Developing a QA Program in Support of Cooperative Group Clinical Trials

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and RPC Staff

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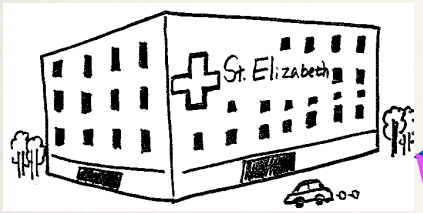
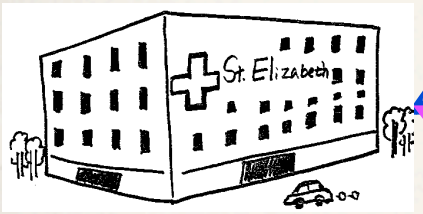
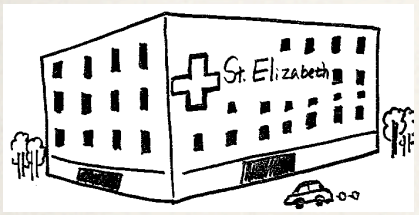
QA Infrastructure for Clinical Trials

Participating Institutions







Cooperative Group

QA Office

Funding Agency

NATIONAL CANCER INSTITUTE

RPC

Radiological Physics Center

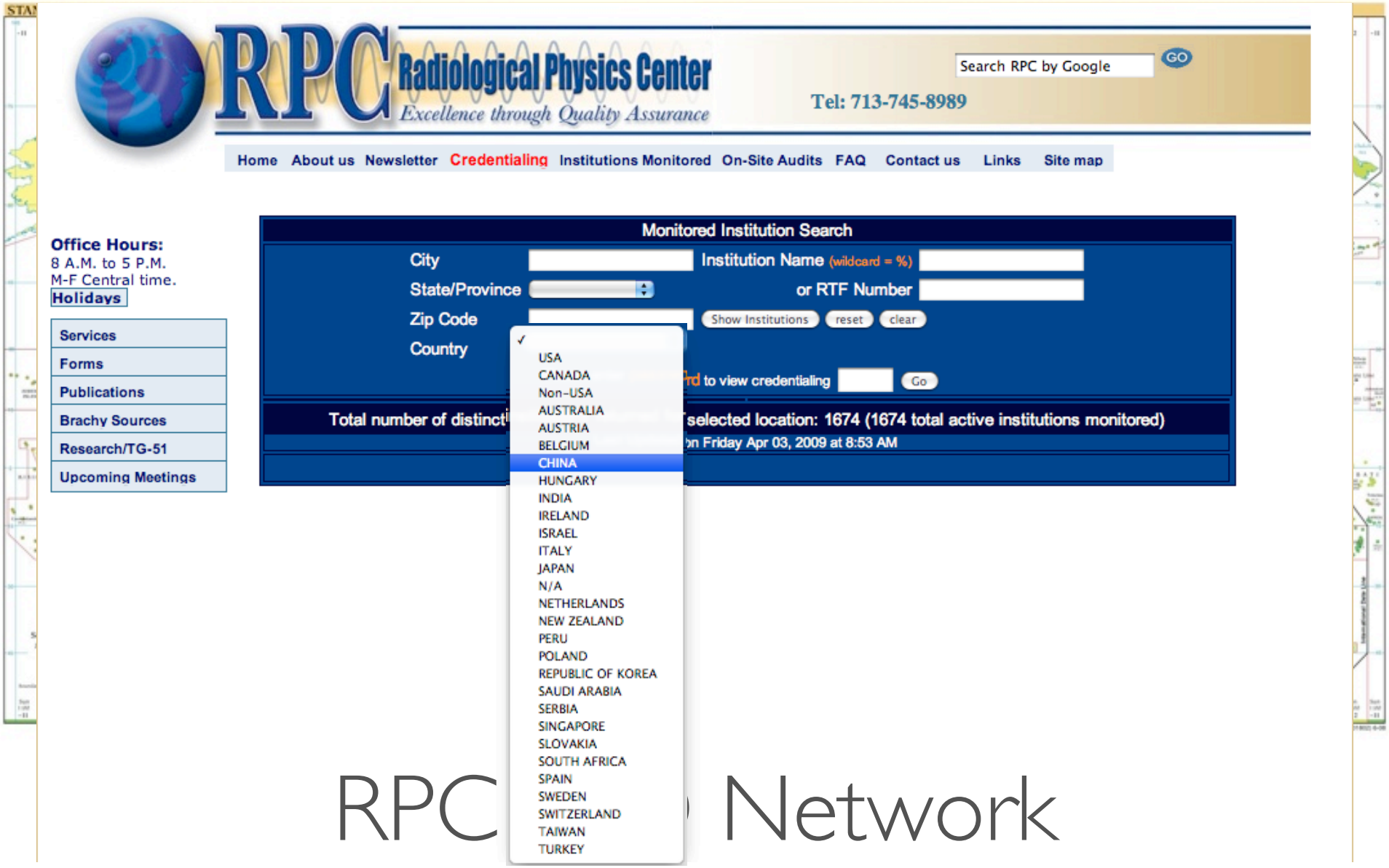
- Formed when AAPM received funding from NCI and announced competition
- Founded in 1968 to monitor institution participation in clinical trials
- Funded continuously by NCI as structure of cooperative group programs have changed
- Now 40 years of experience of monitoring institutions and reporting findings to study groups and community

