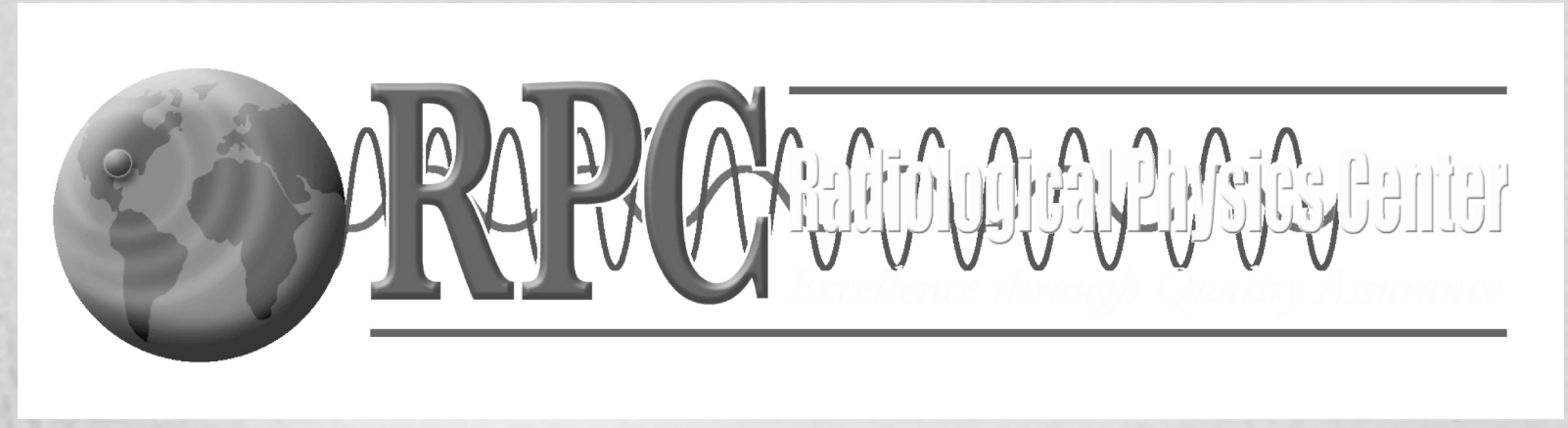
Brachytherapy in Cooperative Group Clinical Trials

Geoffrey S. Ibbott, Ph.D.

and staff of the
Radiological Physics Center



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Issues

- Why is it important to understand requirements of clinical trials?
- Protocol requirements
- Credentialing
- Analysis

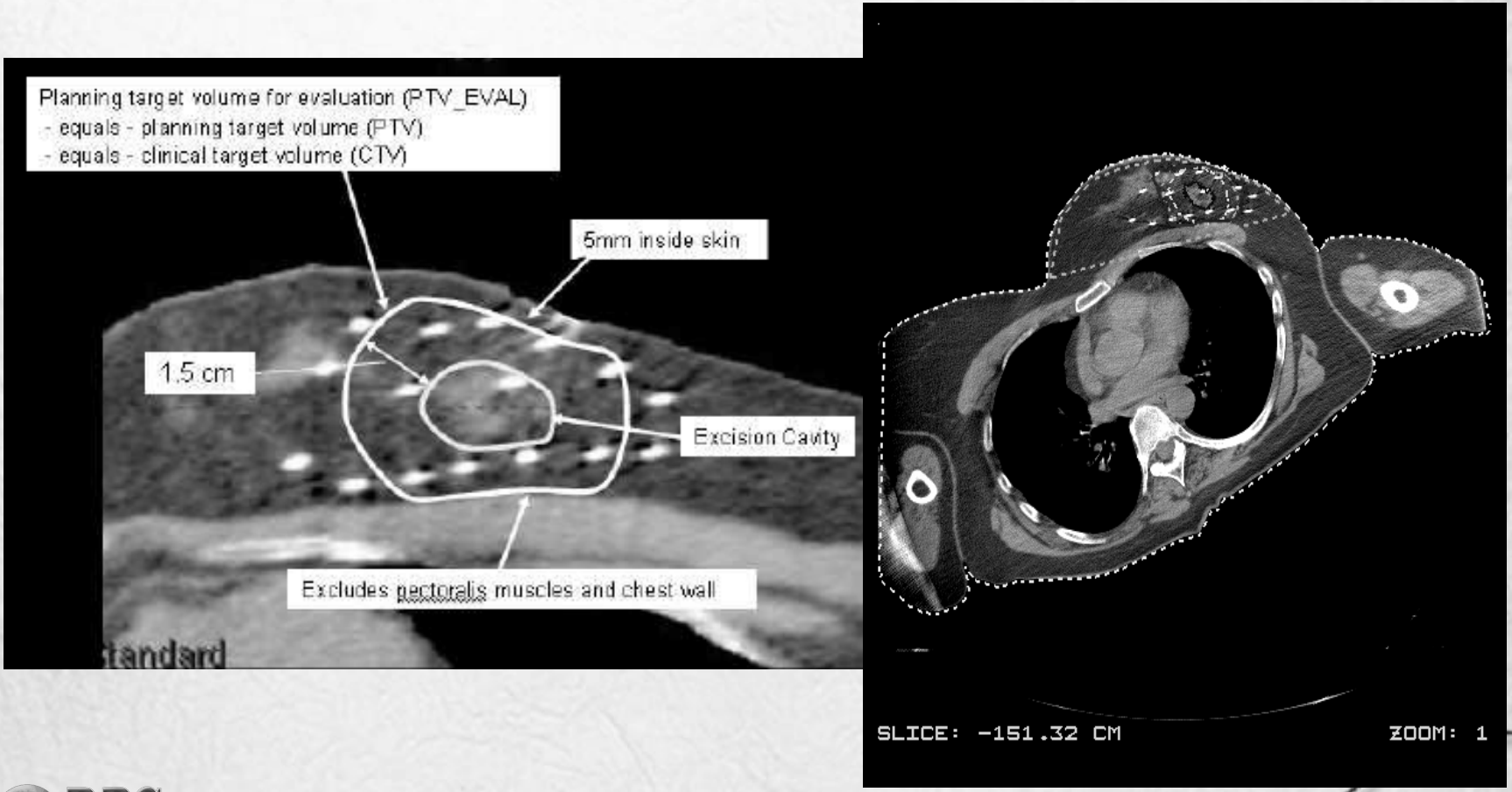
Why is it important?

- Most US radiation therapy facilities participate in clinical trials (~1,400/2,200)
- Patients often put on trials by surgeons and medical oncologists - radiation therapy staff may not be aware
- Clinical trials often raise the standards

Protocol Requirements

- Specification of volumes
  - Many protocols today require ICRU-50/62 terminology
- Specification of procedure
  - PBI specifies HDR Mammosite® or multicatheter
  - Prostate trials require seeds listed on registry
  - GYN trials specify dose distribution
    - Proposals to specify volumes on MRI

Definition of Volumes



Brachy Seed Registry

RPC Radiological Physics Center
Excellence through Quality Assurance

Search RPC by Google GO

Tel: 713-745-8989

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Office Hours: 8 A.M. to 5 P.M. M-F Central time.

