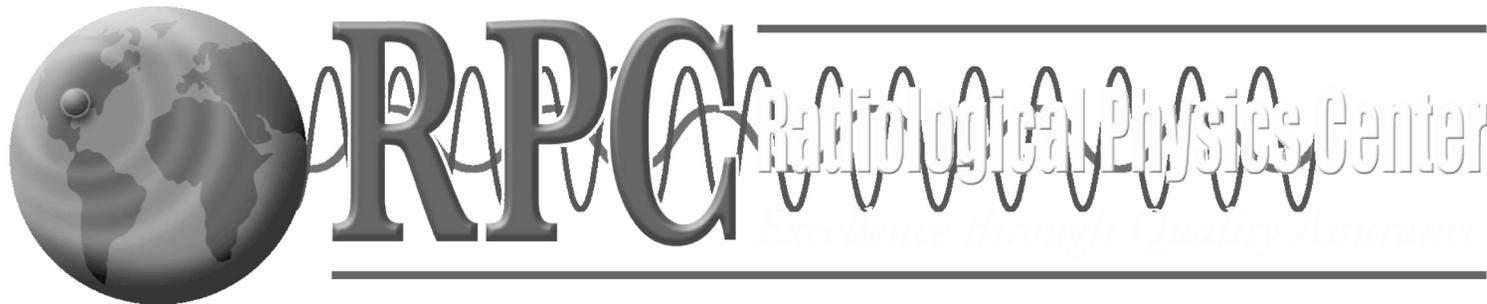


Brachytherapy in Cooperative Group Clinical Trials

Geoffrey S. Ibbott, Ph.D.
and staff of the
Radiological Physics Center



Acknowledgements

- RPC Staff, especially Irene Harris, Franklin Hall, Jessica Lowenstein, Joye Roll and David Followill



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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

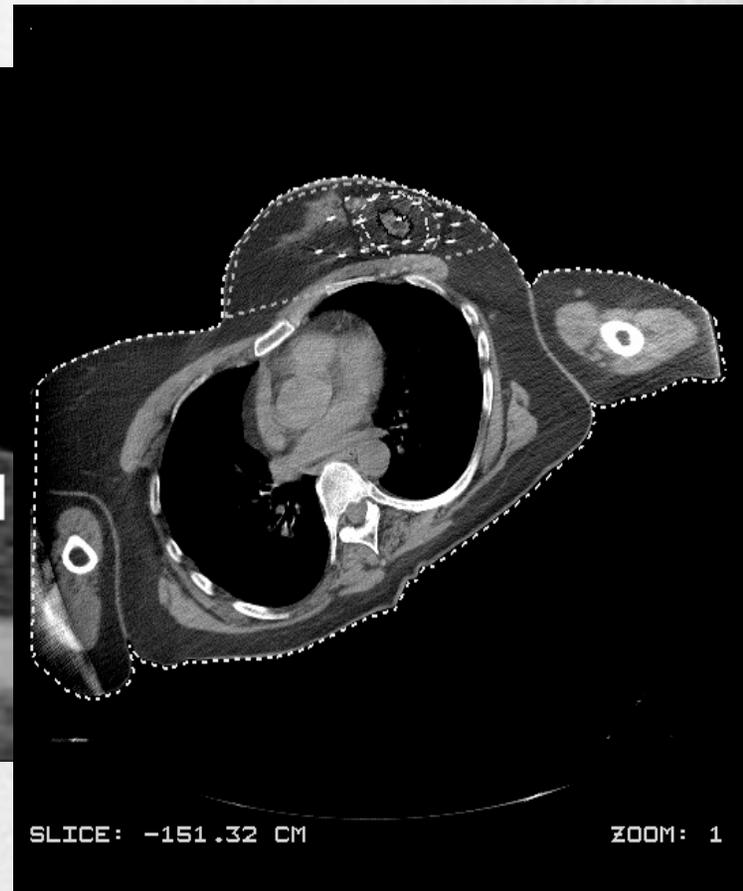
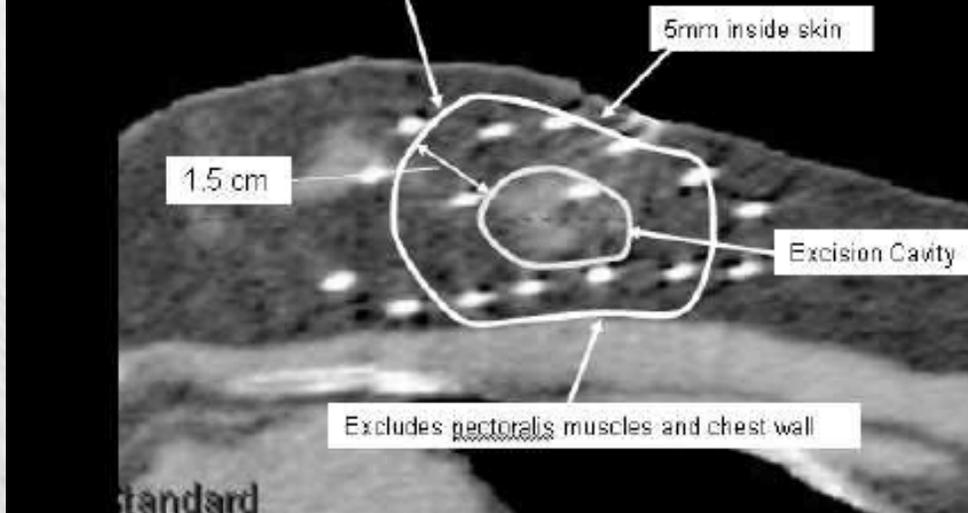
Protocol Requirements

