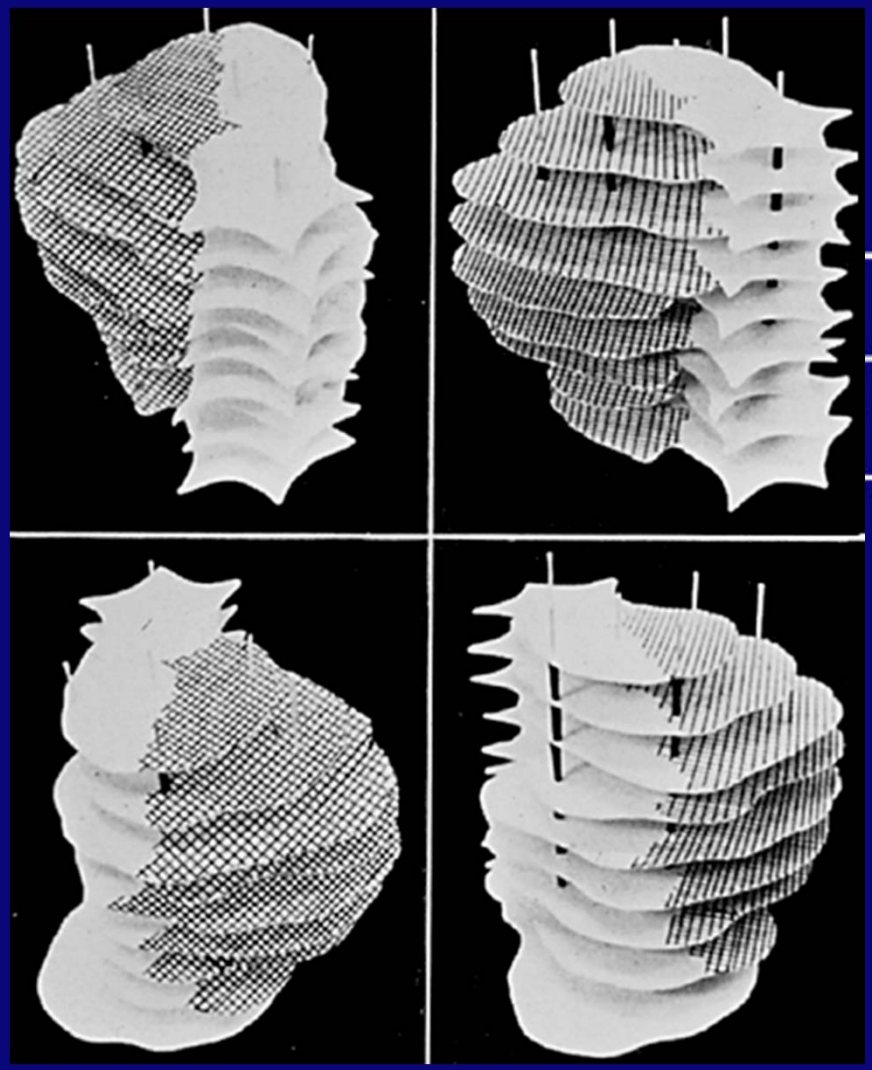
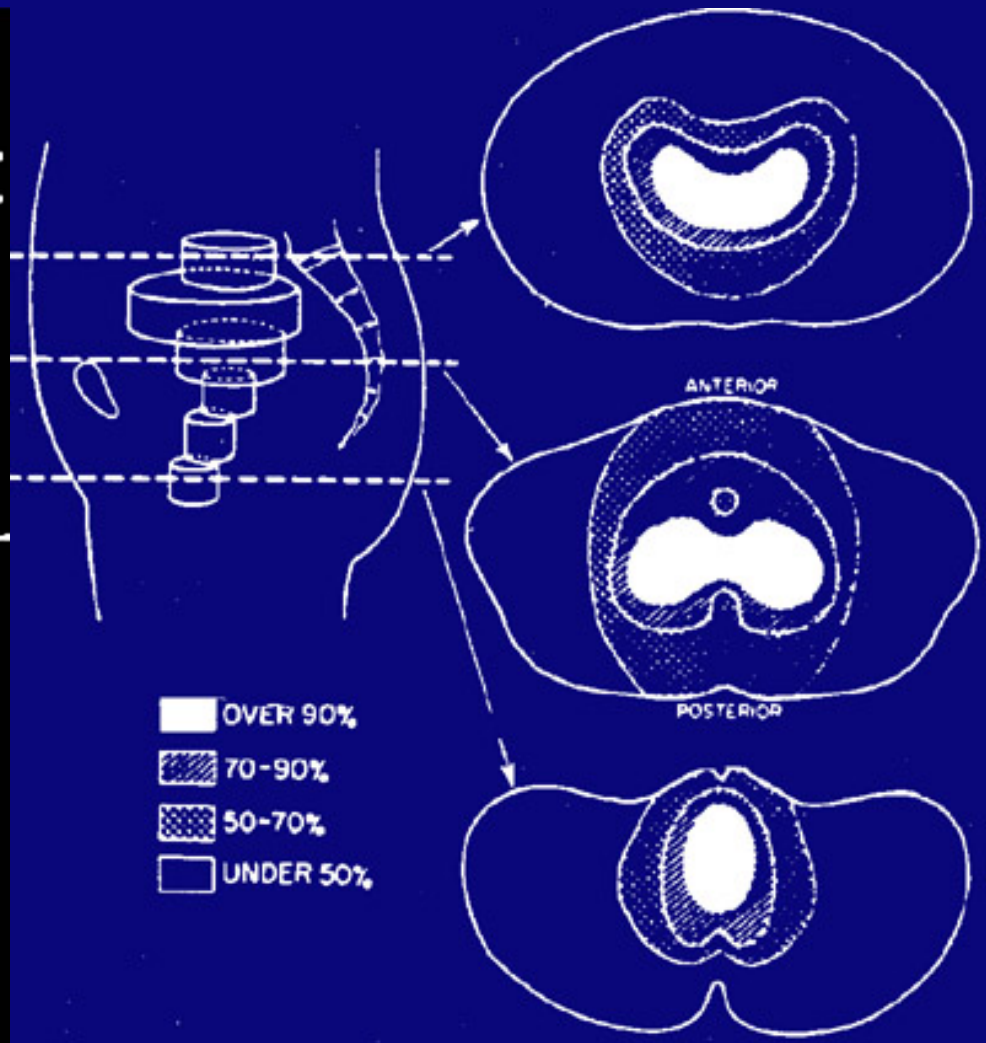
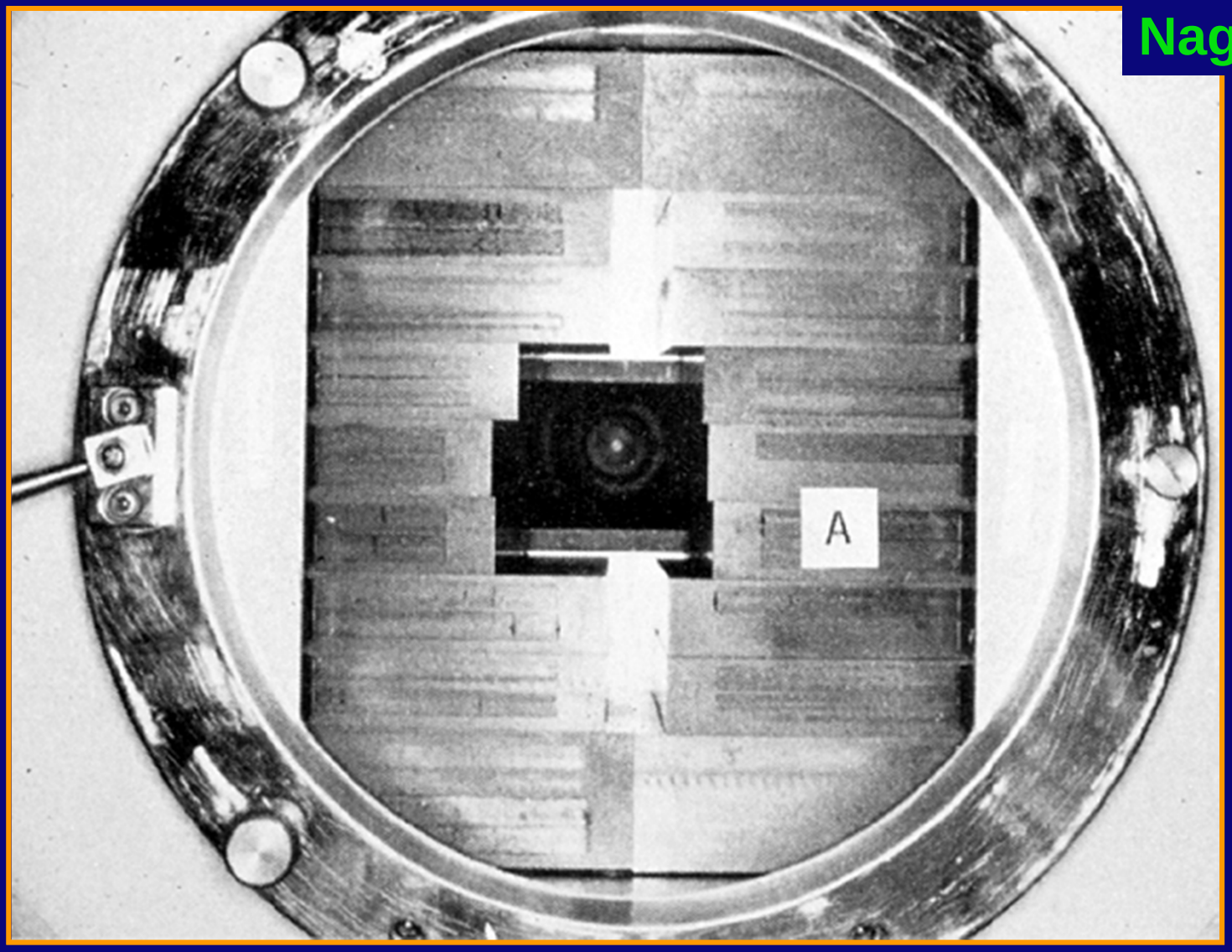
Conformation Therapy: Takahashi



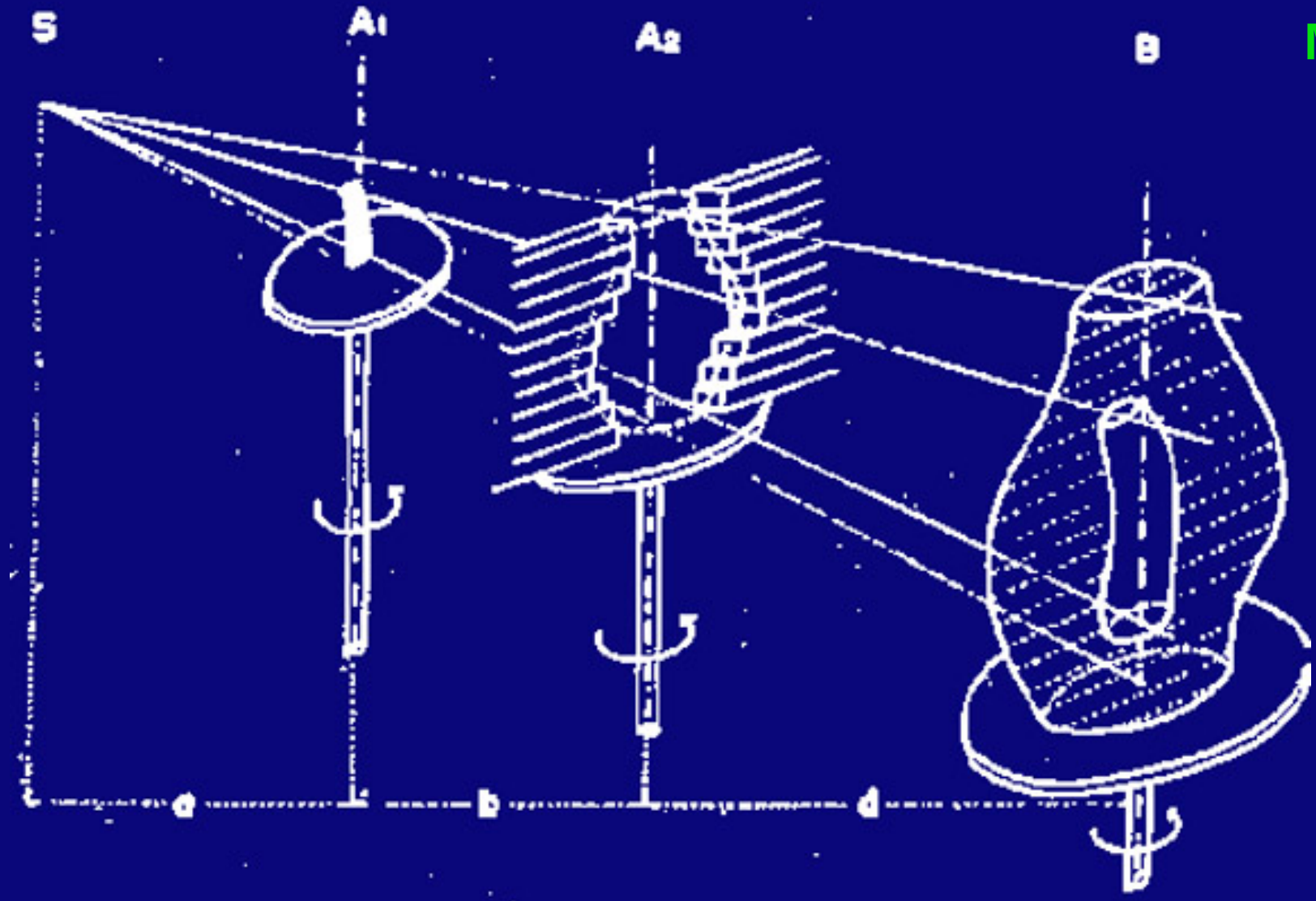


1949–1970s S Takahashi: Acta Radiol Suppl 242: 1-141, 1965

Nagoya



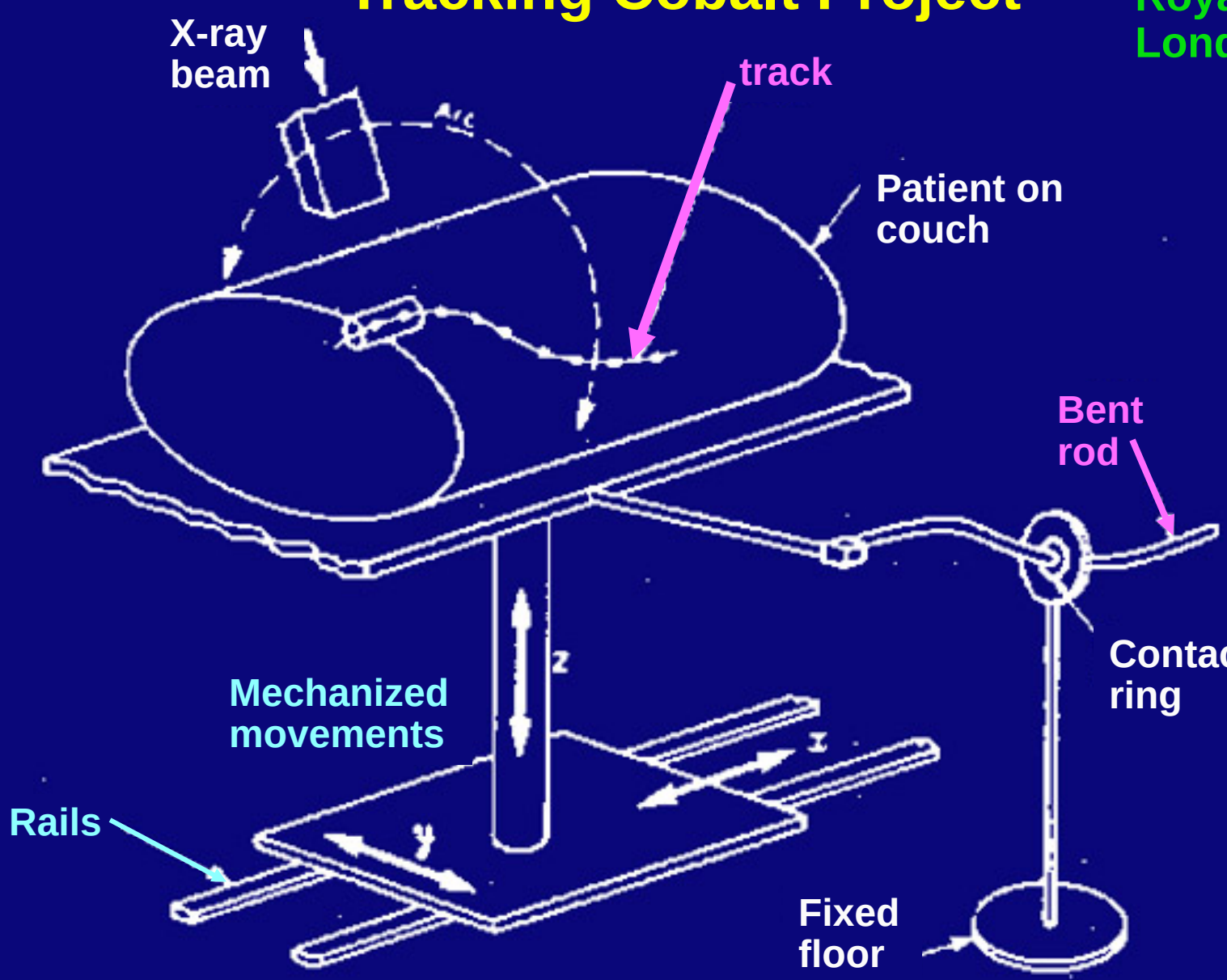
1949-1970s T Kitabatake, S Takahashi: Tohoku J Exp Med 94: 37-43, 1968.



1950s-60s KA Wright, BS Proimos, JG Trump, MI Smedal, DO Johnston, FA Salzman: Radiol 72: 101, 1959.