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Publications
Brachy Sources
Research/TG-51
Upcoming Meetings

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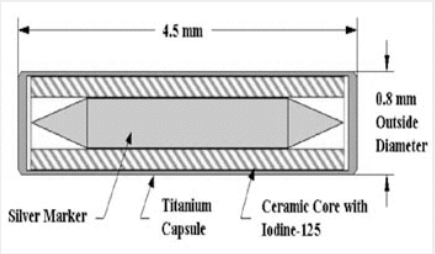
I-Plant Model 3500

Implant Sciences Corporation, 107 Audobon Road, #5
Wakefield, MA 01880 (781) 246-0700



http://www.brachyseeds.com/products/implantseeds/default.html

Distributed by: Implant Sciences Corporation
Customer service: (877) 732-7333
http://www.brachyseeds.com

- Duggan D. M., Johnson B. L., "Dosimetry of the I-Plant Model 3500 iodine-125 brachytherapy source," **Med. Phys. 28(4) 661-670, April 2001**.
- Wallace R., Model 3500 ^{125}I brachytherapy source dosimetric characterization. **Applied Radiation and Isotopes, 56 (4) 581-587, April 2002**
- Rivard, M.J., Comprehensive Monte Carlo calculations of AAPM Task Group Report No. 43 dosimetry parameters for the Model 3500 I-Plant ^{125}I brachytherapy source. **Applied Radiation and Isotopes. 57 (2002) 381-389**

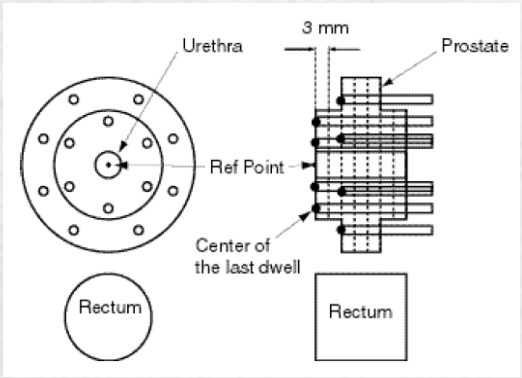
added to Registry, February 7, 2002

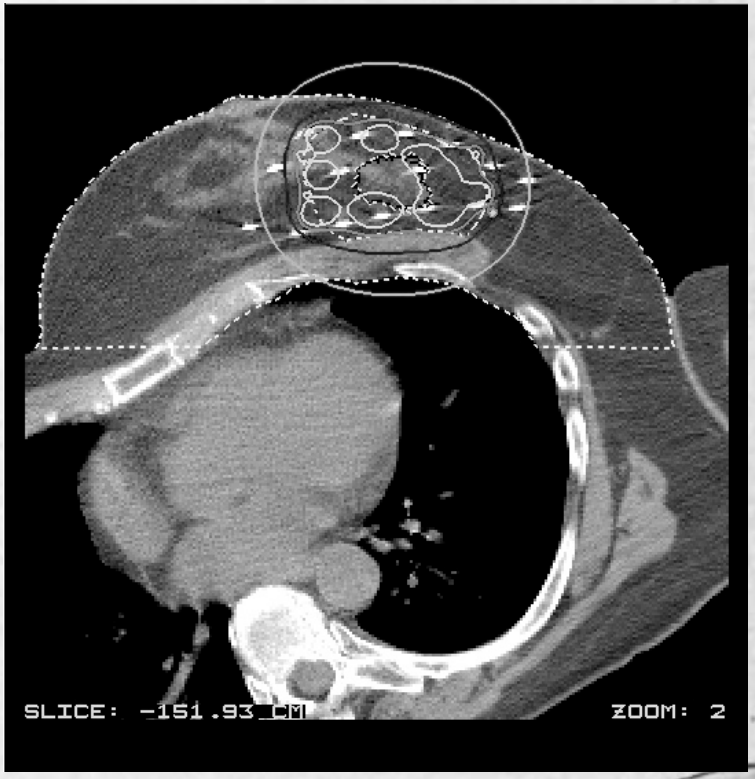
Protocol Requirements (cont'd.)

- Specification of planning system abilities
  - Digital submission to ITC
  - DVHs
  - Dose matrix (e.g., 2 mm x 2 mm x slice thickness)
- Dosimetry (example from RTOG 0232)
  - Variation acceptable: D_{90} for the ETV is greater than 80% of the prescription dose, but less than 90% of the prescription dose, or greater than 130% of the prescription dose.
  - Deviation unacceptable: D_{90} for the ETV is less than 80% of the prescription dose.

Credentialing
LDR and HDR Brachytherapy

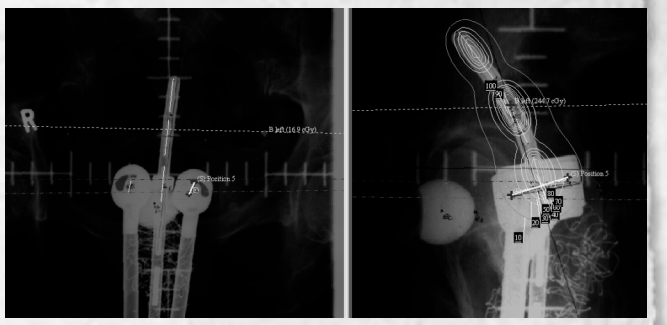
- Evaluate
  - Implant technique
  - Dosimetry
  - Documentation
  - Protocol compliance

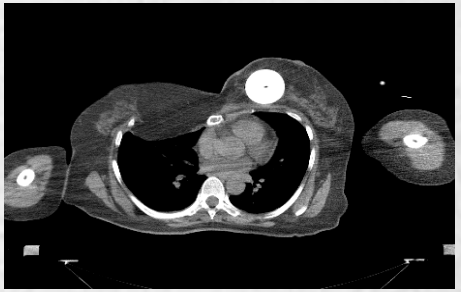




Brachytherapy Studies Requiring Credentialing

- Cervix
  - GOG **165**, **191**
  - RTOG **0116**, **0128**
- Breast
  - RTOG **95-17**
  - RTOG **0413** / NSABP **B-39**
- Prostate
  - NCCTG **N-0052**
  - RTOG **98-05**, **0019**, **0232**, **0321**
  - ACOSOG, CALGB, NCIC





General Credentialing Process

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

Feedback to Institution

Knowledge Assessment Form

ATC CREDENTIALING PROCEDURES FOR PROSTATE IMPLANT PROTOCOLS
KNOWLEDGE ASSESSMENT FORM

Institution _____ RTF# _____
Physicist _____ Radiation Oncologist _____

Protocol Specifications:

Planning:

The CTV is determined from pre ☐ or post ☐ implant _____ images and defined to be

_____.

The PTV is the CTV expanded by the following margins.

lateral _____
anterior _____
posterior _____
cephalad _____
caudad _____

The monotherapy dose prescription is _____ Gy for ^{125}I and _____ Gy for ^{103}Pd.