- 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

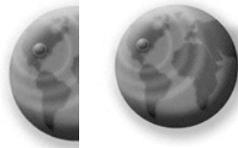
Definition of Volumes

Planning target volume for evaluation (PTV_EVAL)

- equals - planning target volume (PTV)
- equals - clinical target volume (CTV)



Brachy Seed Registry



RPC Radiological Physics Center
Excellence through Quality Assurance

Search RPC by Google

Tel: 713-745-8989

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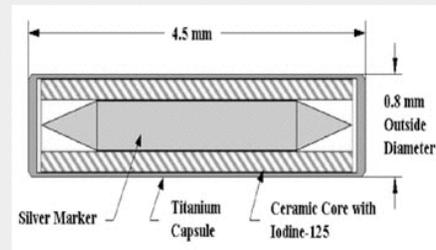
Office Hours: 8 A.M. to 5 P.M. M-F
Central time.

Services	Services
Forms	Forms
Publications	Publications
Brachy Sources	Brachy Sources
Research/TG-51	Research/TG-51
Upcoming Meetings	Upcoming Meetings

[Back to Pre Page](#)

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 ¹²⁵I 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 ¹²⁵I brachytherapy source. **Applied Radiation and Isotopes**, **57 (2002)** 381-389

added to Registry, February 7, 2002



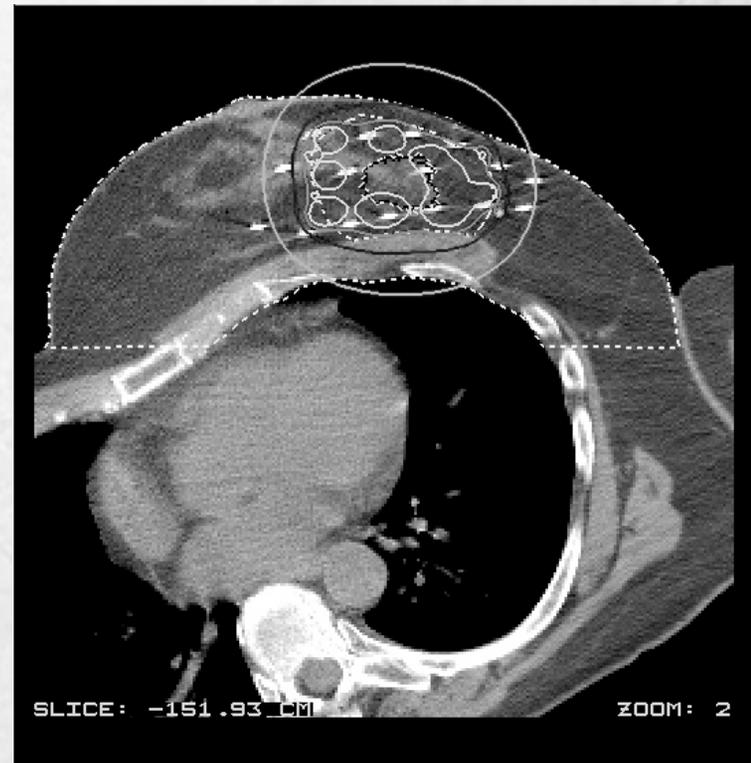
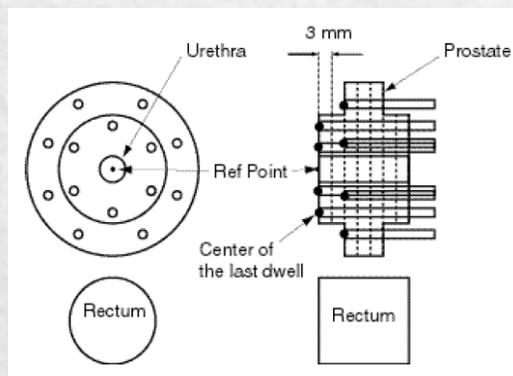
Protocol Requirements (cont'd.)