Tracking Cobalt Project

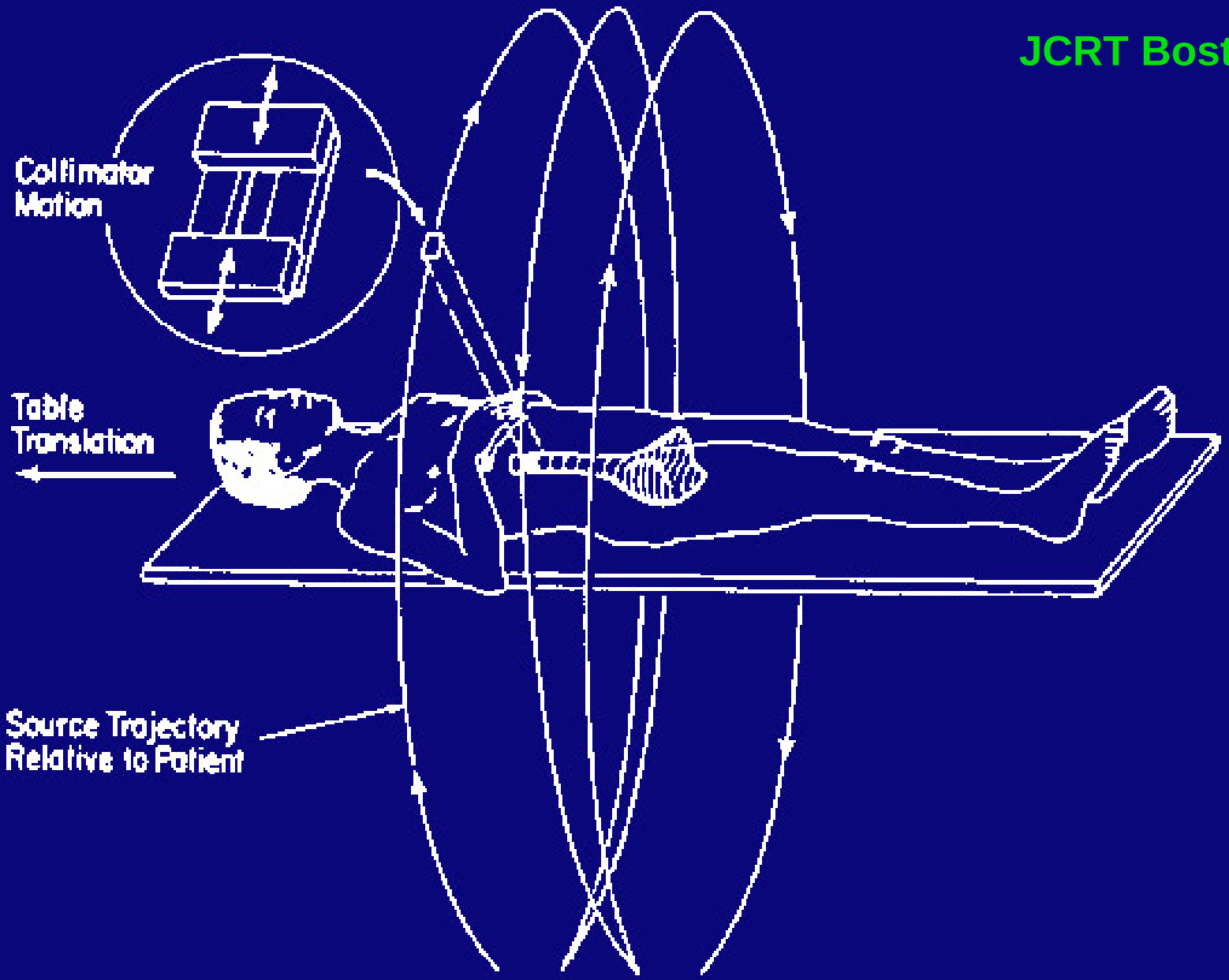
Royal Free, London



1950s – 1980s

Jennings 1985

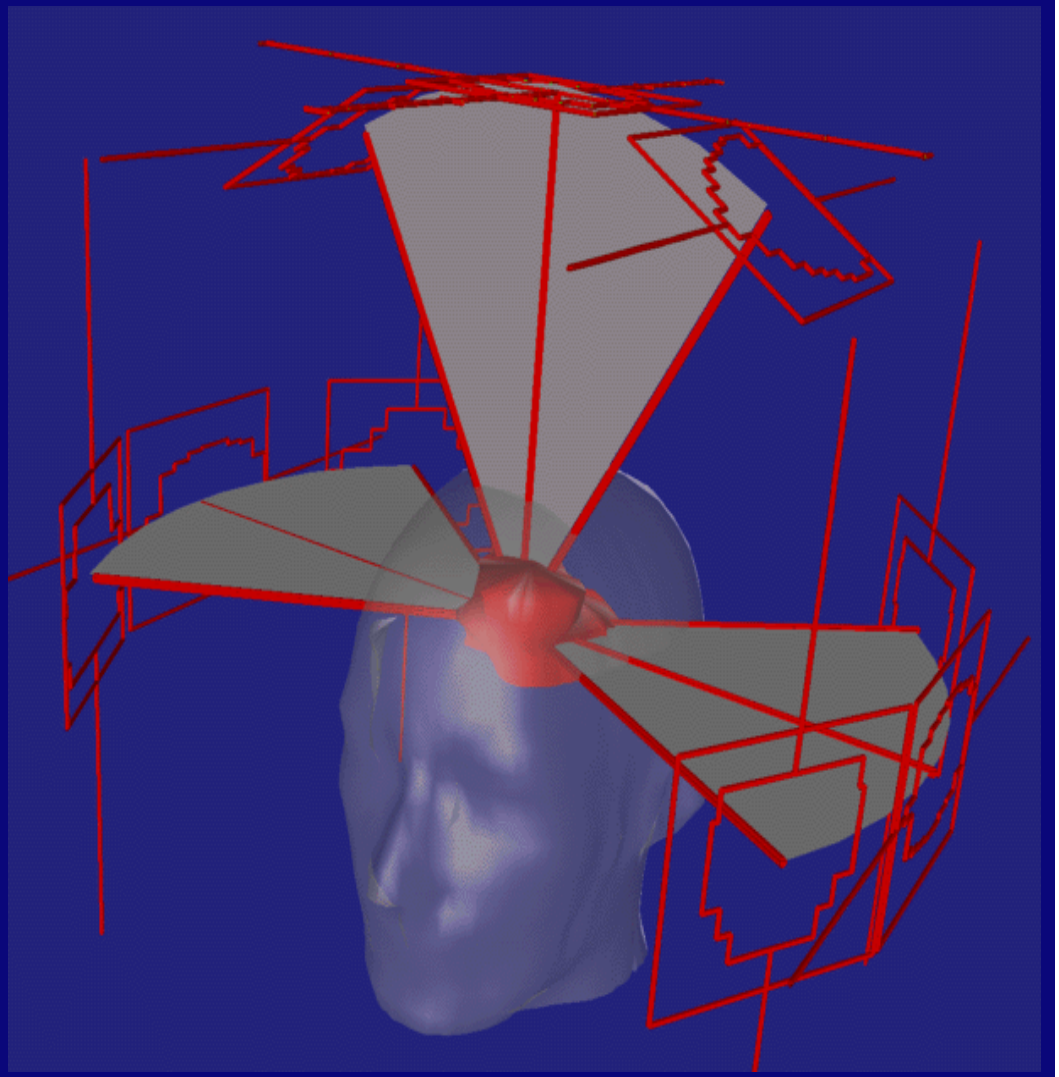
JCRT Boston



1970s-80s L Chin, PK Kijewski, GK Svensson, JR Chaffey, MB Levene, BE Bjarngard: IJROBP 7: 61-70, 1981.

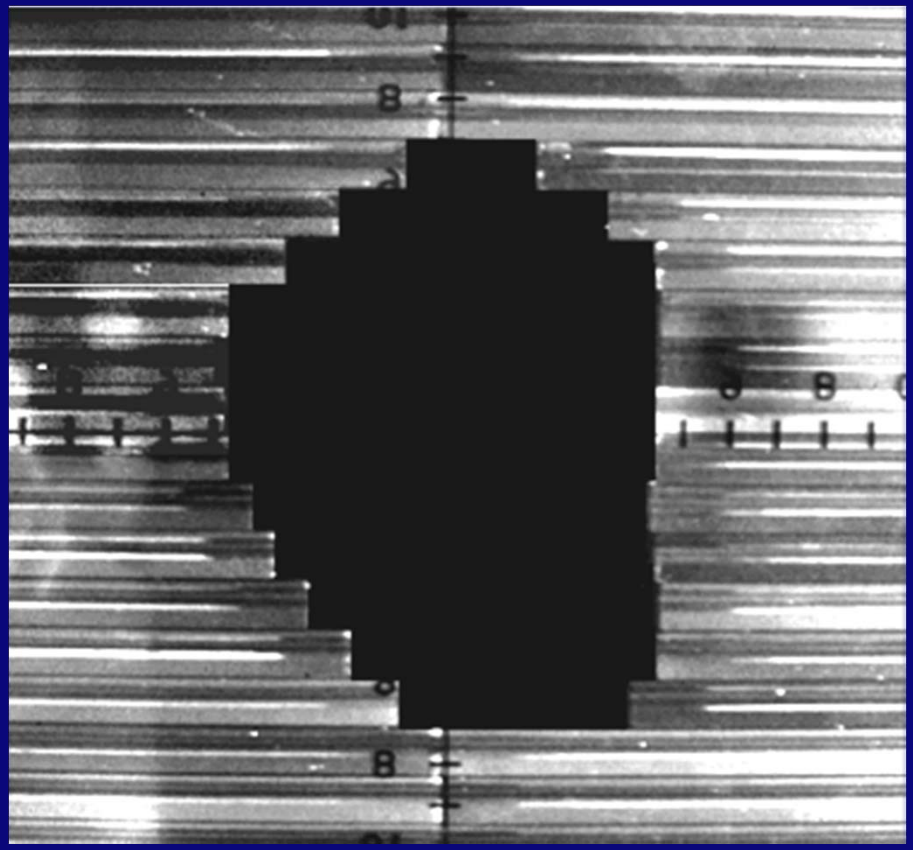
Computer-Controlled Conformal Therapy

Static: Fixed fields



Modern Computer-Control

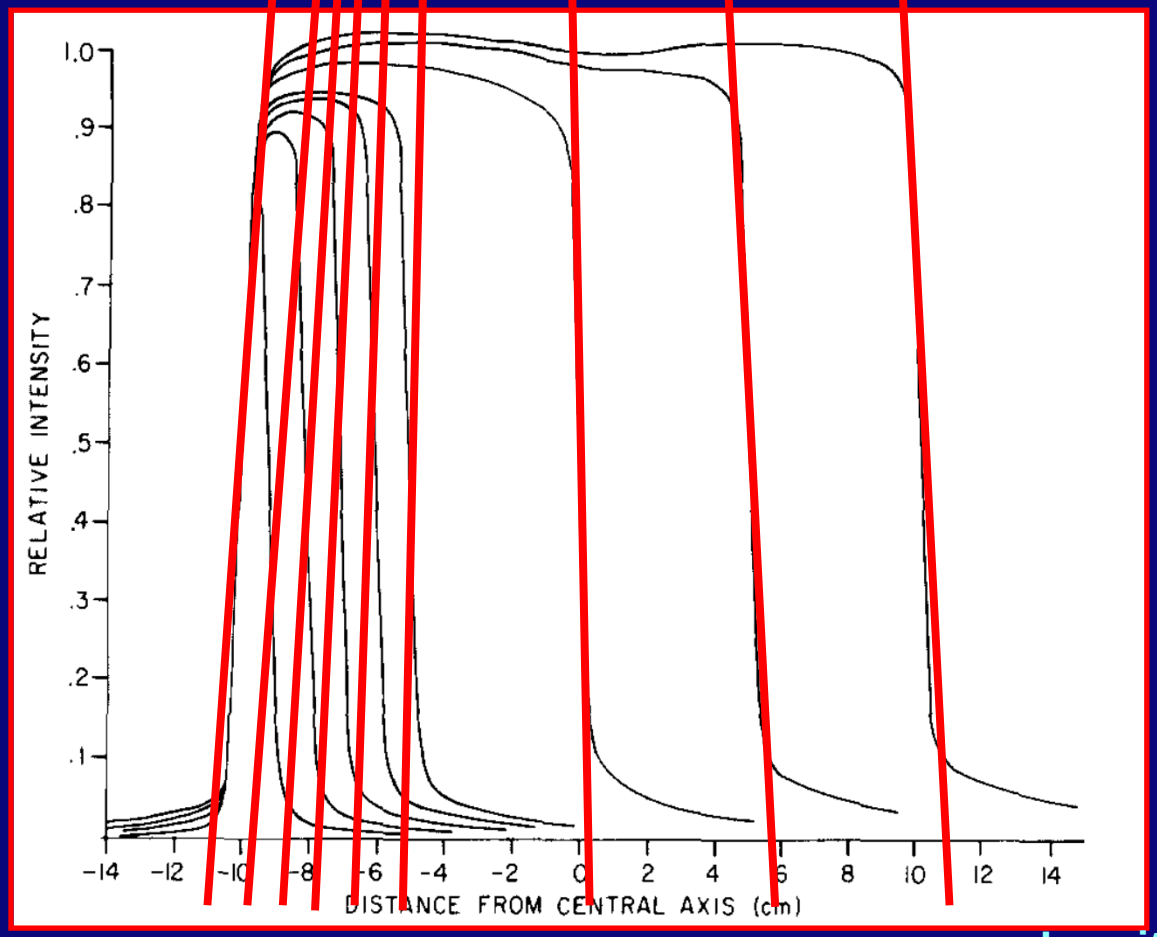
- Modern MLC
- Downloaded plans
- Multiple segment delivery
- Full computer control
- Scanned photon and electron beams

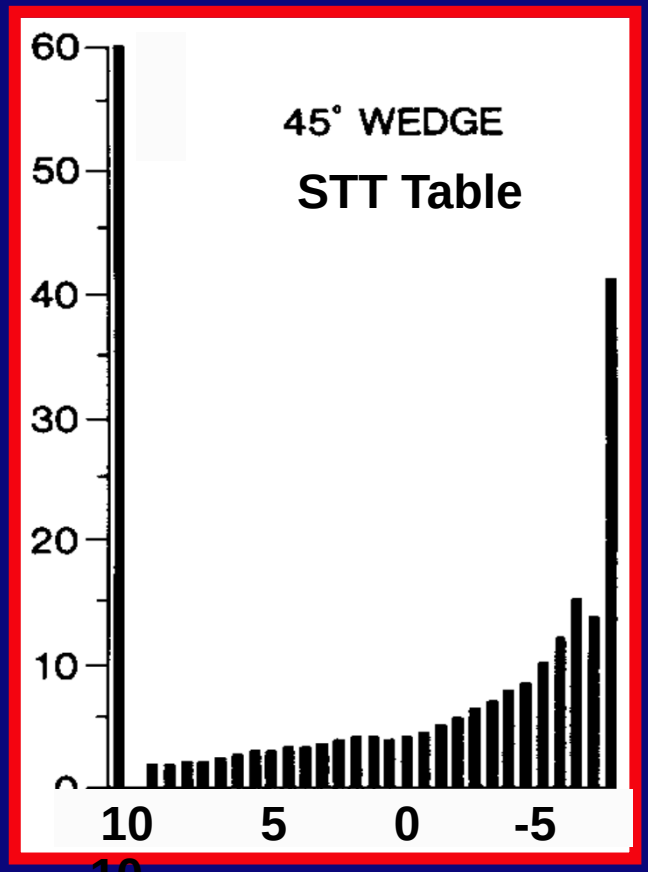


Scanditronix MM50 Racetrack Microtron ~ 1985

Umea, MSKCC, Michigan, Rotterdam, Karolinska

Dynamic Wedge





Leavitt et al, Med Phys 17: 87-91, 1990

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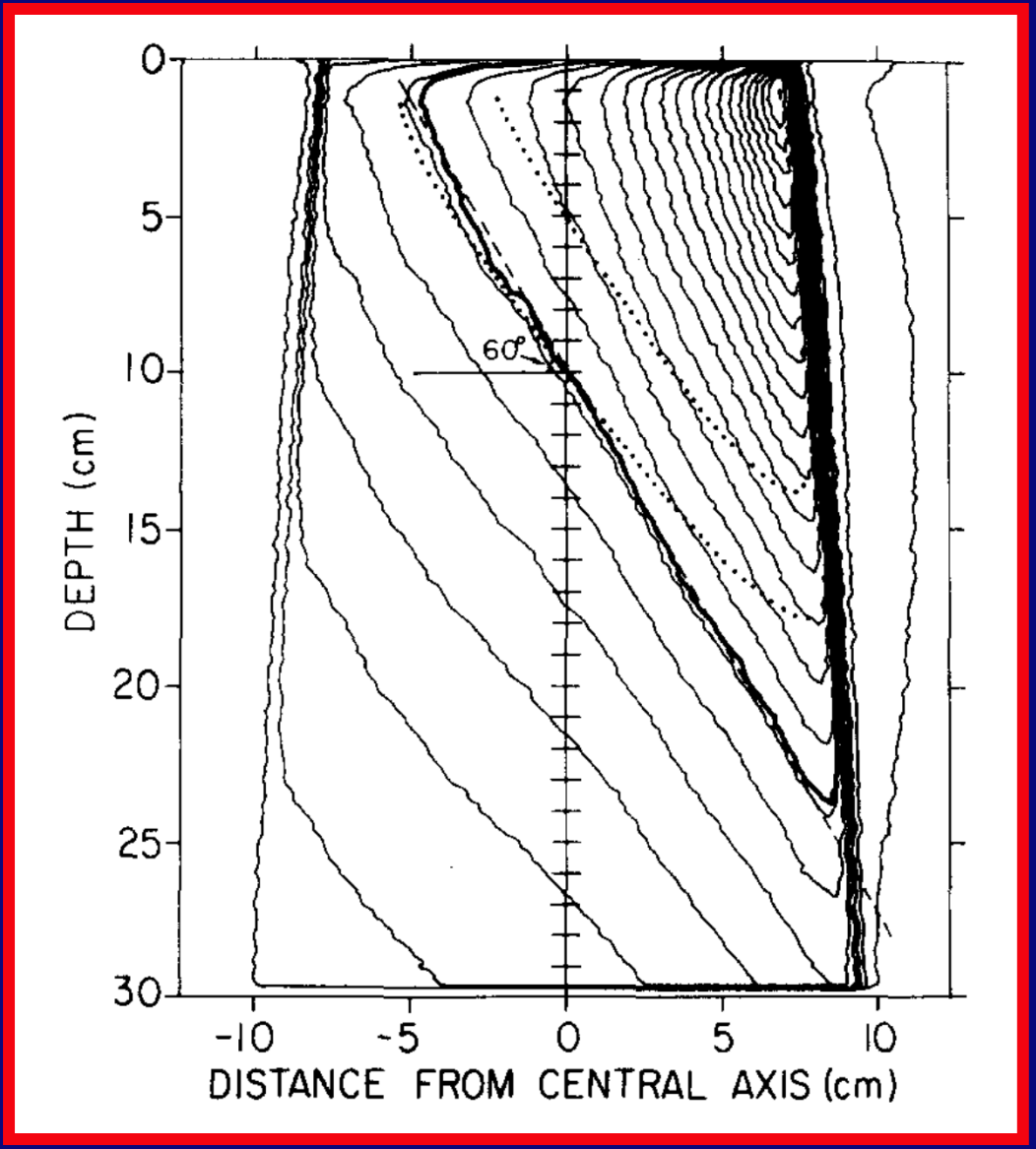
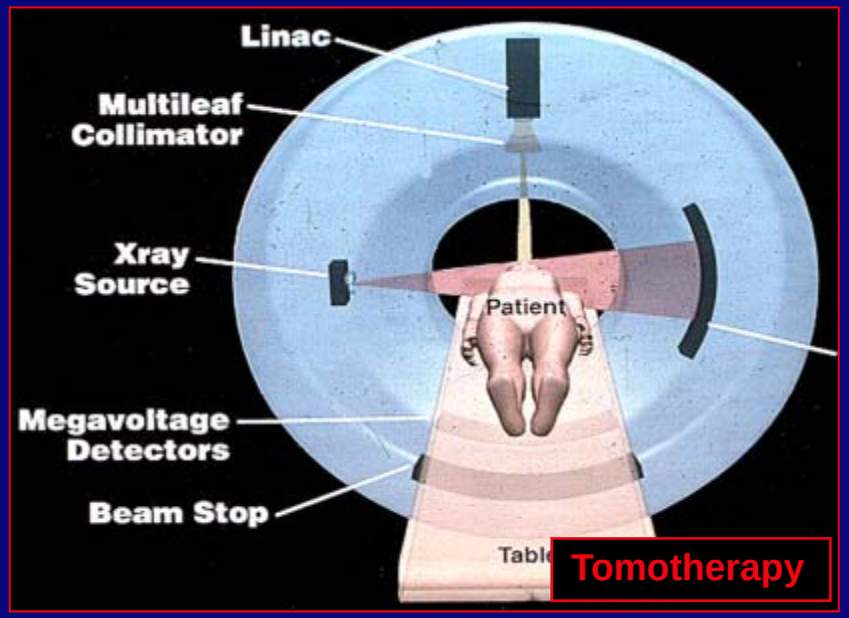
Dynamic Wedge