The boost dose prescription is _____ Gy for ^{125}I and _____ Gy for ^{103}Pd.

Evaluation:

The ETV is determined from pre ☐ or post ☐ implant _____ images and defined to be:

_____.

The urethra will be drawn as:

Facility Questionnaire

II. **Experience of personnel:**

A. For the Radiation Oncologist named above

How many ultrasound guided prostate implants have been performed? _____

Has this person been credentialed previously? by RTOG? ☐ by ACOSOG? ☐ date: _____

B. For the Physicist named above

How many ultrasound guided prostate implants have been planned using ultrasound? ___

How many ultrasound guided prostate implants have been evaluated with post implant CT?

Has this person been credentialed previously? by RTOG? ☐ by ACOSOG? ☐ date: _____

III. **Equipment:**

A. Ultrasound unit (vendor and model): _____

B. CT scanner (vendor and model):_____

C. Treatment planning system

Preplan or Realtime plan:

Vendor and version: _____

How are ultrasound images entered for planning? videotape ☐ digitized ☐

Other (explain): _____

_____

How are prostate and normal tissue contours entered?

Defined on planning system ☐ defined on ultrasound unit and input as above ☐

Other (explain): _____

_____

Is a point source approximation used? Yes ☐ No ☐

If yes, do you use an: anisotropy constant ☐ anisotropy factors ☐

If not, explain your procedures for determining and accounting for seed orientation.

Facility Questionnaire (cont'd.)

IV. **Quality Assurance Procedures: (attach additional sheets if necessary)**

A. Source strength verification:

1. Dosimetry system used for in-house verification of seed activity:

   Vendor: _____ Model: _____

2. How is the calibration of this system directly traceable to NIST? (Attach copies of ADCL certificates)

3. What are the QA procedures to verify that the calibration of this system has not changed?

4. For each seed model, what is the NIST calibration date to which your chamber calibration is traceable?

7. Number of seeds assayed per patient: _____% or _____seeds

8. What is your criterion for agreement with the vendor? +/-5% ☐, +/-7% ☐, +/-10% ☐,

   Other (explain) _____

   _____

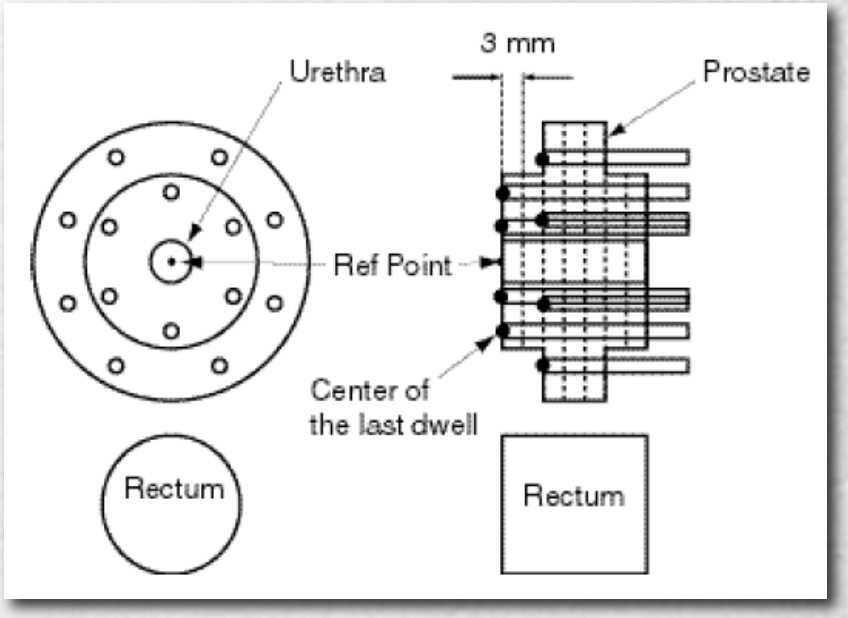
9. What seed strength is used for treatment planning? your own measurements ☐ vendor ☐

QA Requirements

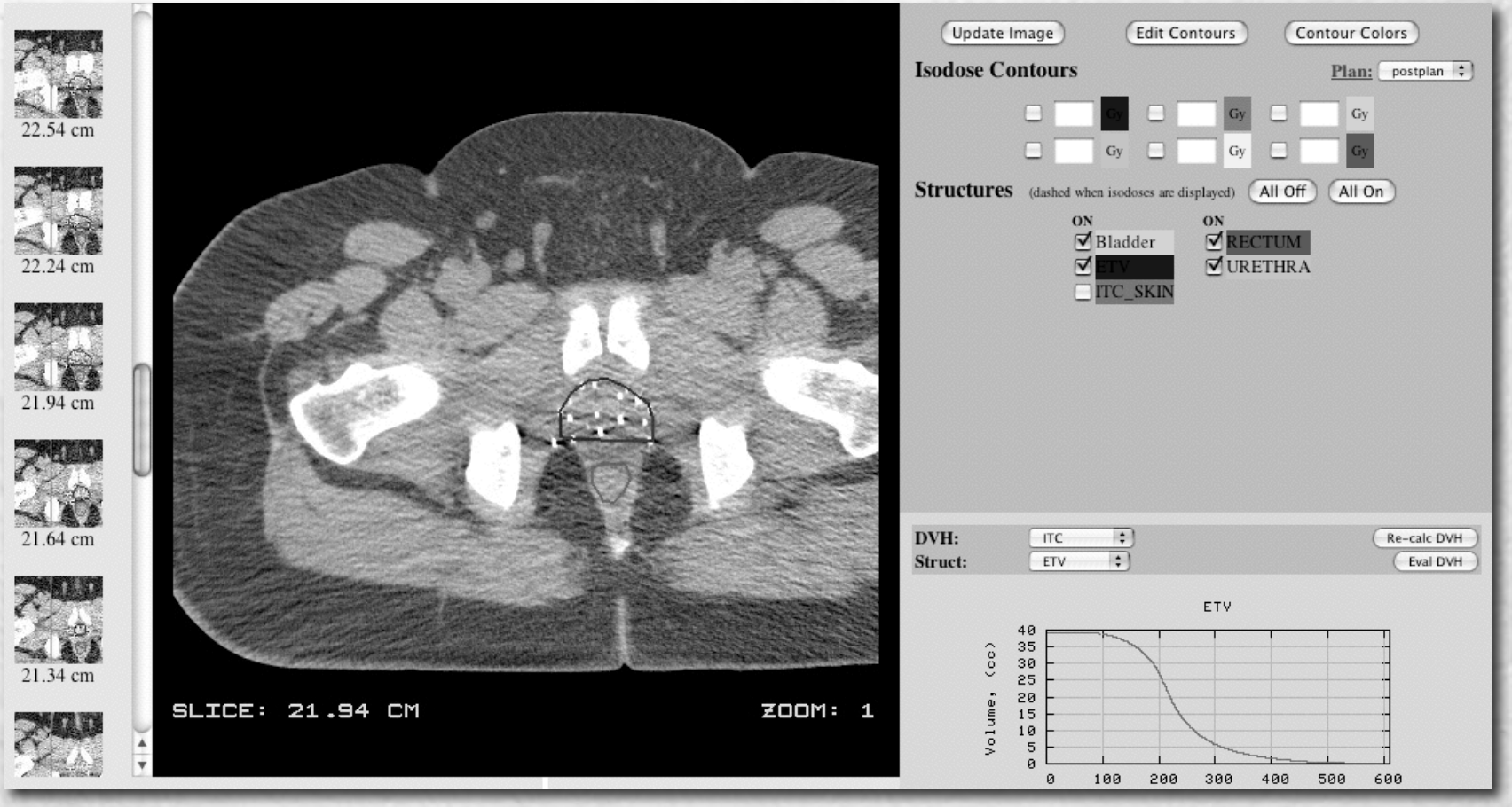
- For prostate brachy, include verification of source strength
- Requires ADCL-calibrated well chamber
- 3rd party radiopharmacy may be used, but must meet same requirements (only 2 have been approved)
- AAPM guidance recommends the physicist perform the verification