Mission

- The mission of the Radiological Physics Center is to assure NCI and the Cooperative Groups that institutions participating in clinical trials deliver prescribed radiation doses that are clinically comparable and consistent. We do this by assessing the institution's radiotherapy programs, helping the institutions implement remedial actions, assisting the study groups in developing protocols and QA procedures, and summarizing our findings for the radiation therapy community.

Components of a QA Program

- Remote audits of machine output
  - 1,674 institutions, 14,188 beams measured with TLD (2008)
- Treatment record reviews
  - Review for GOG, NSABP, NCCTG, RTOG (brachy)
- Independent recalculation of patient dose
  - Continue to find errors
- On-site dosimetry reviews
  - 50 institutions visited (~150 accelerators measured)
- Credentialing
  - Phantoms, benchmarks, questionnaires, rapid reviews



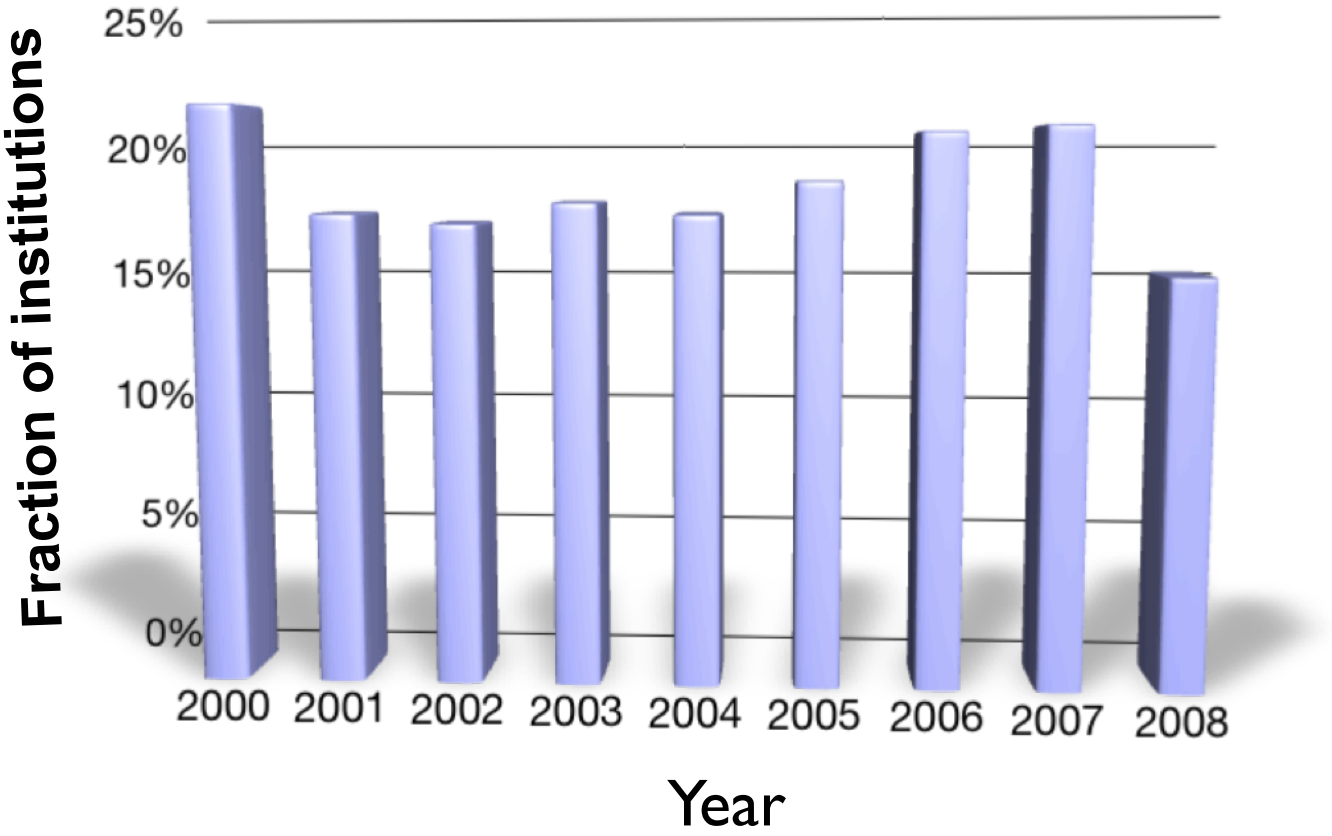
RPC Network

1,674 RT facilities in 27 countries throughout the world, including 52 EORTC members

TLD Irradiation

Institutions receive acrylic block containing dosimeters