- 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

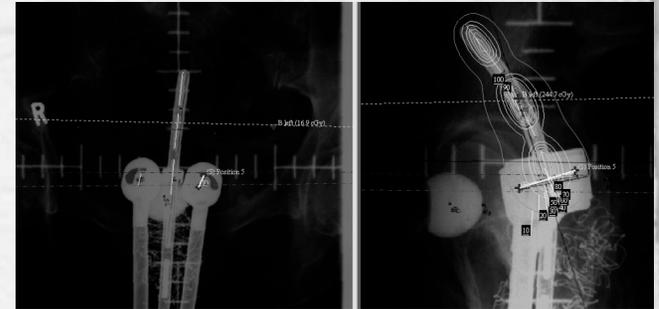
LDR and HDR Brachytherapy

- 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

Prostate Brachytherapy QA

Page 1 of 2

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) _____

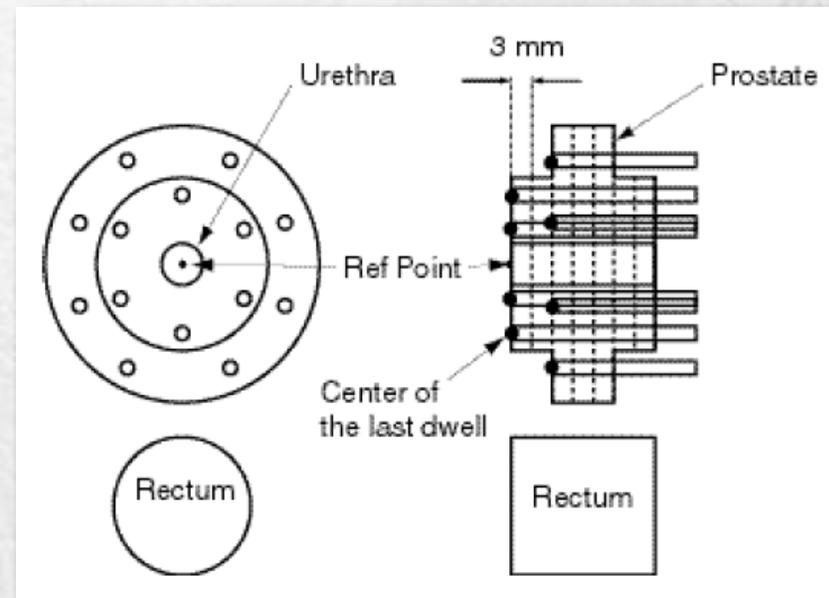
9. What seed strength is used for treatment planning? your own measurements vendor

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

The screenshot displays a radiotherapy planning software interface. On the left, a vertical scroll bar shows a series of CT scan slices with their corresponding vertical positions: 22.54 cm, 22.24 cm, 21.94 cm, 21.64 cm, 21.34 cm, and 21.34 cm. The main window shows a CT scan slice at 21.94 cm, with a zoom level of 1. The slice shows a cross-section of the pelvic region with isodose contours overlaid. The contours are labeled with dose values: 6 Gy, 12 Gy, 18 Gy, 24 Gy, 30 Gy, 36 Gy, and 42 Gy. The 18 Gy contour is highlighted in black. The 24 Gy contour is also highlighted in black. The 30 Gy contour is highlighted in black. The 36 Gy contour is highlighted in black. The 42 Gy contour is highlighted in black. The 6 Gy contour is highlighted in black. The 12 Gy contour is highlighted in black. The 18 Gy contour is highlighted in black. The 24 Gy contour is highlighted in black. The 30 Gy contour is highlighted in black. The 36 Gy contour is highlighted in black. The 42 Gy contour is highlighted in black.

On the right side, there are control panels for 'Isodose Contours' and 'Structures'. The 'Isodose Contours' panel includes buttons for 'Update Image', 'Edit Contours', and 'Contour Colors'. Below these are checkboxes for 'Gy' values: 6 Gy, 12 Gy, 18 Gy, 24 Gy, 30 Gy, 36 Gy, and 42 Gy. The 'Structures' panel includes buttons for 'All Off' and 'All On', and checkboxes for 'Bladder', 'ETV', 'ITC_SKIN', 'RECTUM', and 'URETHRA'. The 'DVH' panel includes dropdown menus for 'ITC' and 'ETV', and buttons for 'Re-calc DVH' and 'Eval DVH'. Below the DVH panel is a graph showing the DVH for ETV. The y-axis is labeled 'Volume, (cc)' and ranges from 0 to 40. The x-axis is labeled 'ETV' and ranges from 0 to 600. The graph shows a curve that starts at 40 cc for 0 ETV and decreases to 0 cc for 600 ETV.

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

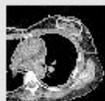
Evaluation of Submitted Plans

The screenshot displays a radiotherapy planning software interface. On the left, a vertical stack of six small CT scan slices is shown, with the current slice highlighted at -102.86 cm. The main window shows a large CT scan of a chest with various anatomical structures outlined in white. Below the scan, the text "SLICE: -102.86 CM" and "ZOOM: 1" is visible. On the right side, there are several control panels:

- Update Image**, **Edit Contours**, and **Contour Colors** buttons.
- Isodose Contours** section with a "Plan:" dropdown set to "fx1_s10" and six checkboxes for isodose levels, each with a "Gy" label.
- Structures** section with a "(dashed when isodoses are displayed)" note and "All Off" and "All On" buttons. It contains two columns of checkboxes:
 - Column 1 (ON): BREAST_CNTR, BREAST_IPSI, LUNG_CNTR, LUNG_IPSI
 - Column 2 (ON): PTV_EVAL, SKIN, SURG_BED
- DVH:** section with a dropdown set to "ITC", a "Re-calc DVH" button, and a "Struct:" dropdown set to "PTV_EVAL".
- PTV EVAL** graph showing "Volume, (cc)" on the y-axis (0 to 90) and dose on the x-axis (0 to 300). The curve shows a sharp drop from 90 cc at 0 Gy to near 0 cc by 100 Gy.