Benchmark Plan (Geometric Case)

- Institution submits calculations for single source, and geometric arrangement
- RPC recalculates doses and DVHs
- Agreement within 5% or 0.5 mm



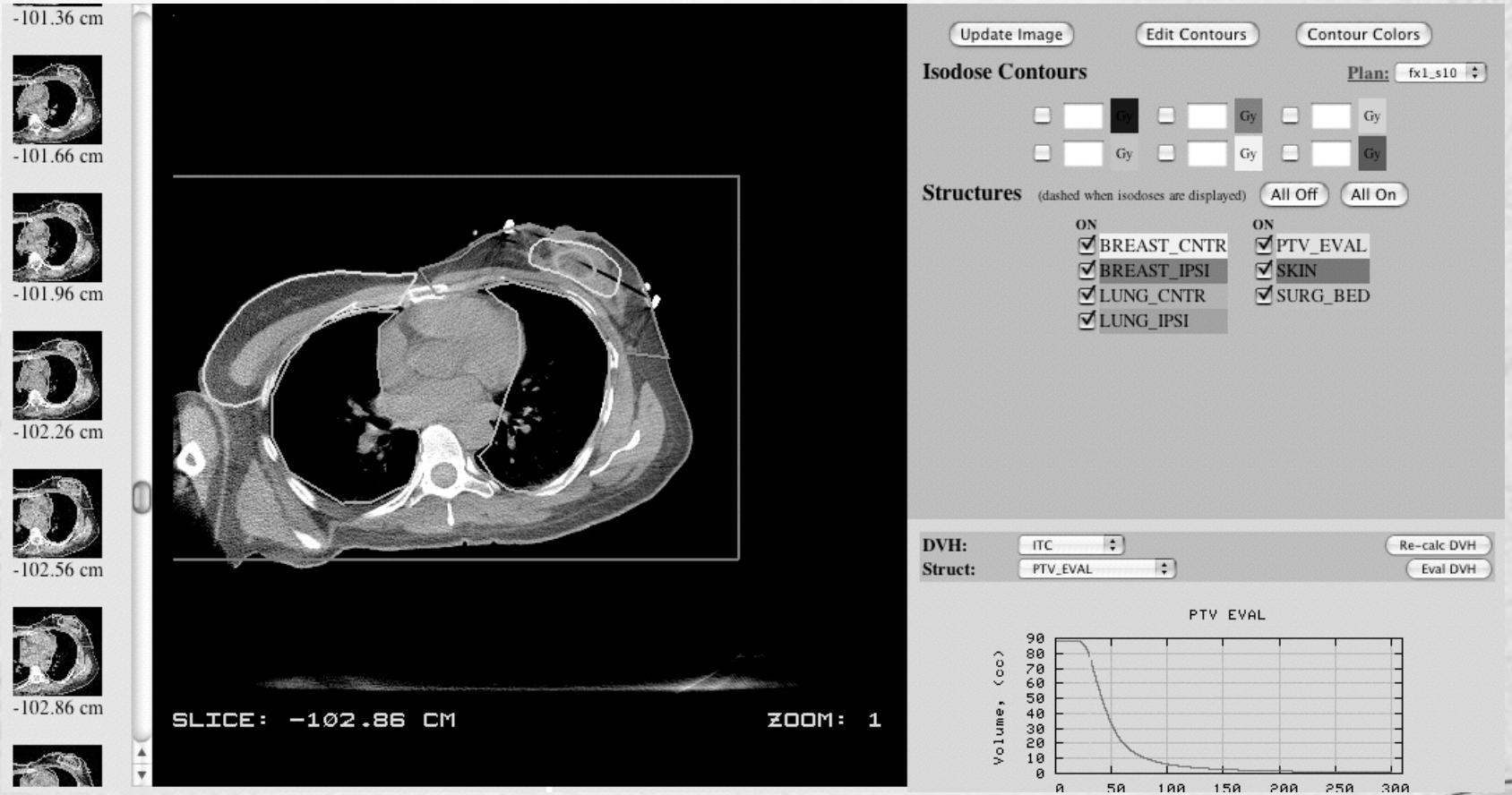
Benchmark Treatment Plan



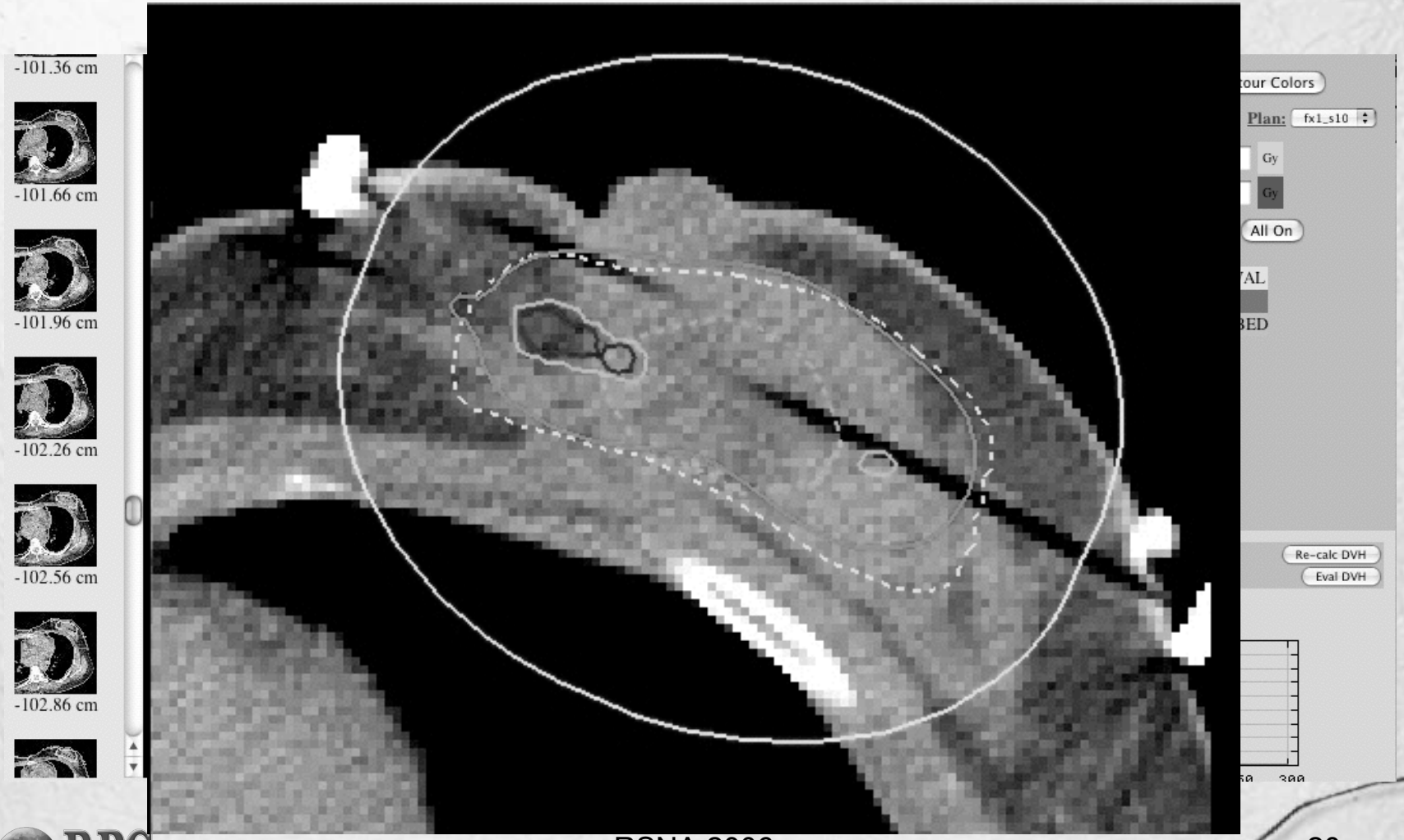
Errors, Inconsistencies, and Misunderstandings Discovered Through Credentialing

- TPS used incorrect grid size, displayed isodoses in error
- TPS truncated dose value; isodose incorrect
- Errors applying NIST 1999 correction
- Misunderstandings about TG-43
- Misunderstanding of protocol, volumes
- Poor brachytherapy technique

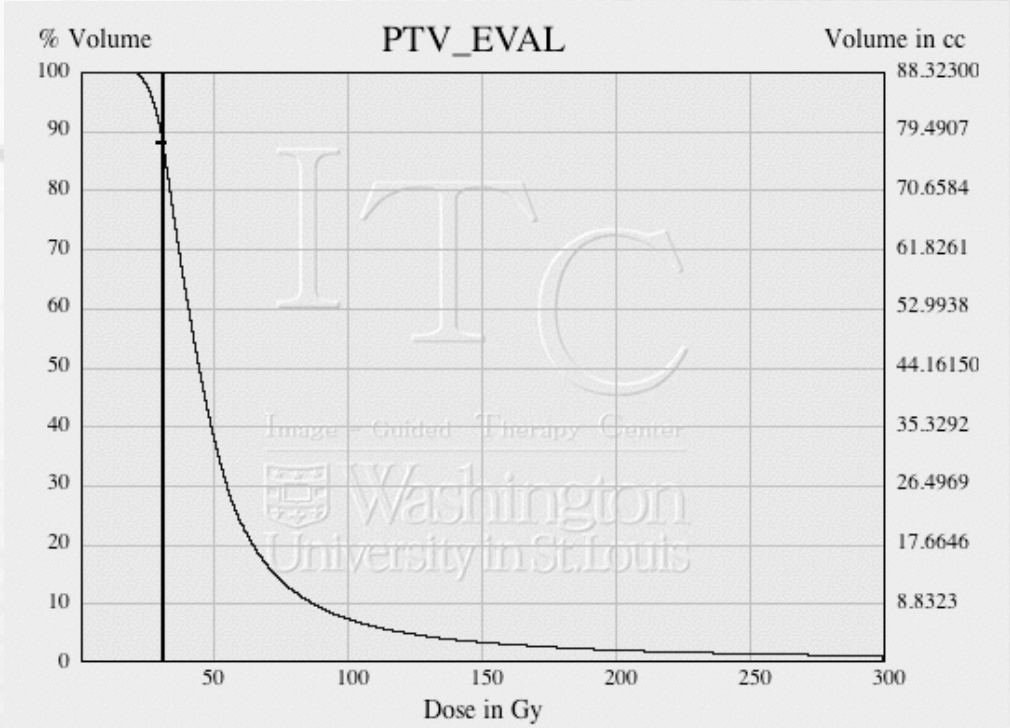
Evaluation of Submitted Plans



Evaluation of Submitted Plans



- Evaluation of Submitted Plans (DVH)



Plan ID	Volume >= D1 %	Volume >= D1 cc	% Vol >= 30.6 Gy	Max Dose	Min Dose	Mean Dose
	88.1	77.84	87.9	300.1	18.1	56.3

V_{90} = 88%

Dose (D1) = 30.6 Gy

30.6 Gy (90%)

Printable Version

Poor Brachytherapy Technique

- Seeds implanted in base of penis
- Rad. Onc. advised to seek training

Credentials Awarded (based on benchmarks)

	Credentials	Institutions
Prostate LDR (0232)	70	63
Prostate HDR (0321)	11	7
Breast 3D CRT (0413)	792	364
Breast Mammosite®	497	245
Breast Multicatheter	115	41
Other 3D CRT (NCCTG)	52	52
Cervix (GOG)	55	46
TOTAL	**1,592**	**611**

