NSABP PROTOCOL B-39
RTOG PROTOCOL 0413

(A RANDOMIZED PHASE III STUDY OF CONVENTIONAL WHOLE BREAST IRRADIATION WBI) VERSUS PARTIAL BREAST IRRADIATION (PBI) FOR WOMEN WITH STAGE 0, I, OR II BREAST CANCER

Quality Assurance Program

QA Program Goals

- Clear and Comprehensive
- Set standards from which to build

- Parameters set to equate PBI techniques
  - As much as possible

Facility Credentialing

- Radiotherapy approval process to assure availability of technical and clinical components needed to comply with protocol
- **Two questionnaires**, facility and knowledge assessment
- Digital submission of CT-based '**Dry Run case**' for each PBI technique
- The Radiologic Physics Center (RPC) will oversee the credentialing process in coordination with the Image-guided Therapy Center (ITC).

Quality Assurance

- Close monitoring and institutional feedback
- Submitted digitally to the ITC, processed and reviewed, second review by Investigators
  - Rapid review
    - First case for each PBI technique from each facility
    - Submitted-reviewed-feedback prior to treatment start
  - Timely review
    - Subsequent 4 cases of each PBI tech.
    - Patient may be treated prior to review.
  - Approval for accrual
    - Following completion of 5 cases for each PBI technique, all 5 will be reviewed together with feedback
    - Judgment on quality - approved for accrual or repeat QA
    - Facility can continue accruing during this period
  - Random case monitoring
    - Random additional case monitoring
    - Judgment on quality - approved for accrual or repeat QA