Institutions with One or More Unacceptable TLD Measurements



Why are TLDs out of criteria?

- Inexperience
- Variations in training
- Mistakes at commissioning
- New technologies pull resources from basic QA procedures

Laoen

Benefits of the TLD Program

- Helps institutions stay vigilant
- Problems contribute to priorities for visits
- May satisfy state/local requirements for independent review
- Identifies problems that have direct impact on every patient treated
- It is a model for other remote programs

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Purpose of Patient Dose Review

- Maintain low uncertainty in doses delivered to protocol patients by discovering and correcting errors
- Provide study groups with accurate dose data

Improve Clinical Trials

RPC Patient Dose Review

- Independent calculation of tumor dose
- Agree within 5% (15% for implants)
- Verify dose, time, fractionation per protocol
- Notify institution if major deviation seen during review to prevent further deviations

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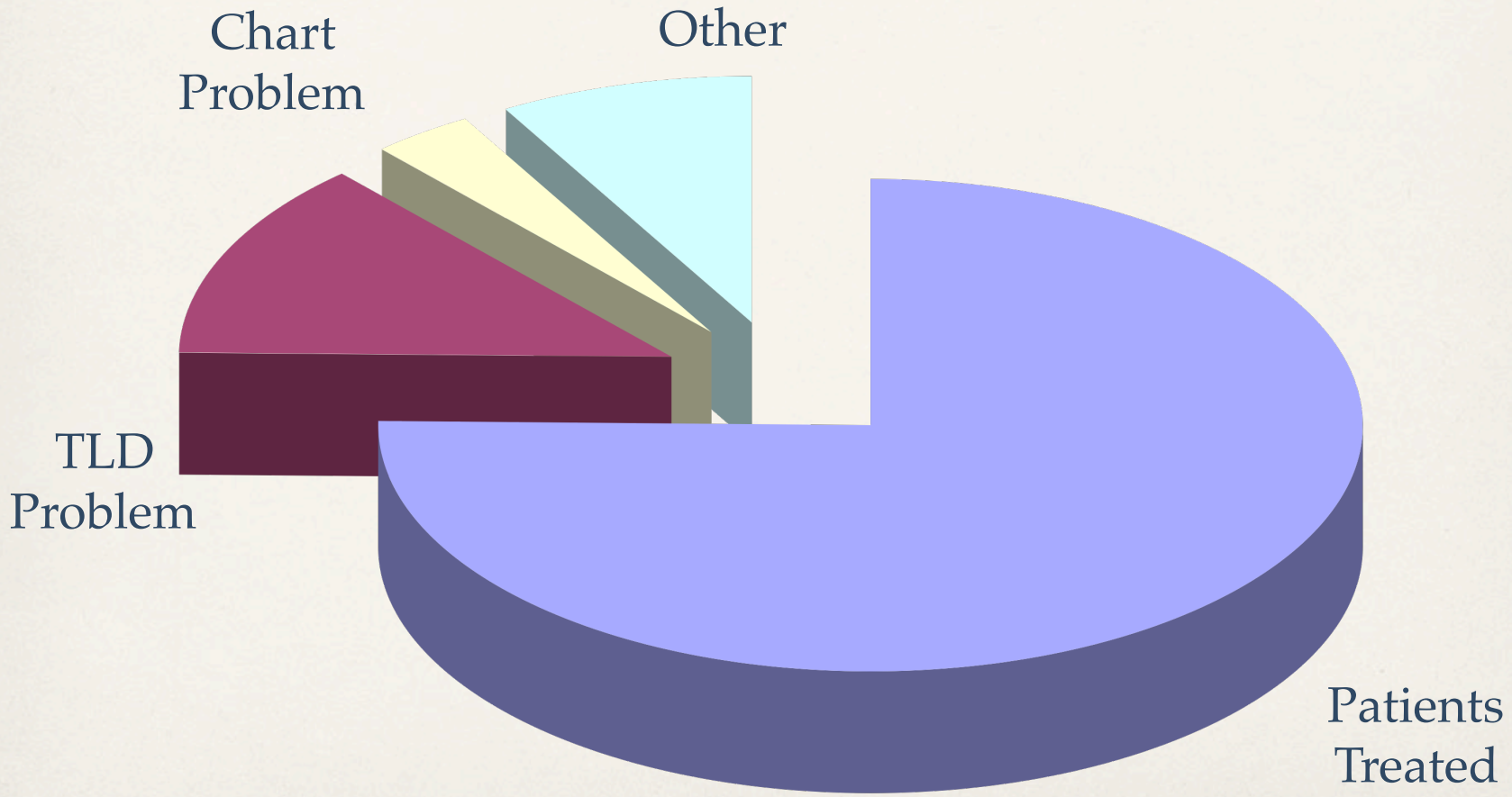
Visit Priority



