

Purpose:

For each of this trial's 3 treatment scenarios an institution must be credentialed. The following are the 3 different arms of the study which involve the use of radiation therapy:

- Arm 1/ Group1A are patients who have had a lumpectomy and will receive standard whole breast radiation therapy.
- Arm 2/ Group 2A are patients who have had a lumpectomy and will receive whole breast radiation therapy and regional nodal irradiation.
- Arm 2/ Group 2B are patients who had a mastectomy and will receive radiation therapy to the chestwall and regional nodal irradiation.

The purpose of credentialing is to verify all personnel involved with treatment planning have read the protocol and can follow the protocol specifications prior to placing a patient on protocol with the end result of limiting the number of protocol deviations. Credentialing also provides feedback to an institution prior to treatment of a patient on trial to correct any mistakes that may occur.

Method:

An institution needs to update their Facility Questionnaire and download the 3 CT benchmark cases representing the 3 treatment groups (1A, 2A and 2B) of the study from IROC Houston's website. The institution may decide which modality (3DCRT/IMRT) to use for each benchmark, however at least one benchmark must be completed for each modality for which the institution wants to be credentialed. IROC Houston reviews these benchmarks using MIM for verification that dose requirements are per protocol.

Method (cont'd):

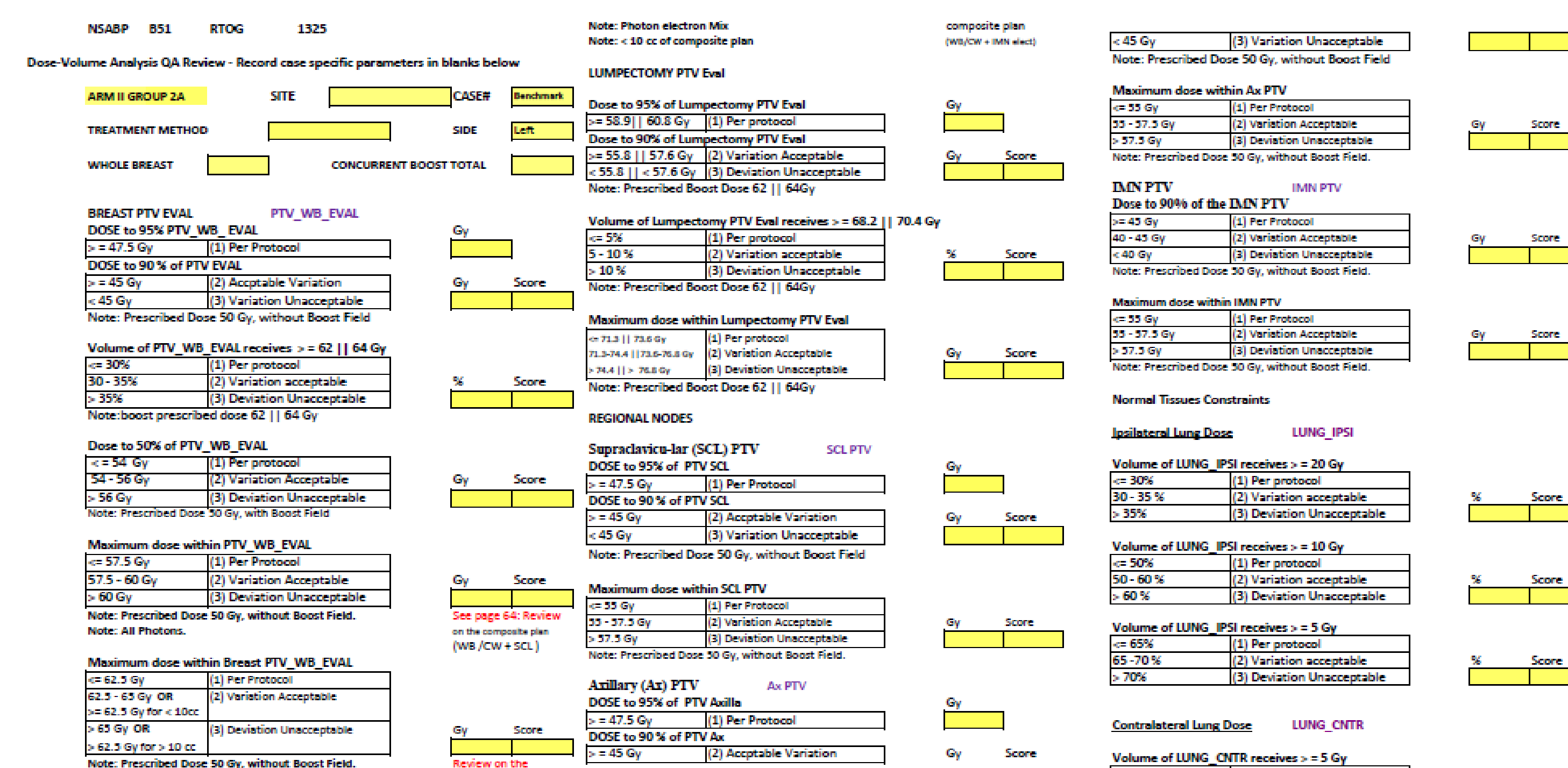


Figure 2: Example of the Dose Volume Analysis (DVA) used for evaluation of treatment plans.