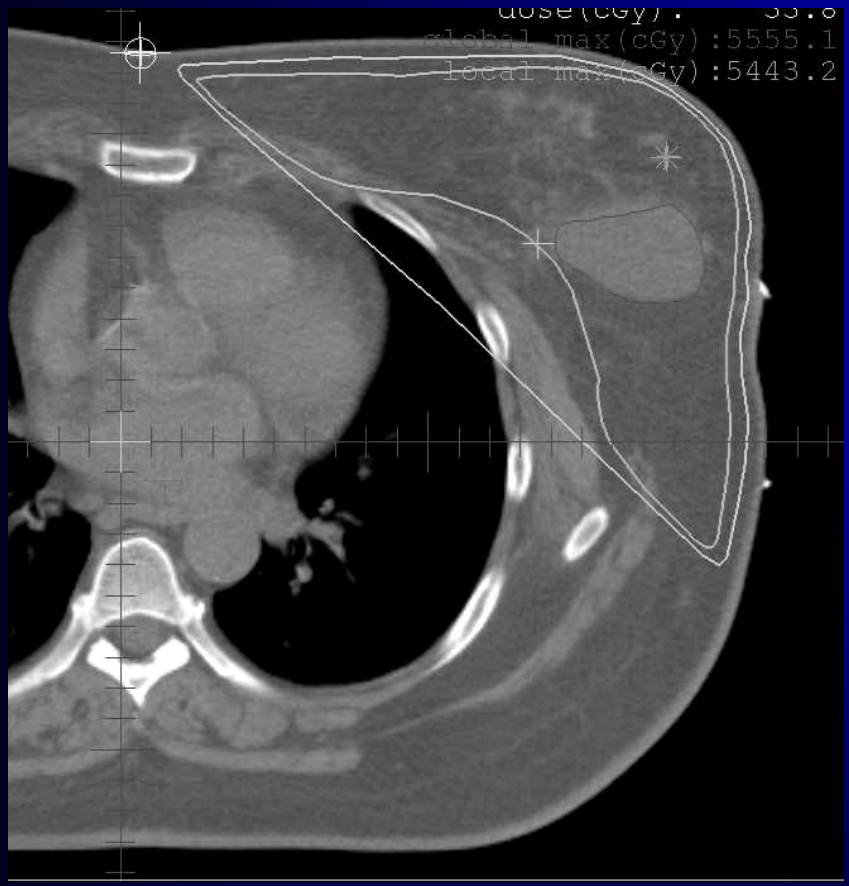
Treatment Delivery QA Guidelines

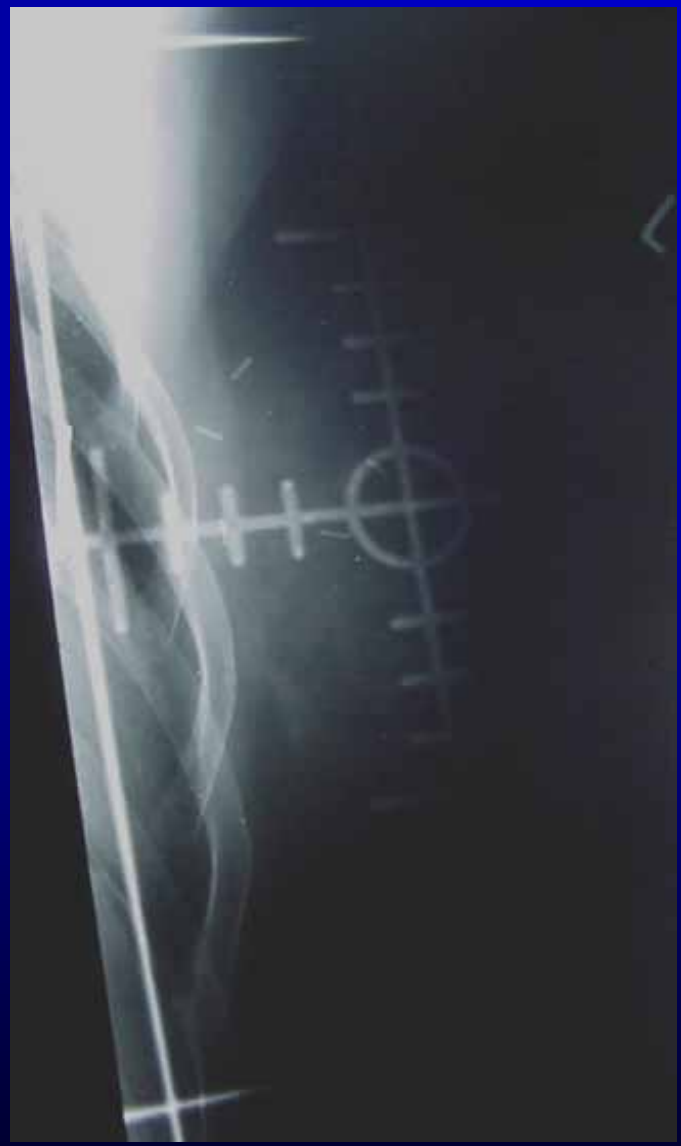
Whole Breast Irradiation (WBI)
vs
MammoSite Brachytherapy
Multi-catheter Brachytherapy
3D Conformal External Beam RT

Guidelines outline
where to end up / target coverage
– how to get there is up to the investigator

WBI

- As in previous studies - added QA to verify target coverage
- Breast only – no regional nodes
- 1.8x28 to 50.4Gy -or- 2x25 to 50Gy
- Boost optional up to 66.4 Gy – no brachytx
- Verification of the lumpectomy cavity coverage within the prescription isodose
  - CT-based
    - cavity is included in ≥ 90% isodose line - single axial CT slice submitted
    - If cavity not seen – submit both CT slice with isodose plan and single axial CT slice from post lumpectomy CT scan
  - Fluoro-based
    - Must have surgical clips placed
    - Fields covering clips with 2 cm margin
    - submit a scanned copy or digital picture of one of the tangent films

