Impact of Complexity and Computer Control on Errors in Radiation Therapy

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CEDARS-SINAI
LEADING THE QUEST

The New York Times

January 24, 2010

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

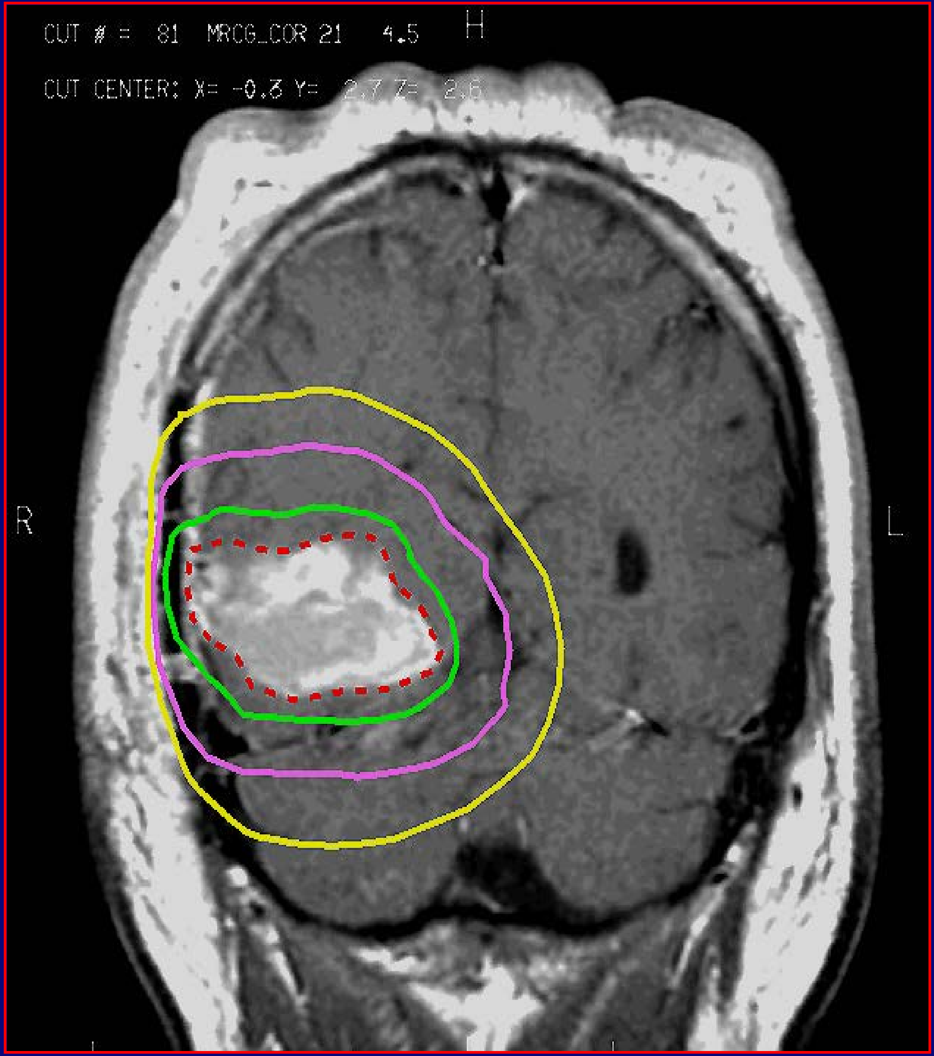
By WALT BOGDANICH

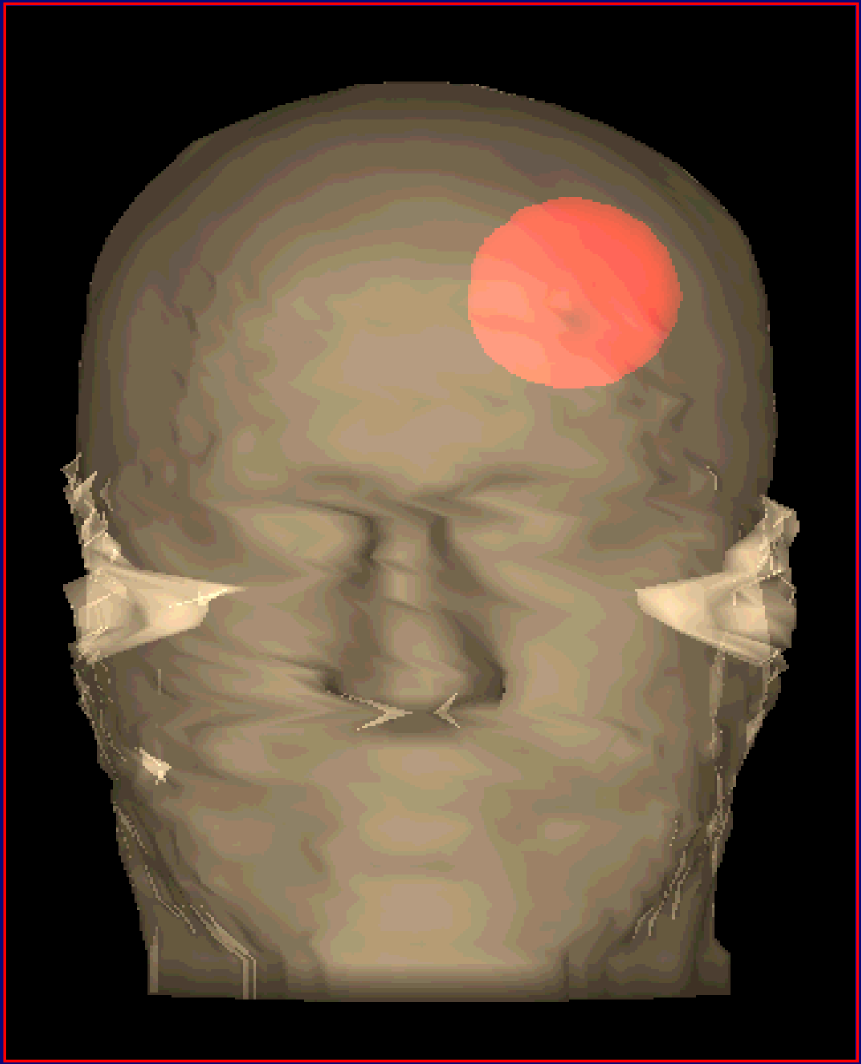
- **H/N patient received 3 x 13 Gy: (open MLC with IMRT MUs)**
- **Breast patient received 27 Fx, w/o large wedge (3.5x expected dose)**

Complexity, Computer Control and Radiotherapy Errors

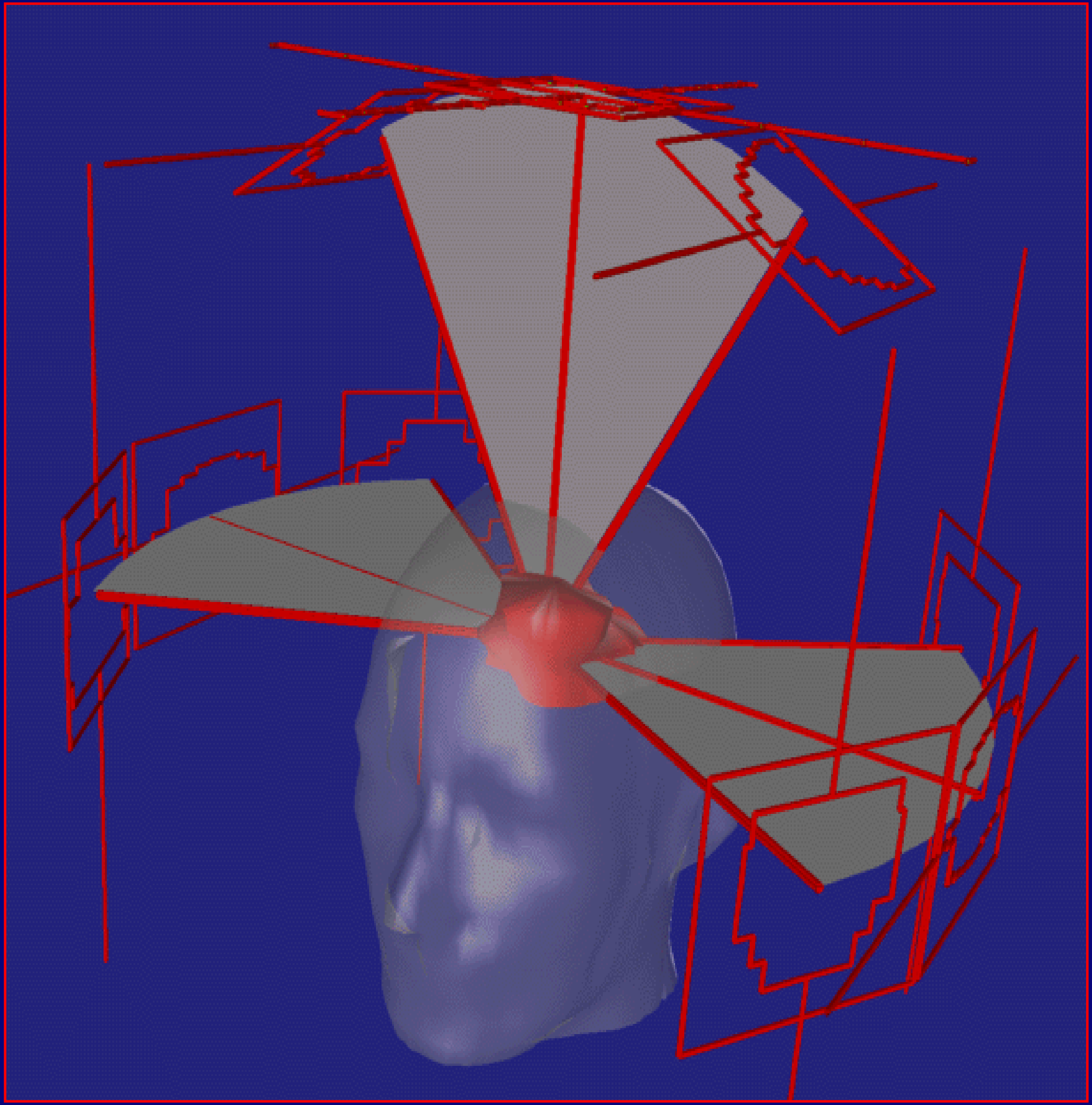
- Basic Radiotherapy Methods
- Changes in Radiotherapy: New Technology, New Goals, New Complexity
- Studying Errors in Radiotherapy
- Efforts to Address Radiotherapy Safety
- Conclusions