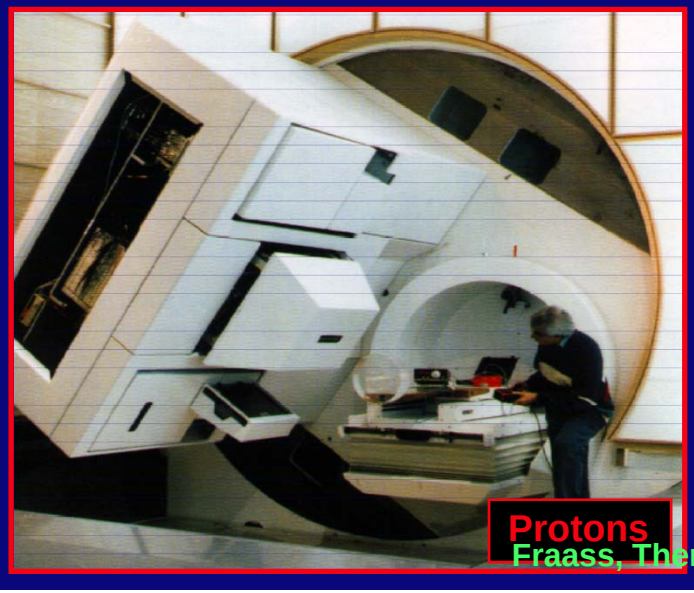
Leavitt et al, Med Phys 17: 87-91, 1990

2014: Virtually all Tx machines use computer-controlled treatment delivery (CCTxD)


Linac+MLC



Tomotherapy


Protons


Cyberknife

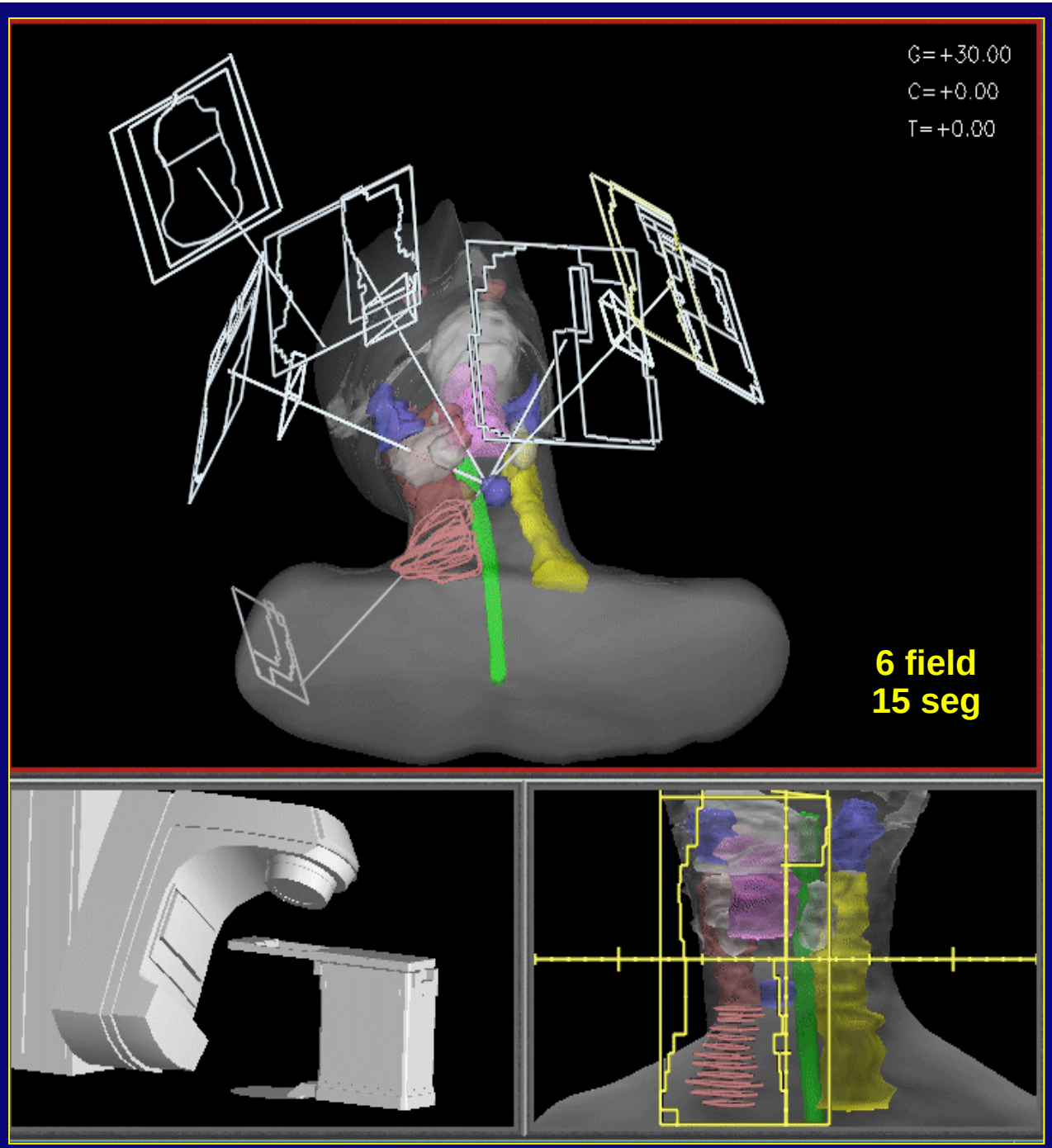
Why Use Computer-Controlled Treatment Delivery?

- Improve simple treatments (efficiency or accuracy)
- Treatments too complicated for manual delivery (e.g. IMRT, radiosurgery, SBRT)

Completely Automated Treatment Delivery
Ave. Tx Time, 33 Prostate Pts,
6 Field Axial Plan with MLC *

Treatment Delivery Type	Time (min)
Normal treatment w/ focused blocks	12
Automated segmental w/ clearance check	6
Automated segmental	4.2

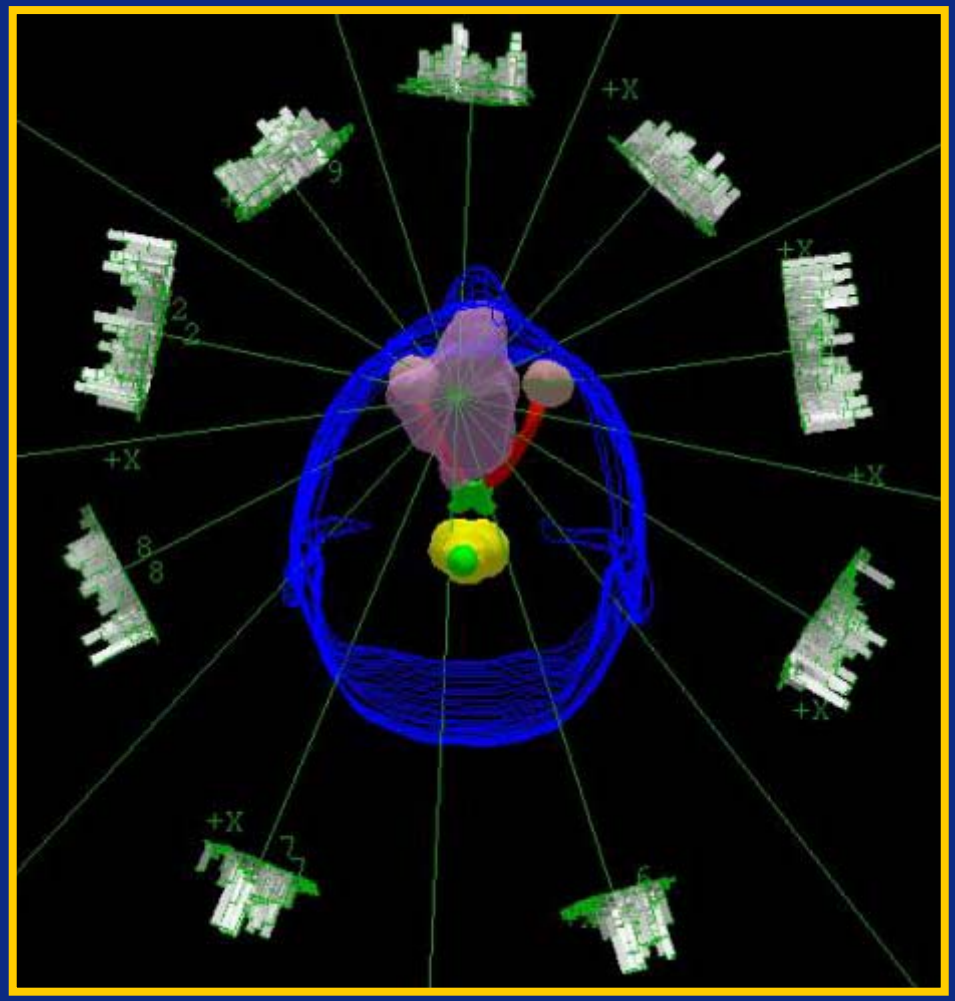
* G.S. Mageras, et al: IJROBP 27 (Suppl. 1): 207-208, 1993 [Abstract]

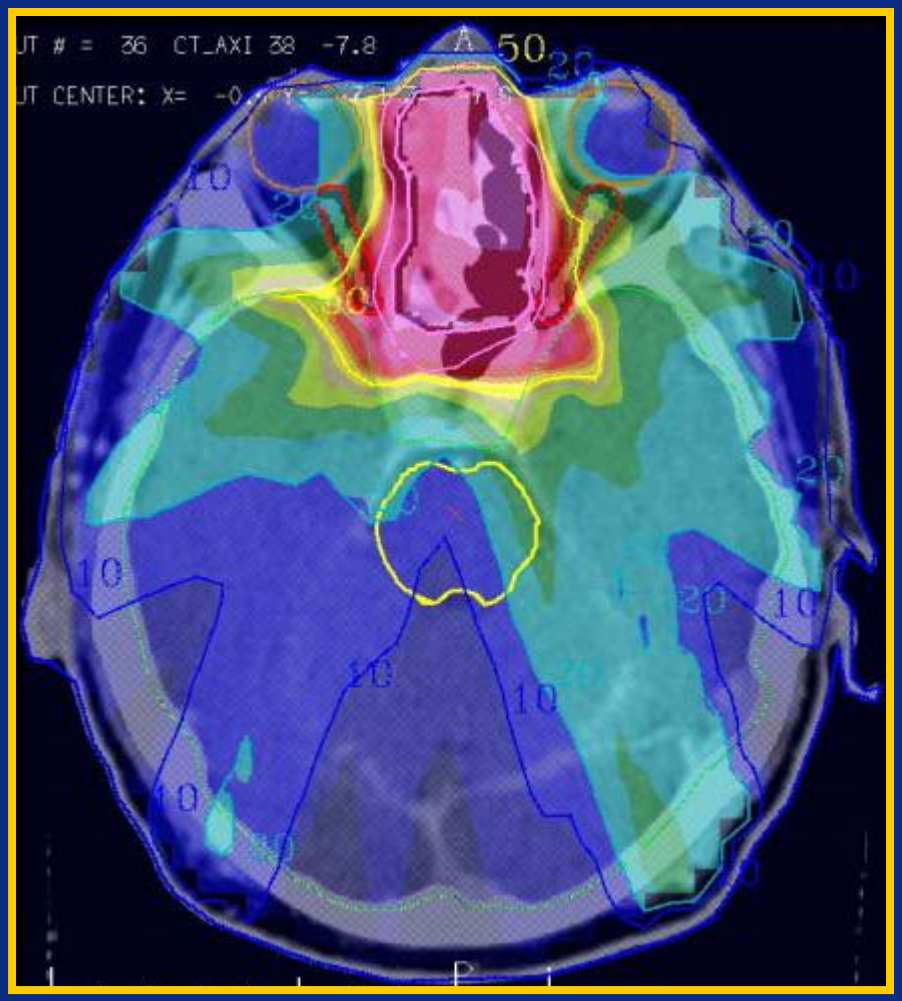


CCRT allows more complex and sophisticated treatments

Example: automated multisegment IMRT with 3D gantry + table motions ("pseudo-isocenter Txs)

IMRT:
Requires Computer Control





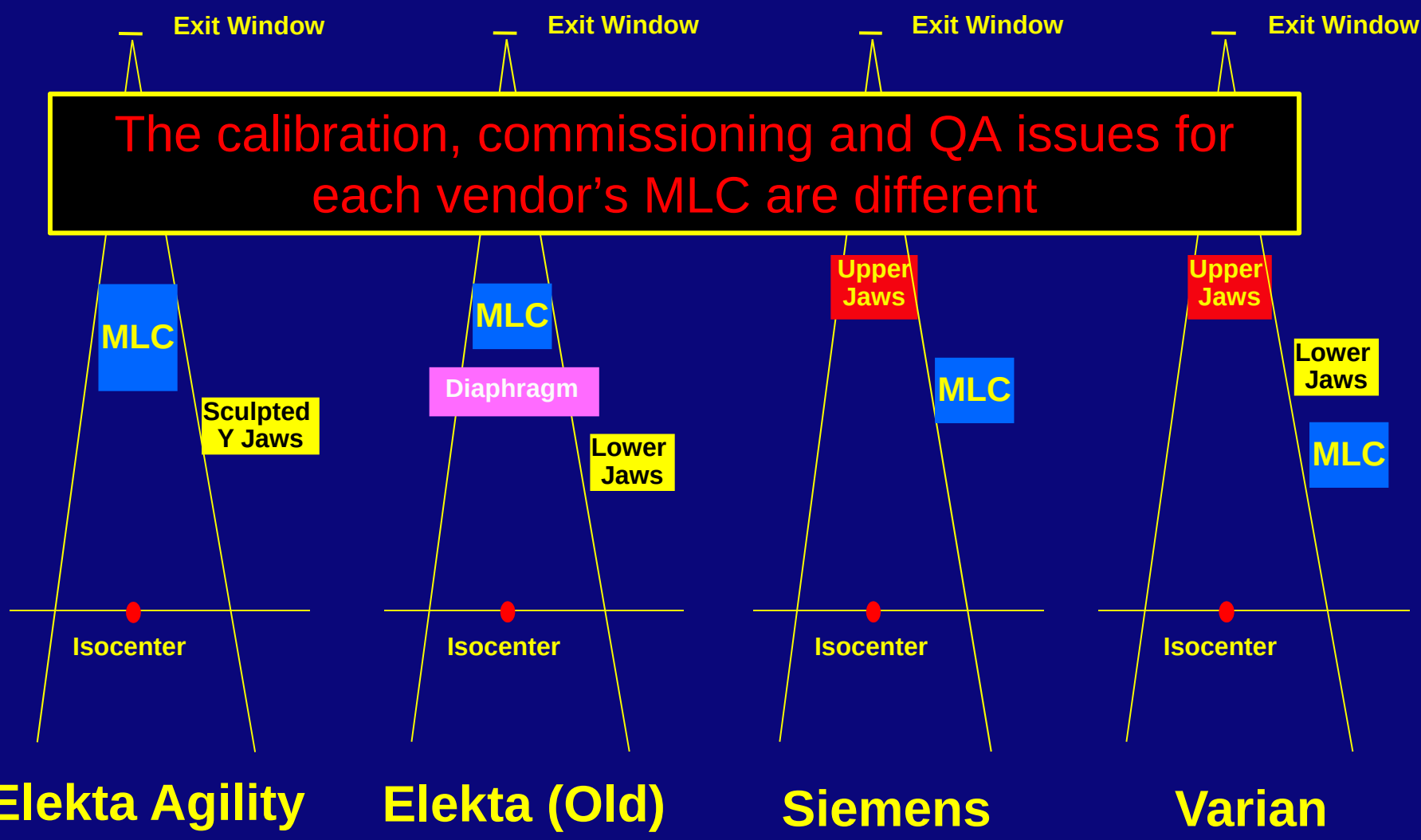
Matuszak

Both technology and process have changed, and both changes require that we change how we think about commissioning, use, and QA for planning and delivery:

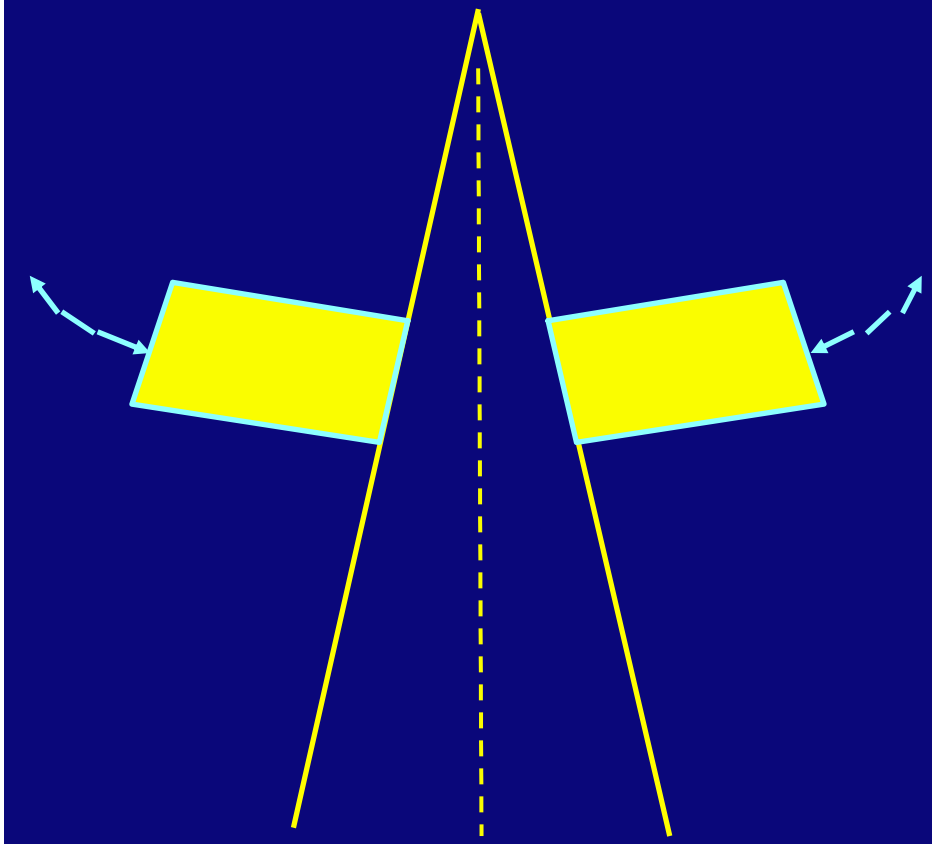
Examples:

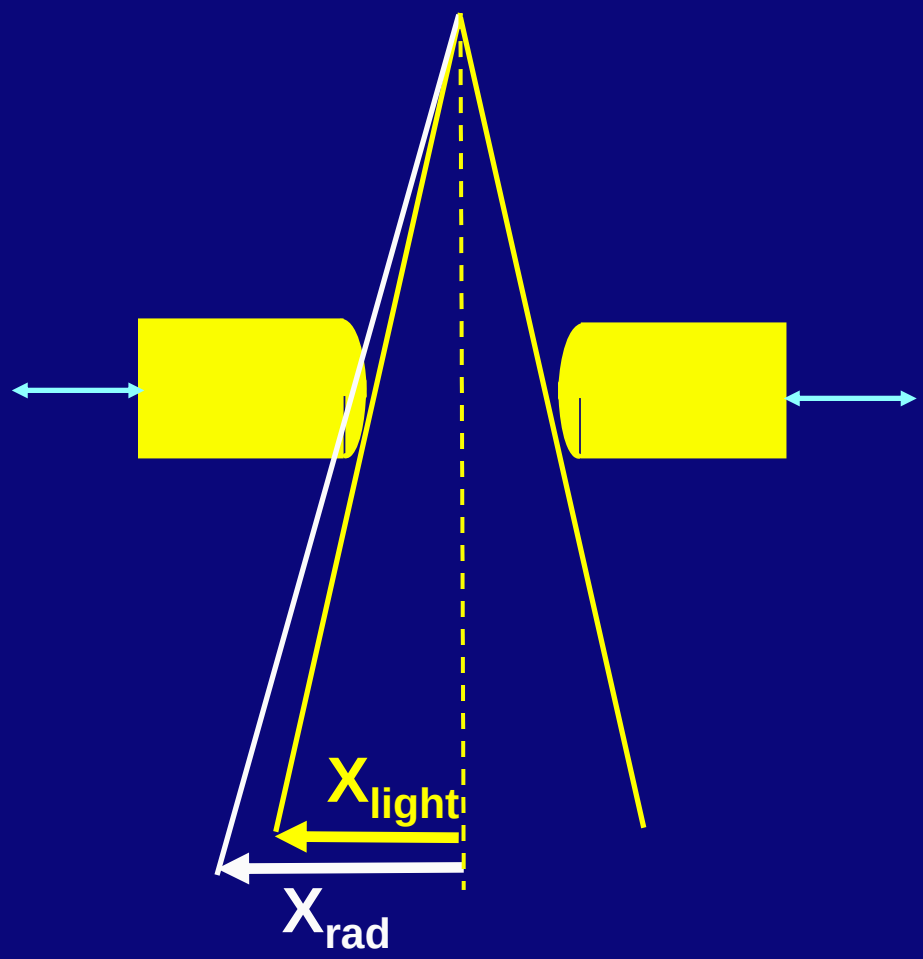
- **MLC Calibration**
- **Tx delivery process**

Collimator Designs



Calibration of Curved Leaf-end MLCs: Non-focused Collimators





Double Focused

Linear, Rounded Leaf Ends

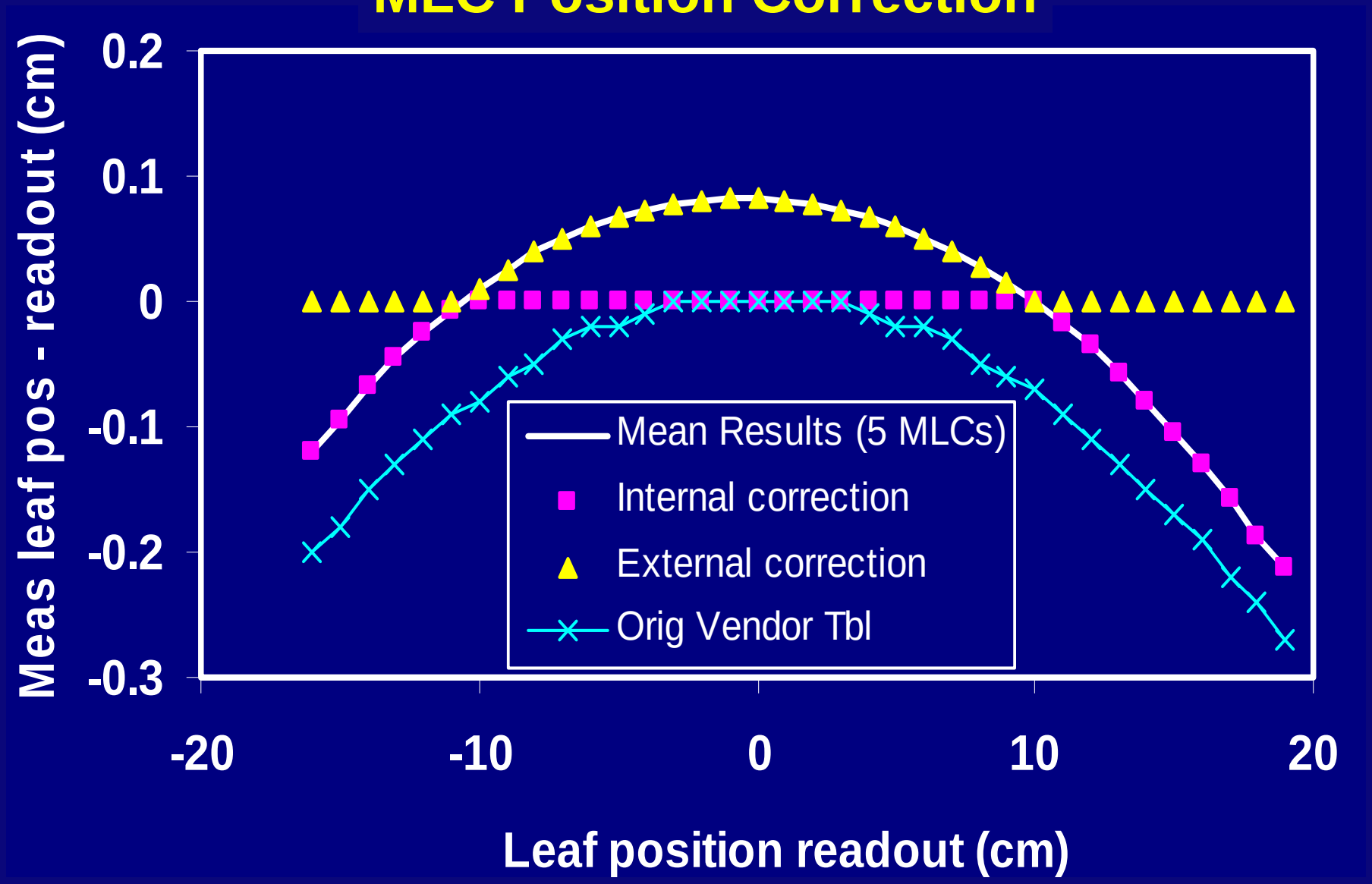
Calibration of Curved Leaf-end MLCs:

Software determines:

- **Physical calibration of leaf motion**
- **Accuracy of MLC readout vs light field**
- **Accuracy of MLC readout vs rad field**

The radiation and light field edges are not supposed to agree - user must choose one or the other for calibration

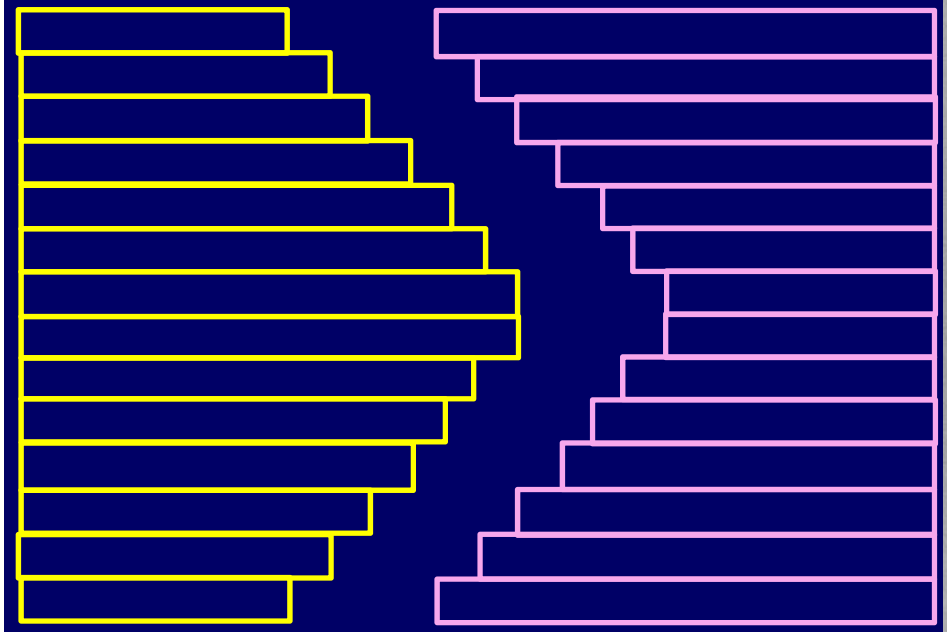
MLC Position Correction



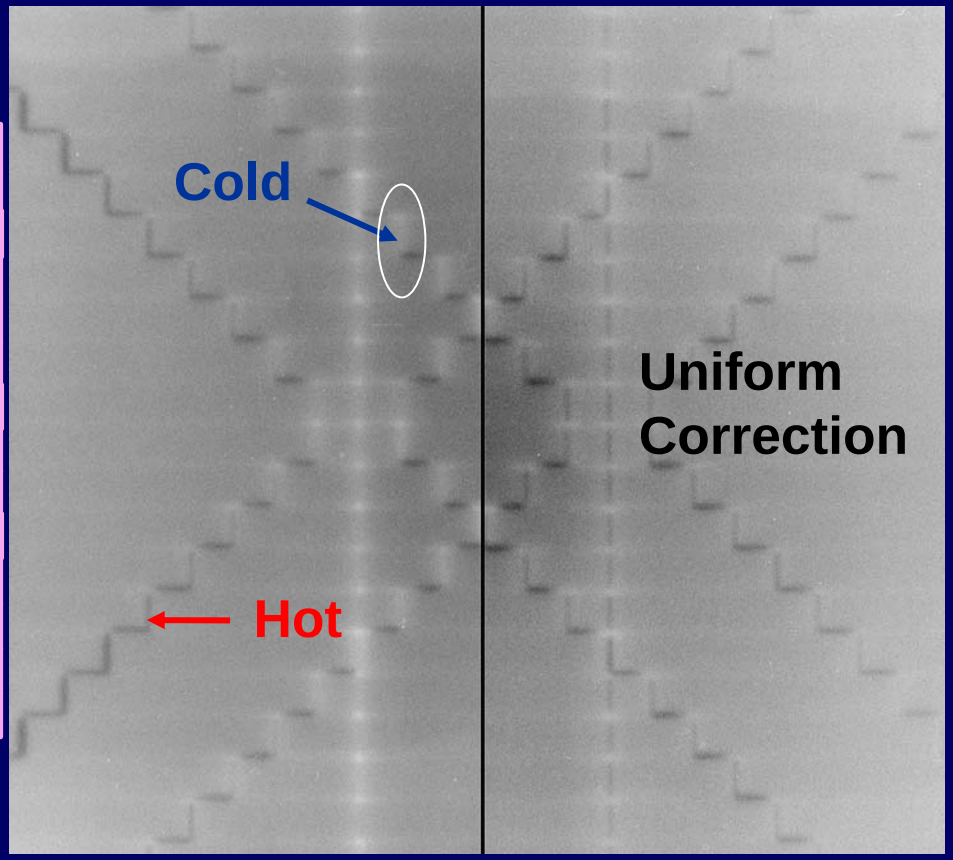
Graves et al, Med Phys 28: 2227-2233, 2001

MLC QA for Calibration/Offset Correction

Use Multiple MLC shapes



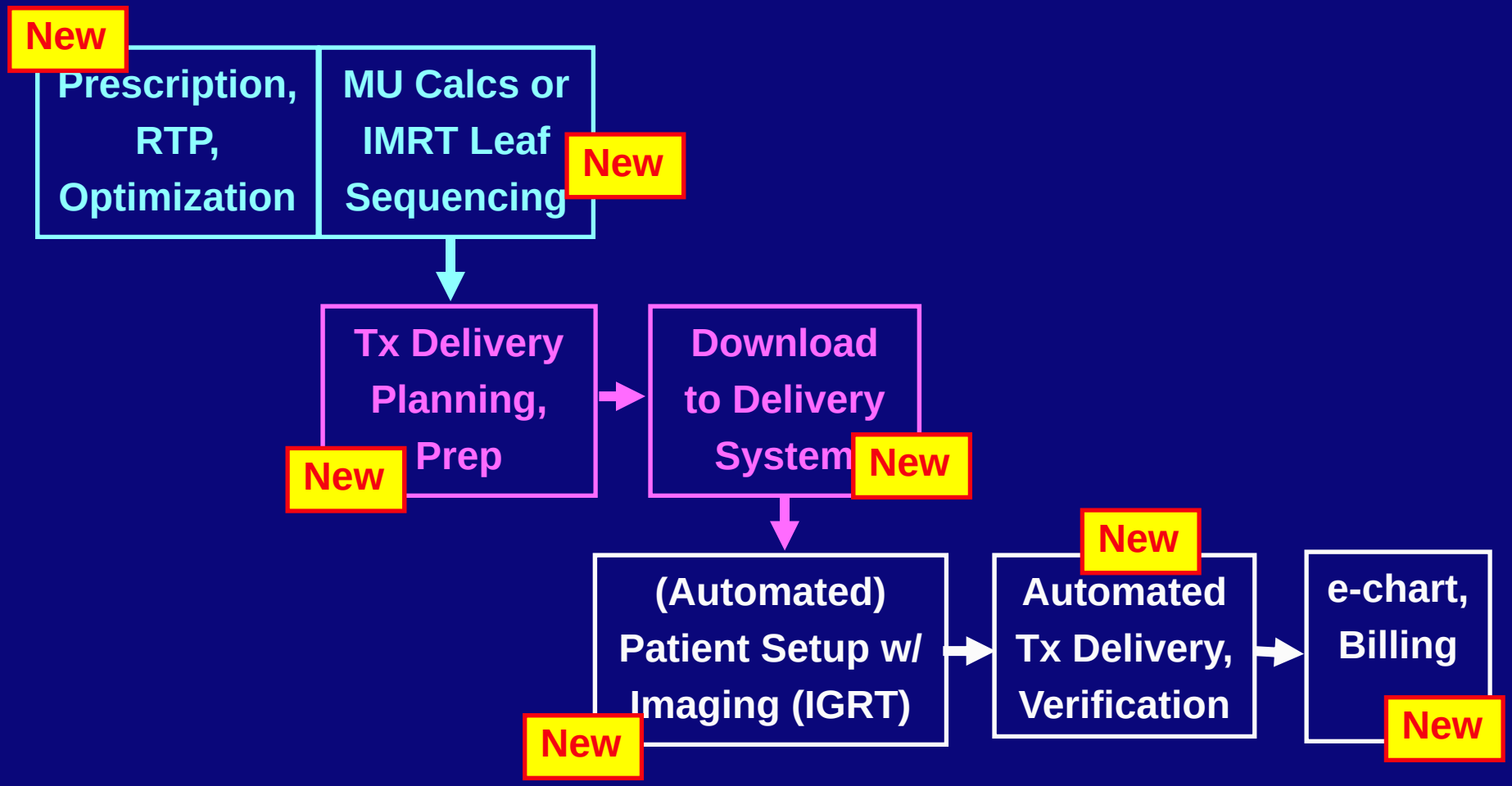
Uncorrected **Corrected**



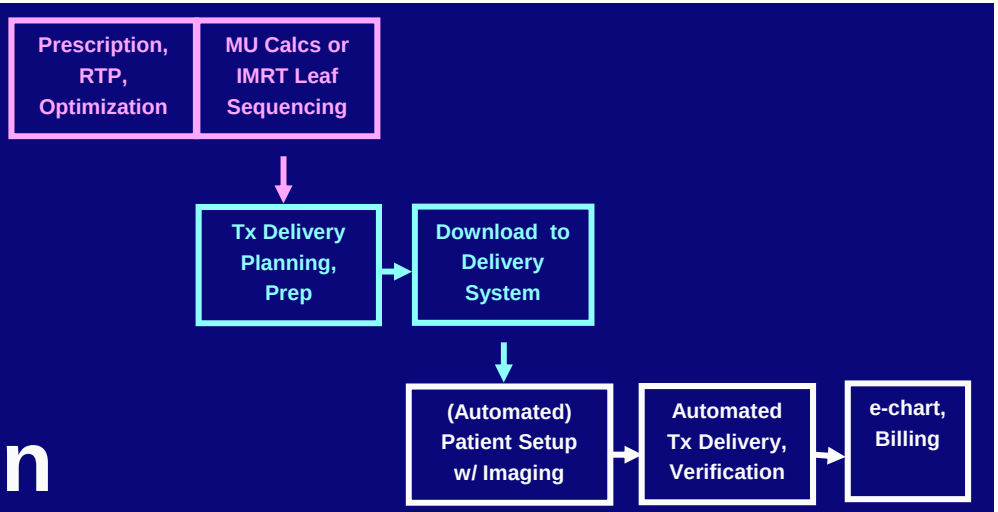
Graves, Med Phys 28: 2227, 2001

Modern Planning/Delivery Process

New



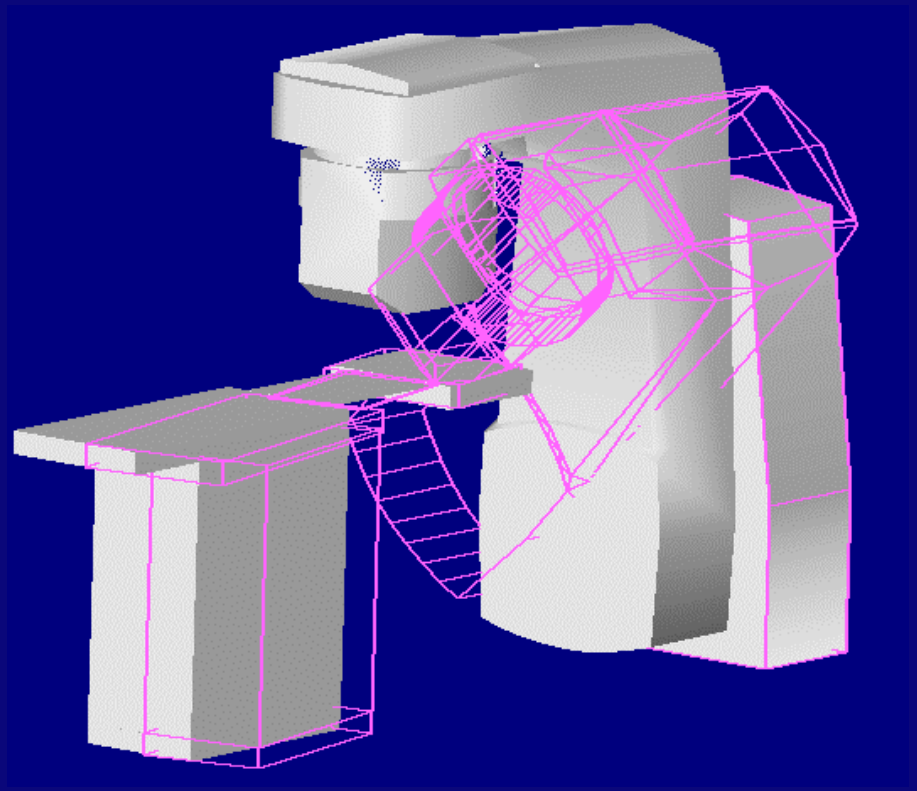
Computer-Controlled Treatment Delivery (CCTxD)