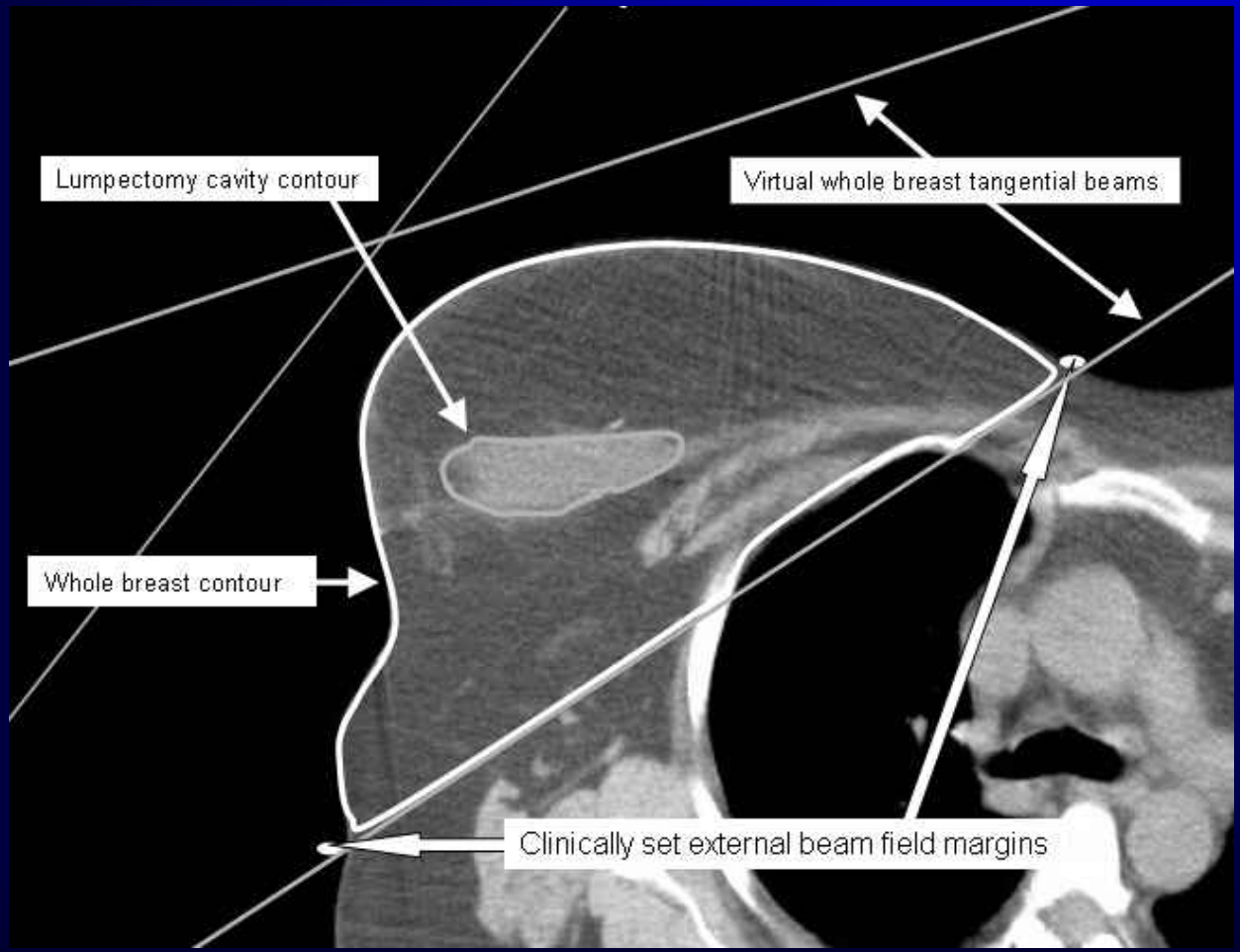

global max(cGy):5555.1
local max(cGy):5443.2



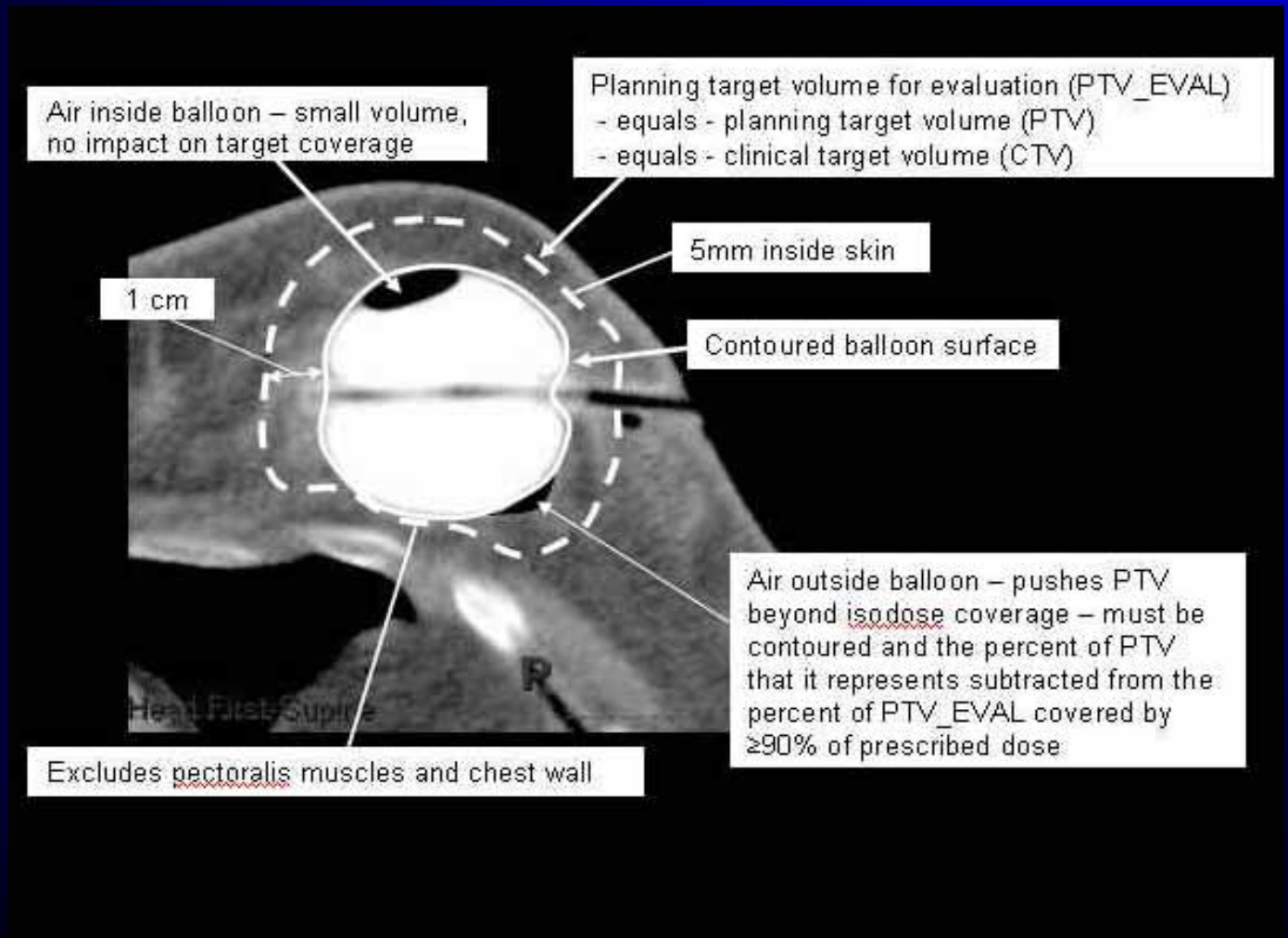
Whole Breast Reference Volume (WBRV)

- Accepted inability to contour breast tissue
- Attempt to standardize and automate process
- Needed for:
  - initial eligibility assessment
    - Cavity volume <35% of WBRV
  - QA/normal tissue dose limitations
    - <60% of WBRV to receive ≥50% of prescribed dose

Whole Breast Reference Volume (WBRV)



MammoSite Brachytherapy
Target Volume Definitions
CTV = PTV = PTV_EVAL = 1.0 cm expansion of cavity
(5mm within skin and bounded by posterior breast extent)



MammoSite Brachytherapy

Dose : 3.4 Gy bid x 5 days – 34 Gy

Normal tissue :

< 60% of the WBRV should receive ≥ 50% of the prescribed dose

Tissue-balloon conformance :

measure trapped air

Balloon symmetry:

physical geometry will not deviate > 2 mm

Minimal balloon surface-skin distance –

ideally ≥ 7 mm,
if 5-7 mm then confirm skin dose <145%.