1. Define the Target Volume(s) and Create an Anatomical Model of the Patient

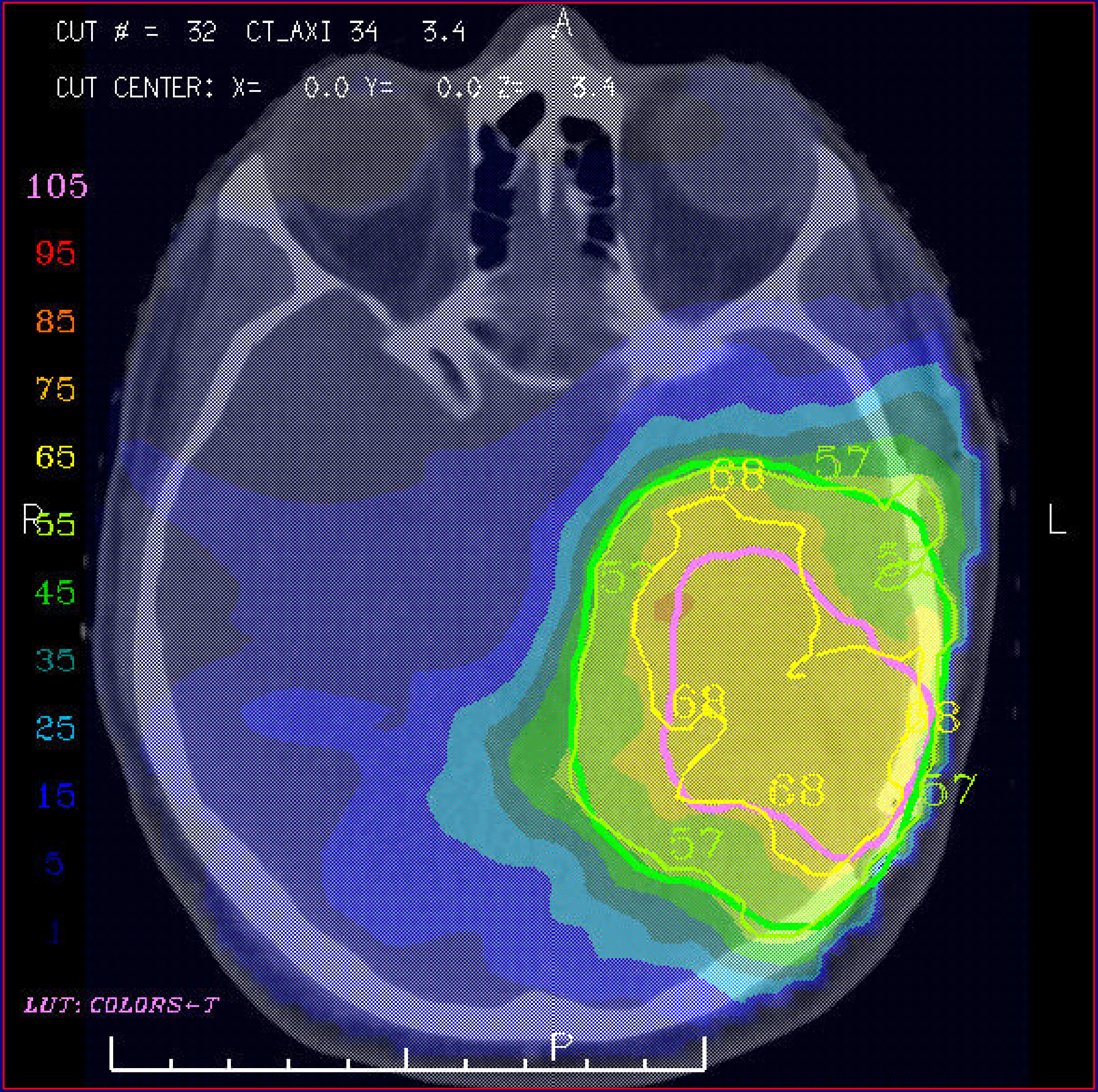




2. Focus Multiple Beams on the Target



3. Calculate and Evaluate the Dose



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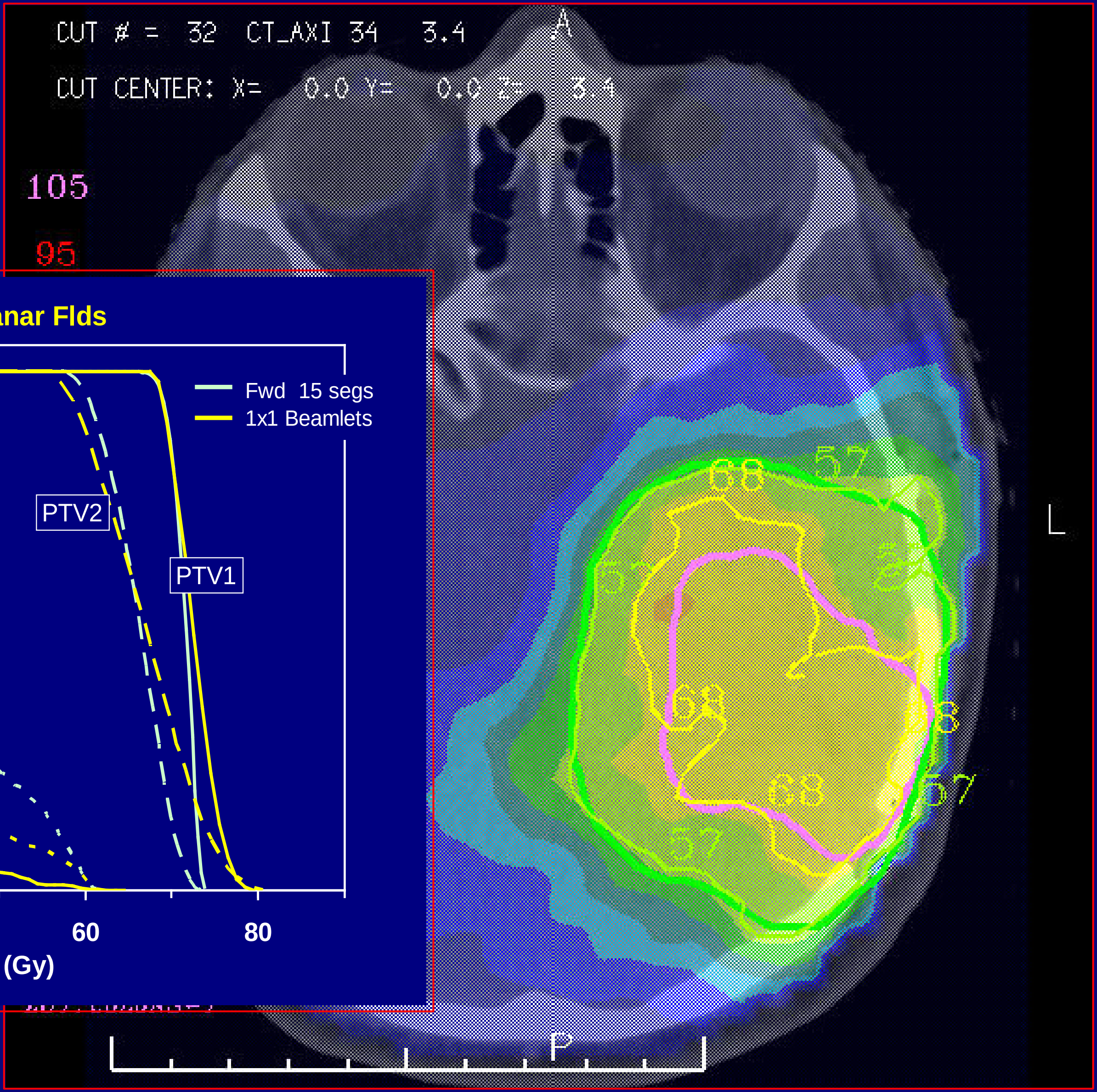

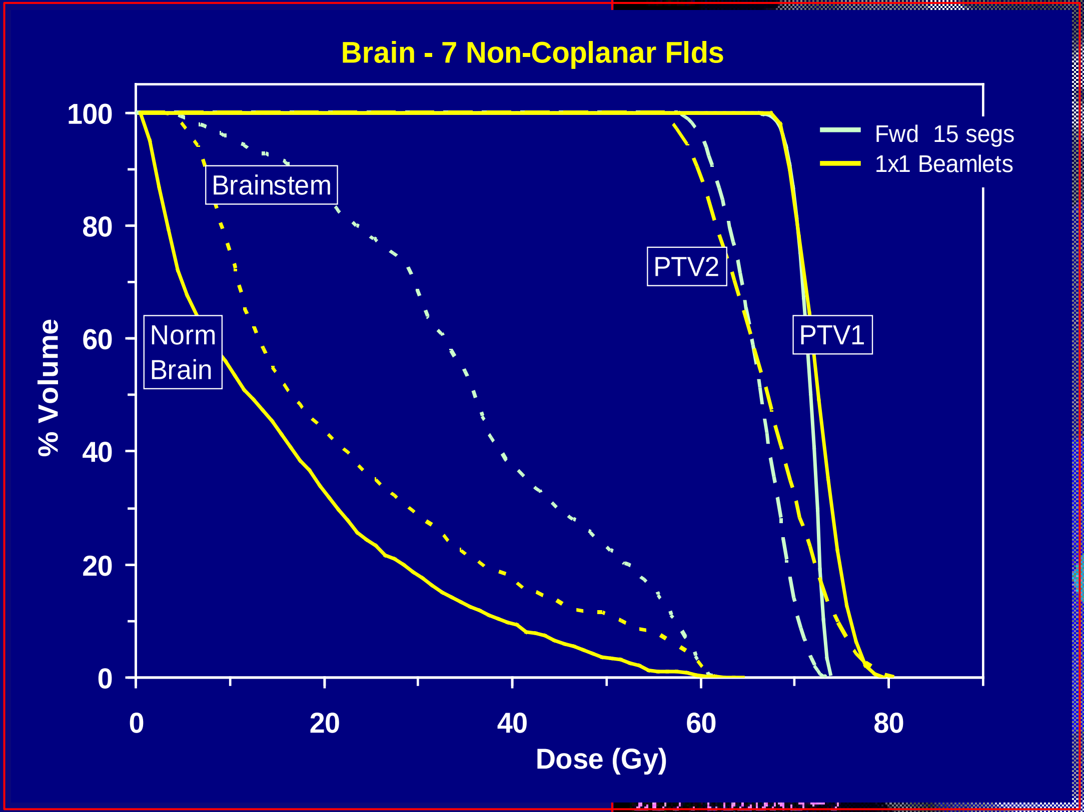

4. Treat the Patient

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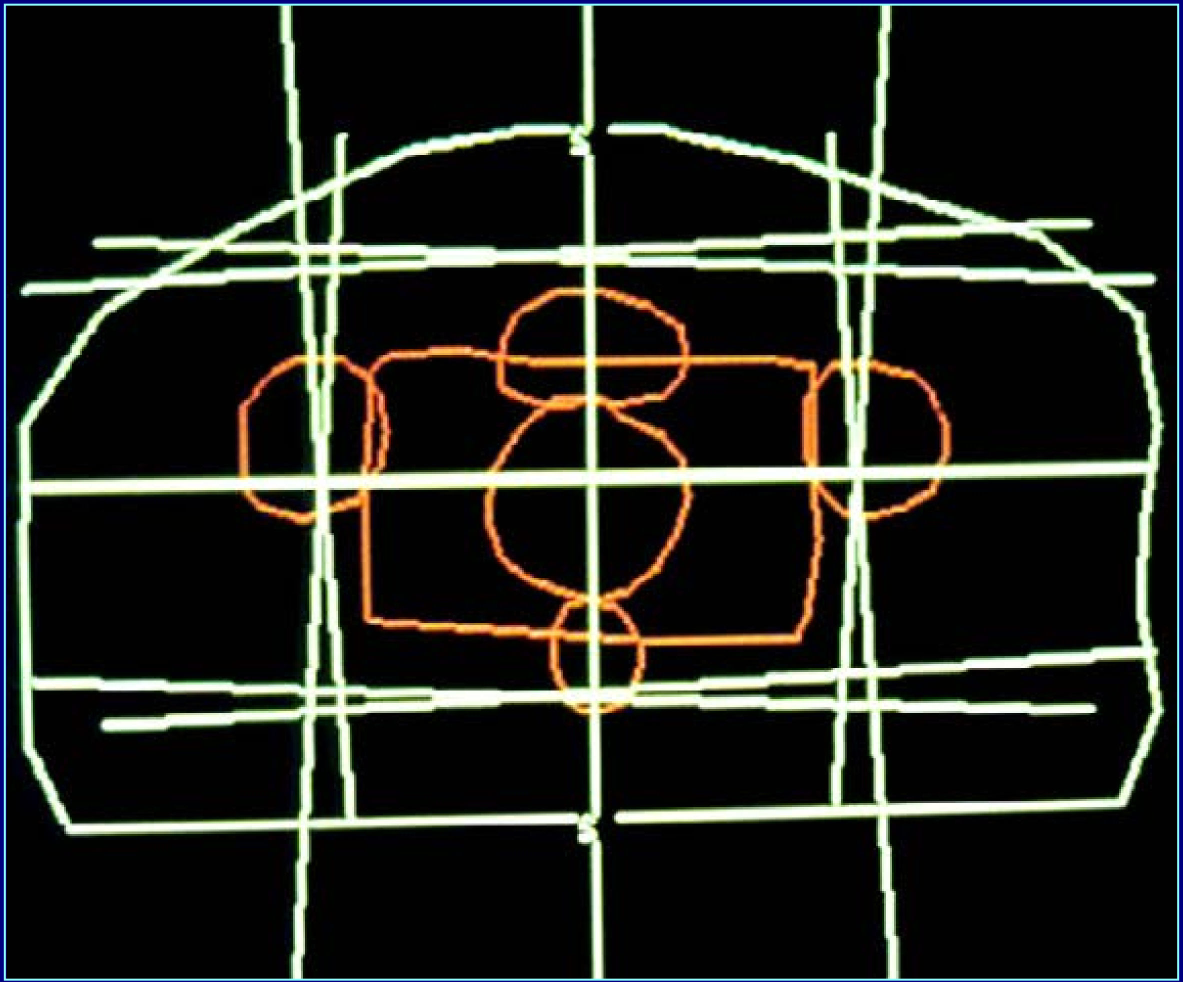
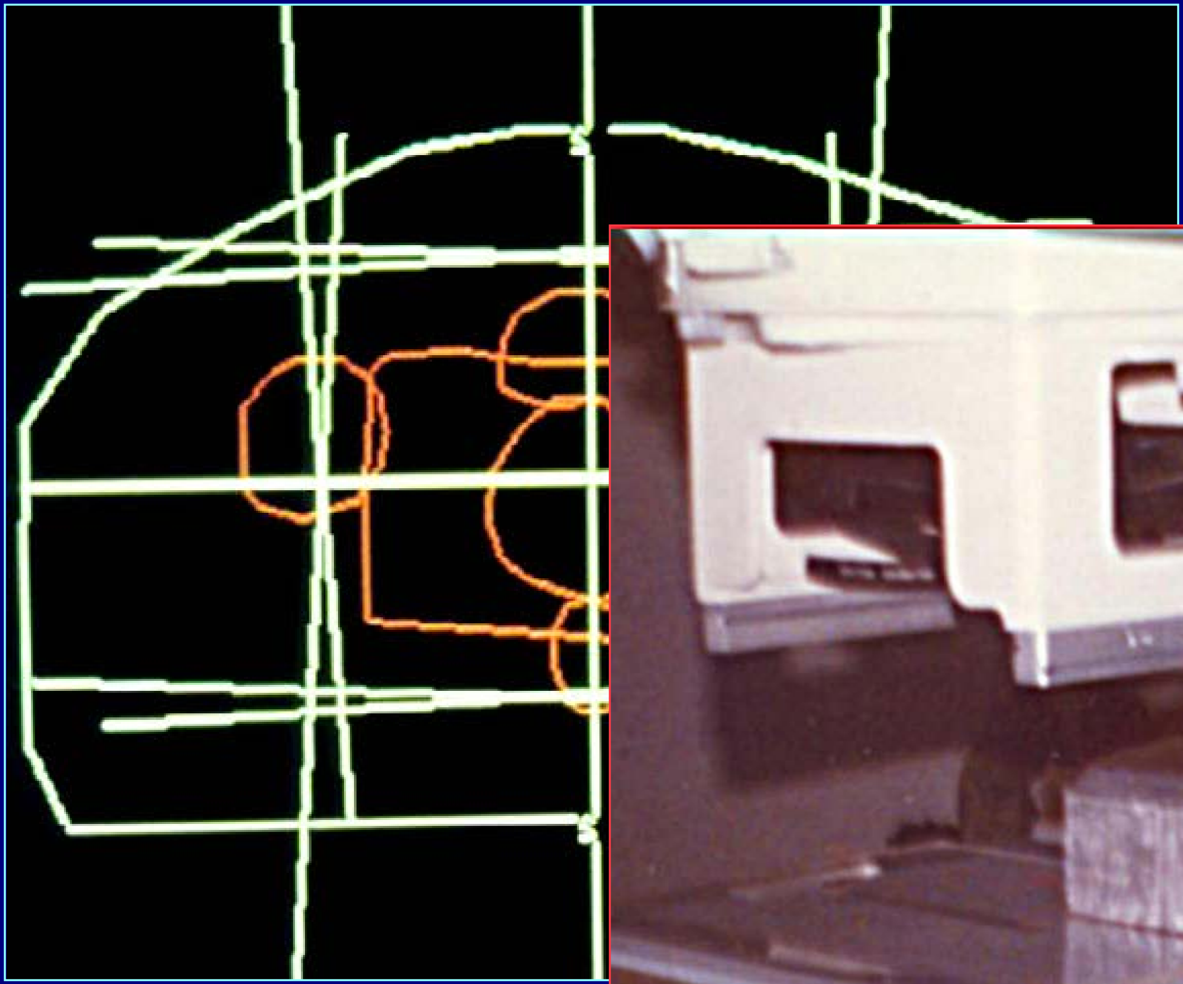
1950s-80s: 2-D Radiotherapy