On-Site Dosimetry Review Visit

- **The <u>only</u> completely independent comprehensive radiotherapy quality audit in the USA and Canada**

  - Identify errors in dosimetry and QA and suggest improvements.
  - Collect and verify dosimetry data for chart review.
  - Improve quality of patient care.

On-Site Dosimetry Review

Selected discrepancies discovered 2004 – 2008

Errors Regarding	Number of Institutions (%)
Review QA Program	127 (77%)
*Wedge Transmission	53 (32%)
*Photon FSD (small fields)	46 (28%)
Off-Axis, Beam Symmetry	42 (25%)
*Photon Depth Dose	34 (21%)
*Electron Calibration	25 (15%)
*Photon Calibration	22 (13%)
*Electron Depth Dose	19 (12%)

*70% of institutions received at least one of the significant dosimetry recommendations.

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Credentialing

Why?

- Education
- Evaluate ability to deliver dose
- Improve understanding of protocol

Reduce deviation rate

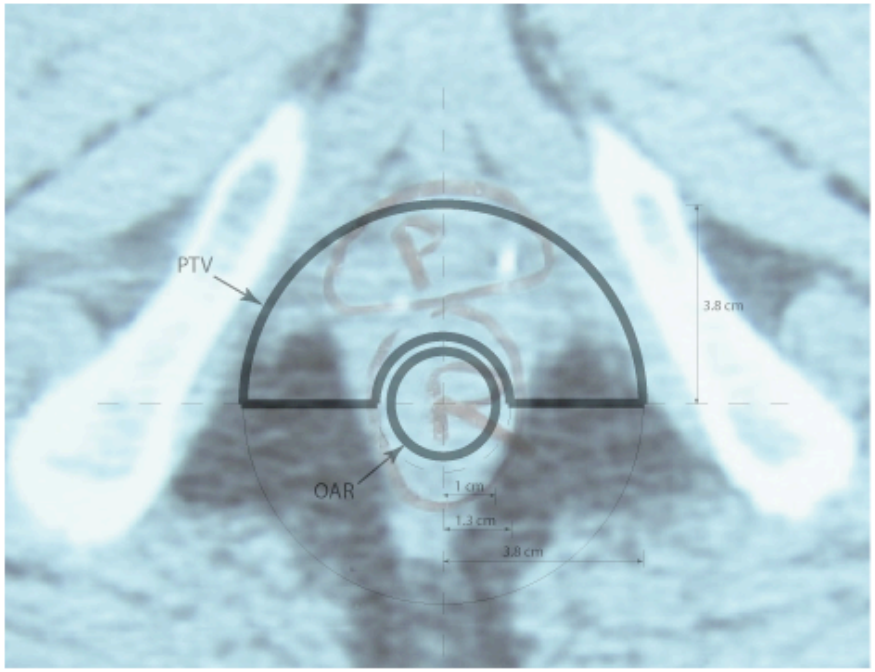
General Credentialing Process

- Previous patients treated with technique
- Facility Questionnaire
- Knowledge Assessment Questionnaire
- Benchmark case or phantom
- Electronic data submission
- RPC QA & dosimetry review
- Clinical review by radiation oncologis