Dose Homogeneity:

Volume of tissue receiving:

150% (V150) of the prescribed dose ≤ 50 cc
200% (V200) of the prescribed dose ≤ 10 cc

MammoSite Brachytherapy

Acceptable:

- All four parameters must be met
- Dose volume analysis of target will:
  - confirm that ≥ 90% of the prescribed dose is covering ≥ 90% of the PTV_EVAL.
  - The volume of trapped air/fluid will be accounted for :

%PTV_EVAL coverage – [(vol trapped air/vol PTV_EVAL) x 100] = ≥ 90%

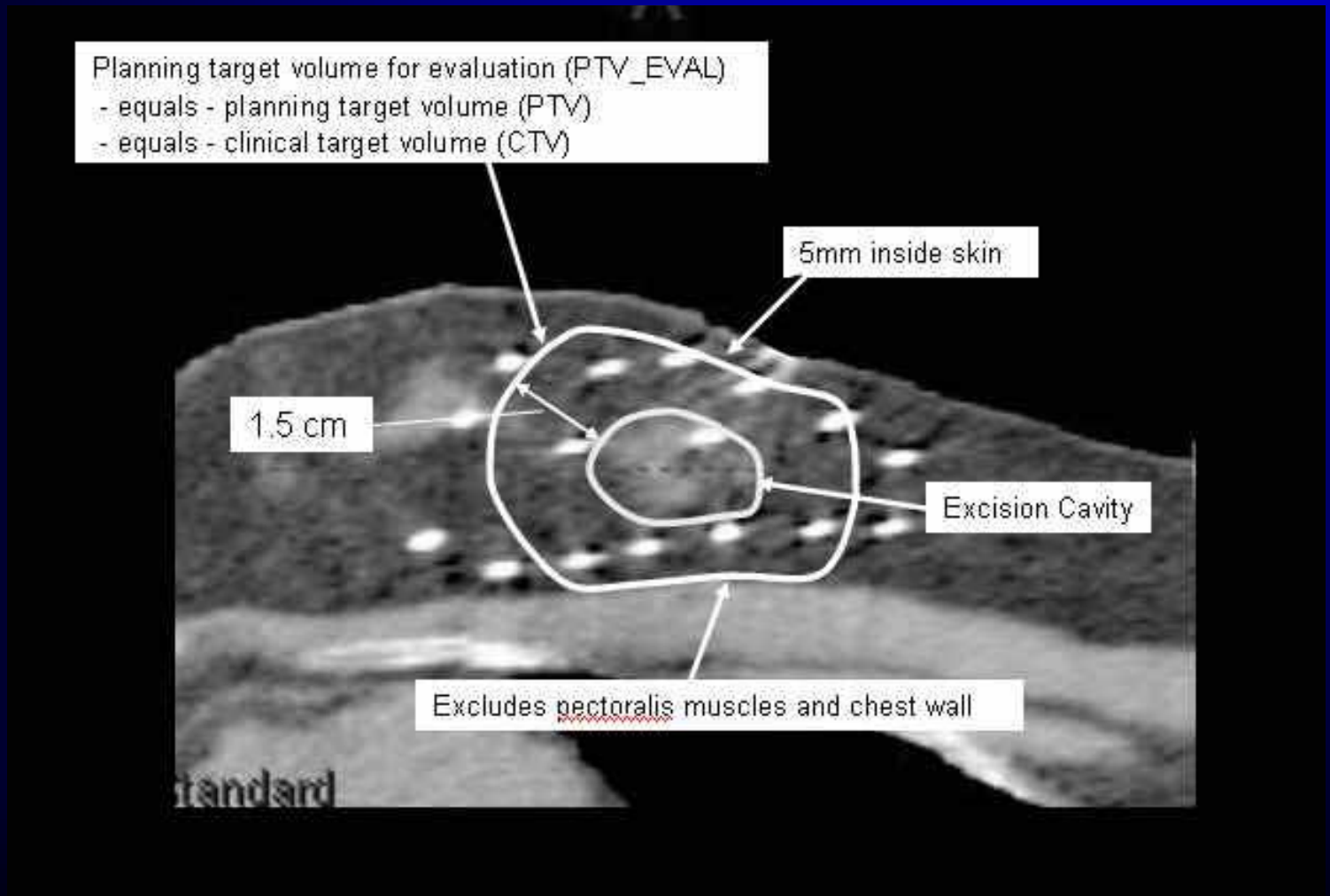
- Critical normal tissue DVHs within < 5%
- Dose delivered over 5-10 days.

MammoSite Brachytherapy

Unacceptable:

- Any of the parameters not met
- Dose volume analysis of the target volume
  - <90% of the prescribed dose and/or <90% coverage of the PTV_EVAL. The volume of tapped air/fluid will be accounted for as previous
- Critical normal structure DVH exceeds 5%
- If dose delivered over a period of time extending >10 days.