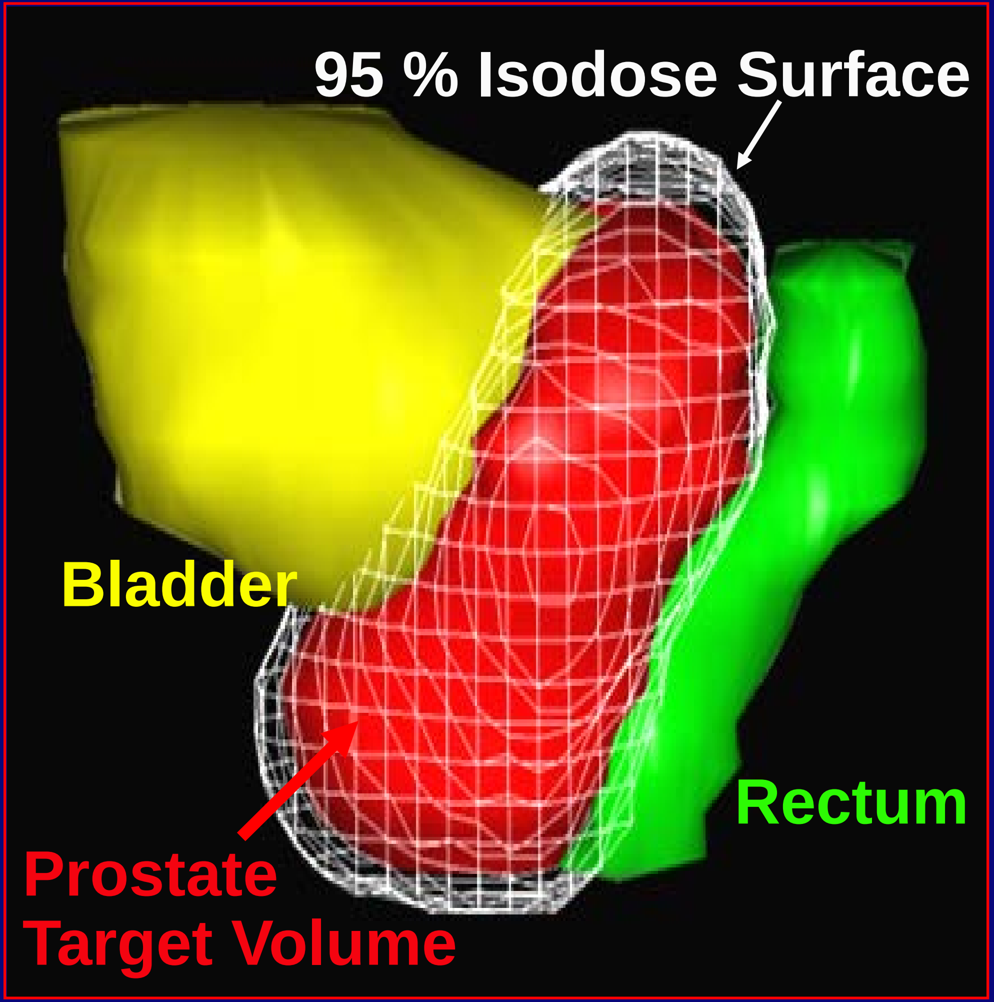


1950s-80s: 2-D Radiotherapy



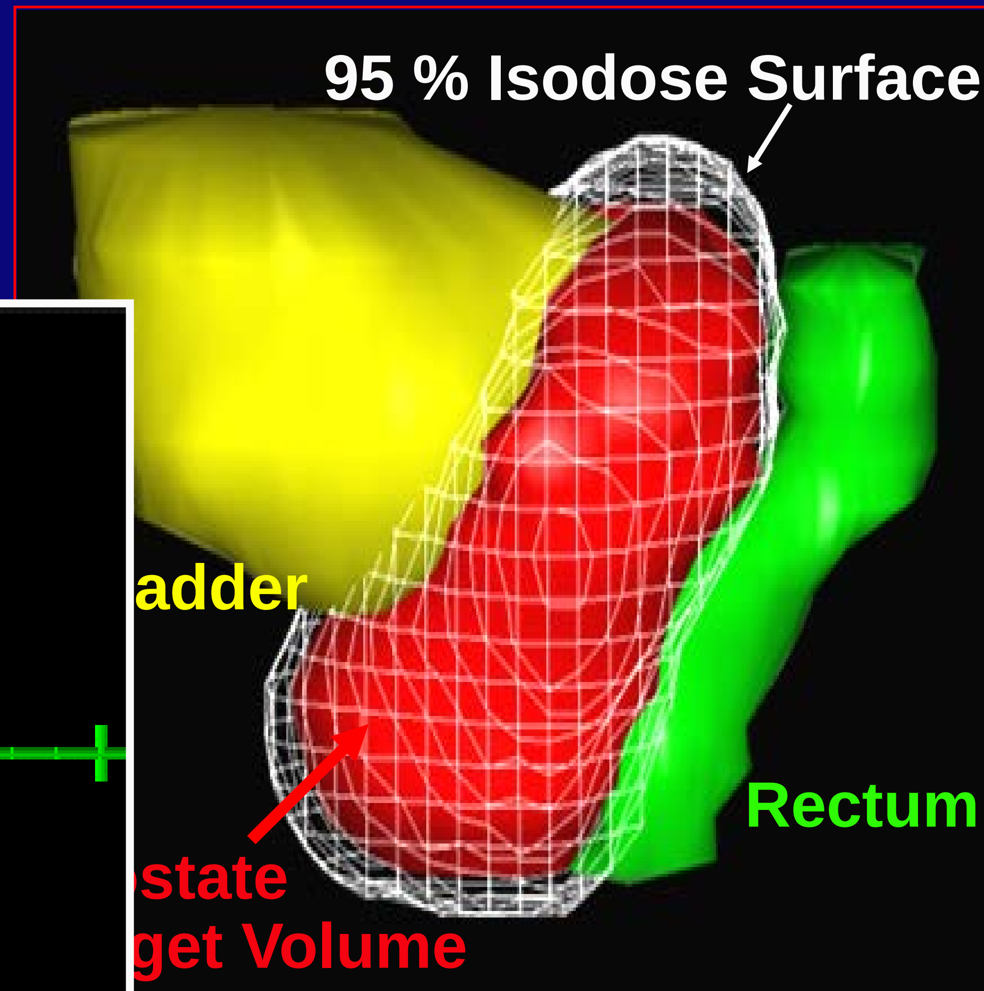
1986 – 1990s: Conformal Therapy

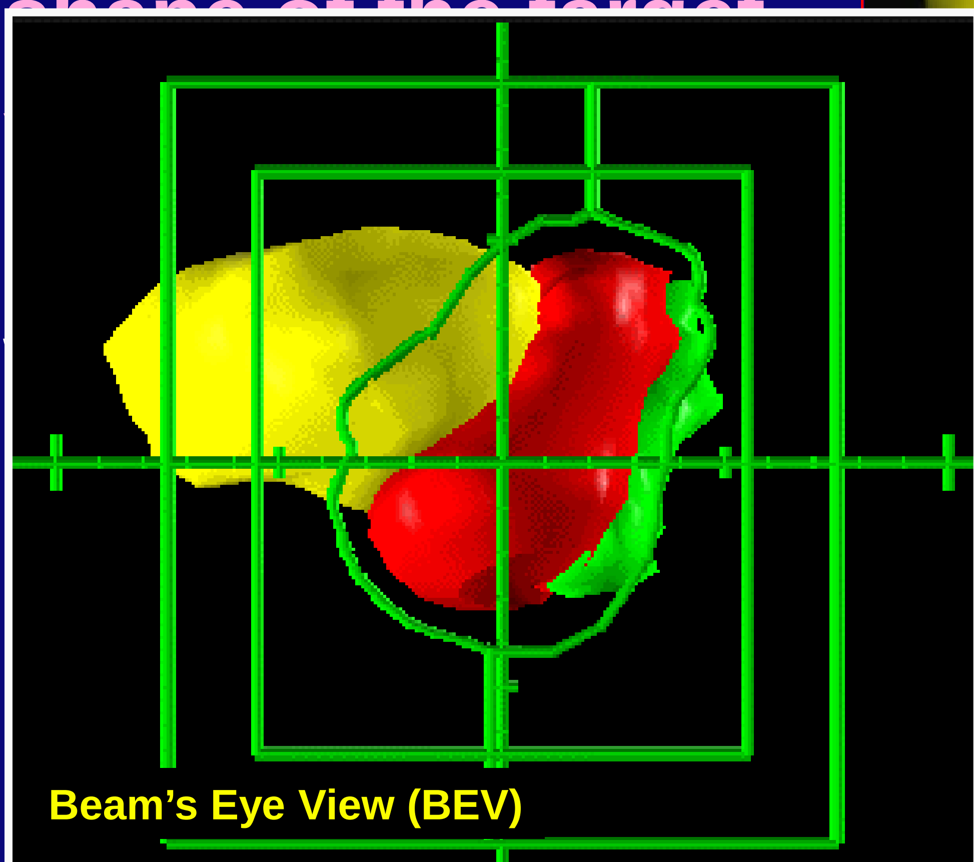
A **dose distribution** that **conforms** to the **shape of the target volume(s),** **in 3-D,** while **minimizing** dose to critical normal structures.



1986 – 1990s: Conformal Therapy

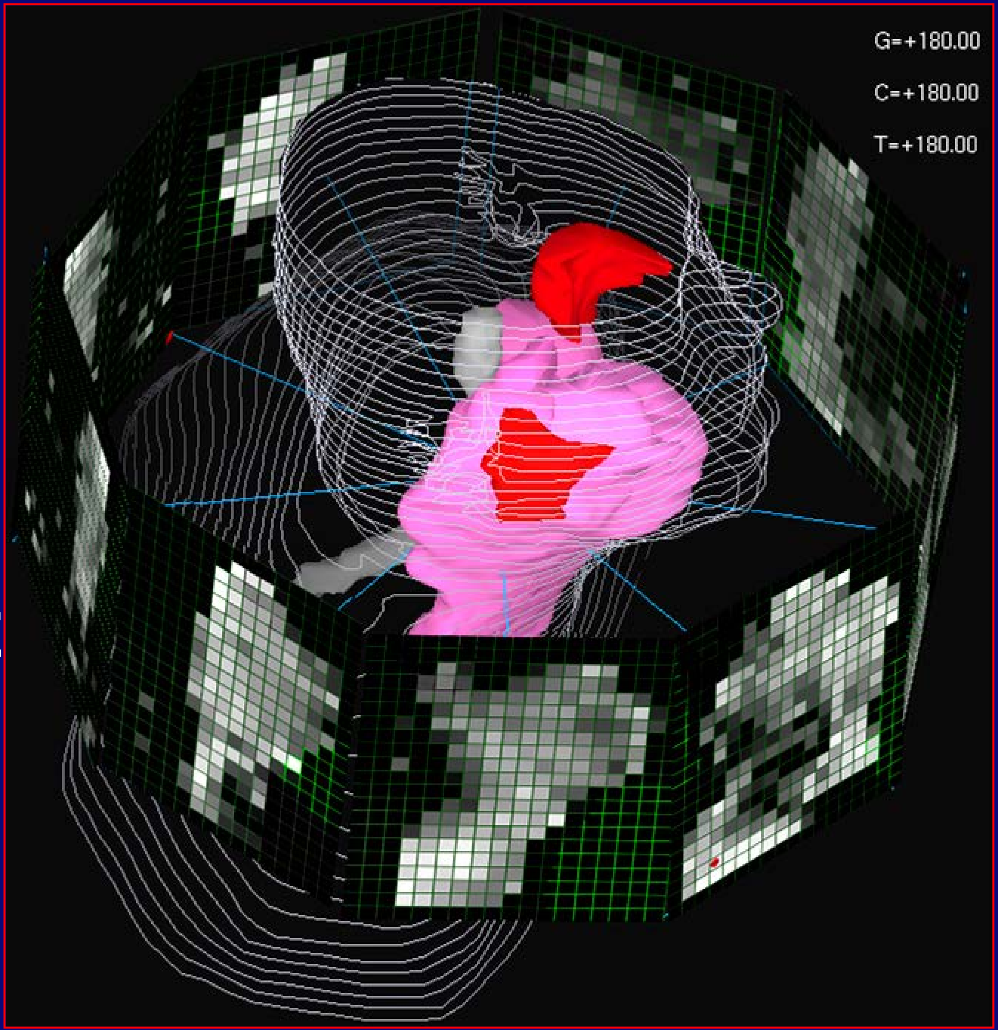
A dose distribution that conforms to the



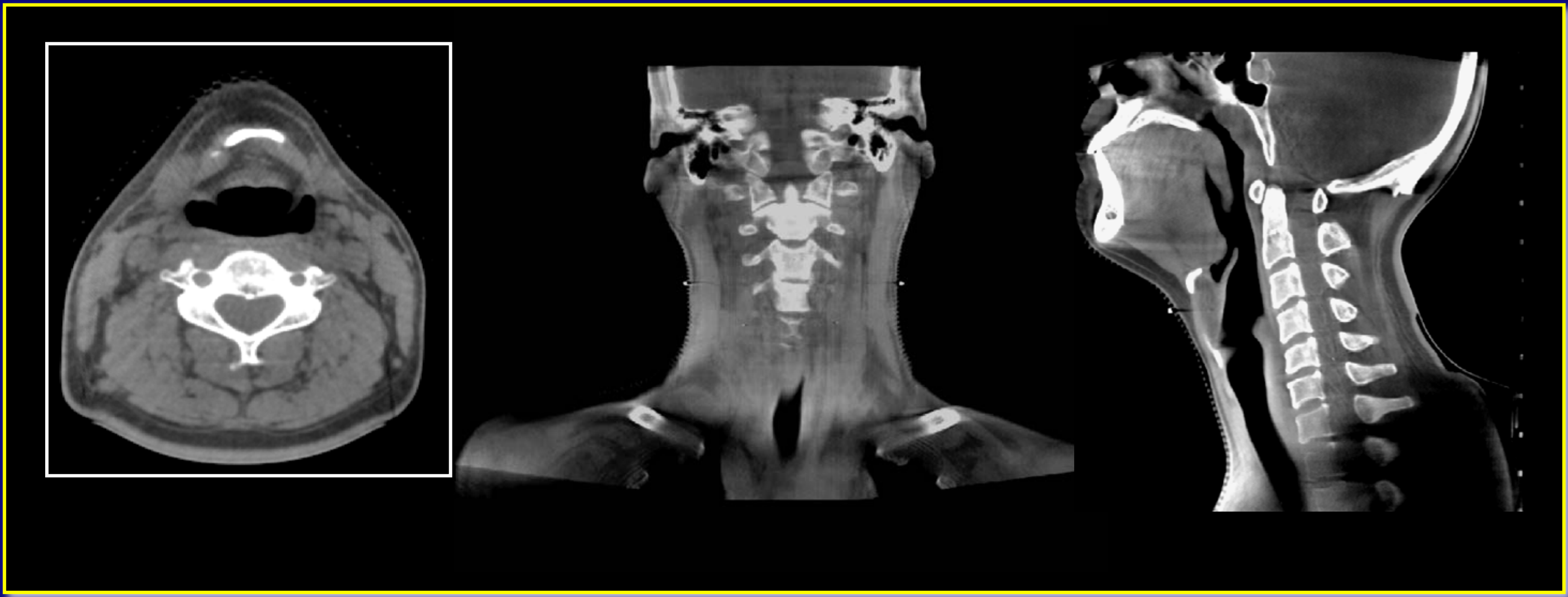


2000s: Conformal Therapy with Intensity Modulated Radiation Therapy (IMRT)

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



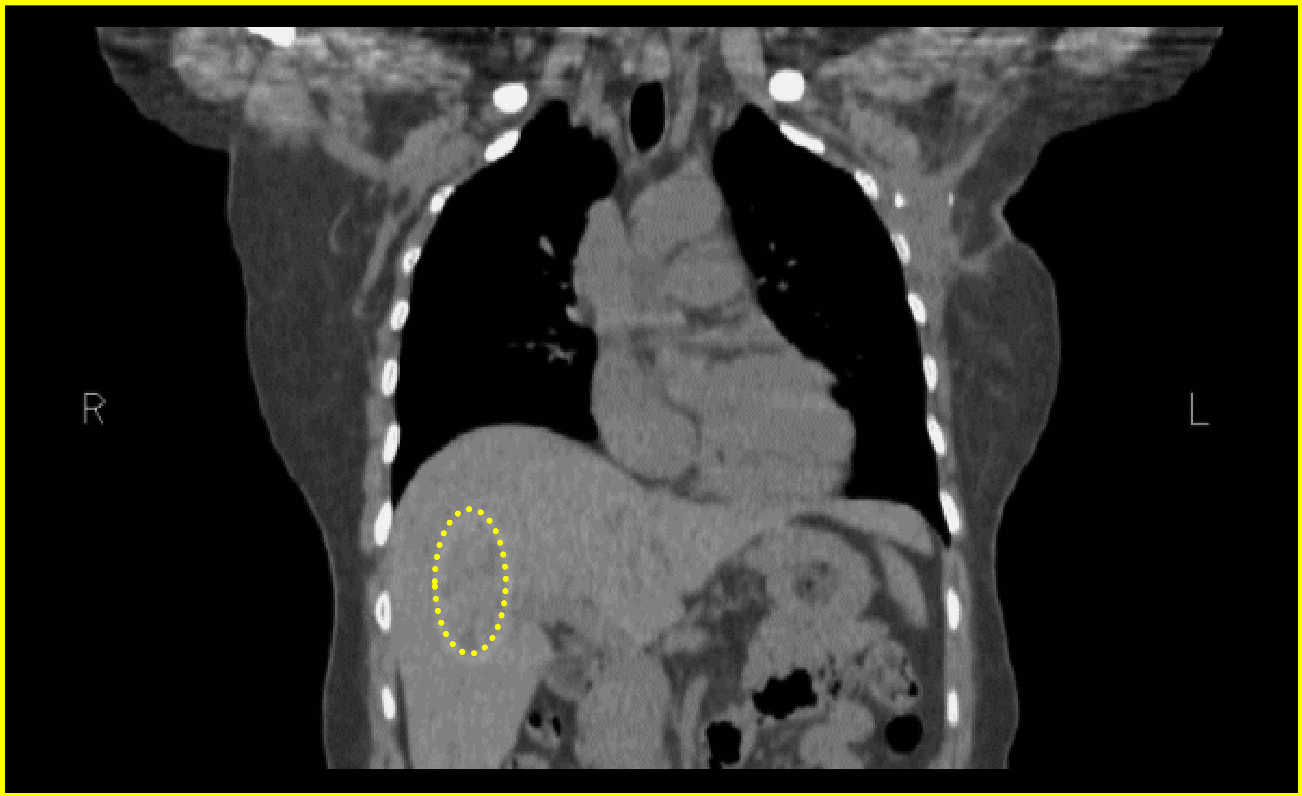
2010: Image-Guided Radiotherapy (IGRT)



Cone beam CT at the treatment unit

Kessler

4D CT + Other Respiratory-Correlated Imaging



Now that we can visualize + monitor motion, where / when do we need to take it into account ?