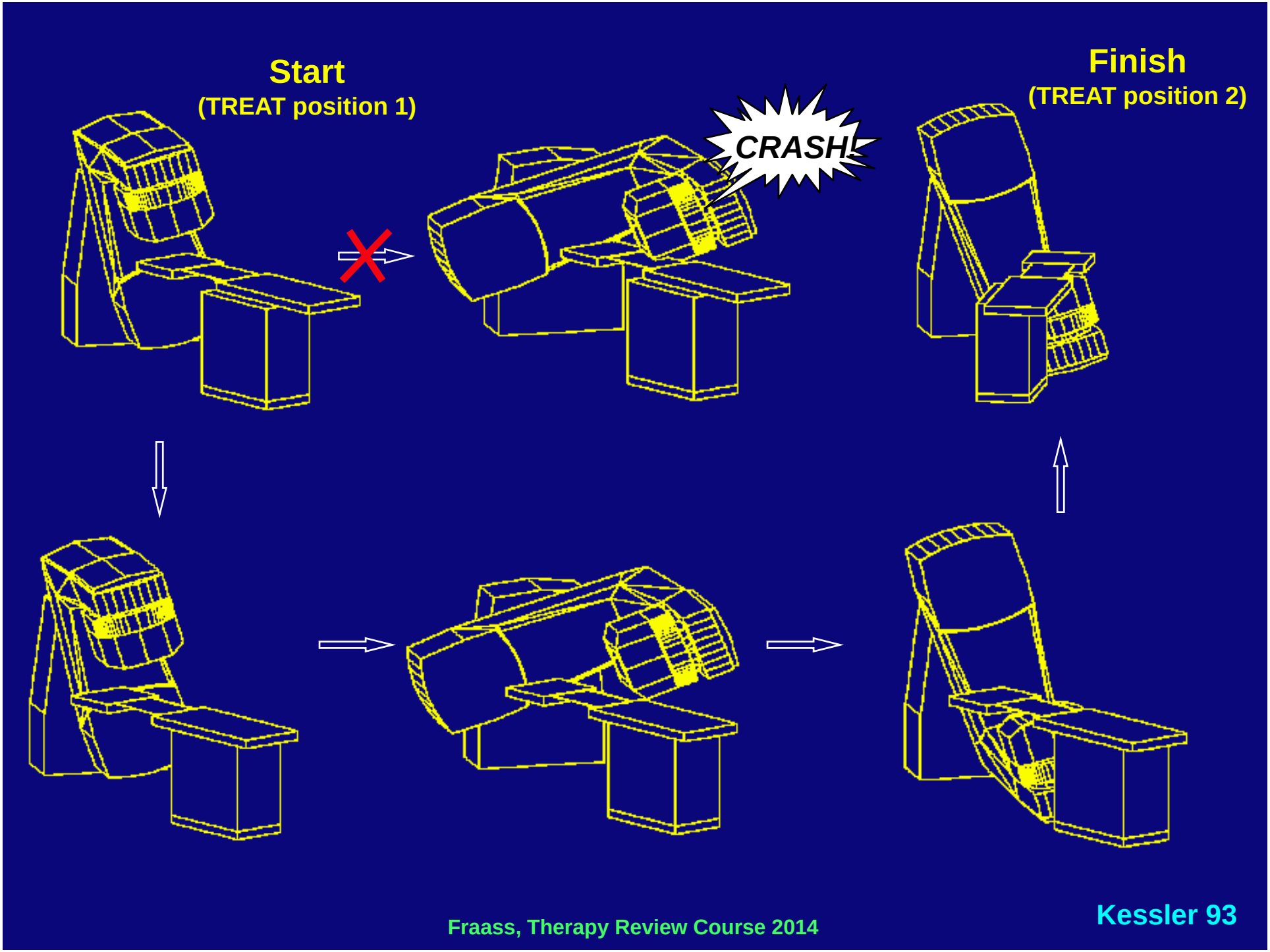


- Process and design are crucial for QA analysis
- Many completely new and changed process steps
- QA for individual steps should not be analyzed separately – whole process must be considered

Computer-Controlled Treatment Delivery

Computer-controlled treatment delivery requires that all motions, trajectories and actions by the delivery equipment be planned and verified before use: This is a big change in the treatment delivery process !




Start
(TREAT position 1)
CRASH!
Finish
(TREAT position 2)
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Kessler 93

Example CCRT Tx Procedure

Seg#	Type	MU	Comments
1.1	Setup	-	Set new iso. ref. pt.
1.2	Film	3.0	Localization portal image
1.3	Move	-	Move to 1st Tx seg
1.4	Tx	132.2	Tx RAO
1.5	Move	-	Shift table lat, rotate gantry
1.6	Move	-	Shift table back, rotate ped
1.7	Tx	122.8	Tx LSPO
1.8	Move	-	Move to intermed. position
1.9	Move	-	Move to dismount position

Treatment Delivery Planning

Prescription, RTP, Optimization

MU Calcs or IMRT Leaf Sequencing

Tx Delivery Planning, Prep

Download to Delivery System

(Automated) Patient Setup w/ Imaging

Automated Tx Delivery, Verification

e-chart, Billing

Convert plan coordinates

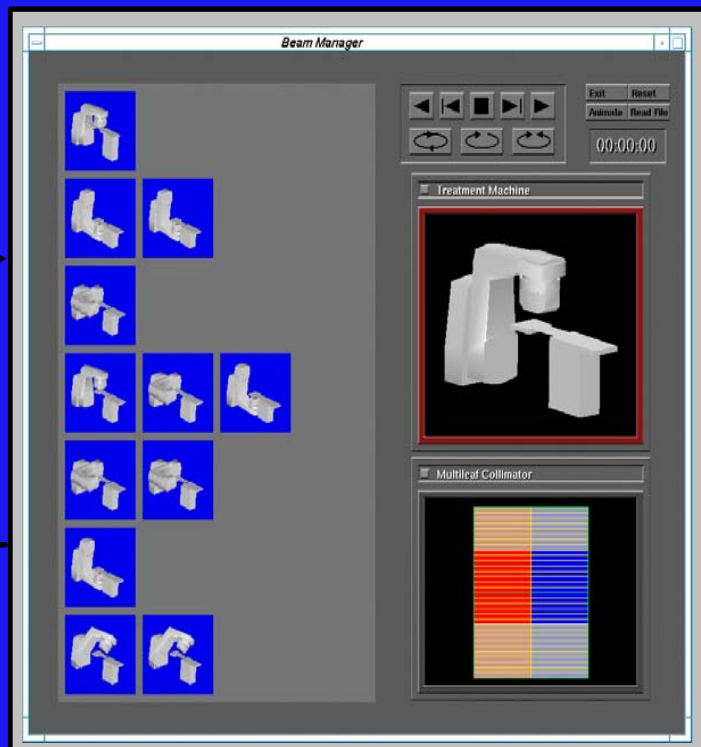
add set-up and verification segments

simulate machine motions

not ok

ok

send to therapy machine



reorder and add

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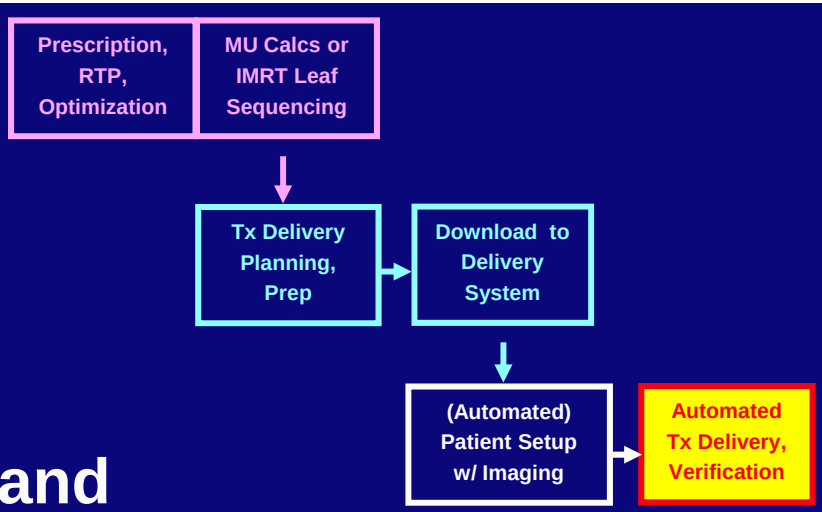
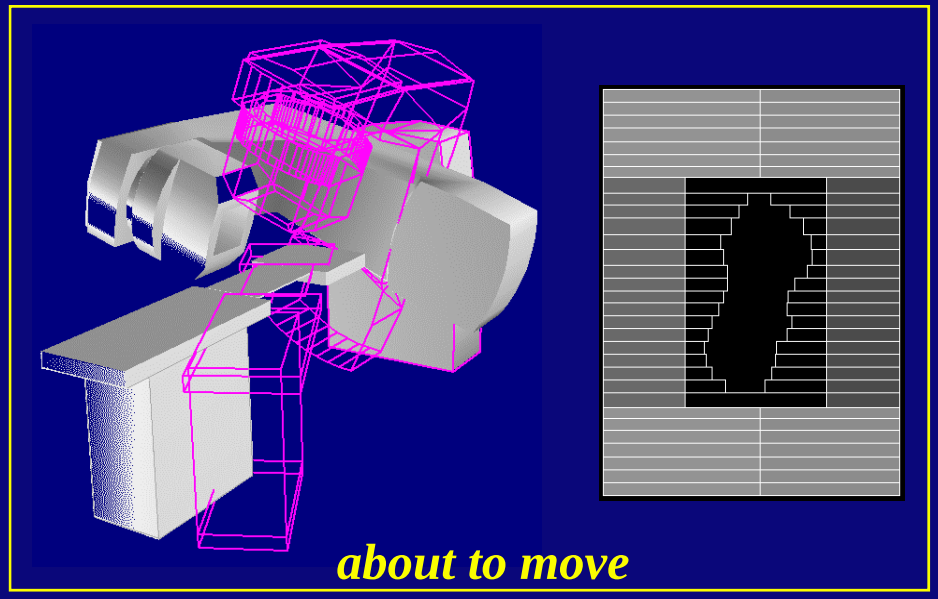
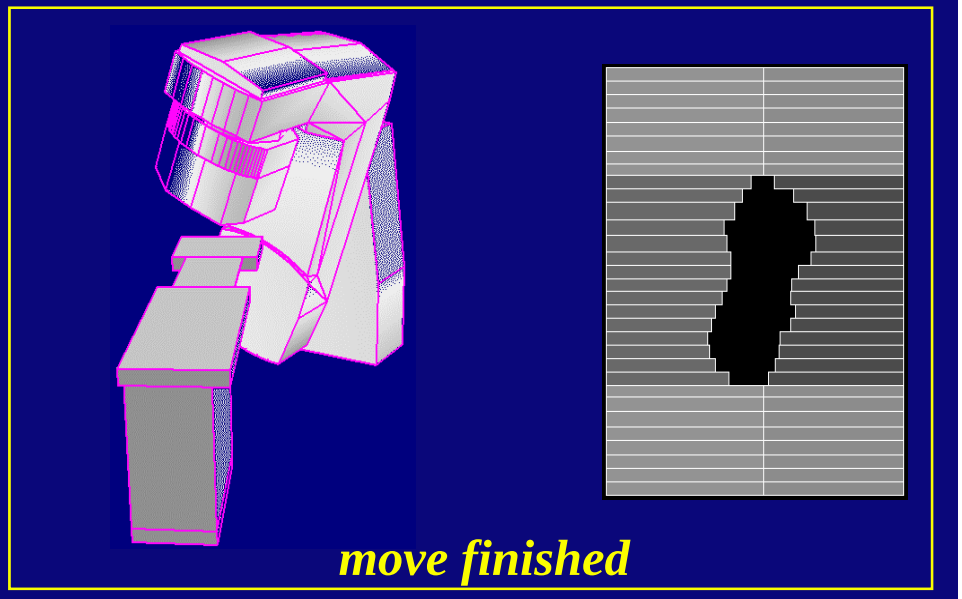
Kessler 93

Tx Delivery Verification



- How involve RTTs?
- Need to convey both qualitative and quantitative info
- Need both Tx Delivery scripts + flexibility





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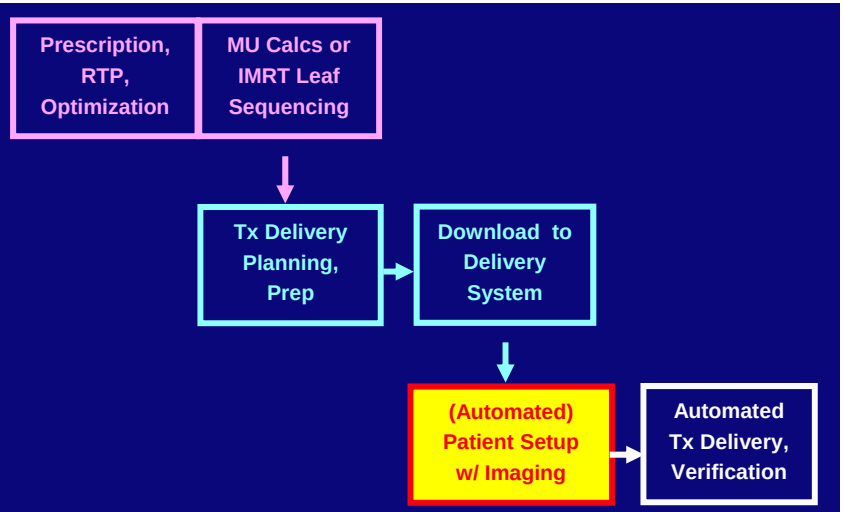
Patient Setup: from Port Films to IGRT

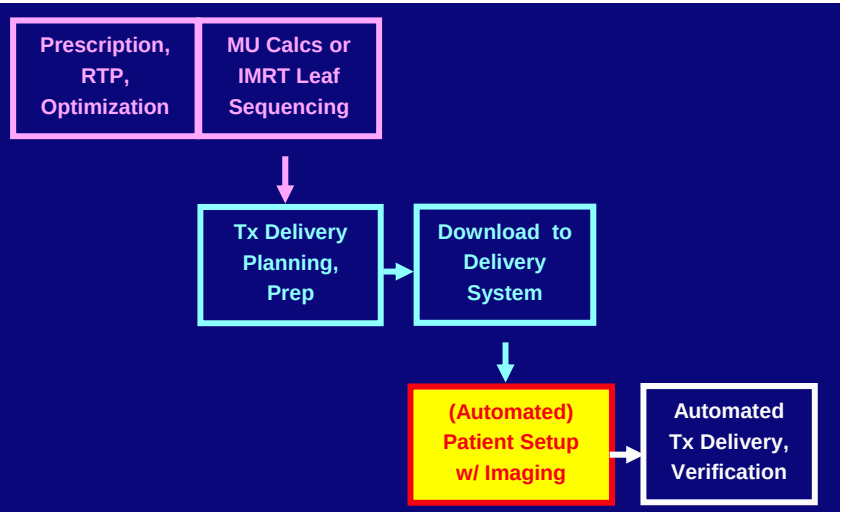


Patient setup has changed:

- from skin marks with weekly orthogonal port films
- to daily Image-Guided Radiation Therapy (IGRT) with automated setup correction

in just a few years

Patient Setup: IGRT

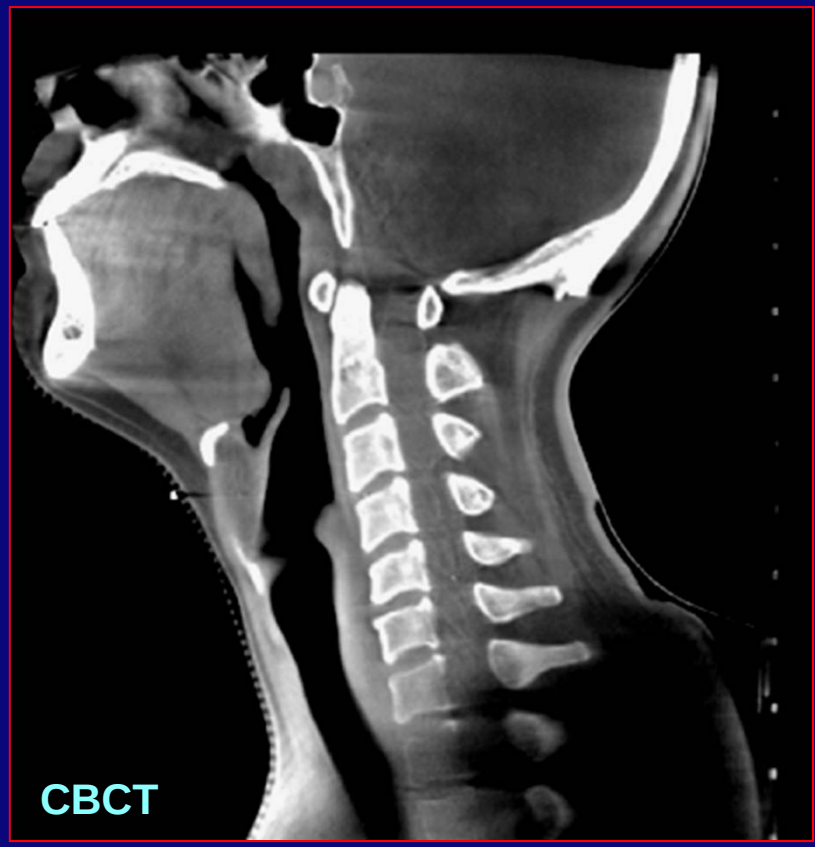


New tools:

- MV Portal Imaging
- Diagnostic X-rays + on-board imaging
- Conebeam CT
- Implanted markers
- RF Markers
- etc…

IGRT-driven set-up changes:

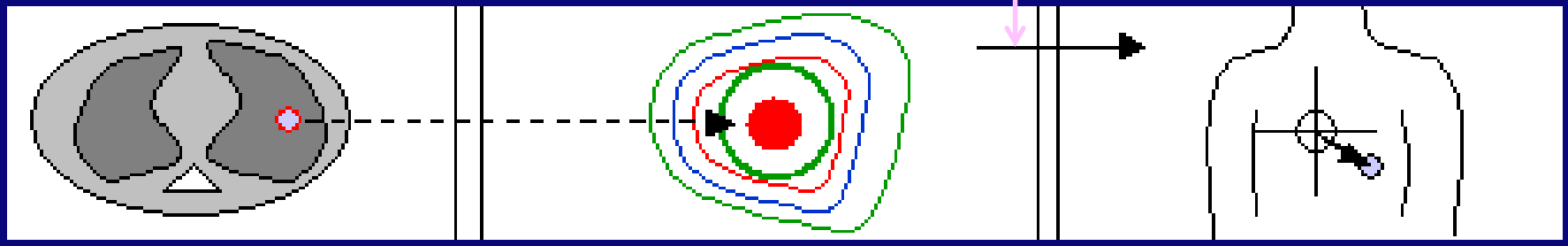
- Delivery process
- User interactions
- Use of delivery system software
- Database needs