Multicatheter Brachytherapy
Target Volume Definitions
CTV = PTV = PTV_EVAL = 1.5 cm expansion of cavity
(5mm within skin and bounded by posterior breast extent)



Multicatheter Brachytherapy

Dose : 3.4 Gy bid x 5 days – 34 Gy

Normal tissue : $<$ 60% of the whole breast reference volume should receive $\geq$ 50% of the prescribed dose

Dose Homogeneity:

Volume of tissue receiving:

150% (V150) of the prescribed dose $\leq$ 70 cc

200% (V200) of the prescribed dose $\leq$ 20 cc

Dose Homogeneity Index will be $\geq$ .75.

DHI = the volume ratio (1 – V150/V100)

Multicatheter Brachytherapy

Acceptable:

- Dose volume analysis of target will:
  - confirm that $\geq$ 90% of the prescribed dose is covering $\geq$ 90% of the PTV_EVAL.
- Dose homogeneity criteria met.
- Critical normal tissue DVHs within 5%
- Dose delivered over 5-10 days.

Multicatheter Brachytherapy

Unacceptable:

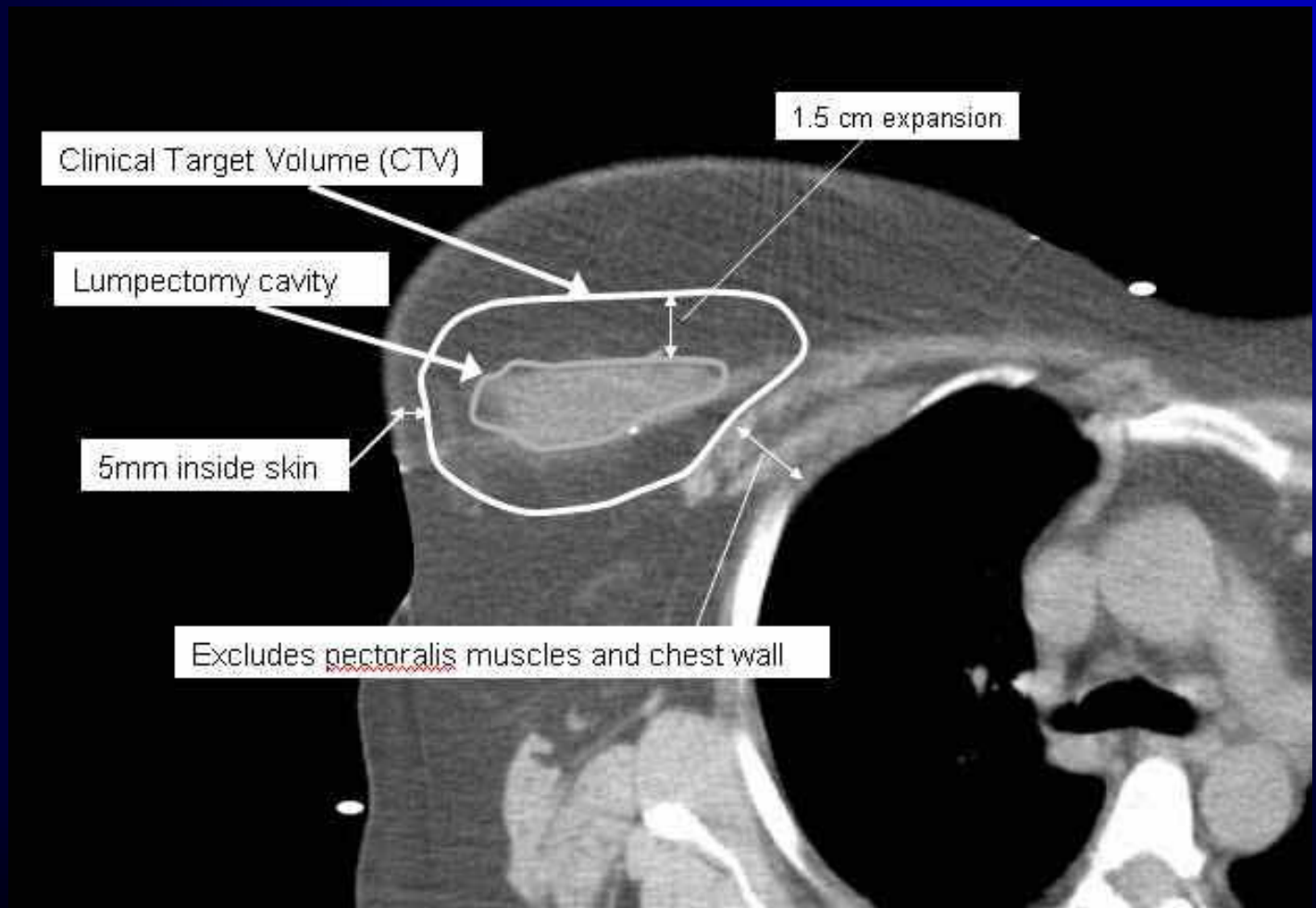
- Dose volume analysis of the target volume
  - <90% of the prescribed dose and/or <90% coverage of the PTV_EVAL.
- Dose homogeneity criteria are not met.
- Critical normal structure DVH exceeds 5%
- Dose delivered over a period of time extending > 10 days.