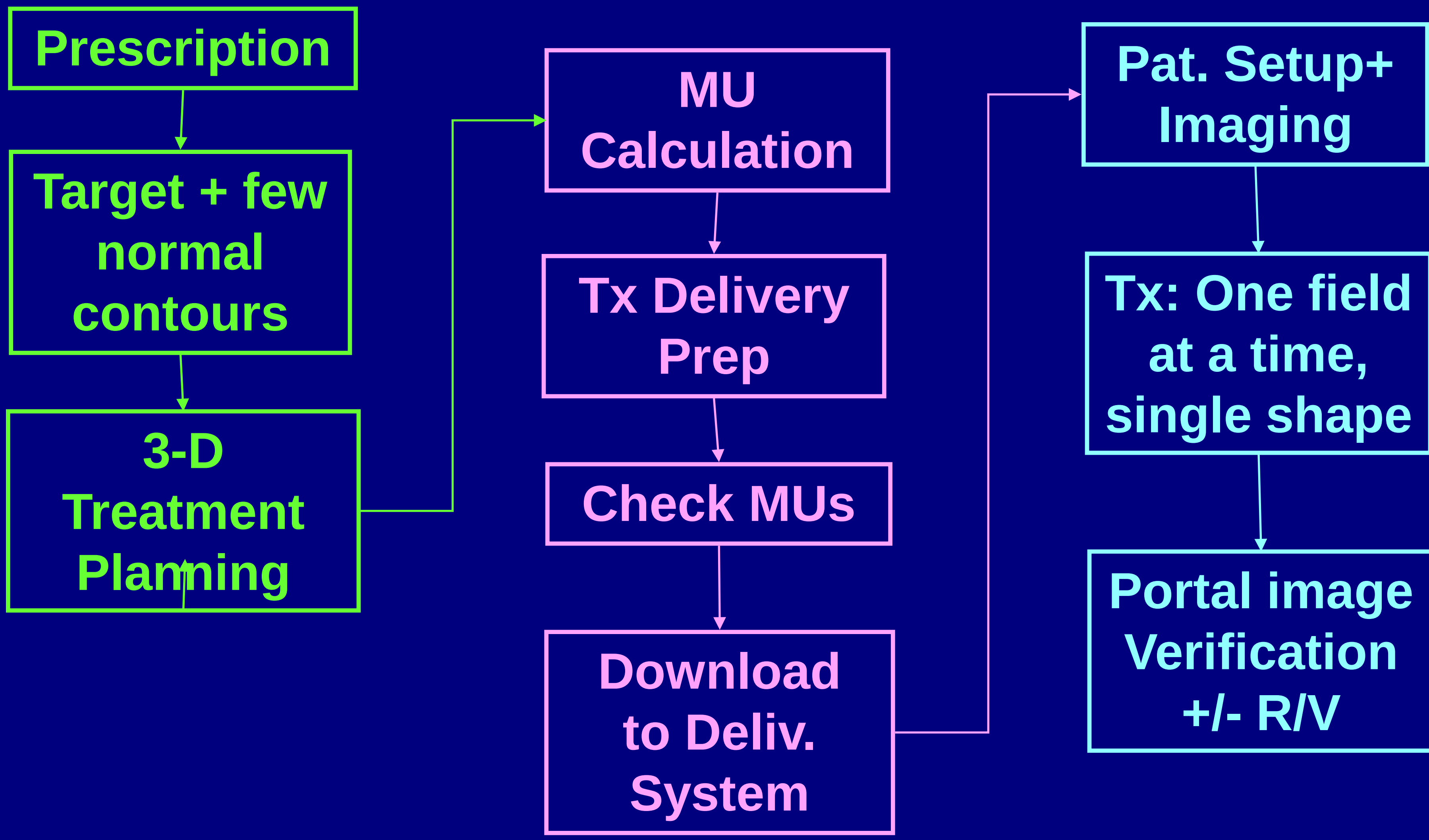
Balter

In recent years, complexity of radiation treatment delivery has increased due to

- 3-D treatment planning
- Conformal radiotherapy
- Computer-controlled treatment machines
- Multileaf collimators
- Intensity modulated radiation therapy (IMRT)
- 4-D everything

Does all the complexity lead to more errors?