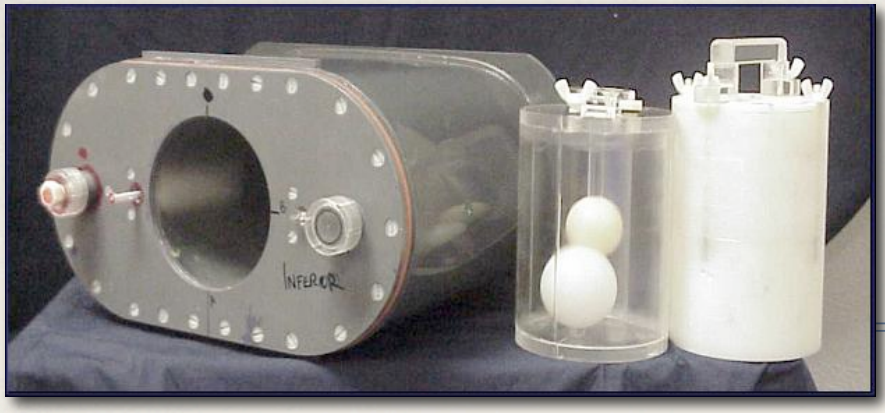
Feedback to Institution

Treatment Planning Benchmark

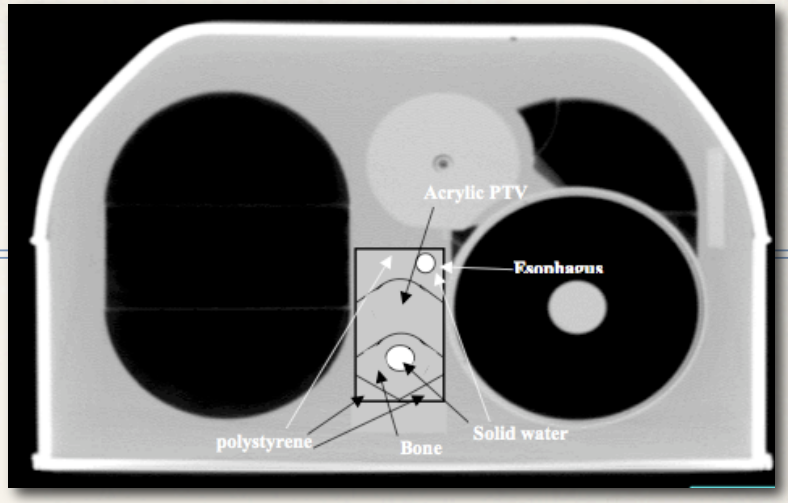
- Demonstrates ability of planner to generate a dose distribution that complies with protocol



RPC Phantoms



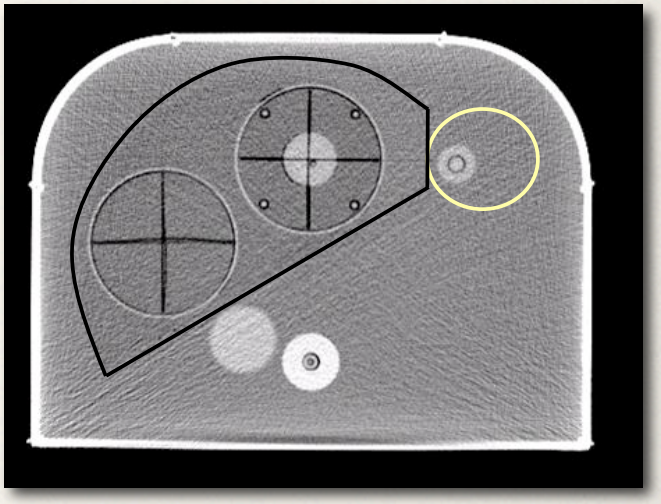
Pelvis (14)



Thorax (15)