3D Conformal External Beam RT

Target Volume Definitions

CTV = 1.5 cm expansion of cavity

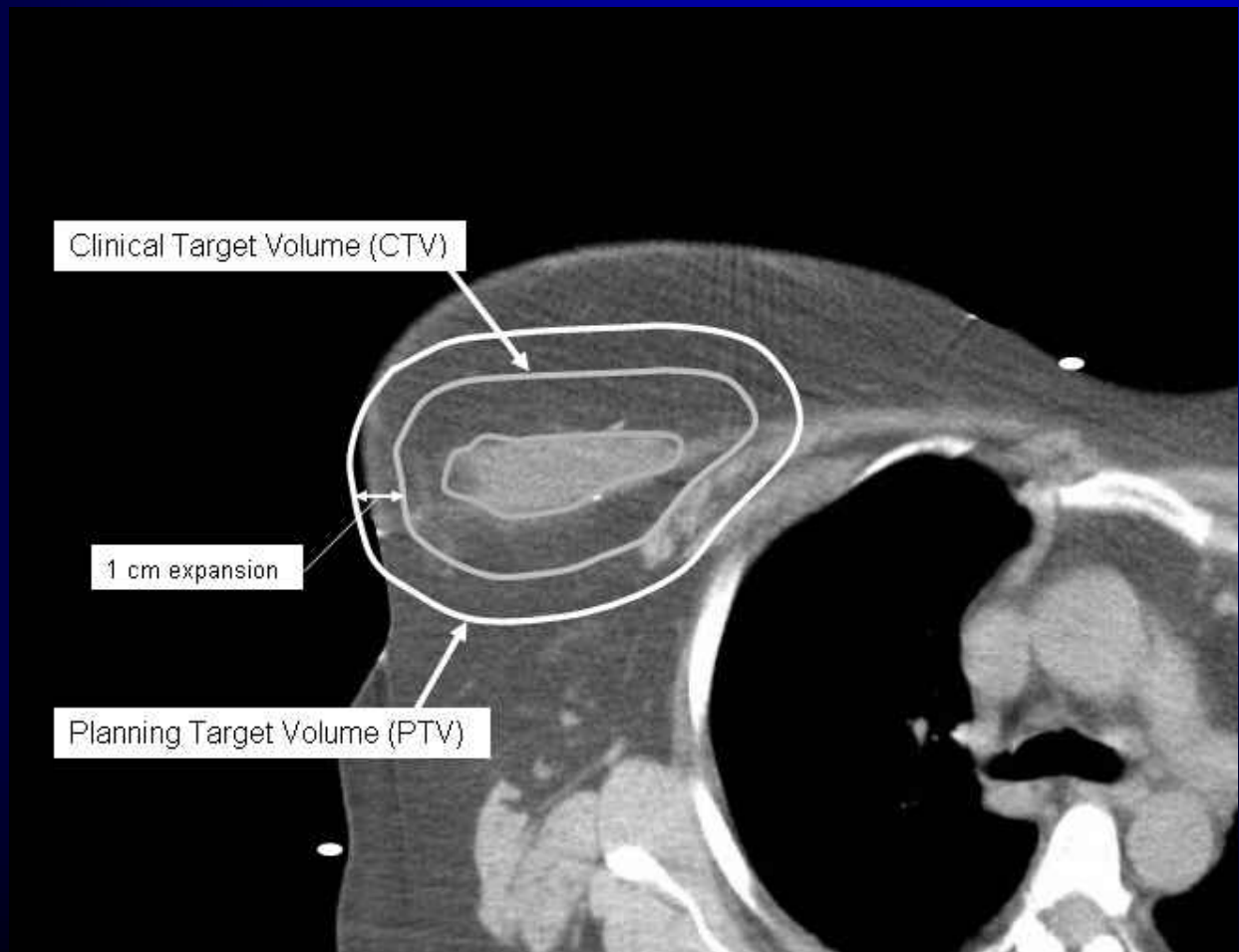
(5mm within skin and bounded by posterior breast extent)