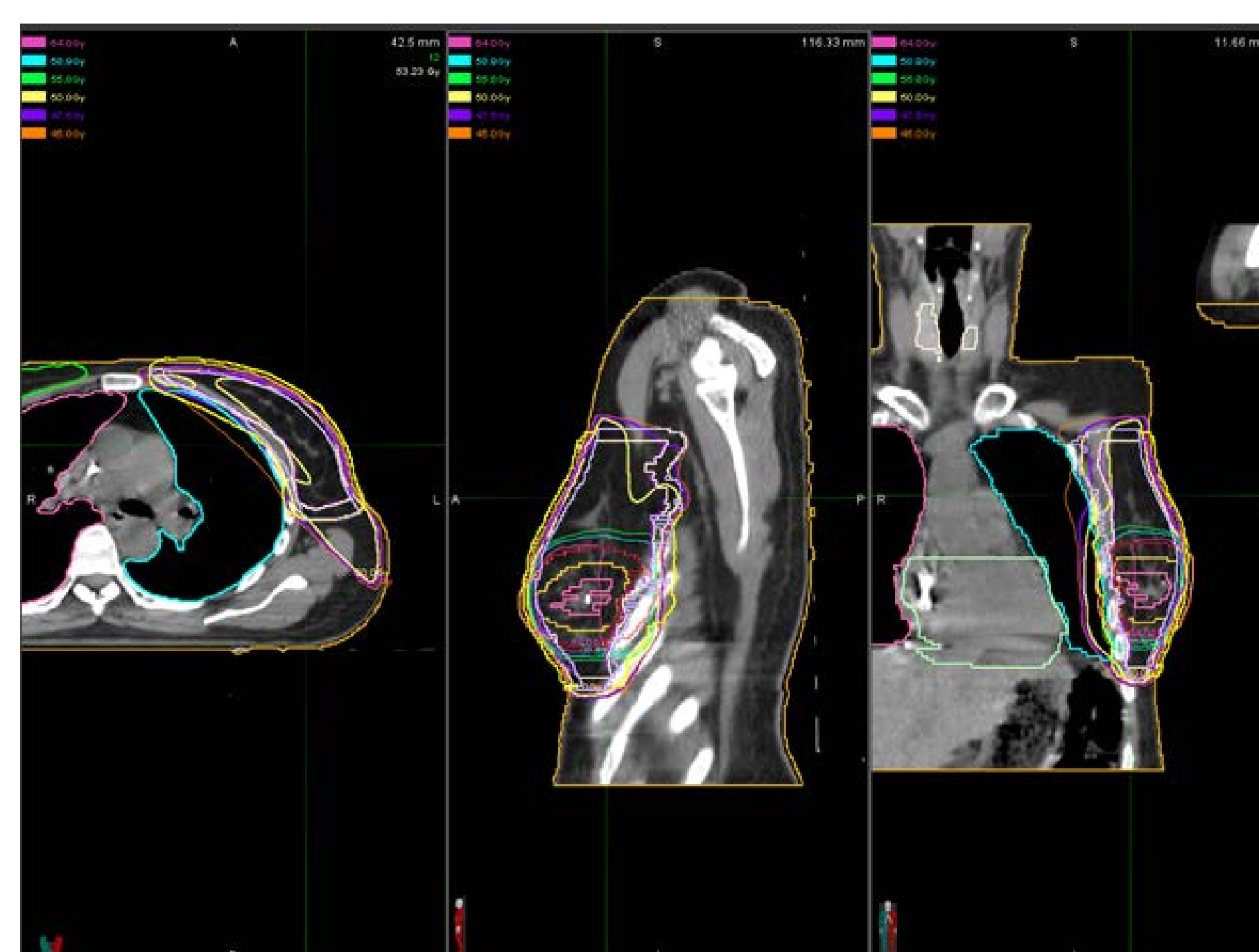


Figure 3: Benchmark for Arm 1/1A