Evaluation of Submitted Plans

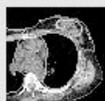
-101.36 cm



-101.66 cm



-101.96 cm



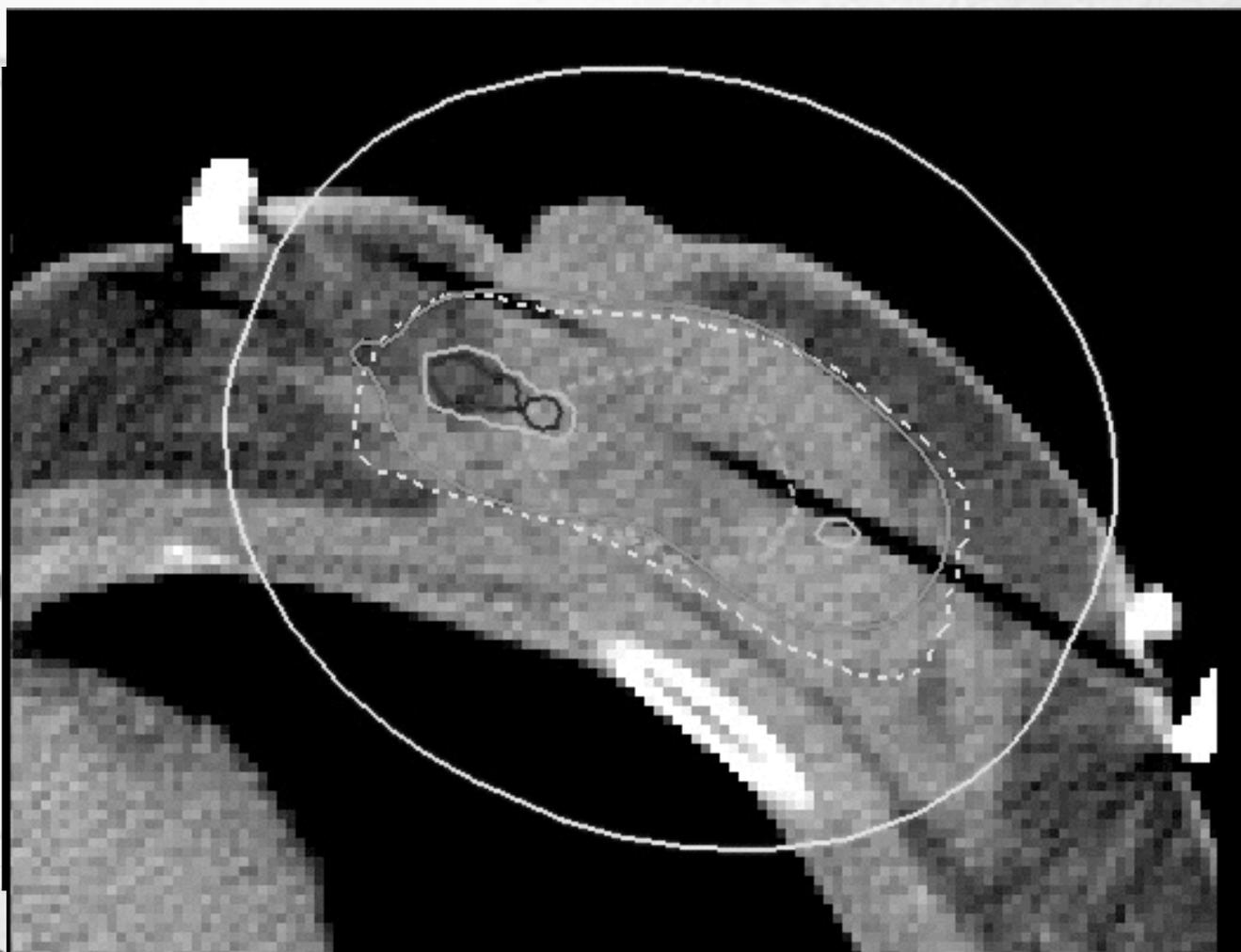
-102.26 cm



-102.56 cm



-102.86 cm



Four Colors

Plan: fx1_s10

Gy

Gy

All On

AL

BED

Re-calc DVH

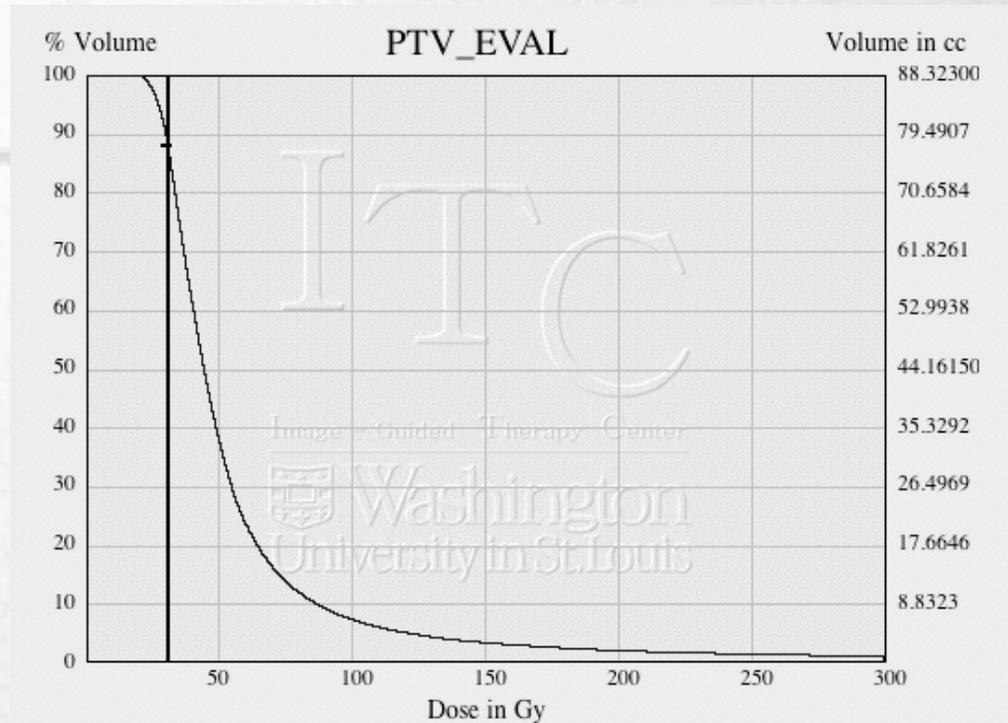
Eval DVH



50 200



- Evaluation of Submitted Plans (DVH)



Plan ID	Volume >= D1 %	Volume >= D1 cc	% Vol >= 30.6 Gy	Max Dose	Min Dose	Mean Dose
16	88.1	77.84	87.9	300.1	18.1	56.3

Dose (D1) = 30.6 Gy

Printable Version