Radiotherapy Planning/Delivery Process



Radiotherapy Planning/Delivery Process

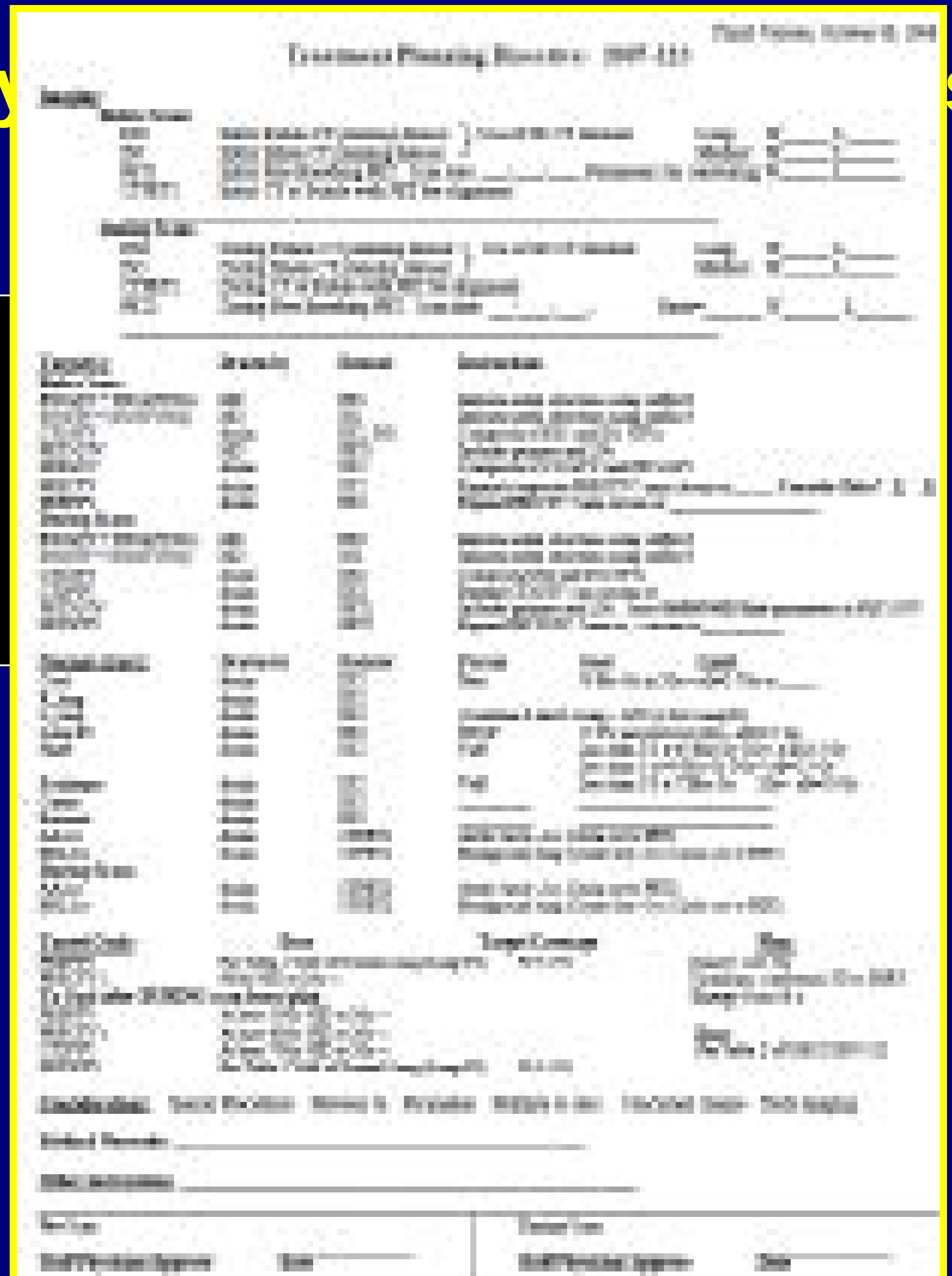
Prescription

IMRT:
Plan Directive

RT: 45 Gy to Isocenter, 2 Gy/Fx

Radiotherapy ... ss

Prescription



IMRT:
Plan Directive

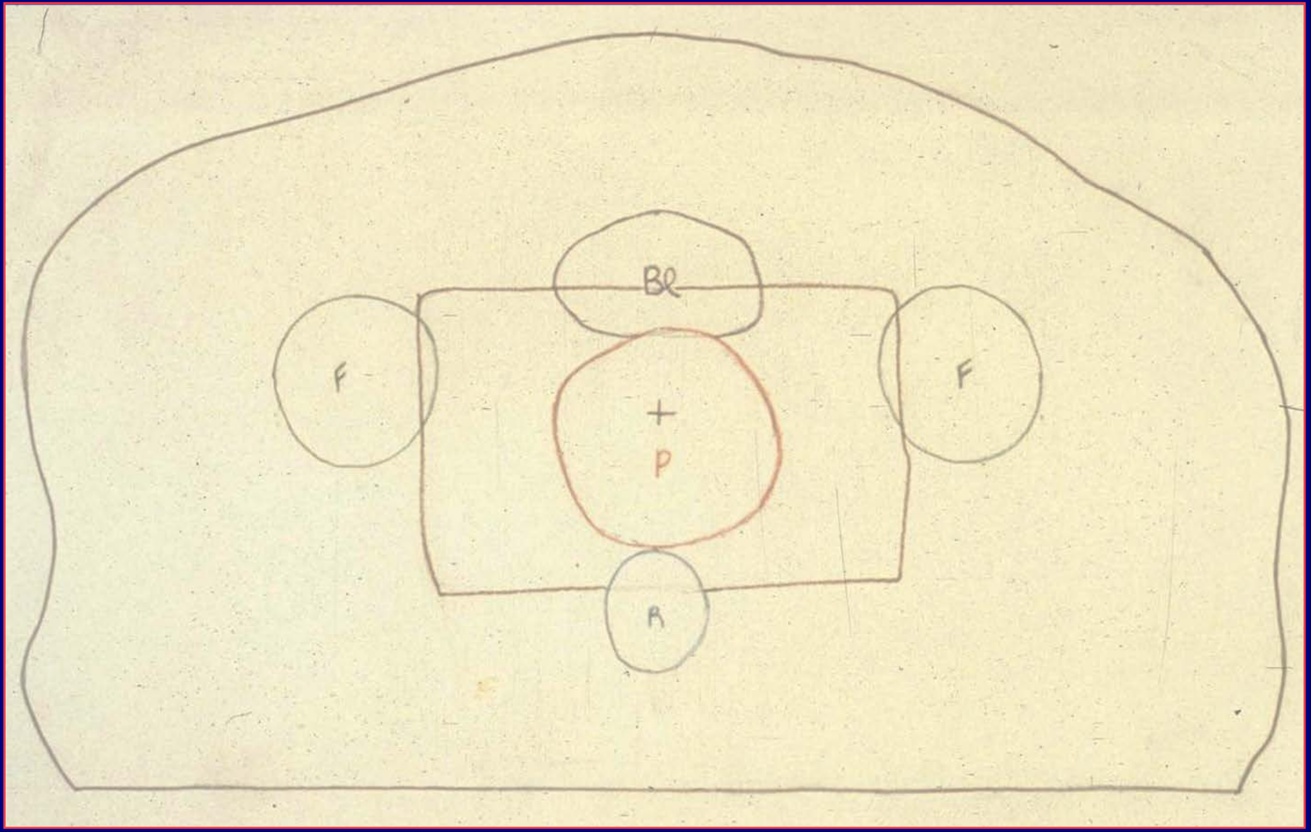
Radiotherapy Planning/Delivery Process

Prescription

↓

Target(s) + normal contours

↓



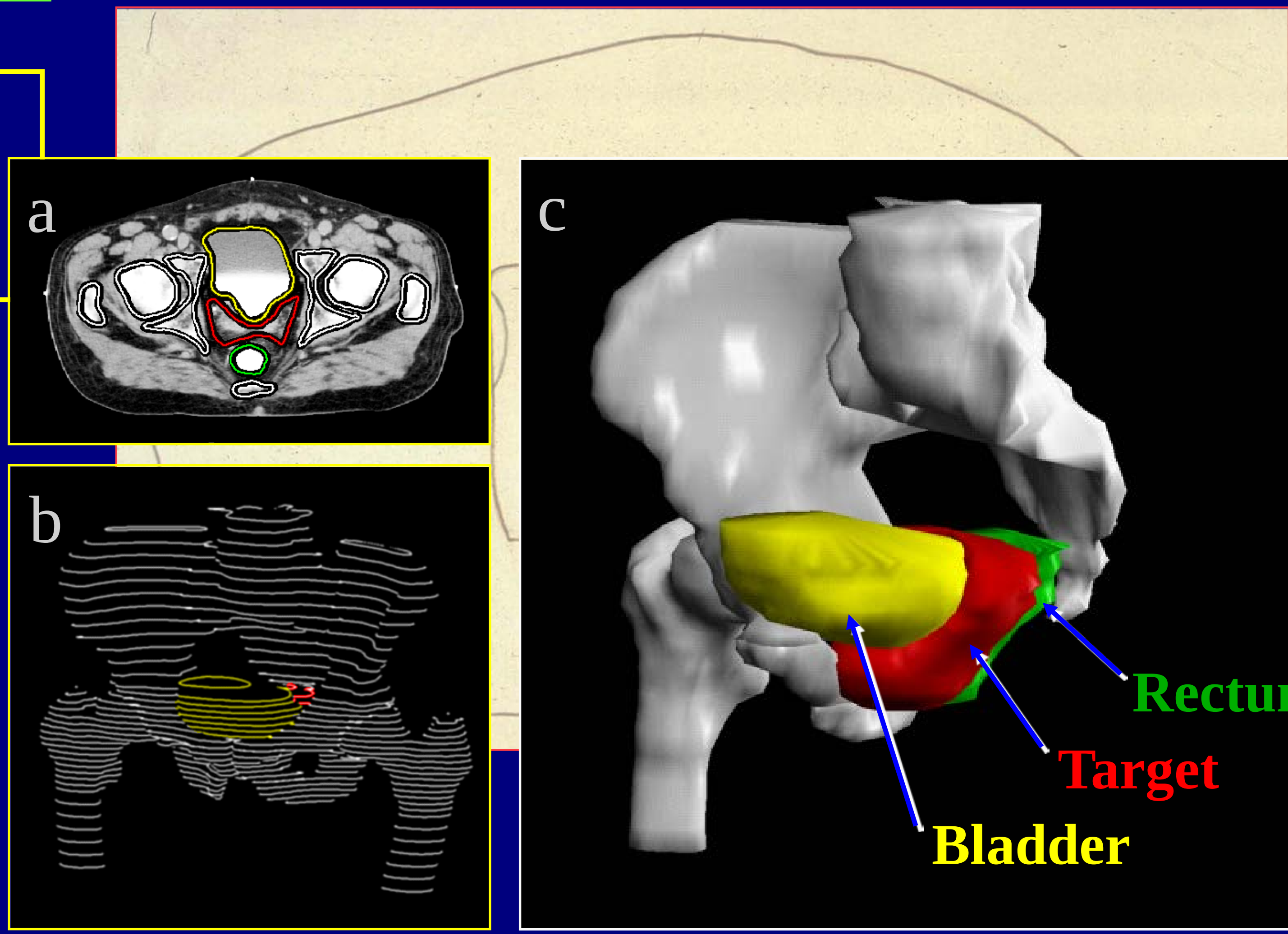
Radiotherapy Planning/Delivery Process

Prescription

↓

Target(s) + normal contours

↓



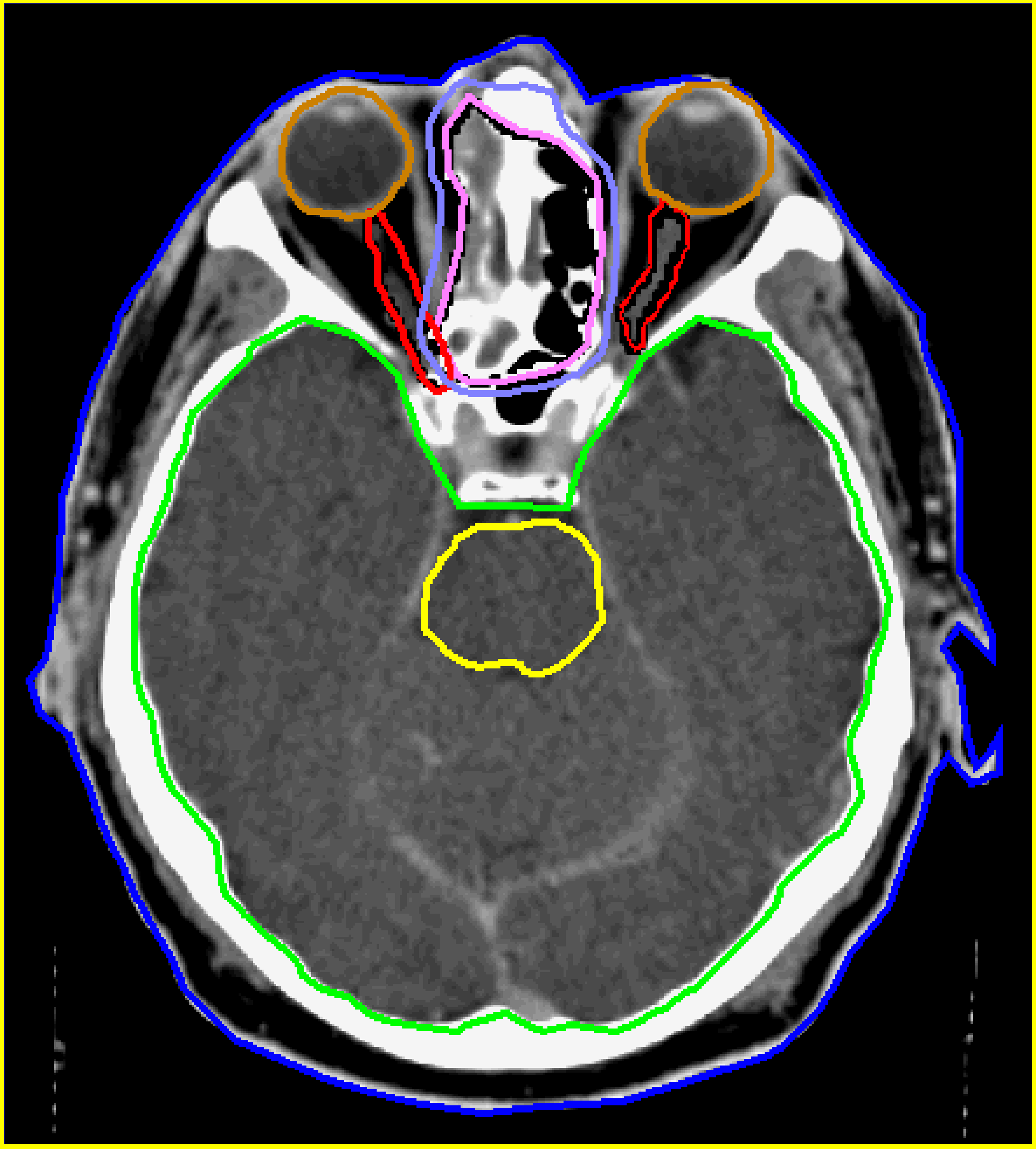
Radiotherapy Planning/Delivery Process

Prescription

↓

Target(s) + normal contours

IMRT: Unlike 3DCRT, must carefully define any structure that you want to influence the plan



Radiotherapy Planning/Delivery Process

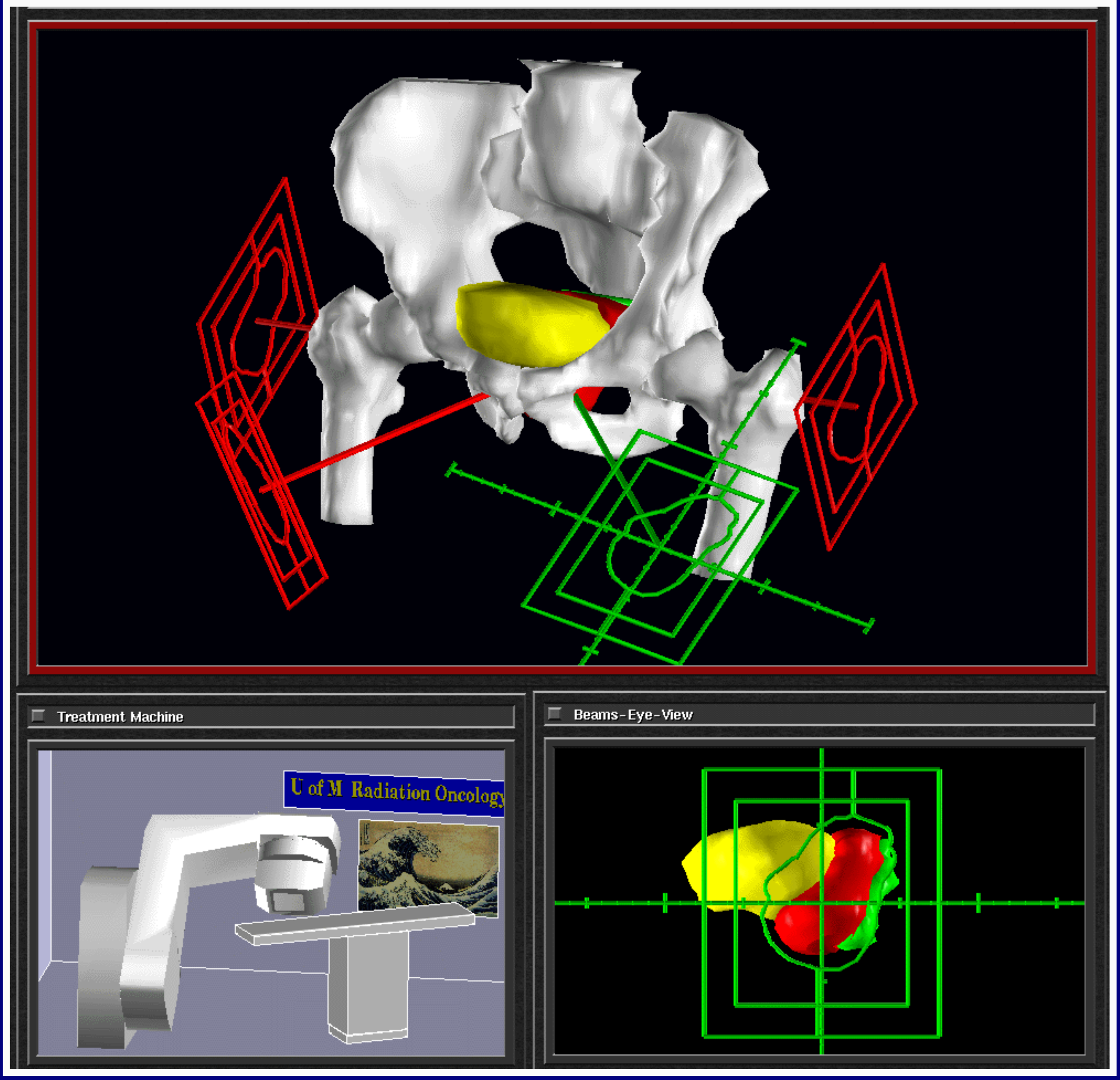
Prescription

↓

Target + few normal contours

↓

3-D Treatment Planning



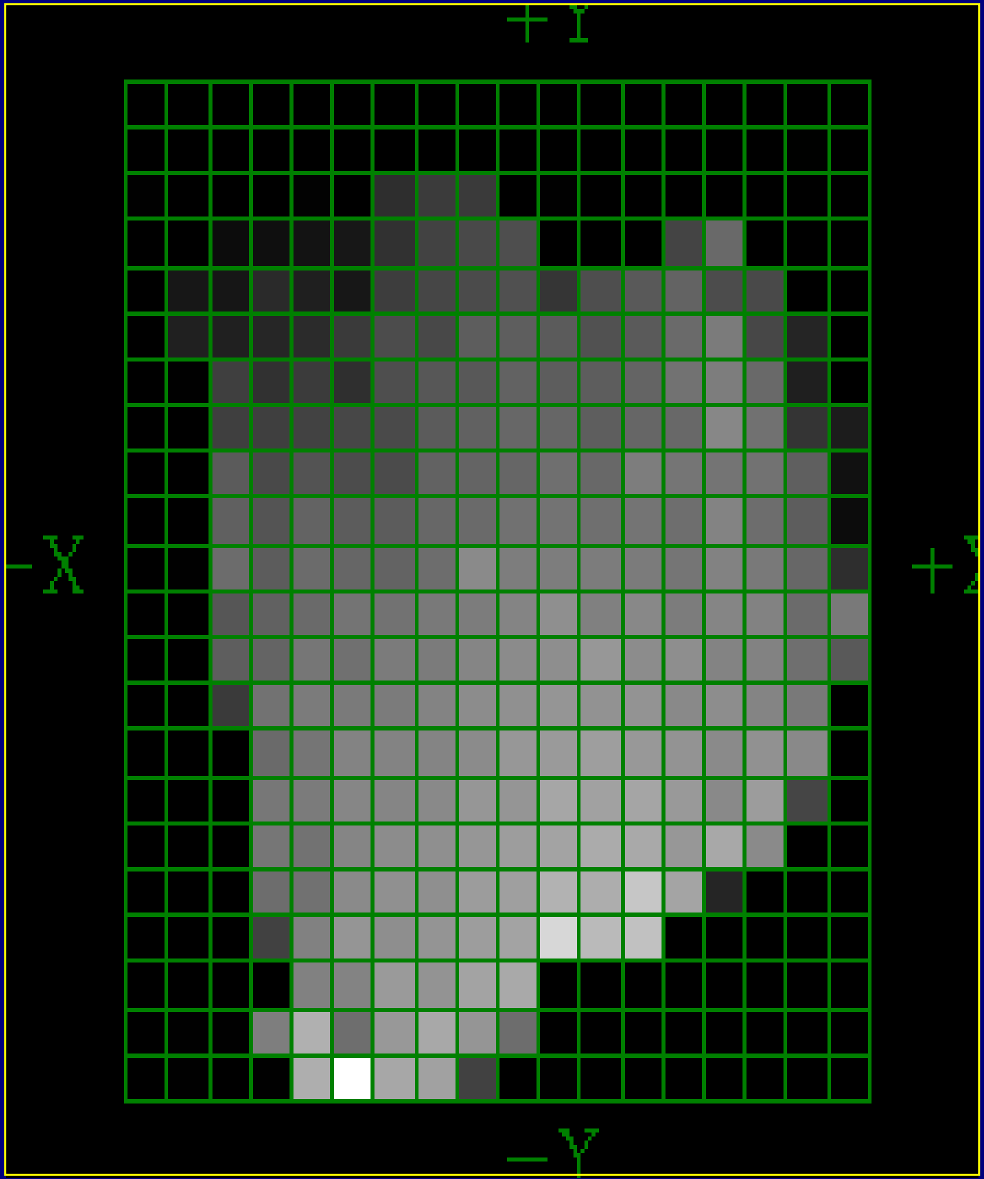
Radiotherapy Planning/Delivery Process

Prescription

Target + few normal contours

Inverse Treatment Planning

IMRT: Each beam divided into many beamlets



Radiotherapy Planning/Delivery Process

Prescription

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Head/Neck IMRT protocol planning objectives for Inverse Planning

Structure	Objectives
PTV1	**70 Gy (mean +/- 3%, min 93%, max 115%)**
PTV2	**60 Gy (mean +/- 3%, min 93%, max 115%)**
Nodal Boost PTV	**70 Gy (mean +/- 3%, min 93%, max 115%)**
High Risk Nodal PTV	**64 Gy (mean +/- 3%, min 93%, max 115%)**
Low Risk Nodal PTV	**57.6 Gy (mean +/- 3%, min 93%, max 115%)**
Spinal Cord	**Less than or equal to 45 Gy**
Spinal Cord + 5 mm	**Less than or equal to 50 Gy**
Brainstem	**Less than or equal to 54 Gy**
Right Parotid	**Mean dose less than or equal to 26 Gy**
Left Parotid	**Mean dose less than or equal to 26 Gy**
Mandible	**Less than or equal to 70 Gy**
Submandibulars	**Minimize dose**
Oral Cavity	**Less than or equal to 70 Gy**