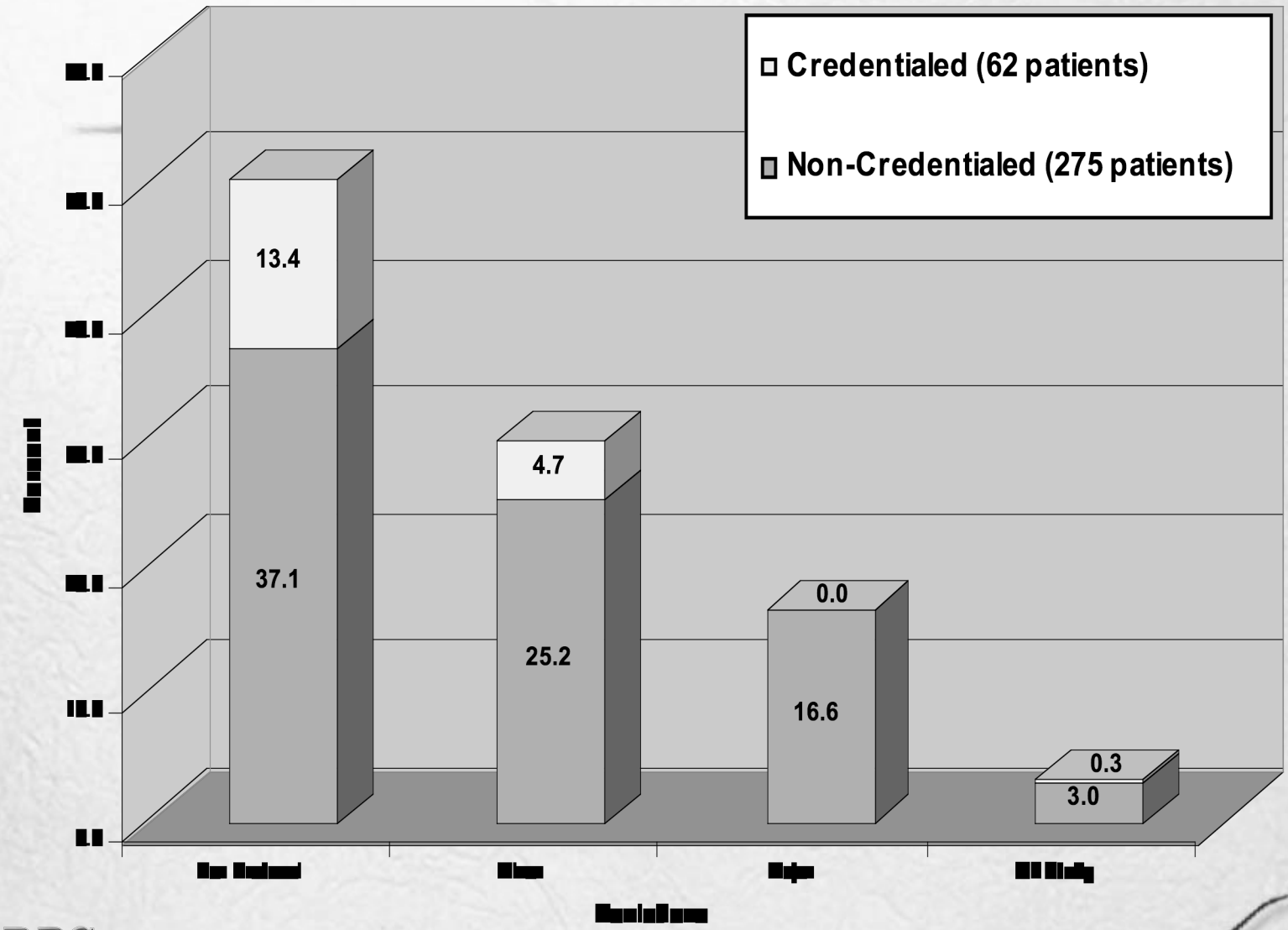
Results of Credentialing
(closed studies)

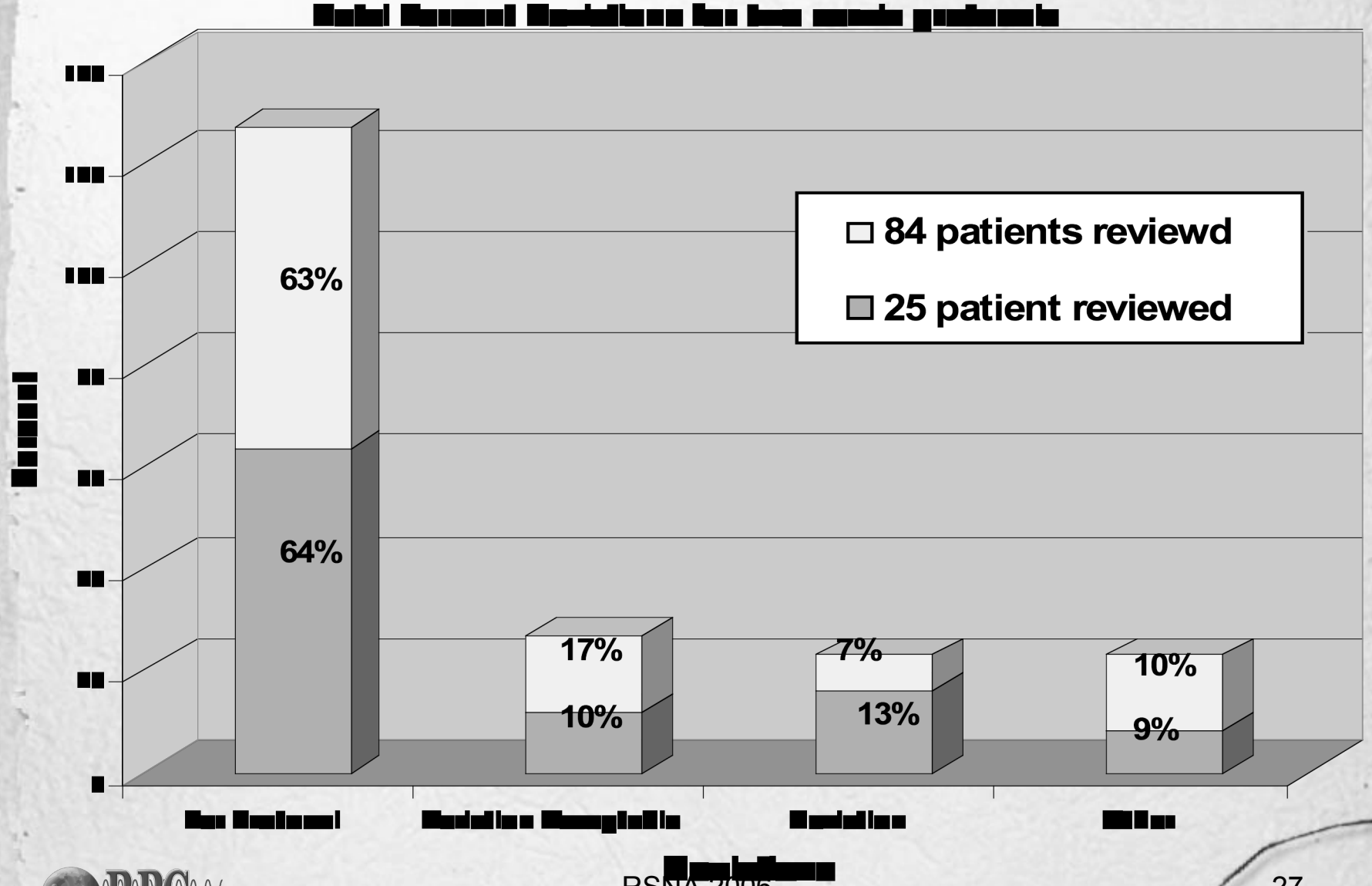
Study	Major Deviations	Minor Deviations	Number of Patients
GOG 165 HDR Cervix Credentialed inst	0	15	70
RTOG 95-17 HDR & LDR Breast (all)	0	4	100
RTOG 0019 LDR Prostate (values for dose only)	0	6	117 reviewed (total 129 eligible)