3D Conformal External Beam RT

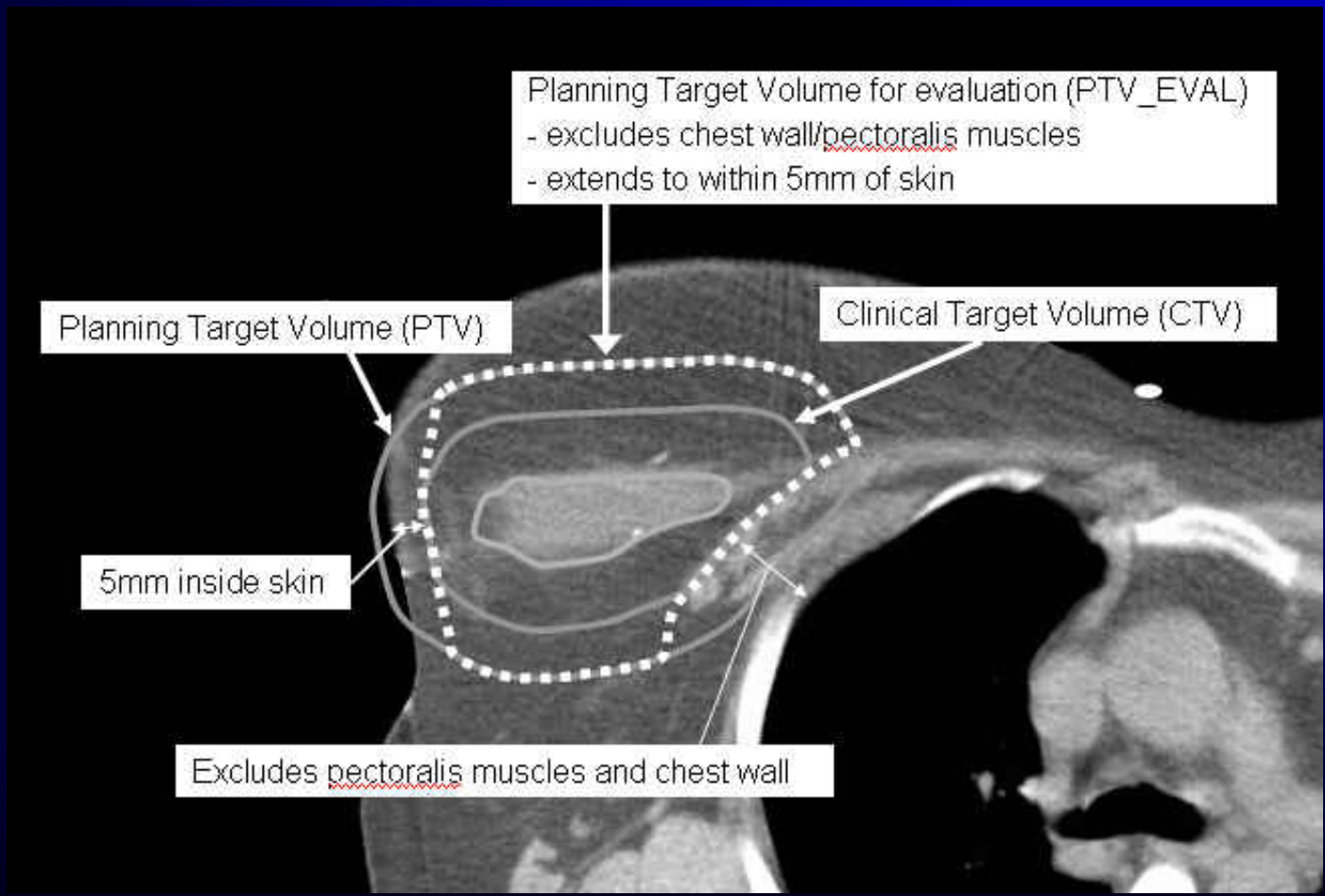
Target Volume Definitions

PTV = 1.0 cm expansion of CTV
(breathing motion and set-up error
– used for design of field aperture)



3D Conformal External Beam RT Target Volume Definitions

PTV_EVAL = PTV limited to 5mm within skin and bounded by posterior breast extent (used for target coverage evaluation



3D Conformal External Beam RT

Dose : 3.85 Gy bid x 5 days – 38.5 Gy

Normal tissue : All to be contoured

- *Uninvolved Normal Breast*:
  - Ideally, $<$ 60% of the whole breast reference volume should receive $\geq$ 50% of the prescribed dose
  - $<$ 35% of the whole breast reference volume should receive the prescribed dose.
- *Contralateral breast*:
  - The contralateral breast reference volume should receive $<$ 3% of the prescribed dose to any point.
- *Ipsilateral lung*:
  - $<$ 15% of the lung can receive 30% of the prescribed dose.
- *Contralateral lung*:
  - $<$ 15% of the lung can receive 5% of the prescribed dose.
- *Heart (right-sided lesions)*:
  - $<$ 5% of the heart should receive 5% of the prescribed dose.
- *Heart (left-sided lesions)*:
  - The vol. of the heart receiving 5% of the prescribed dose (V5) will be <40%
- *Thyroid*:
  - maximum point dose of 3% of the prescribed dose.

3D Conformal External Beam RT

Acceptable:

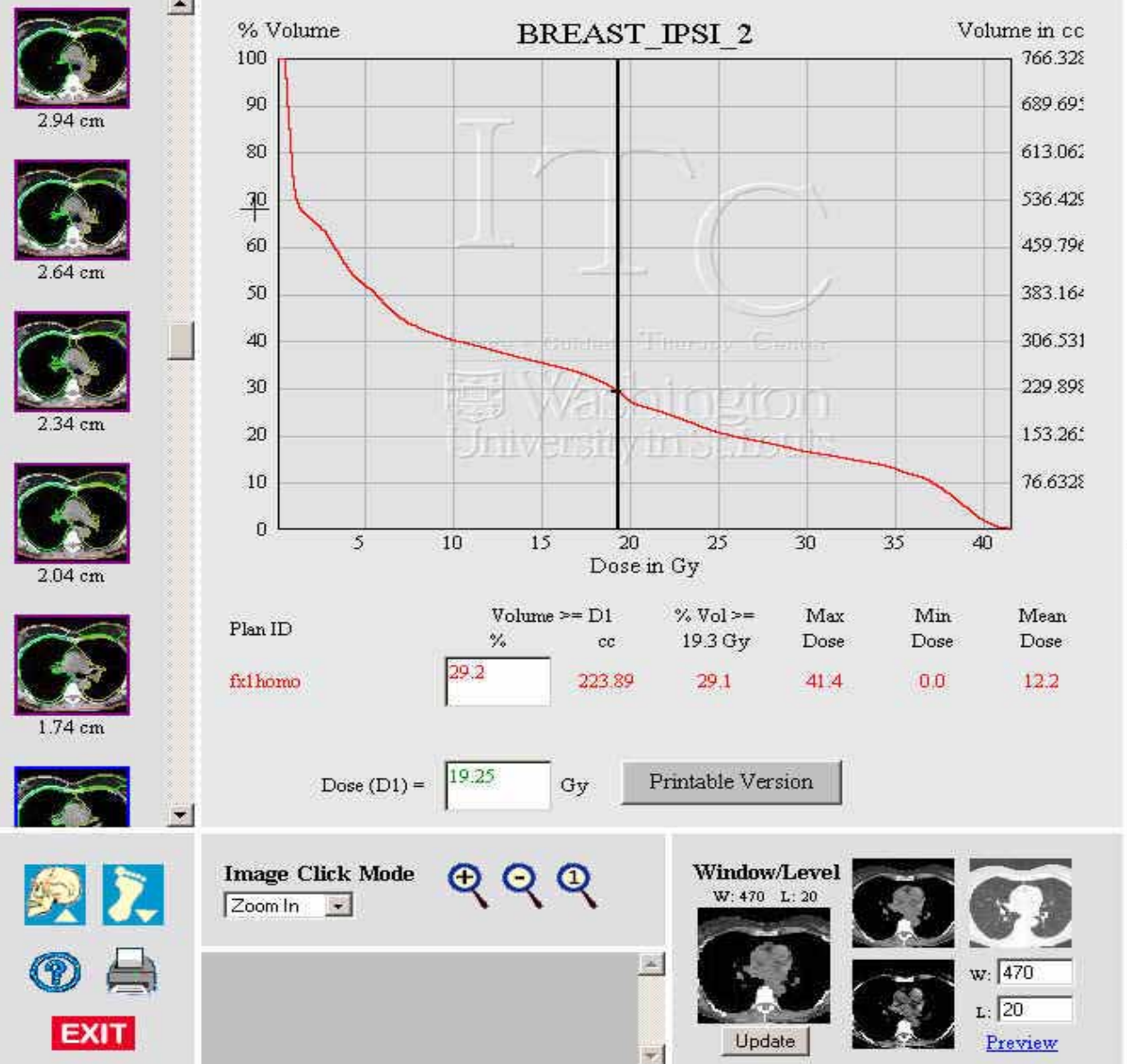
- Dose volume analysis of target will:
  - confirm that $\geq$ 90% of the prescribed dose is covering $\geq$ 90% of the PTV_EVAL
- Critical normal tissue DVHs within 5%
- Maximum dose does not exceed 120% of prescribed dose.
- Dose delivered within 5-10 days.

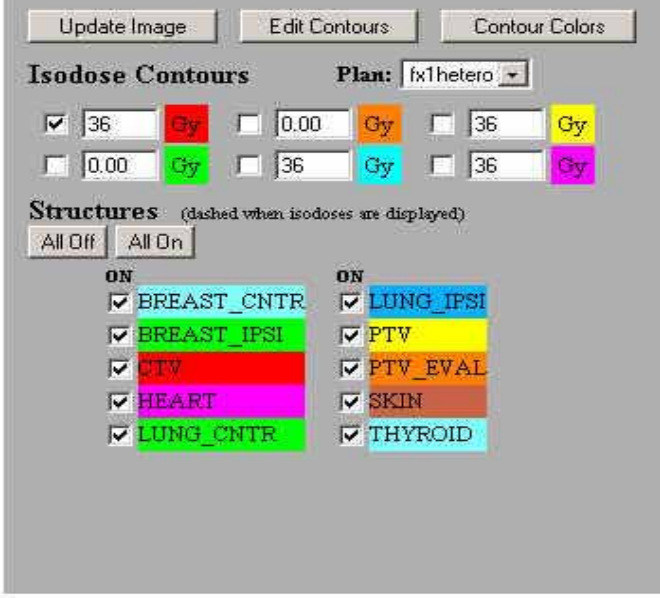
3D Conformal External Beam RT

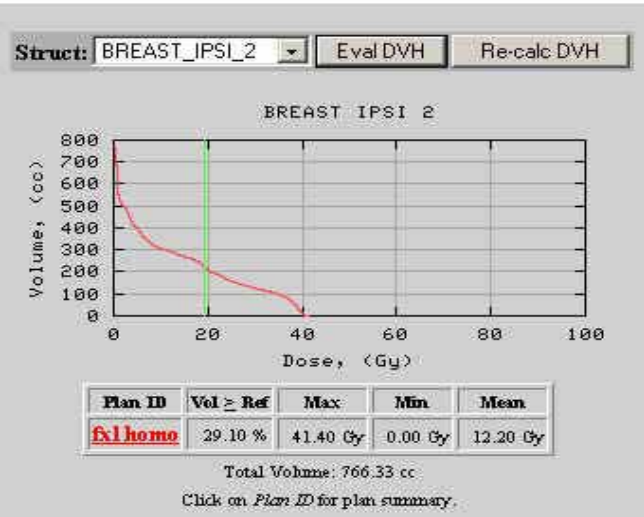
Unacceptable:

- Dose volume analysis of the target volume
  - <90% of the prescribed dose and/or <90% coverage of the PTV_EVAL.
- Critical normal structure DVH exceeds 5%
- Maximum dose does exceed 120% of prescribed dose.
- Dose delivered over a period of days extending > 10 days.

Digital Submission to ITC







QA Program – NSABP/RTOG

- Tremendous amount of work
- Restrictive
- Necessary to assure conclusions reliable