Radiotherapy Planning/Delivery Process

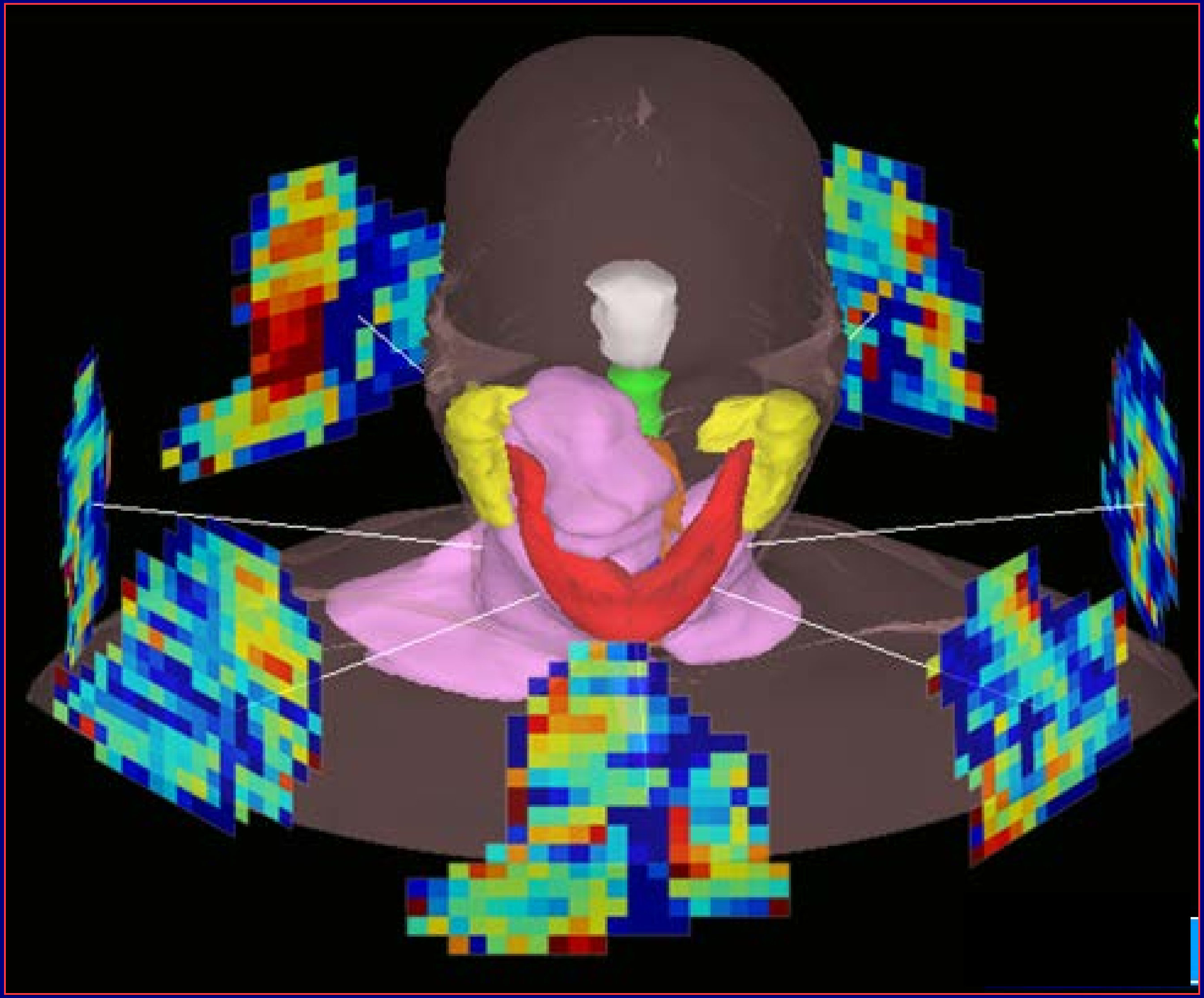
Prescription

↓

Target + few normal contours

↓

Inverse Treatment Planning



Radiotherapy Planning/Delivery Process

MU Calculation

↓

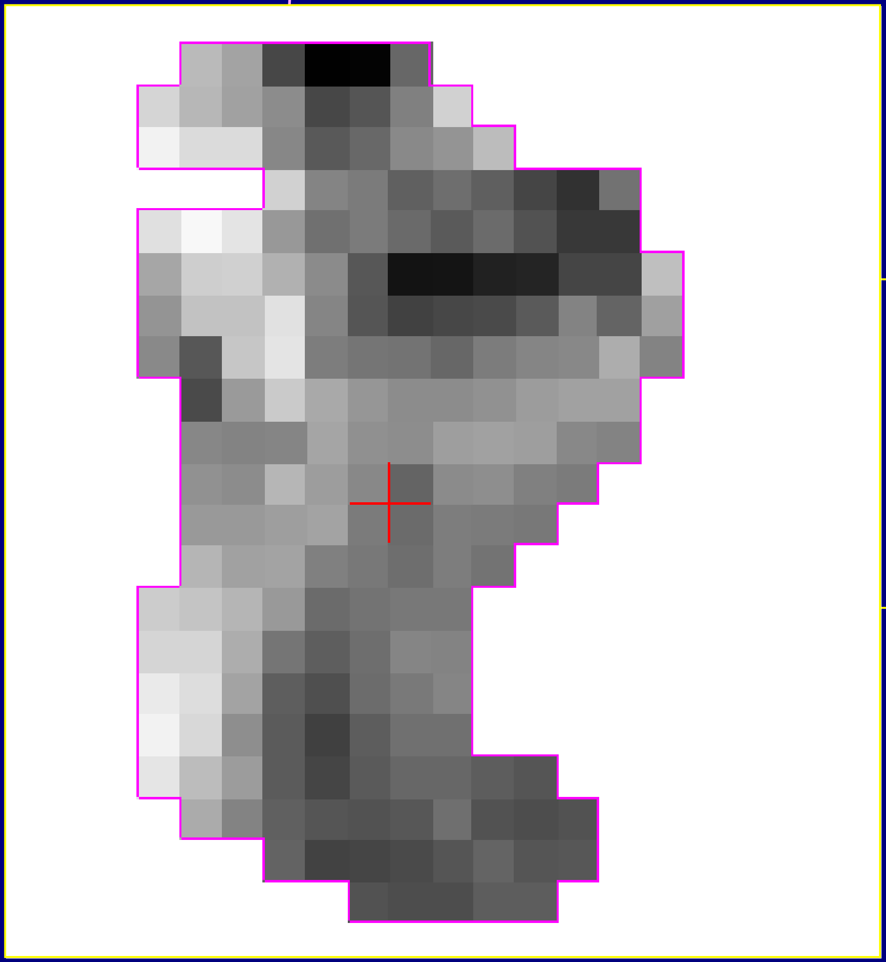
Tx Delivery Prep

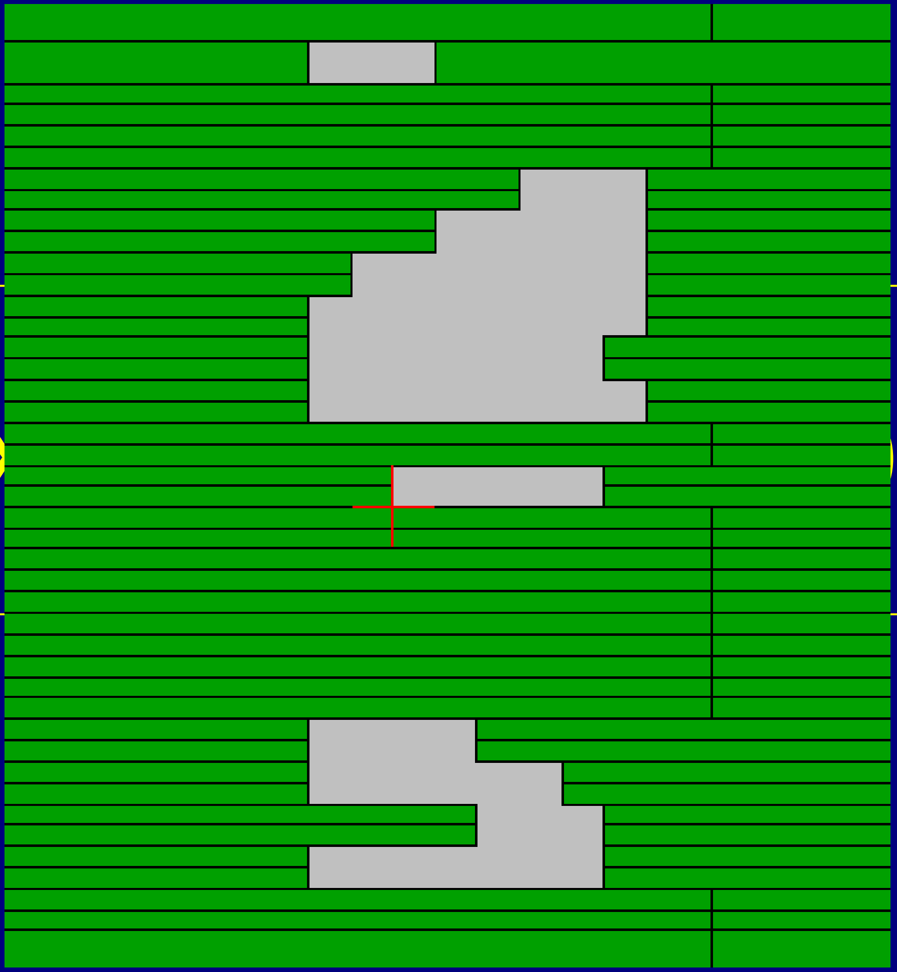
$$MU = Dose / (Cal \times TPR \times Scp \times ISL \ldots)$$

Radiotherapy Planning/Delivery Process

MU Calculation

IMRT: MLC Sequencing algorithm to calc MLC trajectories and intensities





Radiotherapy Planning/Delivery Process

MU Calculation

Tx Delivery Prep

Check MUs

Check by hand:

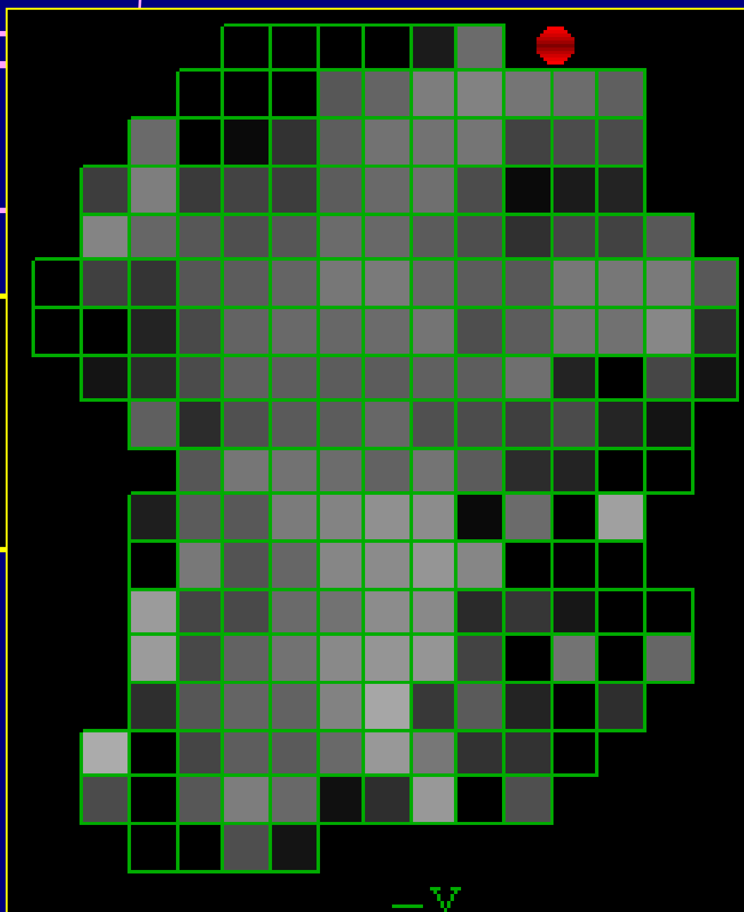
Dose = MU x Cal x TPR x Scp x ISL . . .)

Radiotherapy Planning/Delivery Process

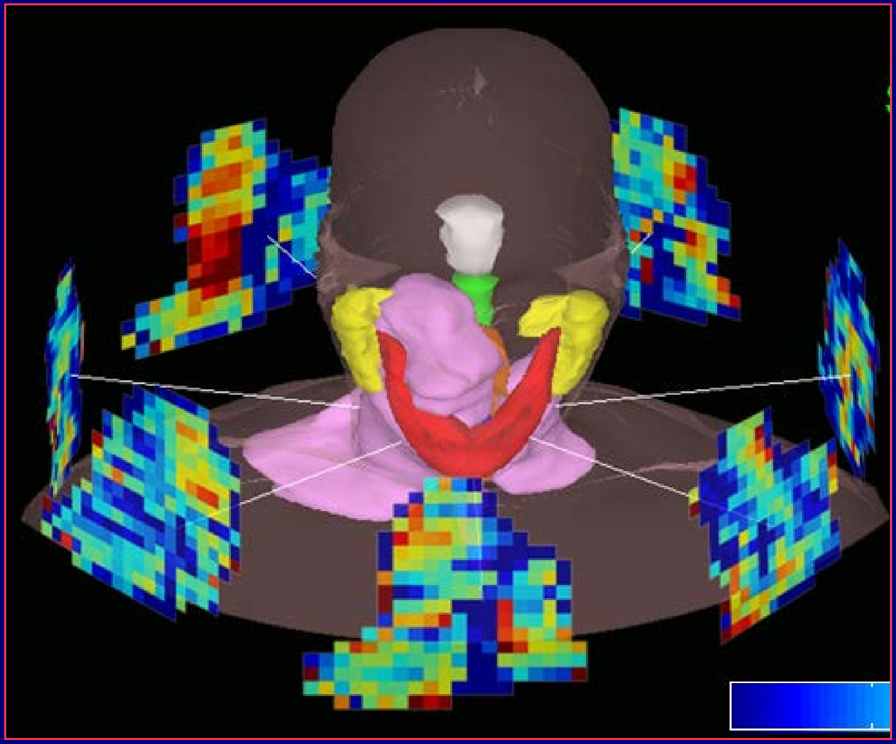
M
Calcu

T

Patient-specific IMRT QA : Measure delivered IMRT distribution in phantom, each field, then composite for plan