$V_{90} = 88\%$

30.6 Gy (90%)

Poor Brachytherapy Technique



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

Credentials Awarded (based on benchmarks)

	<u>Credentials</u>	<u>Institutions</u>
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)

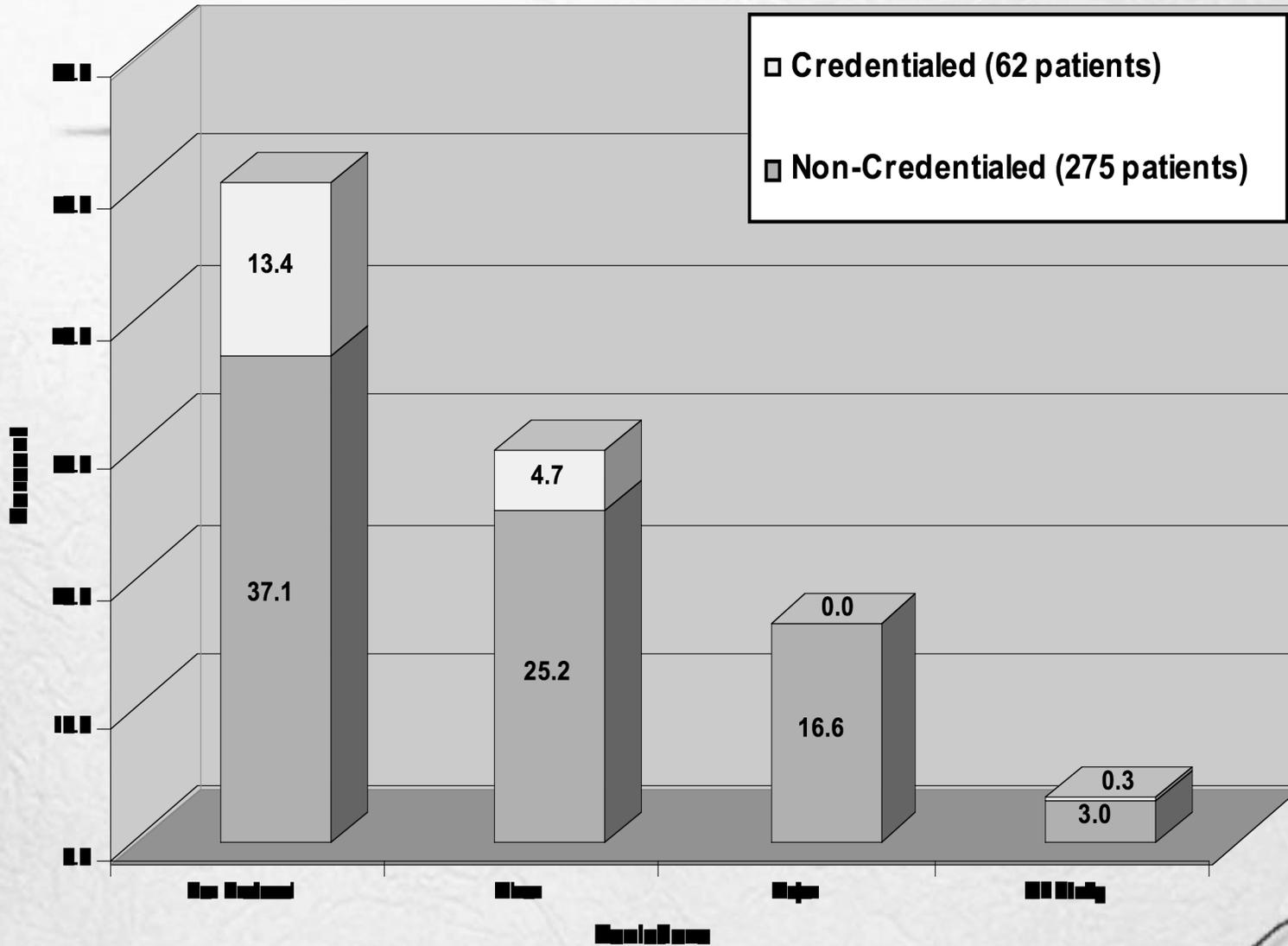
Study	Major Deviations	Minor Deviations	Number of Patients
GOG 165 HDR Cervix Credentialed inst	0	15	70
RTOG 95-17 HDR & LDR Breast (all)	0	4	100
RTOG 0019 LDR Prostate (values for dose only)	0	6	117 reviewed (total 129 eligible)