High Quality IGRT

Do QA of transfer of IGRT params to Tx Unit

Target + Normal Tissue Definition	Margin Design + Treatment Planning	Imaging, Adjustment + Delivery



Delineation – Peer Review	Pick margins consistent with process + data	Consistent IGRT procedure at Tx Unit

IG performance data

Review IG results to confirm PTV coverage and OAR avoidance

ASTRO IGRT White Paper: D Jaffray et al: Assuring Safety and Quality in Image-guided Delivery of Radiation Therapy. PRO 3: 167-170 (2013)

Recommendations for Safe + Effective IGRT

Recommended IGRT Infrastructure

- Create a multi-professional team responsible for IGRT
- Daily, monthly, annual QA for all IGRT subsystems
- Device + process training for all staff performing IGRT
- End-to-end testing of all new IGRT procedures, document before release
- Process-specific procedures + documentation for IGRT
- Identify who is responsible for IGRT correction decisions
- Site-specific planning procedures (margins), linked to IGRT

ASTRO IGRT White Paper: D Jaffray et al: Assuring Safety and Quality in Image-guided Delivery of Radiation Therapy. PRO 3: 167-170 (2013)

Recommendations for Safe + Effective IGRT

Recommended Patient-specific Procedures

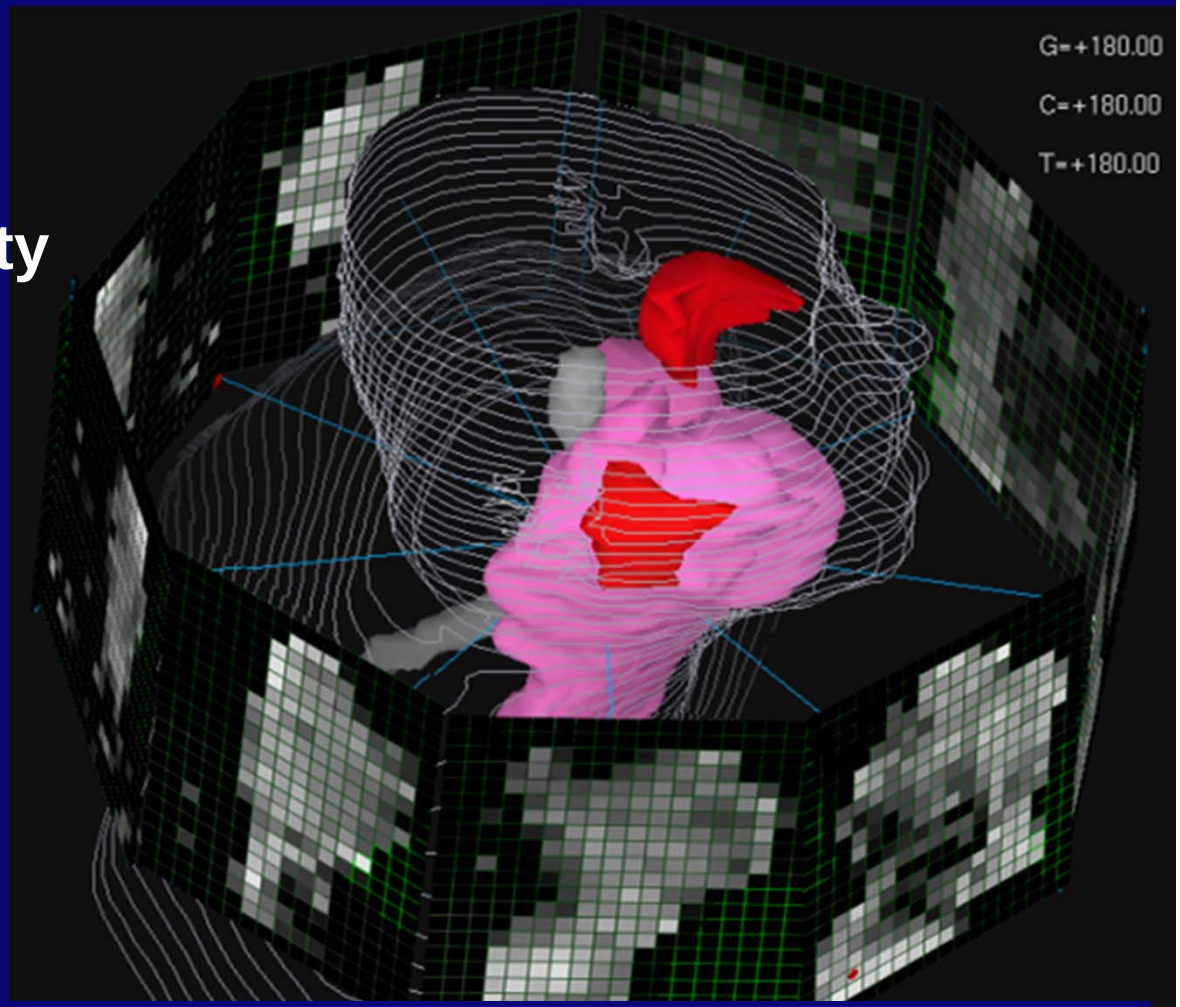
- Multi-professional peer review of PTVs. Peer review of GTV/CTVs by RadOncs
- Verify creation and transfer of IGRT ref data to IGRT systems
- Reporting mechanism for IGRT variances in treatment process

Remember, doing the image guidance wrong causes a 100% dose error to both target and normal tissues !

ASTRO IGRT White Paper: D Jaffray et al: Assuring Safety and Quality in Image-guided Delivery of Radiation Therapy. PRO 3: 167-170 (2013)

Intensity Modulated Radiation Therapy (IMRT)

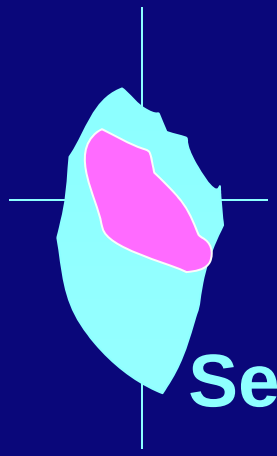
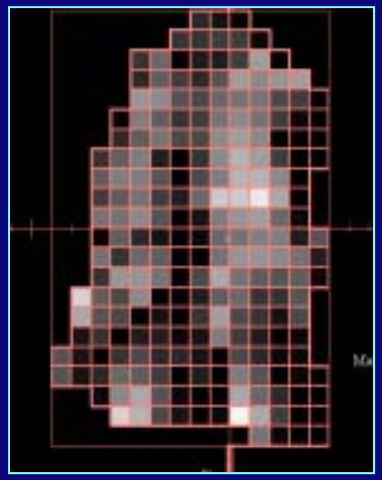
Computer-controlled radiation beam intensity modulation to create sophisticated dose distributions using dynamic or segmental CCRT delivery techniques



IMRT Collaborative Working Group: Intensity modulated radiotherapy: current status and issues of interest. Int J Rad Oncol Biol Phys 51: 880-914, 2001.

Intensity Modulated Radiation Therapy (IMRT)

Planning — **Forward Planning** or **Inverse Planning**

Beam Components —  **Segments** or  **Beamlets**

Delivery	**SMLC (2-150 segs/fld)**	**VMAT/RapidArc**
	DMLC	**Tomotherapy**
	Compensators	**Cyberknife**

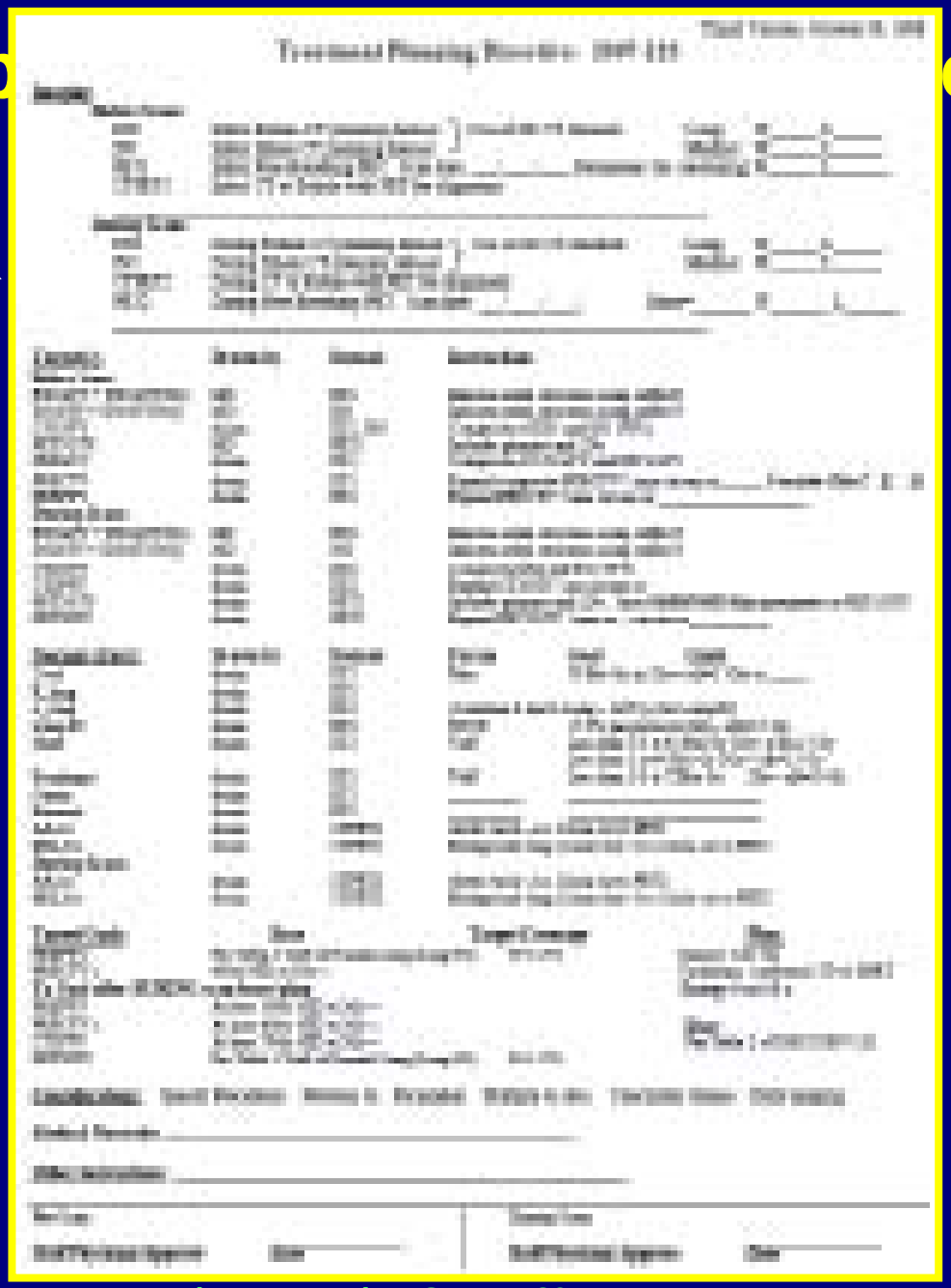
Safety Considerations for IMRT

- How is the IMRT planning/delivery process different than standard conformal therapy?