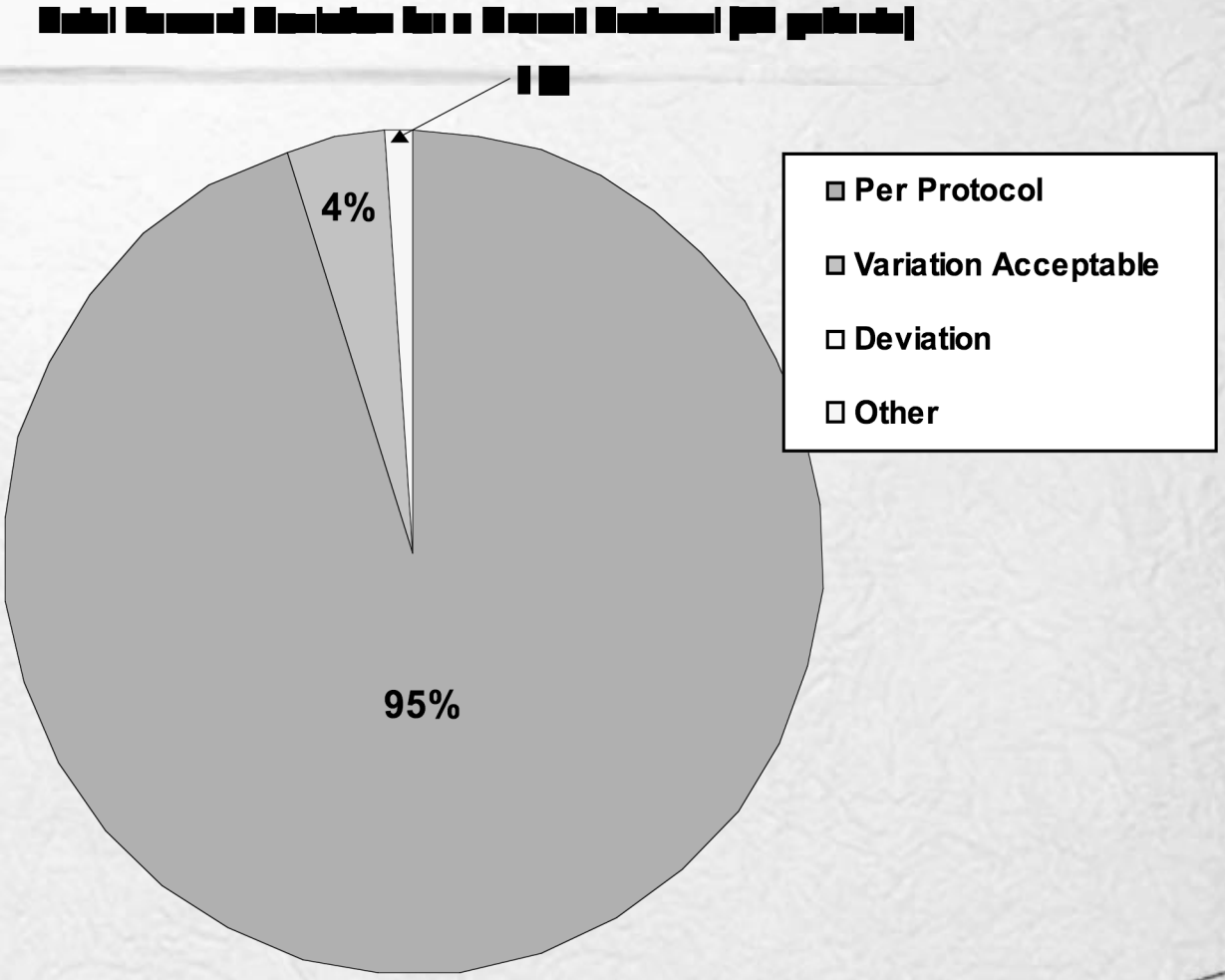
Results of Credentialing

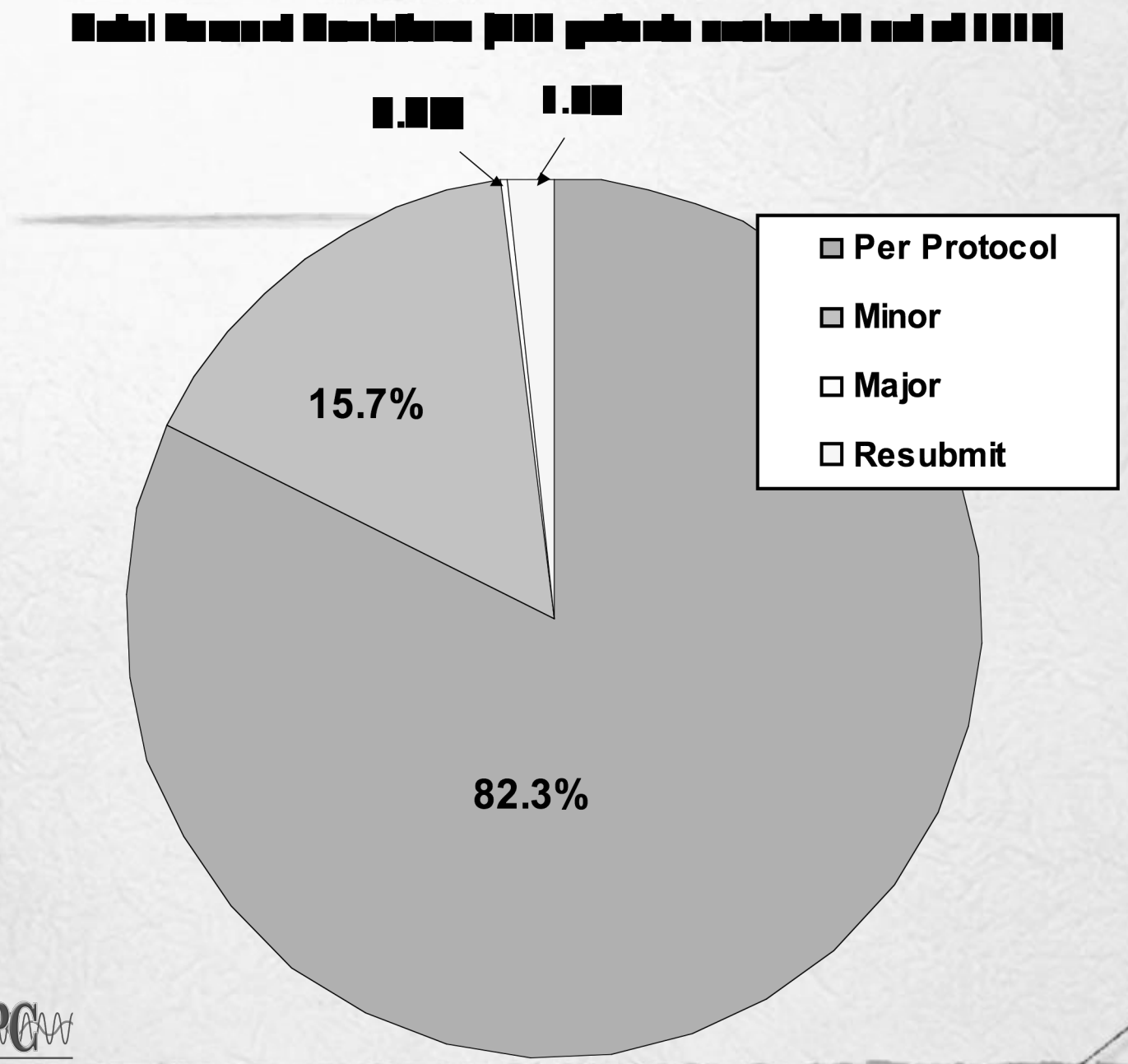
(closed studies)