Results of Credentialing

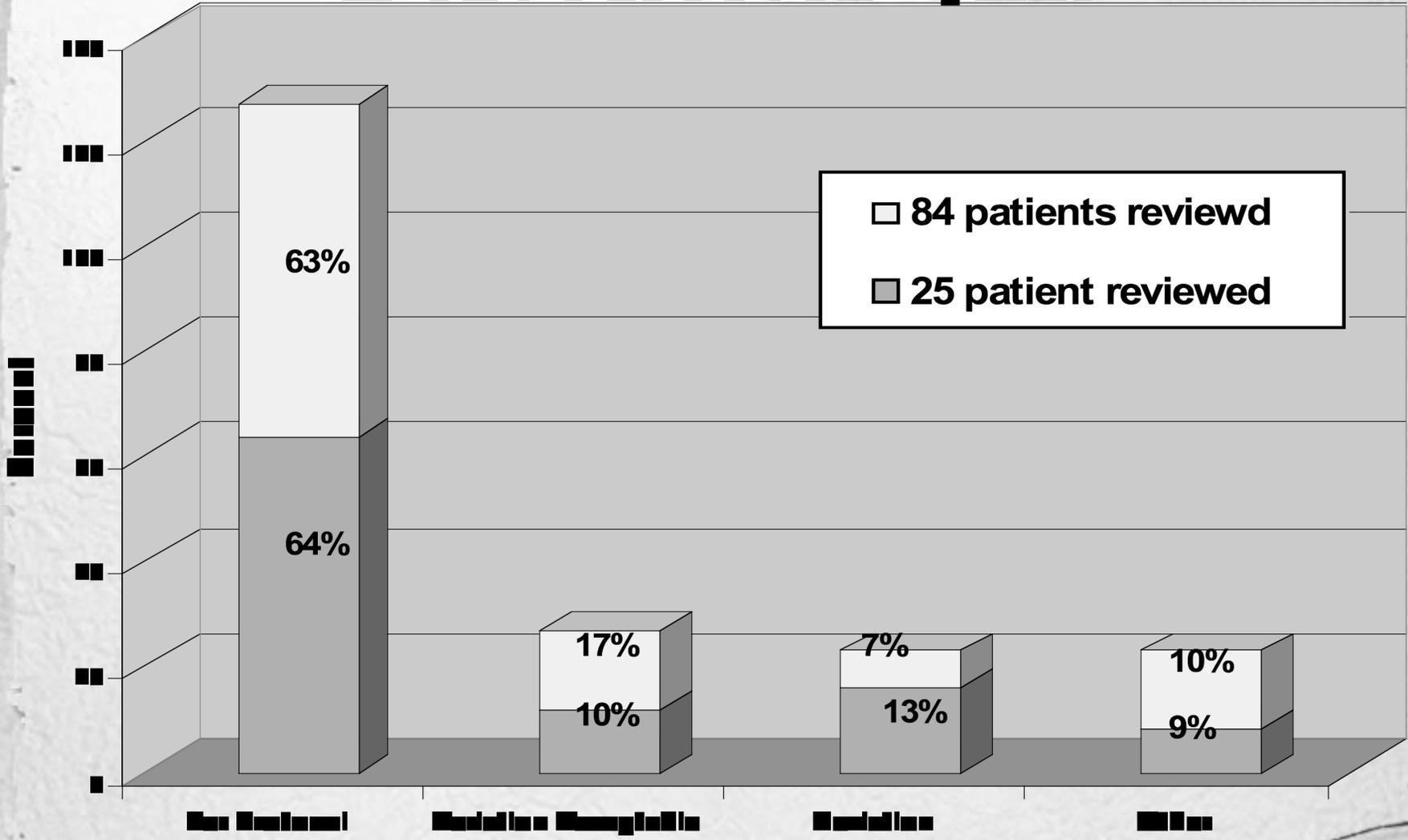
(closed studies)

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)