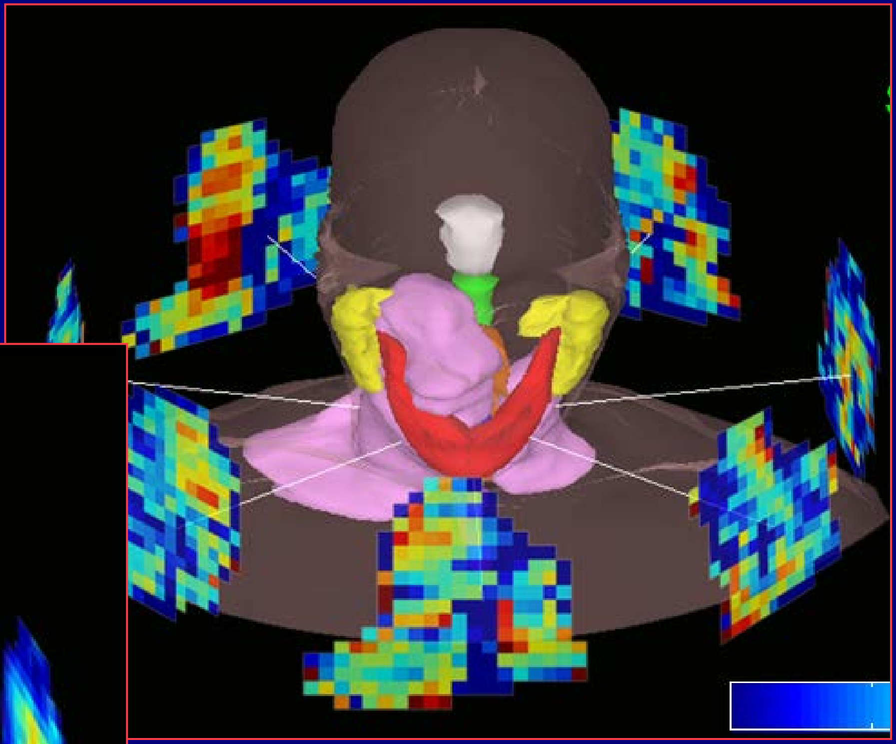


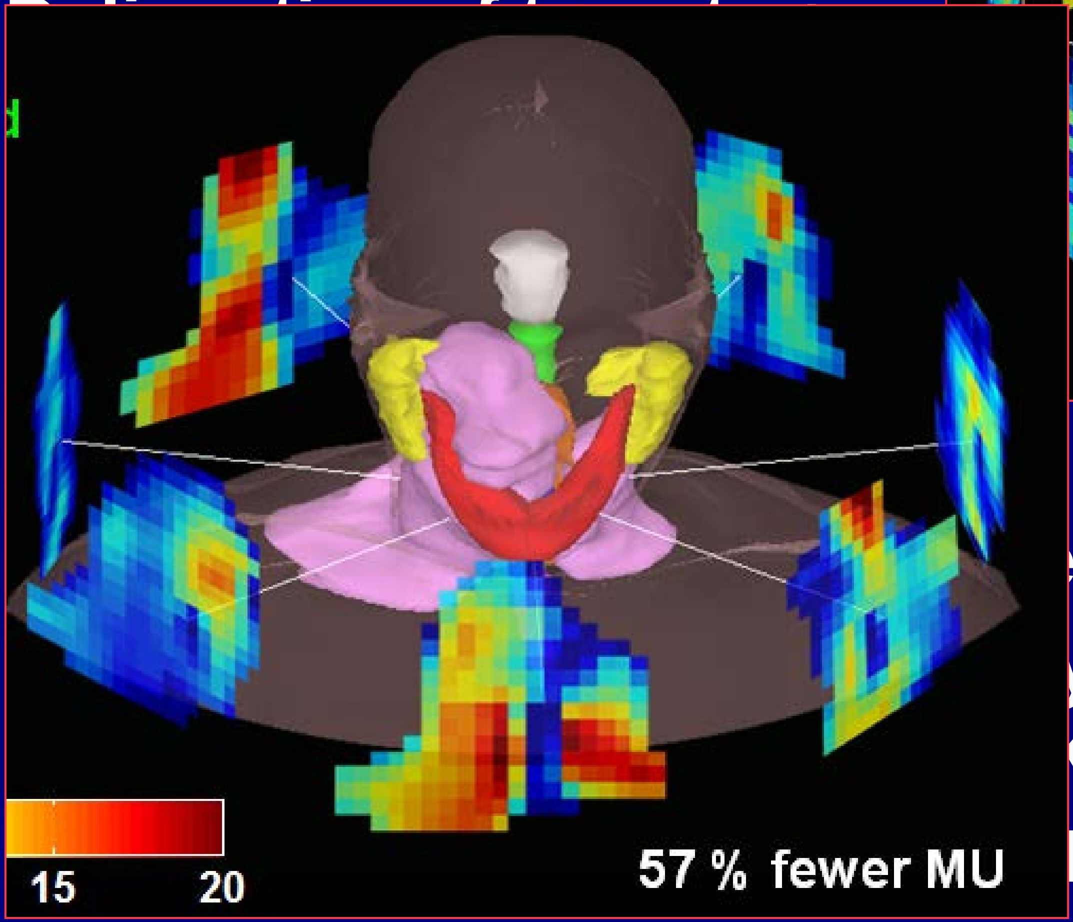
Some Technical Safety Issues for IMRT



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

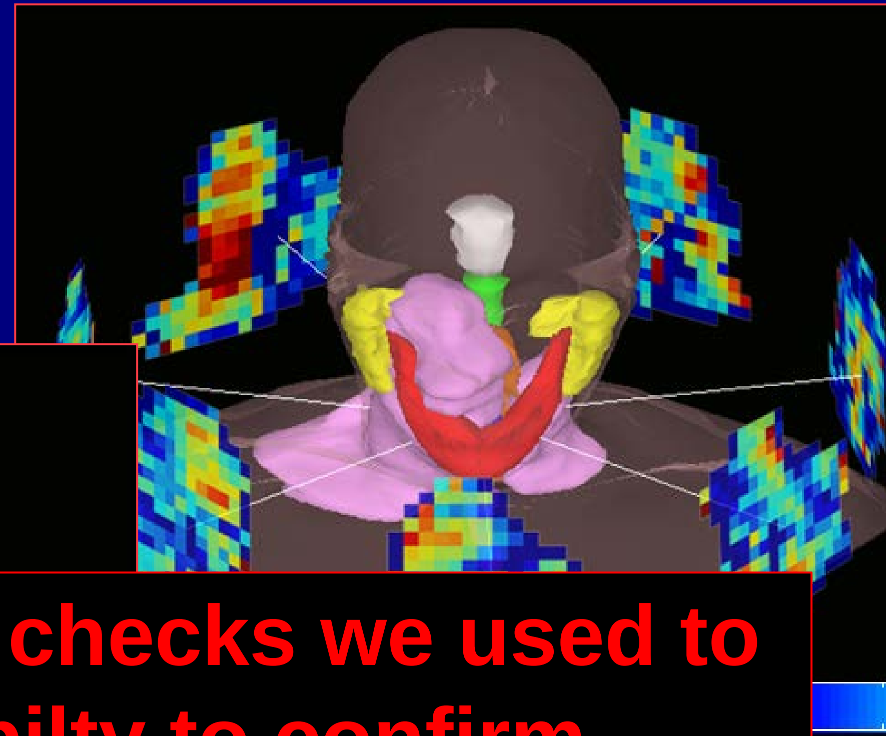
Some Technical Safety Issues for IMRT





- …ections not intuitive
- …y related to dose – …ks
- …lUs not possible
- Plan, beams, MUs not intuitive

Some Technical Safety Issues for IMRT



Most of the intuitive checks we used to have, and the abilty to confirm "reasonability", can no longer be done by therapists - or anyone

- y related to dose –
  ks
- lUs not possible
- Plan, beams, MUs not intuitive

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Radiotherapy Errors
(detected with independent Record/Verify System)

Error Rate	Author
3 % / Session	Kartha, 1977
1% / Field	Podmaniczky 1985
0.18% / Field	Macklis, 1998 *

* Some errors caused by R/V

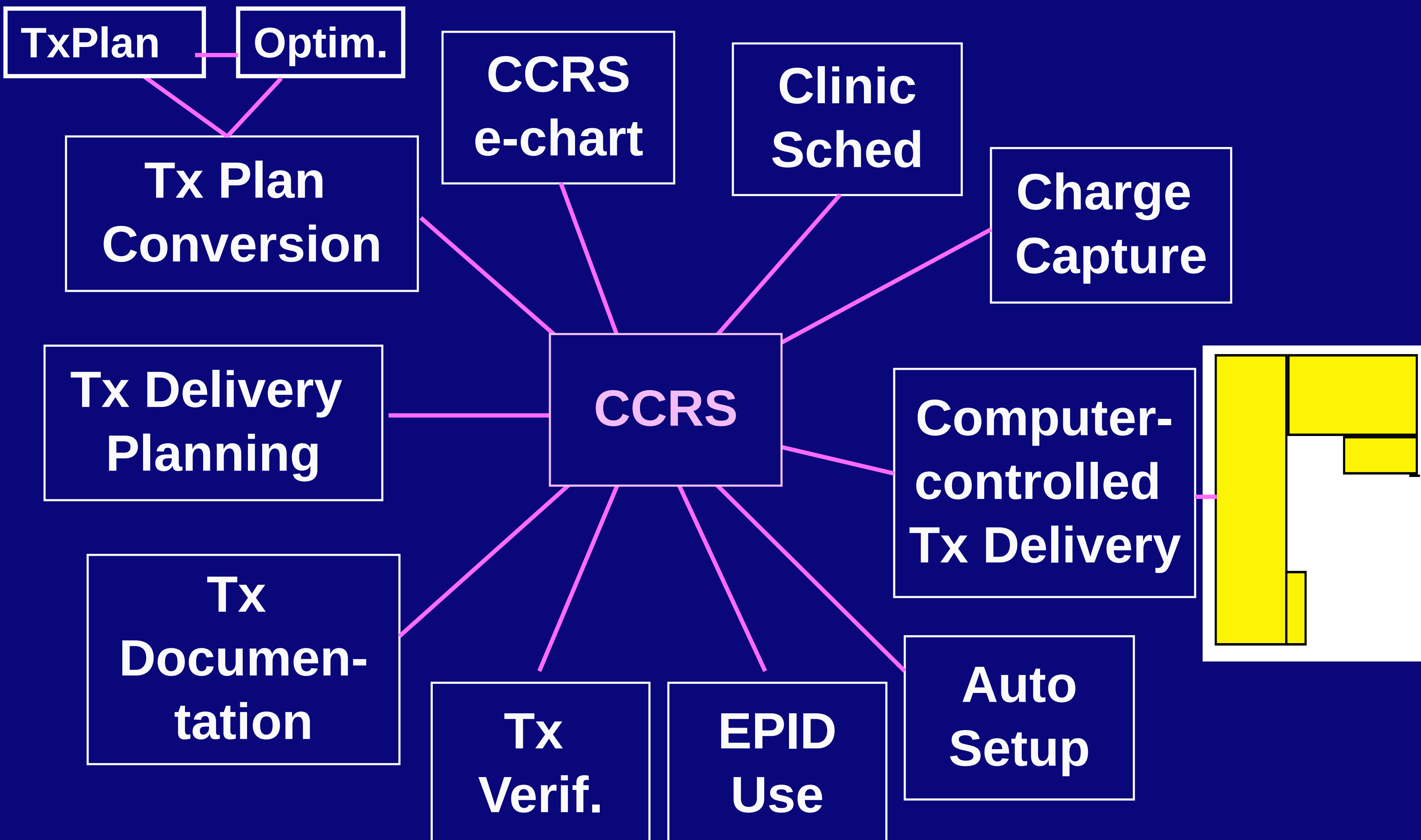
% of Errors “due to” Record/Verify

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

R/V-Related Errors

- Solution: Integrate the R/V system into the planning/delivery system
- However, this removes the independence of the R/V system.
- We are left with an integrated computer-controlled treatment delivery system

UM-CCRS: Computer-controlled Conformal Radiotherapy System



1988-2001

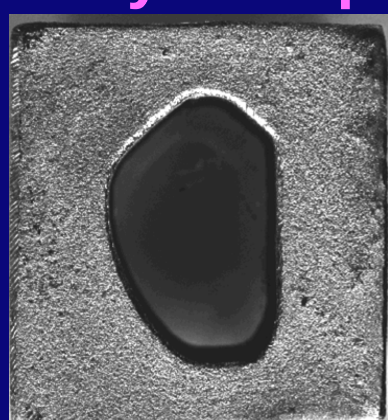
Does computer-controlled Tx delivery decrease error rates, in spite of an increase in Tx complexity ?

- Had opportunity to compare errors between manual and computer-controlled Tx (UM CCRS)
- All ExtBeam Txs 7/96 thru 9/97 were studied (>34k fractions)
- Tx delivery errors from QA logs, retrospective e-chart analysis, logged by therapists

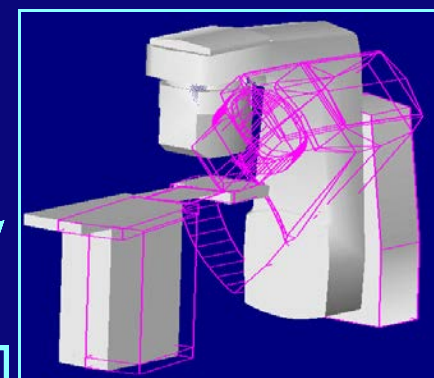
Fraass et al, Int J Rad Onc Biol Phys 42: 651-659, 1998

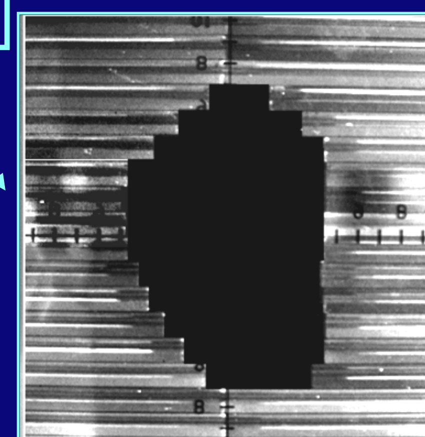
Manual vs. Computer-Controlled Radiation Therapy

Machine:	M1 C6-100	M2 C1800	M3 C2100CD	M4 Microtron
Computer Control	none	none	mostly	full control
Treatment Delivery Method	Manual: Individual flds set by therapists			
Field Shaping				



CCRS

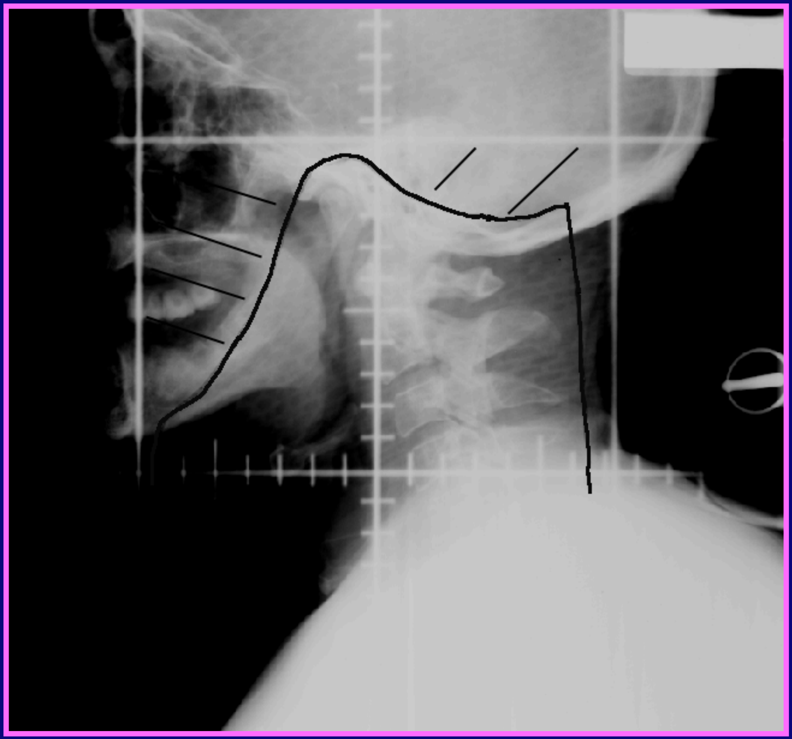




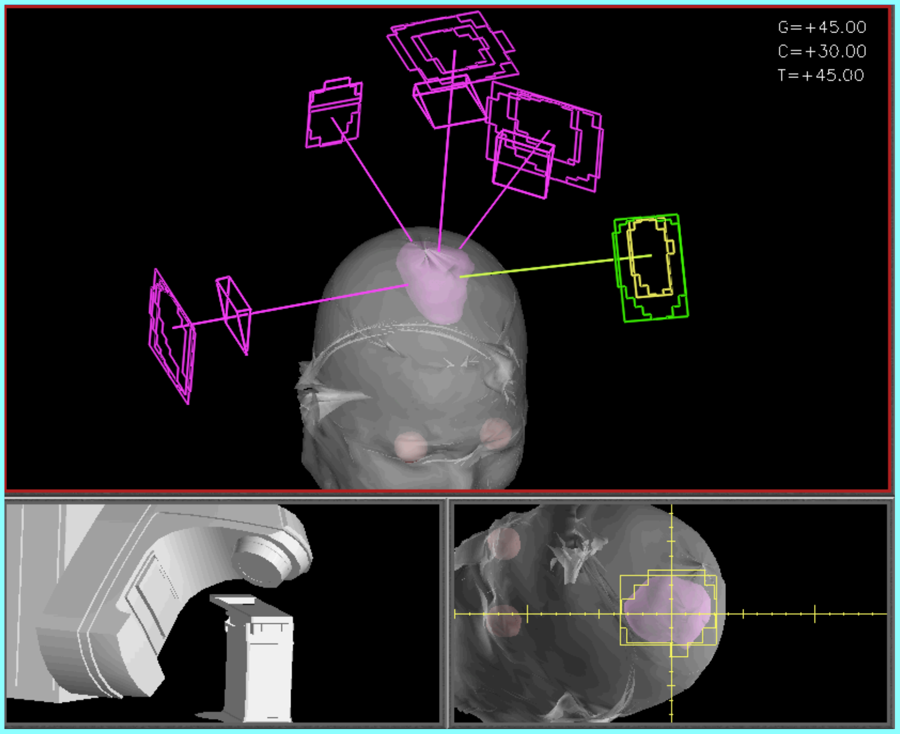
Increasing Plan Complexity

Machines:

M1 → **M4**



Few-Field Plans w/ Blks



High Dose Brain Tx:
5 fields/9 segs, CCRS

Tx Delivery Error Analysis

(34k Tx sessions, 114k segments)

Machine Errors (%/Segment)

Errors	M1	M2	M3	M4
Machine Setup	.03	.13	.02	.003
Accessories	.09	.09	.02	.003
Total/Segment (%)	.12	.22	.03	.006

Expect that these errors are under-reported, probably are 1-2 %

Fraass IJROBP 42 (1998)

Almost no way to find random setup errors for manual setup, except weekly portal images.