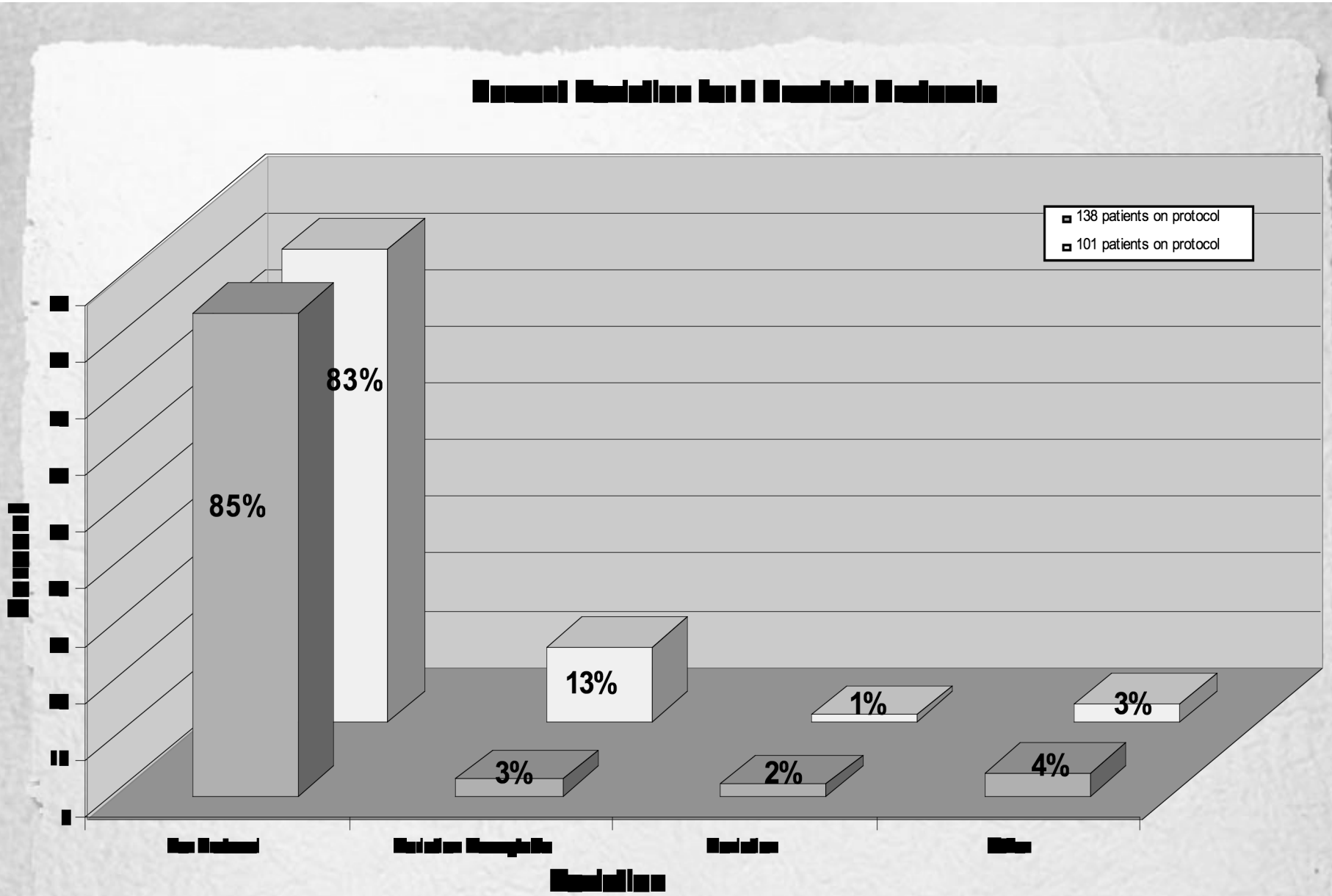
Study	Major Deviations	Minor Deviations	Number of Patients
GOG 165 HDR Cervix Credentialed inst	0	15	70
Non-credentialed	57	87	275
RTOG 95-17 HDR & LDR Breast (all)	0	4	100
RTOG 0019 LDR Prostate (values for dose only)	0	6	117 reviewed (total 129 eligible)


Credentialed (62 patients)
Non-Credentialed (275 patients)
13.4
37.1
4.7
25.2
0.0
16.6
0.3
3.0


84 patients reviewd
25 patient reviewed
63%
64%
17%
10%
7%
13%
10%
9%


4%
95%
Per Protocol
Variation Acceptable
Deviation
Other


1.4%
1.4%
15.7%
82.3%
Per Protocol
Minor
Major
Resubmit


138 patients on protocol
101 patients on protocol
85%
83%
13%
3%
2%
1%
4%
3%

Summary

- Many brachytherapy patients treated on trials
- Physicists need to be familiar with trials
- Credentialing improves quality of trials
- Credentialing does not limit participation but delays while institution corrects problems
- Feedback even when institutions pass
- Clinical trials contribute to improved radiation therapy