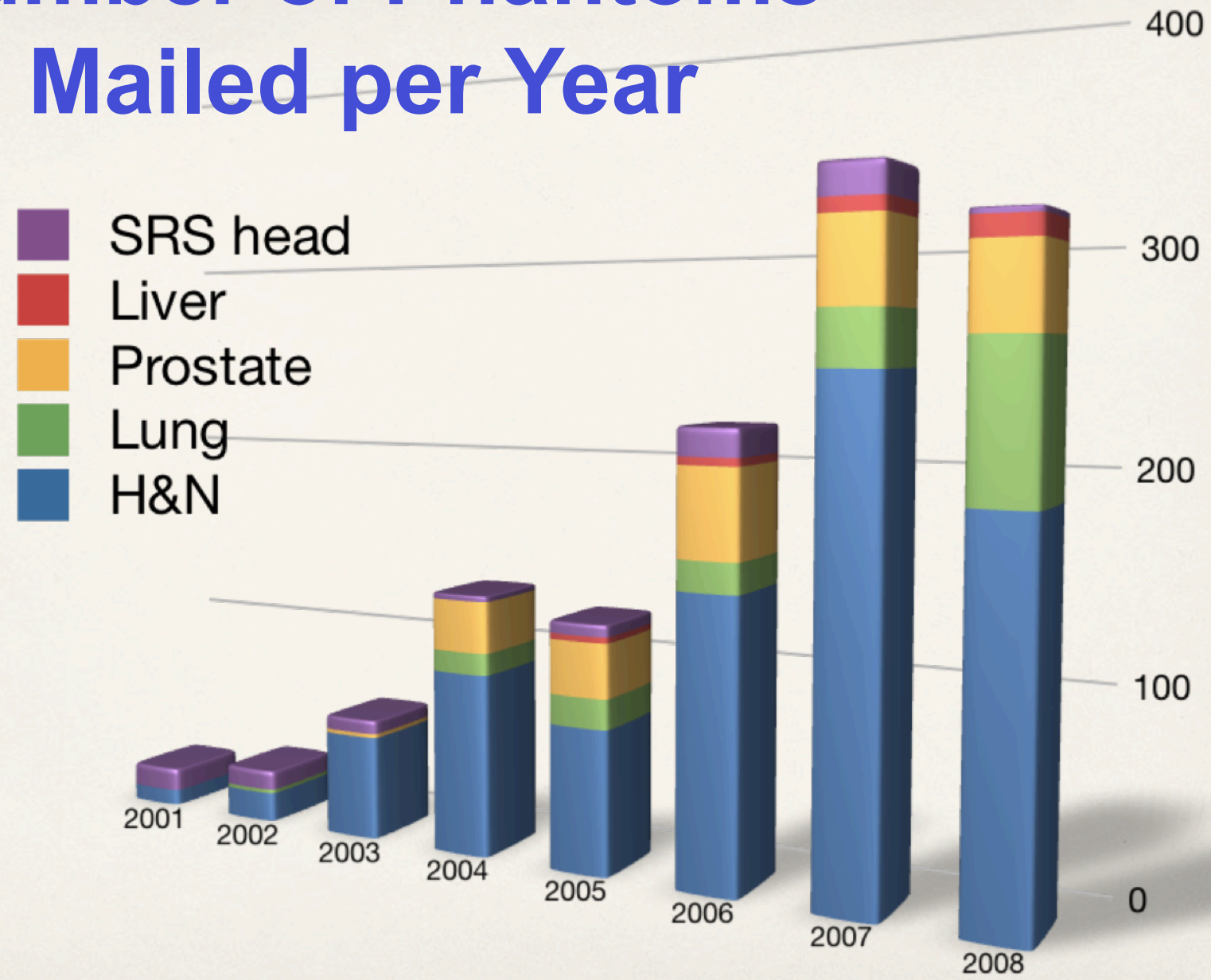
H&N (30)

SRS Head (4)