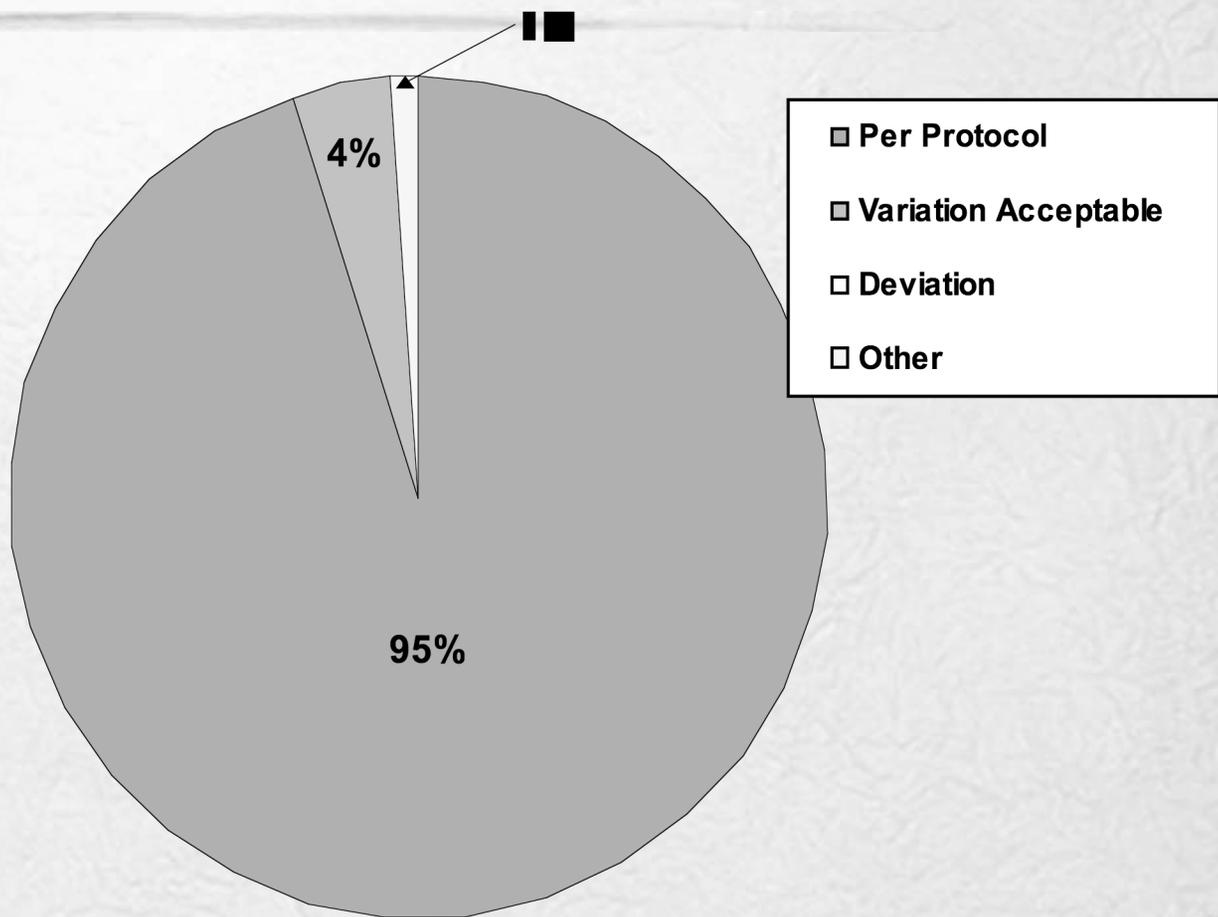
**Total Annual Revenues for Accredited and Non-Accredited Institutions
(000 dollars)**



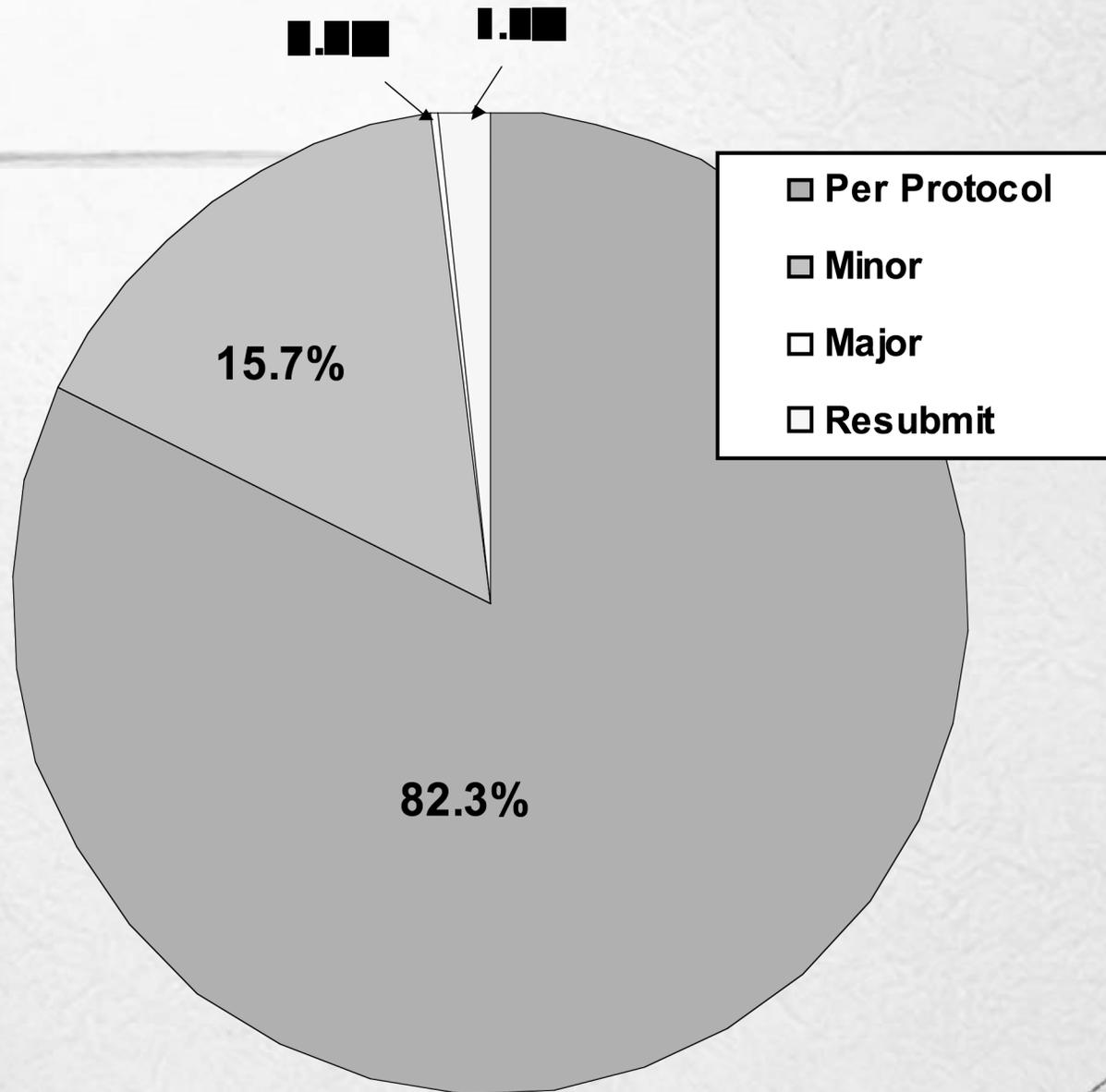
Total Annual Submissions for Low grade gliomas