Radiotherap cess

Prescription

IMRT:
Plan Directive

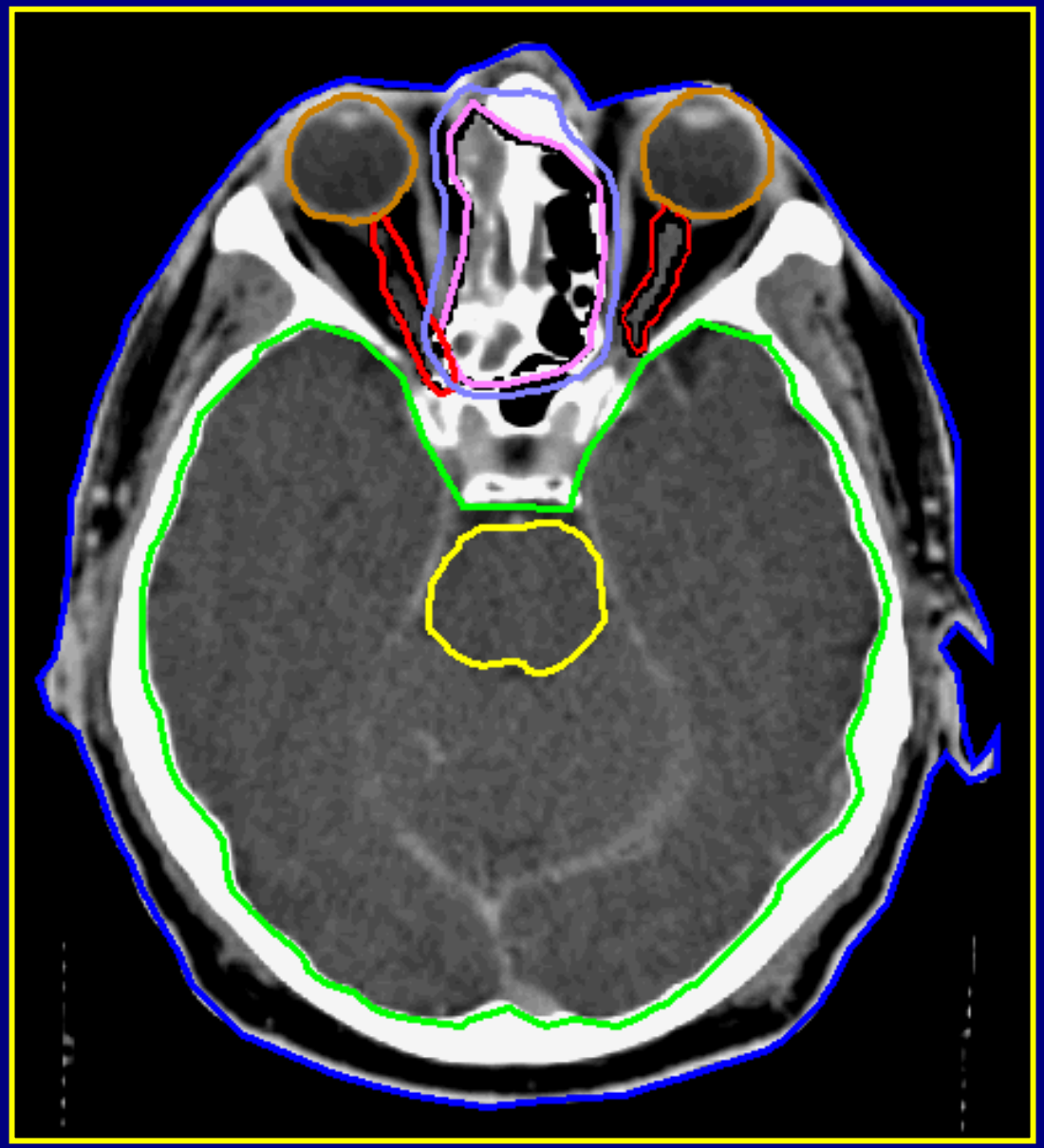


Radiotherapy Planning/Delivery Process

Prescription

↓

Target(s) + normal contours



Fraass, Therapy Review Course 2014

Radiotherapy Planning/Delivery Process

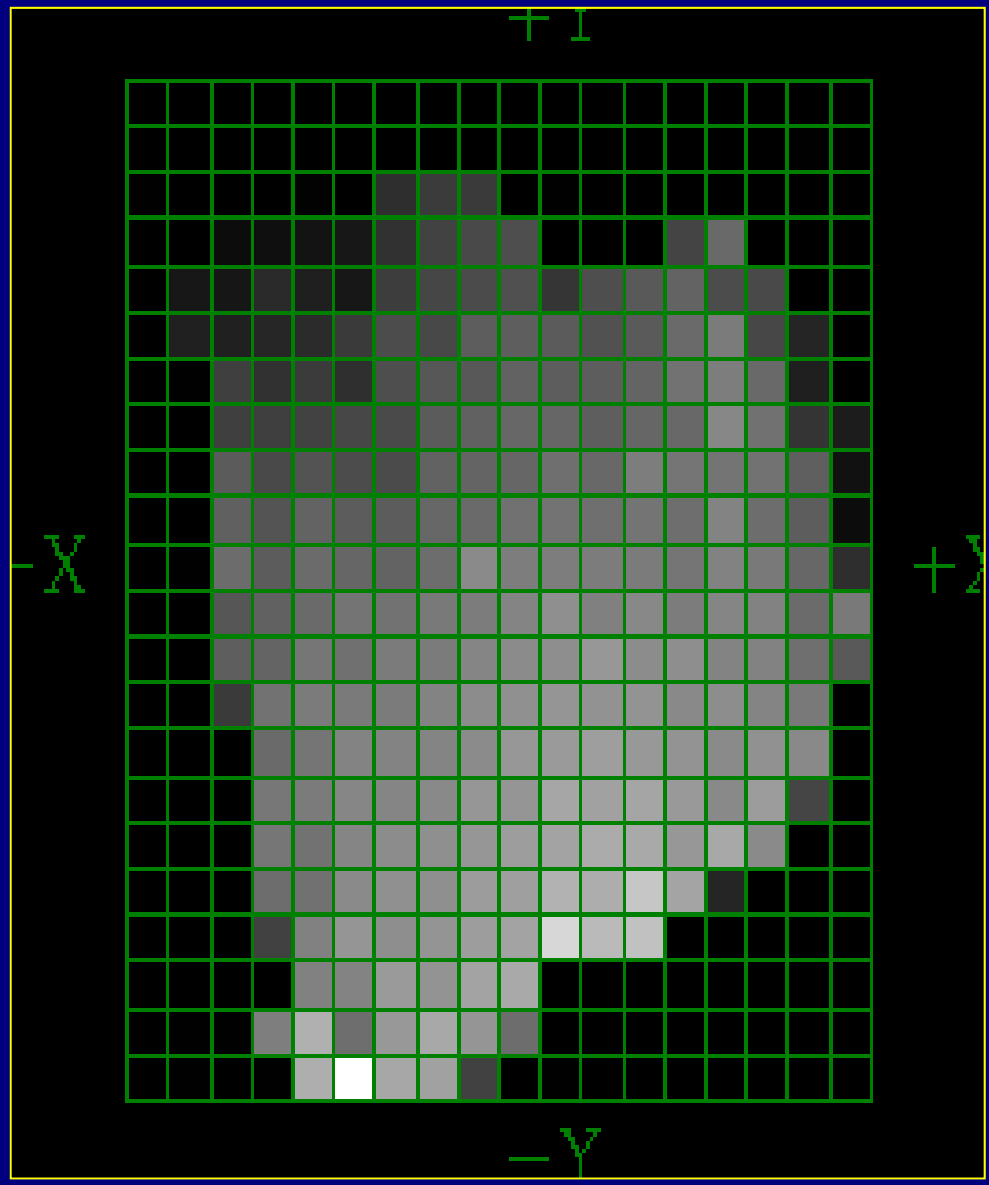
Prescription

↓

Target(s) + normal contours

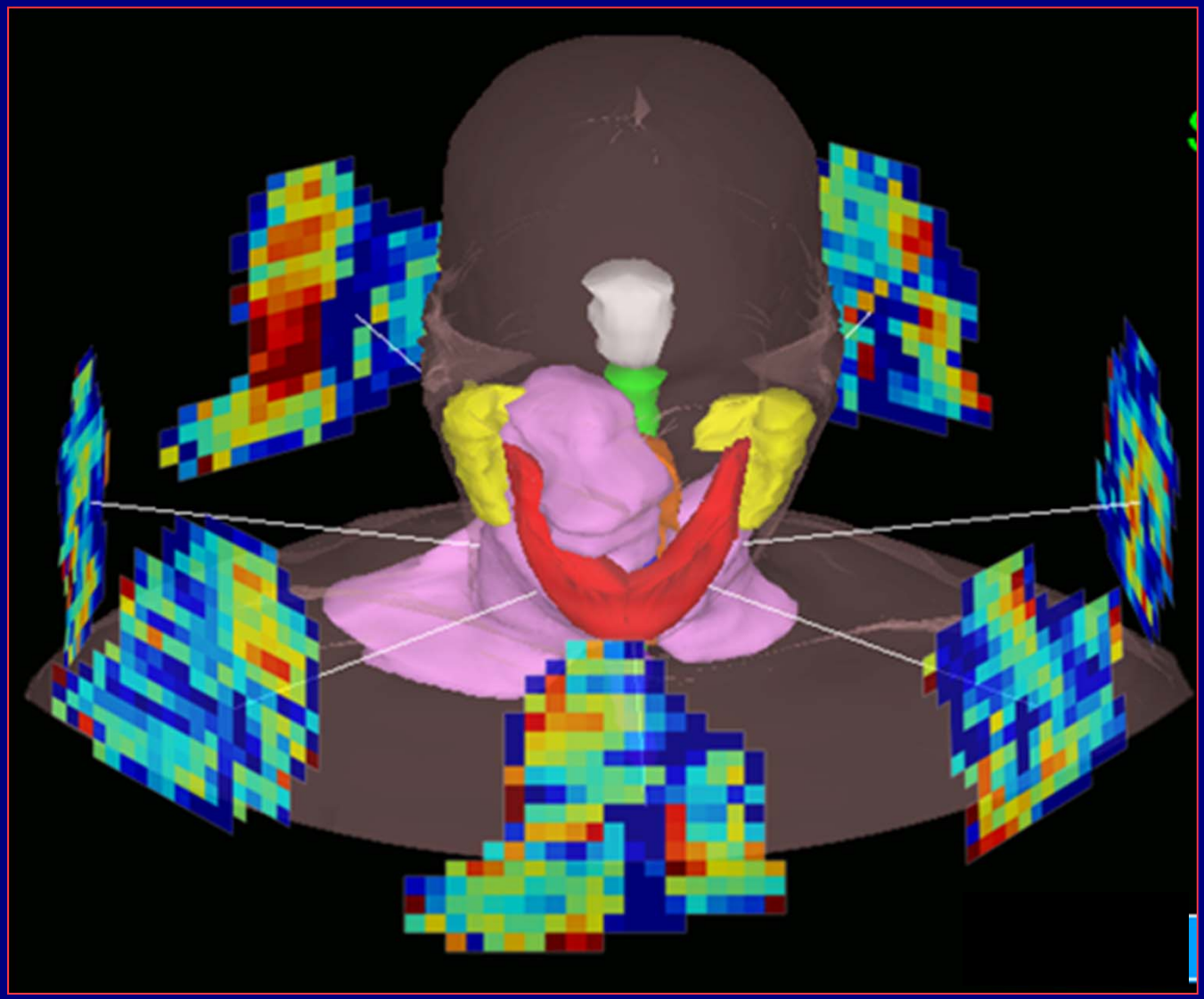
↓

Beams



Radiotherapy Planning/Delivery Process

- Prescription
- Target(s) + normal contours
- Beams
- **Planning: Inverse Plan Optimization**

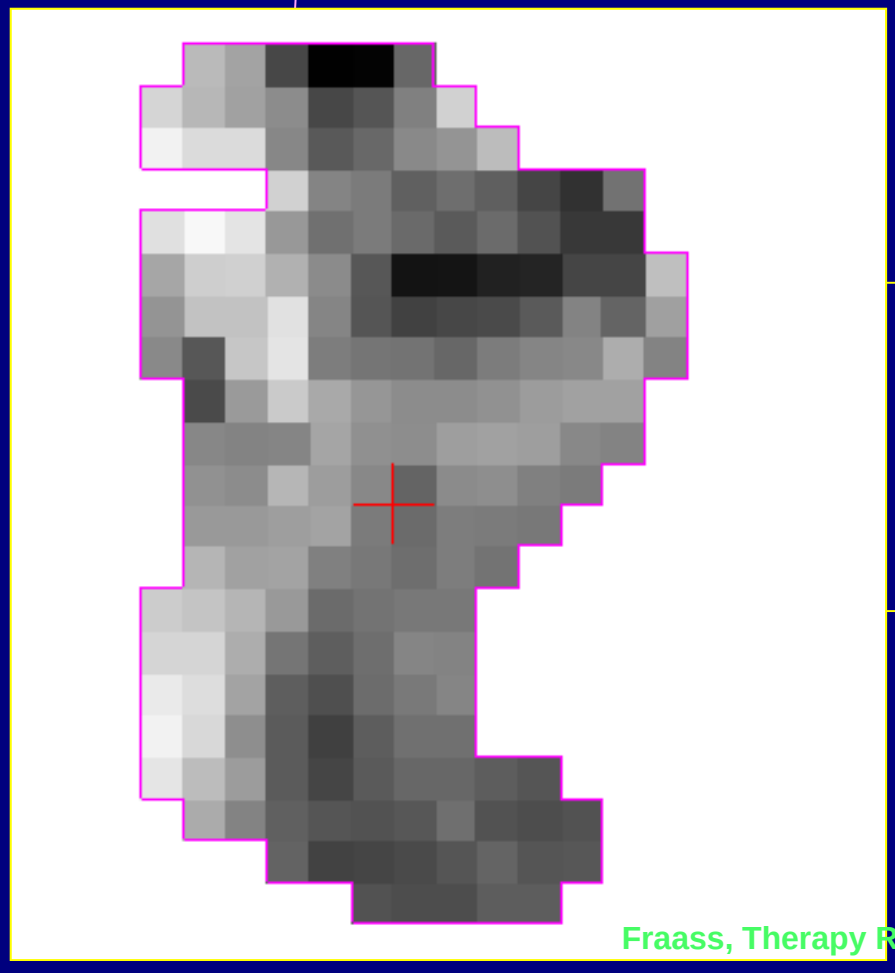


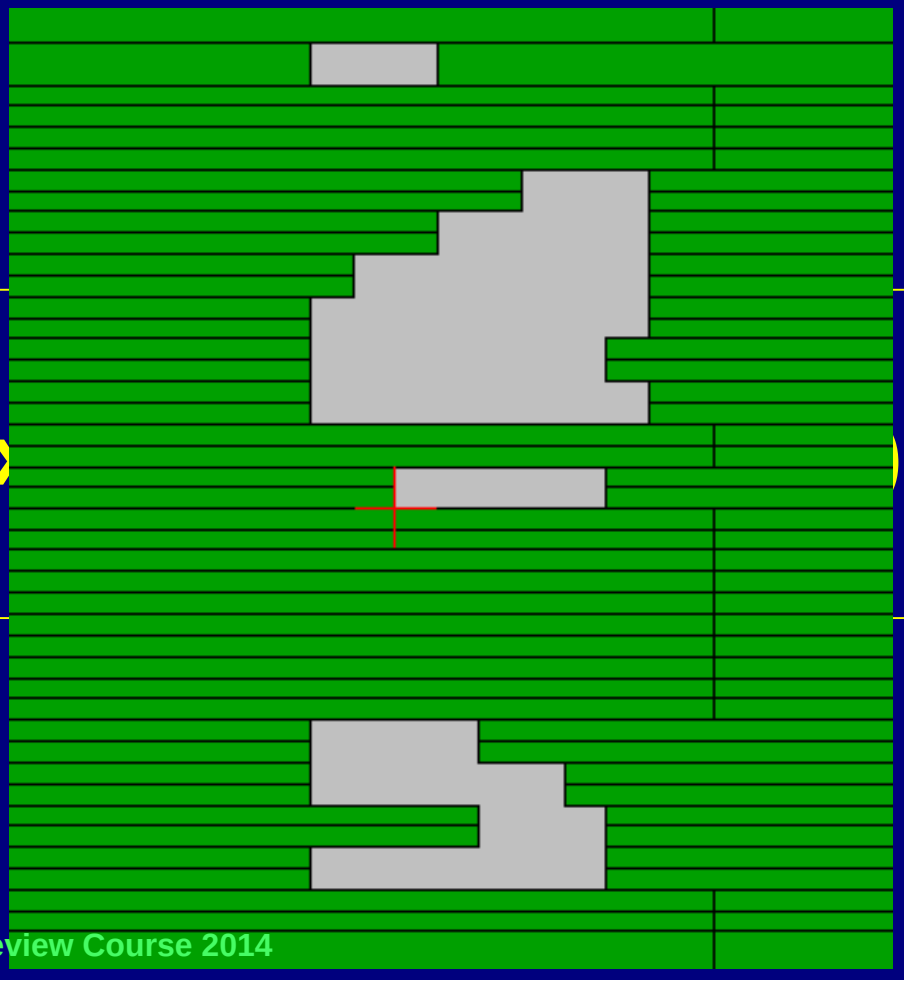
Fraass, Therapy Review Course 2014

Radiotherapy Planning/Delivery Process

MU Calculation

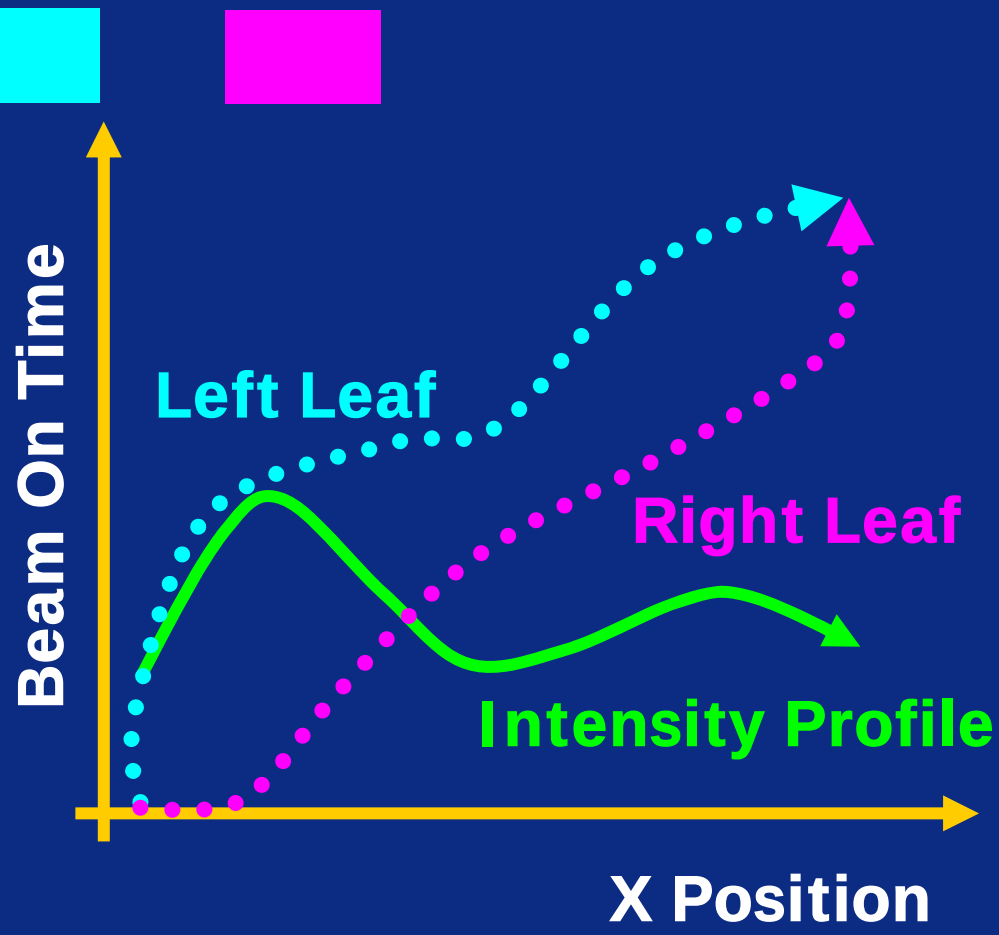
IMRT: MLC Sequencing algorithm to calc MLC trajectories and intensities





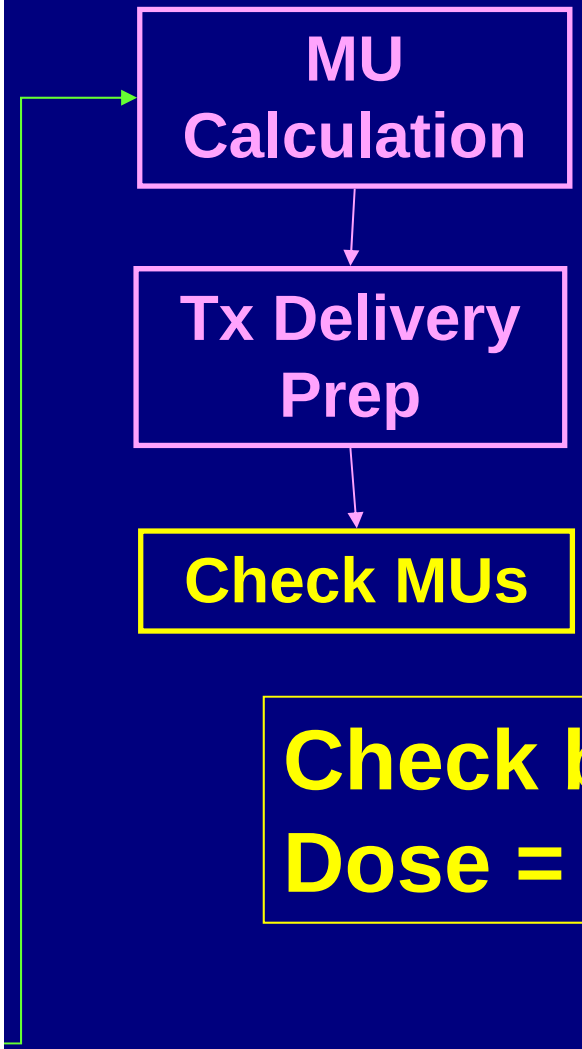
Dynamic MLC Delivery

- Sliding Window
- Leaves are in motion while the beam is on
- Leaf speeds are variable depending on field to be delivered



Matuszak

Radiotherapy Planning/Delivery Process



Check by hand:
Dose = MU x Cal x TPR x Scp x ISL . . .)

Radiotherapy Planning/Delivery Process

M
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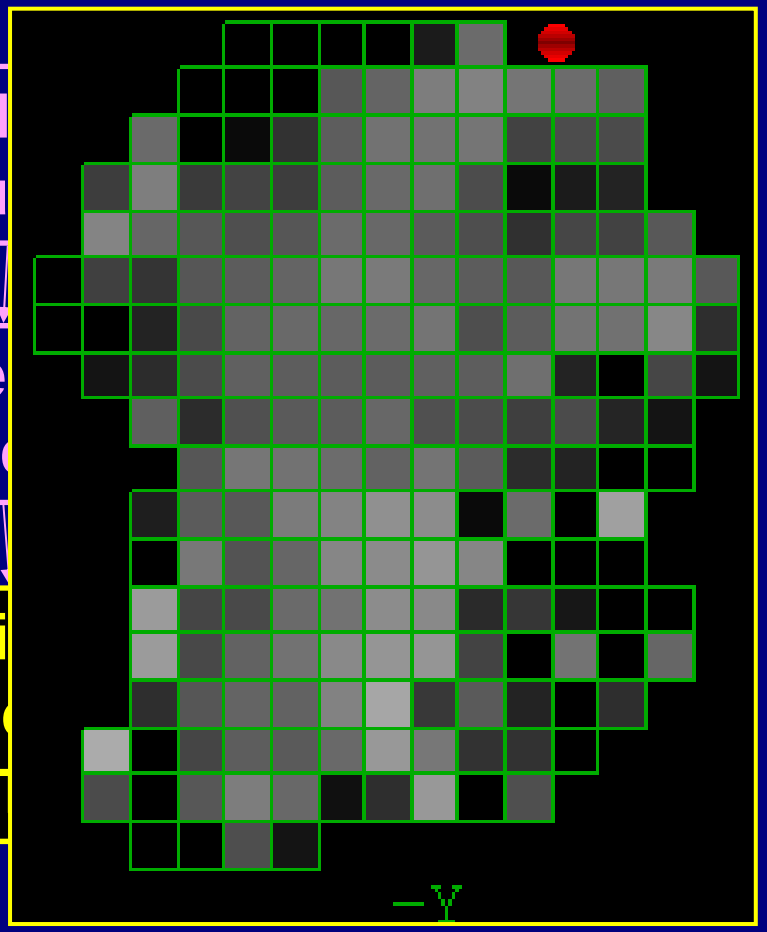


Patient-specific IMRT QA : Need to check: 1) delivered intensities, 2) dose in phantom (per field), 3) composite for plan

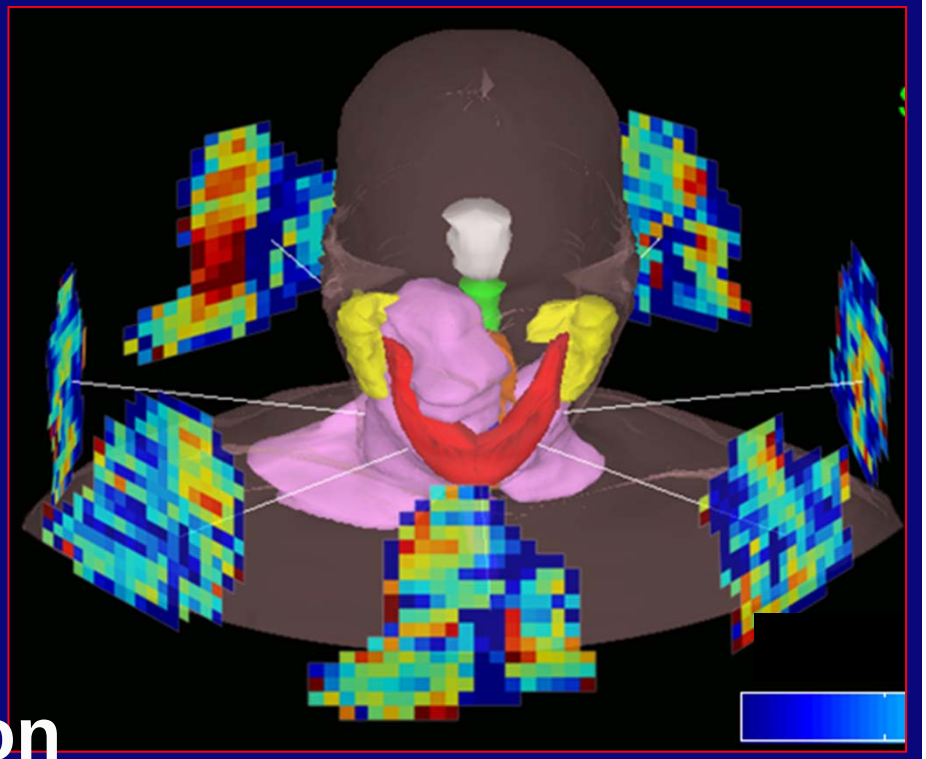
Tx Delivery Issues: IMRT, VMAT, . . .