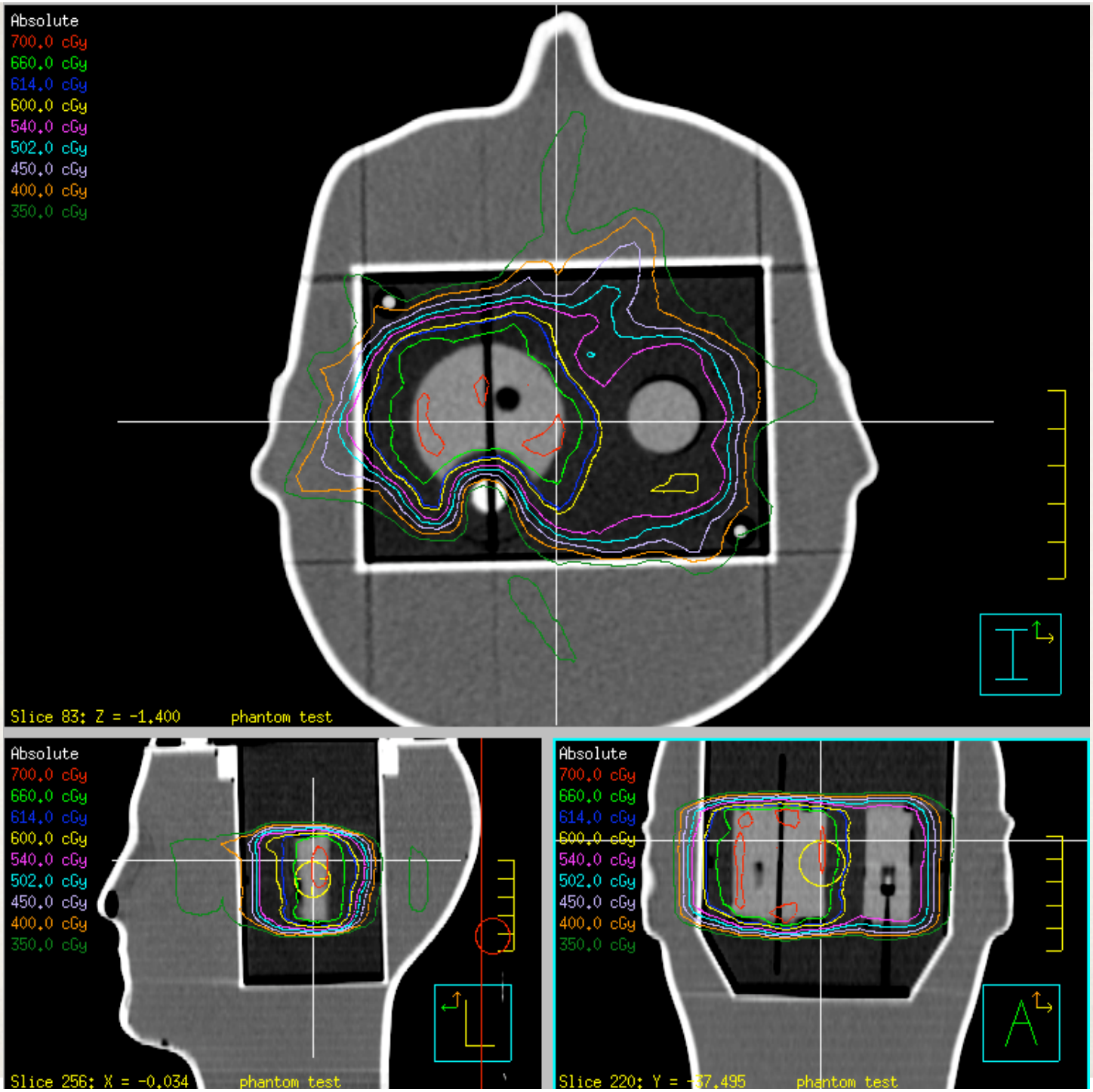


Liver (2)