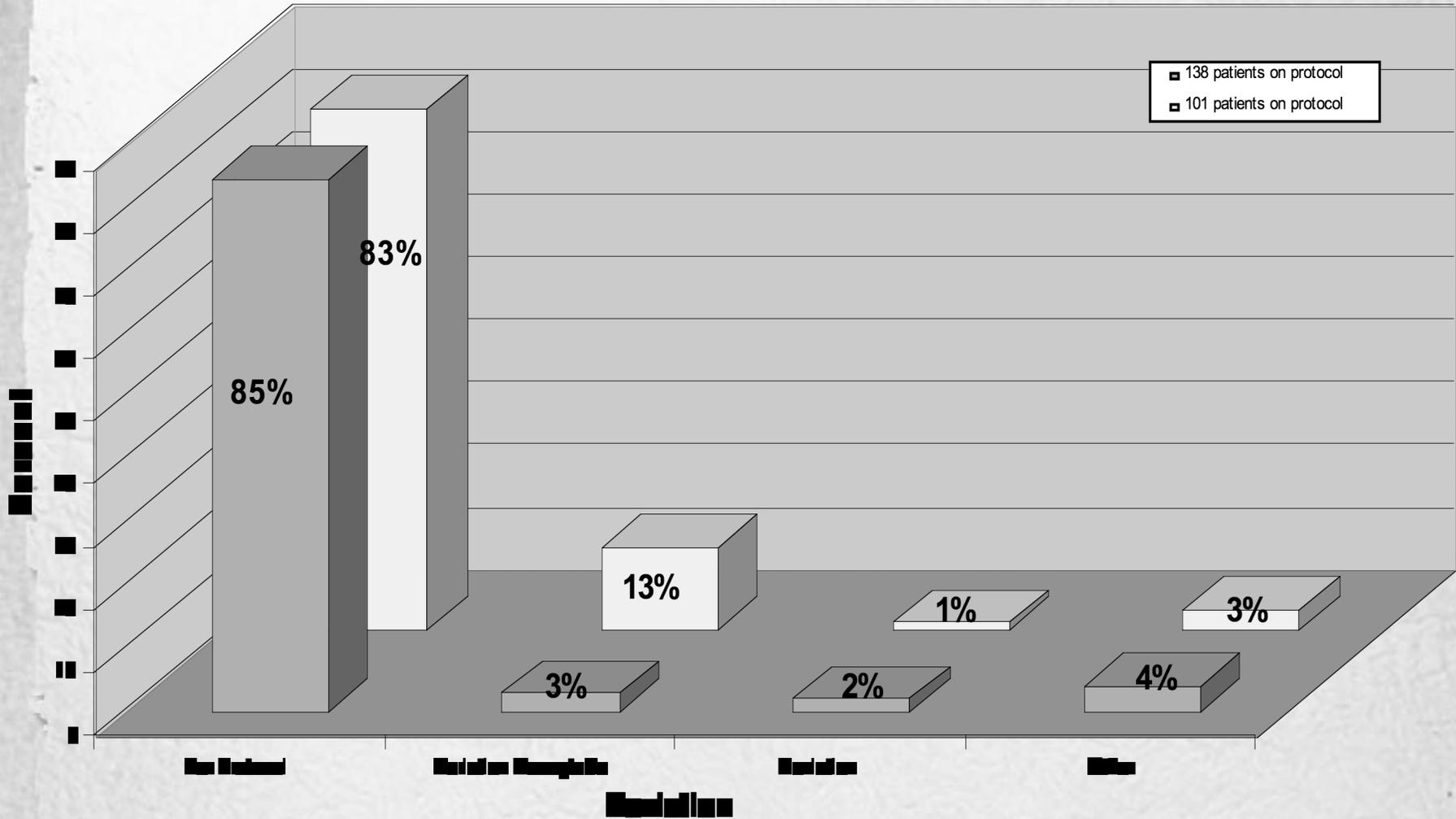
Total Research Deviations for a Clinical Protocol (2004-2006)



Total Revised Resolutions (All journals combined) out of 1000



General Statistics for 2 Studies



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