Setup+Prescription Errors (%/session)

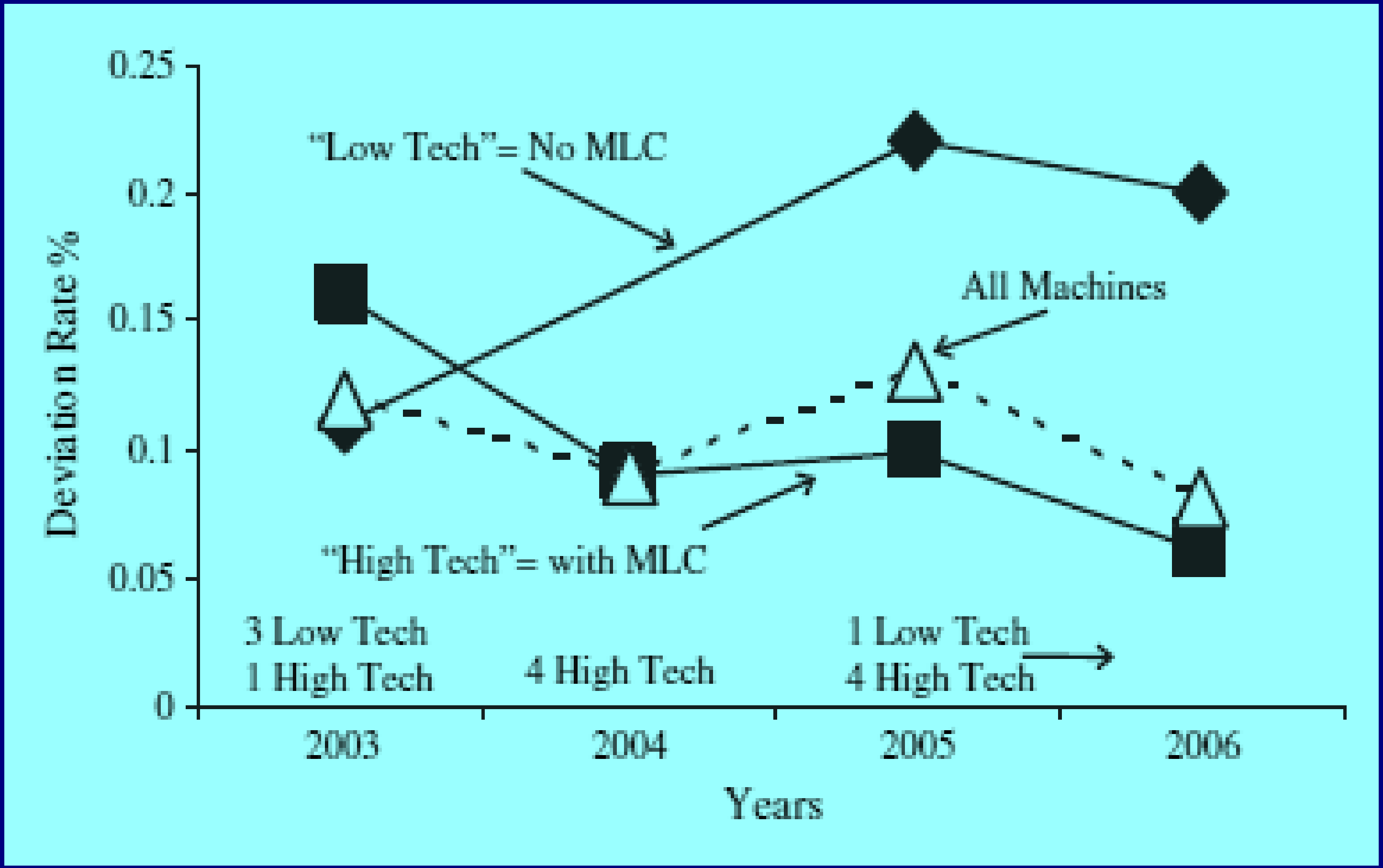
Errors	M1	M2	M3	M4
Patient setup	.03	.07	.21	.12
Patient/Plan choice	0	0	.04	.03
Prescription/Chart	.01	.10	.04	.03
Total/session (%)	.05	.17	.28	.18

No way to identify these manual errors

- Automated QA check of daily table coords highlights all setup inconsistencies
- One specific process problem: 90% of these errors

Fraass IJROBP 42 (1998)

Low Tech vs High Tech: Training, Process, QA Expectations



Deviation rate as MLC technology was introduced

LB Marks, KL Light, JL Huggs, DL Georgas, EL Jones, MC Wright, CG Willett, FF Yin: The impact of advanced technologies on Tx deviations in radiation treatment delivery. IJROBP 69: 1579-1586, 2007

Technology, by itself, is not the problem

Type of Error	Rel. Risk (95% CL)	p
MLC	1.9 (1.3 - 2.9)	0.001
External Blk	4.4 (3.1 - 6.3)	< 0.001
External Wdg	1.3 (0.8 – 1.9)	0.28
Internal Wdg	2.6 (1.4- 4.5)	0.001

- External Block required direct daily actions by RTT, while MLC was set by control system
- External Wdg had direct visual check by RTT, while programmed internal Wdg did not.

G Huang, G Medlam, J Lee, S Billingsley, JP Bissonnette, J Ringash, G Kane, DC Hodgson: Error in the delivery of radiation therapy: results of a QA review: IJROBP 61: 1590-1595, 2005

Despite Complexity, Errors Can Decrease

Type	Non-IMRT	IMRT	P
Error	0.21 %	0.03 %	
Error and Potential Error	0.40 %	0.14 %	0.0004

24,775 courses over 3 years.
3 academic and 16 community practices

- Multivariate analysis of higher severity and any error correlated with reduced errors with IMRT.
- No significant difference between academic and community practices.
- No change in error frequency despite 39 changes by centralized Quality Improvement Committee

AC Olson, RE Wegner, C Scicutella, DE Heron, JS Greenberger, S Huq, G Bednarz, JC Flickinger: QA Analysis of a Large Multicenter Practice: Does Increased Complexity of IMRT Lead to Increased Error Frequency? IJROBP 81: S565, 2011

Should We Avoid Complexity ?

Is complexity associated with improved overall survival?
1733 NSCLC (IIIB) patients >65 yrs

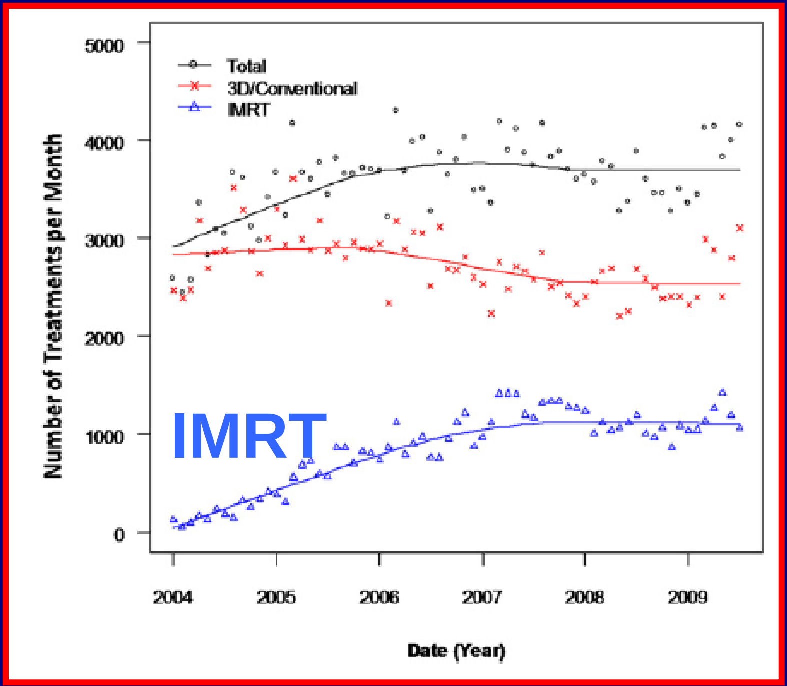
Patients	RT Planning	Hazard Ratio *
148	Simple	-
1138	Intermediate	0.75 (0.62 – 0.91)
447	Complex	0.69 (0.55 – 0.86)

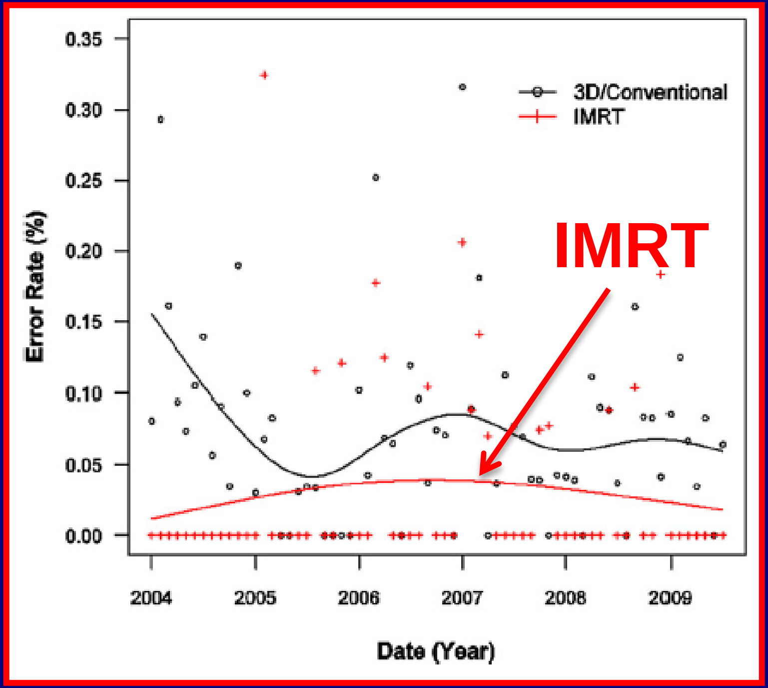
* p = 0.0002

B Goldsmith, J Cesaretti, JP Wisnivesky: Radiotherapy Planning Complexity and Survival after Treatment of Advanced Stage Lung Cancer in the Elderly. Cancer 115: 4865-4873, 2009

IMRT vs 3D/Conventional

Type of Tx	Error Rate (95% CL)	p
3D/Conventional	0.07% (0.06 – 0.09%)	0.0008
IMRT	0.03% (0.02 – 0.05%)	





DN Margalit, YH Chen, PJ Catalano, K Heckman, T vivenzio, K Nissen, LD Woldsberger, RA Cormack, P Mauch, AK Ng: Technological advancements and error rates in RT delivery. IJROBP 81: in press, 2011

Errors Detected by Systematic In Vivo Dosimetry

7519 patients, in vivo dosimetry (5 years)

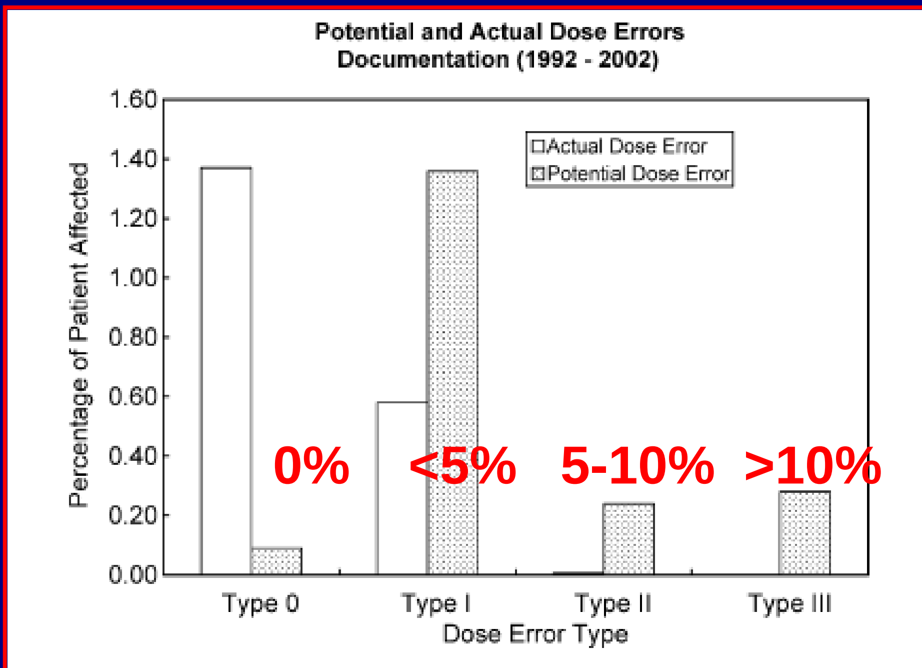
Tx Preparation		Tx Execution	
3	Prescription	7	Tx Setup
3	Planning	19	Delivery
46	Calculation	1	Technical Failure

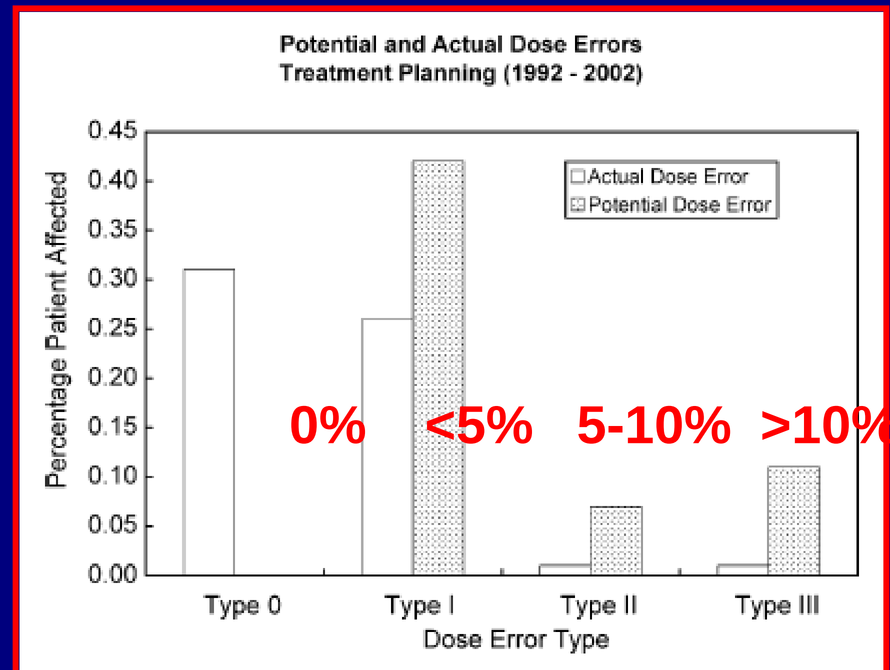
78 / 79: involved human error

A Noel, P Aletti, P Bey, L Malissard: Detection of errors in individual patients in radiotherapy by systematic in vivo dosimetry. Radiotherapy and Oncology 34:144-151, 1995

How Big are the Errors ?

13,385 patients, 10 years





TK Yeung, K Bortolotto, S Cosby, M Hoar, E Lederer: Quality assurance in radiotherapy: evaluation of errors and incidents recorded over a 10 year period. Radiotherapy + Oncology 74: 283-291, 2005

A big challenge:
The rate of dosimetrically-significant errors (>10%) is << 0.1 %, so we are looking for such errors in 1-2 patients per year in a normal clinic

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The New York Times

January 24, 2010

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One note: nearly all the error-related studies discussed earlier were performed and published before these articles

Good Results of the NY Times Publicity:

Various National Safety-Related Initiatives

- Has led to introspection within many depts, opening windows for analysis + action
- Publicity has led to new involvement in QA + safety issues within ASTRO, AAPM, ACR etc:
- New analysis and initiatives by FDA
- AAPM Task Groups – Safety, not just QA
- Safety White Papers (ASTRO et al)
- Work toward National Event-Reporting Program
- Safety Stakeholders Initiative – Vendors + Orgs (ASTRO, AAPM, etc)

Bad Results of the NY Times Publicity ?

A few incorrect conclusions "learned" from the NY Tmes IMRT error:

1. We can fix this with one new QA test . . .

   But almost all errors have many contributing factors

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

   But what about recent stereotactic calibration errors?

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

   But testing cannot find all errors

4. More rigorous practice standards and/or accreditation, by themselves, will prevent this

   But catastrophic errors happen to good people

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

NO.

- We must evaluate risks, processes, potential failure modes
- We must better prioritize our safety/QA efforts
- We must spend our efforts on the most frequent, severe, and risky problems, not just the problems amenable to QA

Conclusions

- Radiotherapy is immensely more complex than 20 years ago, but complexity in RT is neither bad nor good – it’s just different
- Error rates, especially for clinically significant errors, are very low
- The types of errors which occur now are very different: New QA approaches are required
- Improving radiotherapy safety requires:
  - Comprehensive efforts for each treatment method
  - Process-oriented safety analysis and QA
  - Careful, complete QA programs in each clinic
  - Realistic + sophisticated guidance from regulators and other organizations