Number of Phantoms Mailed per Year

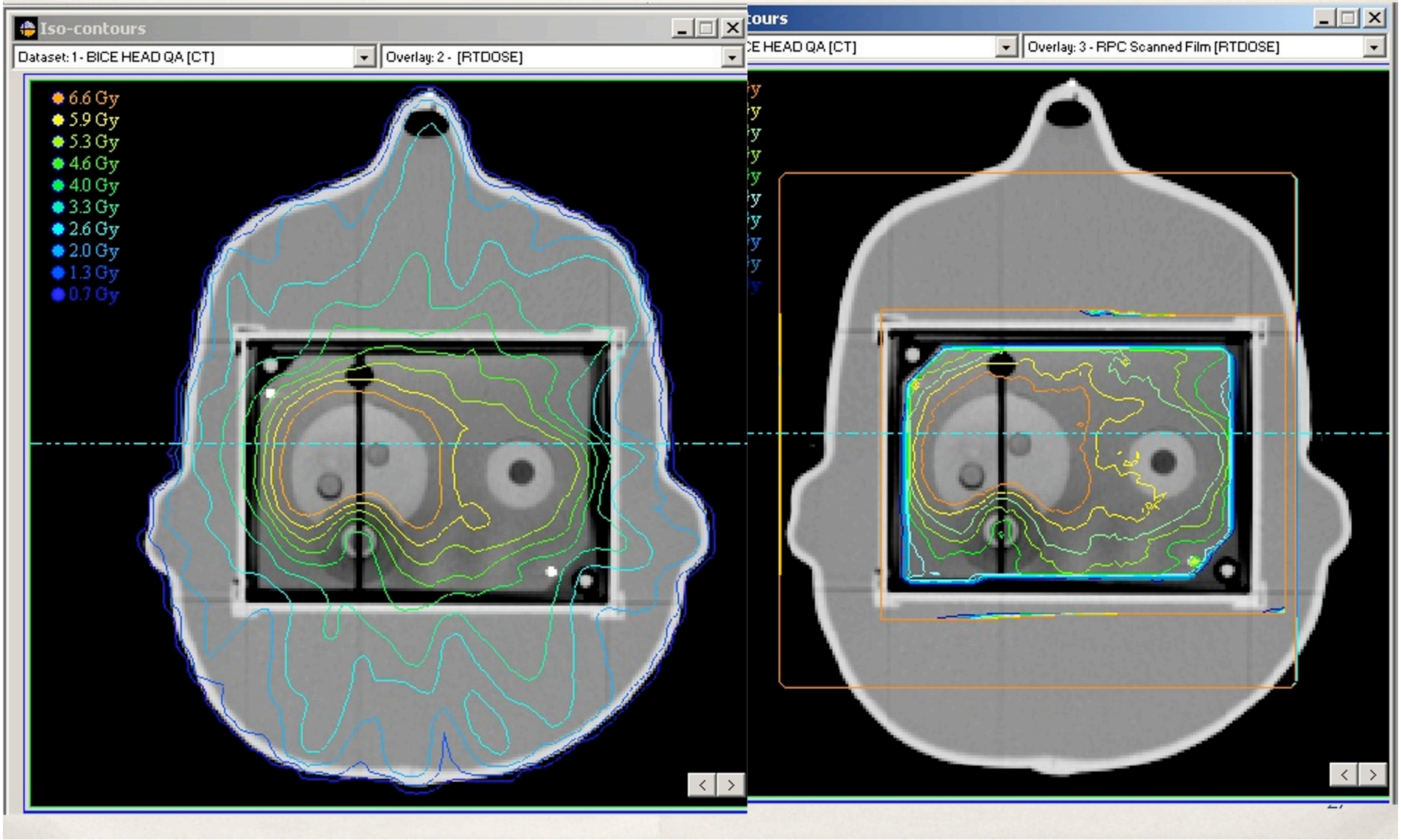


Treat phantom as if it were a patient


Absolute
700.0 cGy
660.0 cGy
614.0 cGy
600.0 cGy
540.0 cGy
502.0 cGy
450.0 cGy
400.0 cGy
350.0 cGy
Slice 83: Z = -1.400
phantom test
Absolute
700.0 cGy
660.0 cGy
614.0 cGy
600.0 cGy
540.0 cGy
502.0 cGy
450.0 cGy
400.0 cGy
350.0 cGy
Slice 256: X = -0.034
phantom test
Absolute
700.0 cGy
660.0 cGy
614.0 cGy
600.0 cGy
540.0 cGy
502.0 cGy
450.0 cGy
400.0 cGy
350.0 cGy
Slice 220: Y = -37.495
phantom test


Deliver
treatment

RPC Compares Treated Distribution with Plan



Phantom Results

Comparison between institution's plan and delivered dose.

Criteria for agreement: 7% or 4 mm DTA (5%/5mm for lung)

Site	Institutions	Irradia-tions	Pass
H&N	472	631	75%
Pelvis	108	130	82%
Lung	67	77	71%
Liver	15	18	50%

Explanations for Failures

Explanation	Minimum # of occurrences
incorrect output factors in TPS	1
incorrect PDD in TPS	1
IMRT Technique	3
Software error	1
inadequacies in beam modeling at leaf ends (Cadman, et al; PMB 2002)	14
QA procedures	3
errors in couch indexing with Peacock system	3
equipment performance	2
setup errors	7

Value of QA

- Meets goal of improving compliance with protocol
- Reduces deviations
- Detected significant errors, misunderstandings, equipment failures, QA issues

✤http://rpc.mdanderson.org

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