- Plans are too complicated to check by hand – requires computer-based checks
- It is very difficult for RTTs to know whether the right things are happening
- For highly conformal plans, sub-millimeter details can make a difference (total dose, hot spots, etc)
- Note, problems can lead to large overdoses (e.g., recent mis-administrations in which MLC files were disconnected from delivery, leading to IMRT MUs without MLC motions)

Computer Controlled Tx Delivery: History, Issues and Safety

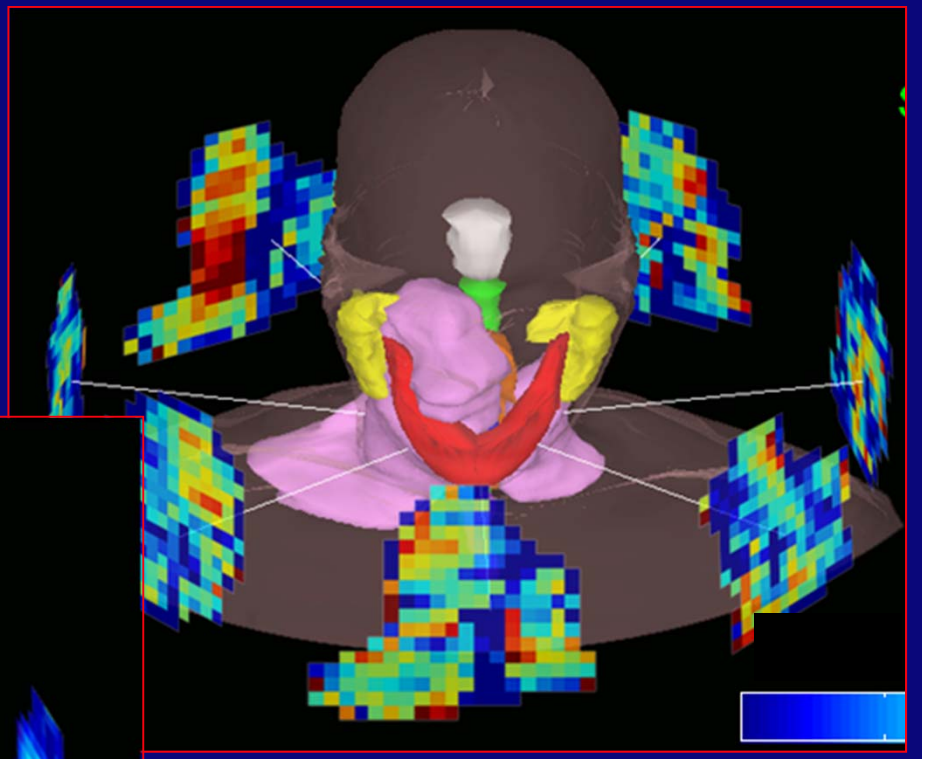
- Manual Treatment Delivery
- Modern Computer-Controlled Treatment Delivery (CCTxD)
- IMRT, IGRT, VMAT, 4-D:more complex!
- Safety/QA Issues for CCTxD, IMRT
- Conclusions

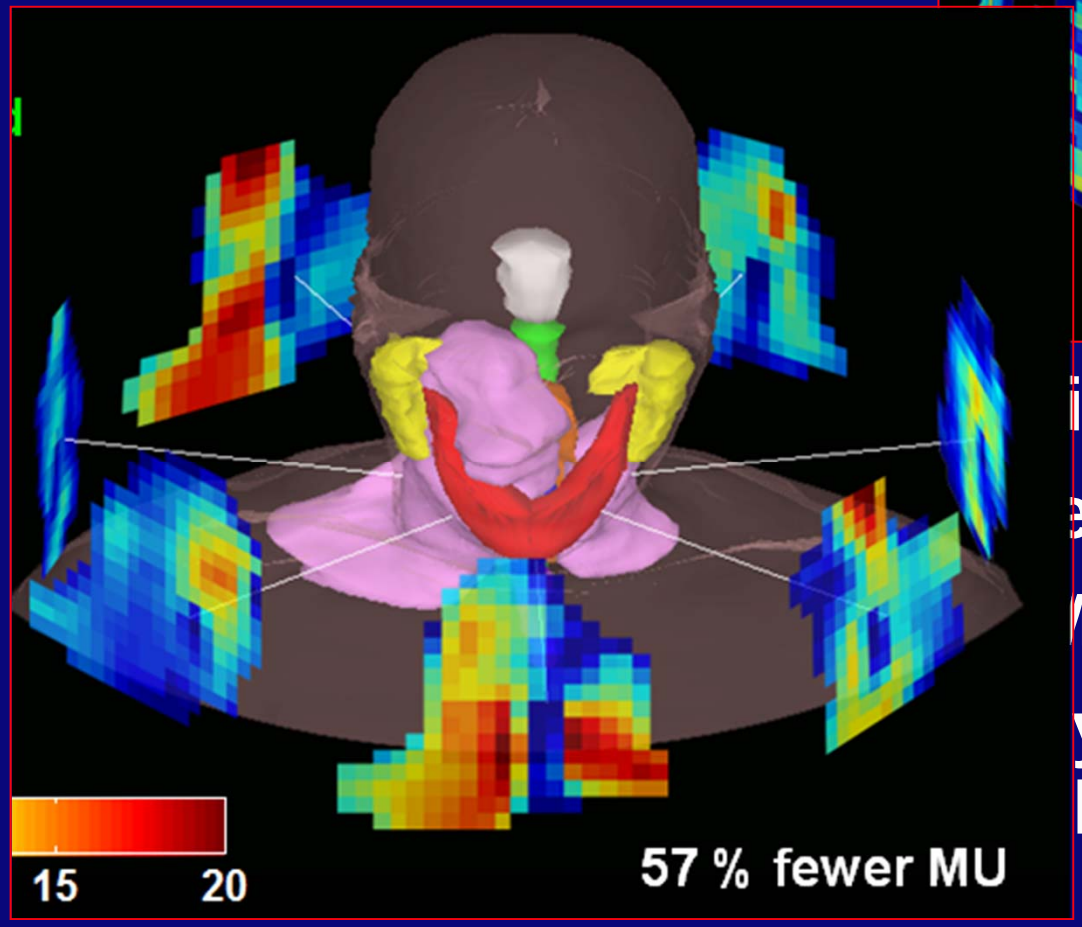
Some Technical Safety Issues for IMRT



- Delineation of targets + normal tissues is crucial
- Good vs bad plan determined by optimization cost function – not direct clinical input
- Beam shapes, intensities, directions not intuitive
- Hand checks of plan, MLCs, MUs not possible
- Monitor Units (MU) not directly related to dose. No back of the envelope checks - MUs not intuitive

Some Technical Safety Issues for IMRT





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The New York Times

January 24, 2010

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

IMRT Overtreatment, NY, 2005

- IMRT plan passed IMRT QA, Tx started. Then plan was changed after 2 days
- Plan download hung, was terminated with Ctrl-Alt-Del. Led to incomplete Tx script (no MLC files for IMRT)
- IMRT QA not performed (due to small plan changes, timing ?)
- Pt nausea + mask distracted RTTs during Tx
- Pt got >13 Gy/Fx x 3 Fx (IMRT MUs, open MLC)
- Causes: Plan change, rushed prep, poor software design, ignoring error messages, etc.

Safety/QA Issues for Computer-Controlled Treatment Delivery

A few comments on Safety and QA

Good Results of the NY Times Publicity: Various National Safety-Related Initiatives

- Publicity has led to introspection within many depts, opening windows for analysis + efforts, within ASTRO, AAPM, ACR etc
- Congressional hearings in 2010
- FDA: June 2010 meeting w/ vendors and users, re-evaluation of 510K process, etc.
- ASTRO Safety White Papers (in Pract Rad Onc)
- IHE-RO Safety Use Cases
- ASTRO/AAPM Radiation Oncology Incident Learning System, just opened as a PSO
- Stakeholders Safety Initiative (vendors+users)

What should we NOT learn from the NY IMRT event ?

1. We can fix this with one new QA test

   Almost all errors have many contributing factors!

   - Control system error?
   - RTTs too busy (complex Tx and difficult patient situation) ?
   - Would this have happened if the MD had not changed the Tx plan after only a few Fxs?
   - All problems followed from the change which disrupted normal process and QA

What should we NOT learn from the NY IMRT event ?

2. High-tech treatment techniques are the problem...

- **What about the recent Linac radiosurgery system calibration error – caused by use of the wrong detector system ?**
- **Or the earlier error with an Excel spreadsheet which led to miscalibration – Excel is hardly high tech**
- **Or leaving the wedge out of the field?**

What should we NOT learn from the NY IMRT event ?

3. The vendors and FDA just need to make error-free software and control systems. . . .

- **More testing by vendors will prevent all problems?**
- **The FDA can QA a vendor's control system?**
- **Users always use things correctly, pay attention to all warnings, never get impatient...**
- **It is possible to prove correctness of modern distributed control systems in a large networked medical center environment?**

What should we NOT learn from the NY IMRT event ?

4. I could go on . . .

- For each incident that we ever hear about, there are more that are unknown or not widely reported
- We need:
  - To understand the string of faults which combined to let these events occur
  - To know when related events have happened elsewhere
  - Detailed investigation and information,so we can know for sure what the real issues and dangers are, and how to address the problems

Recent QA and Safety Guidance

ASTRO Safety White Papers

(full reports: www.practicalradonc.org)

- Moran et al: Safety Considerations for IMRT. PRO 1: 190-195,2011
- Solberg et al: SRS and SBRT, PRO 2: 2-9, 2012
- Jaffray et al: IGRT. PRO 3: 167-170, 2013
- Marks et al: Peer Review. PRO 3: 149, 2013
- Thomadsen et al: HDR. PRO 4: 65-70, 2014

ASTRO/Intersociety Blue Book (2012)

Zeitman et al: Safety is no Accident. www.astro.org

Recent QA and Safety Guidance

AAPM Task Groups

- TG 147: QA for Non-Radiographic Positioning. MedPhys 39: 1428-1747, 2012
- TG 179: QA for CT-based IGRT. MedPhys 39: 1946, 2012
- TG 135: QA for robotic radiosurgery, Med Phys 38, 2914, 2011
- TG 101: Stereotactic body RT. Med Phys 37: 4078, 2010
- TG 148: QA for tomotherapy: Med Phys 37: 4817, 2010
- TG 119: IMRT commissioning. Med Phys 32: 5359, 2009
- TG 142: QA of med. accels. Med Phys 36: 4197, 2009
- IMRT: AAPM IMRT subcom. Med Phys 30: 2089, 2003
- Soon: TG-100: Use of FMEA for RT QA, IMRT example. (2014)

Computer-Controlled Treatment Delivery

Therac 25 Accidents:

- 11 Therac-25 machines installed
- 6 accidents involving massive overdoses, 1985-87
- Major recall 1987
- Patients died – doses ~ 40-50 Gy per exposure (in seconds)
- Poor control system design, therapists using controls differently than the way the system was designed, and other issues.

Therac 25 and Computer Control

"Most accidents involving complex technology are caused by a combination of organizational, managerial, technical, and sometimes sociological or political factors. Preventing accidents requires paying attention to all the root causes, ..." Leveson NG, Turner CS: An investigation of the Therac-25 Accidents. IEEE Computer, July 1993, pp. 18-41.

Medical Accelerator Safety Considerations: AAPM TG35. J Purdy et al, Med Phys 20: 1261-1275, 1993

Computer Control System QA

- The more you know about the design specs, system requirements, and hazard analyses, the better you will be able to design and perform QA testing relevant to your clinic
- Obtain relevant QA documentation from vendor
- Use documentation to design detailed tests of potential weak spots for your clinical process
- There will always be bugs
- You need to commission your delivery and treatment management systems: showing they work is not commissioning!

There are lots of different safety issues!

Given all the bad things that can happen, we must do much more QA

NO !

We must evaluate the problems, risks, and processes, then prioritize our efforts so we spend our QA efforts on the most frequent, severe, and risky problems

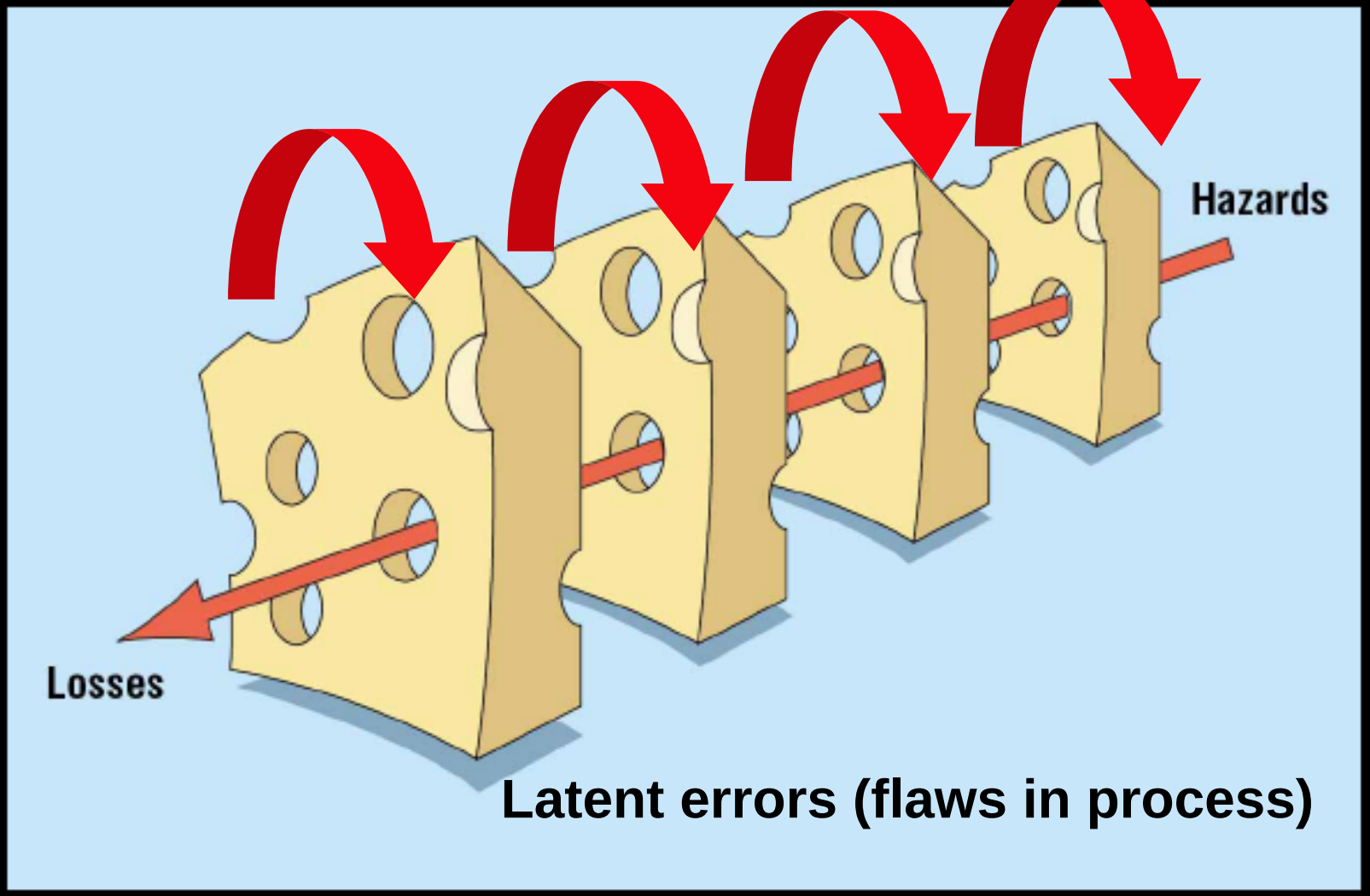
An Example: Awareness of Risks

Choice: we have chosen to tune our machines identically (how identical?) so we can switch patients between machines - to help improve flow and patient satisfaction

Possible Risks (for example):

- More setup errors due to new RTTs treating an unfamiliar patient
- Potential variations in mechanical and dosimetric parameters (table sag, etc)
- Plan must be downloaded to new control system each day – more possibility for plan transfer failure (e.g. the NYTimes IMRT error)

Swiss Cheese Model



James Reason: *BMJ* 2000;320:768–770

Process-Oriented Risk-Aware Quality Methods

Systematic application of specific tools that improve process control, producing more consistent outcomes which are closer to optimal and reduce the risk of mistakes, errors, or hazardous outcomes

Frank Rath, U Wisc

Process-Oriented Risk-Aware Quality Methods

AAPM TG100:

Application Of Risk Analysis Methods To Radiation Therapy Quality Management

Saiful Huq, Benedick Fraass, Peter Dunscombe, John Gibbons, Geoff Ibbott, AJ Mundt, Sasa Mutic, Jatinder Palta, Frank Rath, Bruce Thomadsen, Jeff Williamson, Ellen Yorke

2003 – 2014 (so far)

Process-Oriented Risk-Aware Quality Methods ("FMEA")

1. Map the process to be studied
2. Analyze how the process can fail, and what the effects of the failures will be: [FMEA: Failure modes and effects analysis]
3. Once all the failure modes and effects are identified, map how the faults propagate: [FTA: Fault tree analysis]
4. Find efficient ways to minimize propagation of errors through the process: [QM, QA, QC]

Process-Oriented Risk-Aware Quality Methods
Keys to Success

- Create multidisciplinary team
- Attack specific process
- Define and control appropriate scope
- Careful choice of prioritization scheme
- Accept (and take to heart) that QA is not a "technical matter" and that quality is dependent on everyone in the team, not just the people "doing QA"

Process Safety and QA

The vendors are not responsible for everything !

We each need to understand what kinds of errors we could have, <u>in our own clinic</u>, and how we can prevent them

Computer Controlled Tx Delivery: History, Issues and Safety

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- IMRT, IGRT, VMAT, 4-D:more complex!
- Safety/QA Issues for CCTxD, IMRT
- Conclusions

Summary

- Computer-controlled Tx machines have become standard, but much work is still needed on the treatment process for such systems
- Computer-controlled Tx makes more complex (+ better) treatments practical, but has forced re-evaluation of safety and QA
- Computer-controlled Tx decreases random errors, but makes the process more sensitive to systematic errors: different QA is needed
- We need to continually work to improve our processes so we can decrease the probabilities that a catastrophic error will occur

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Computer-Controlled Treatment Delivery

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