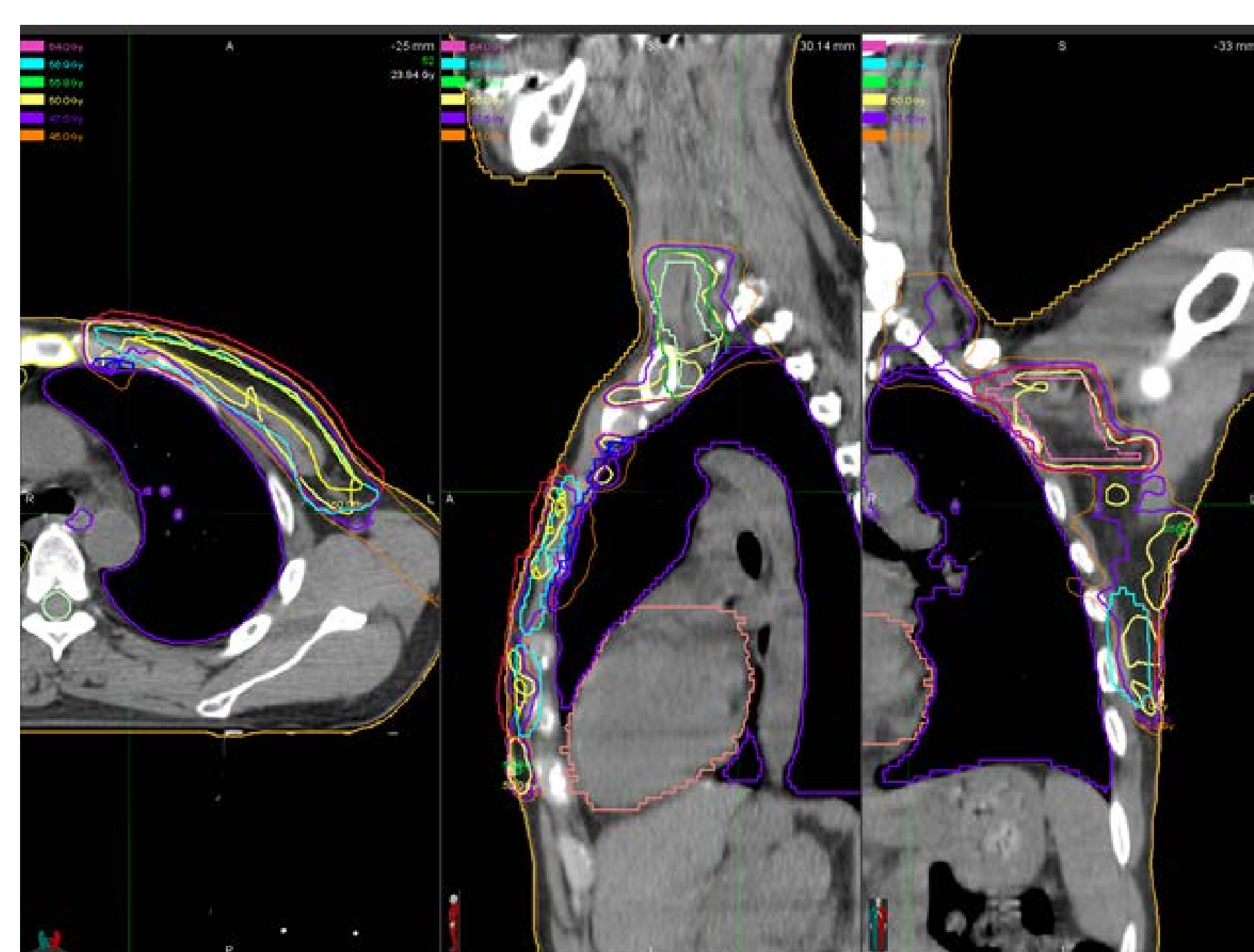


Figure 4: Benchmark for Arm 2/2A

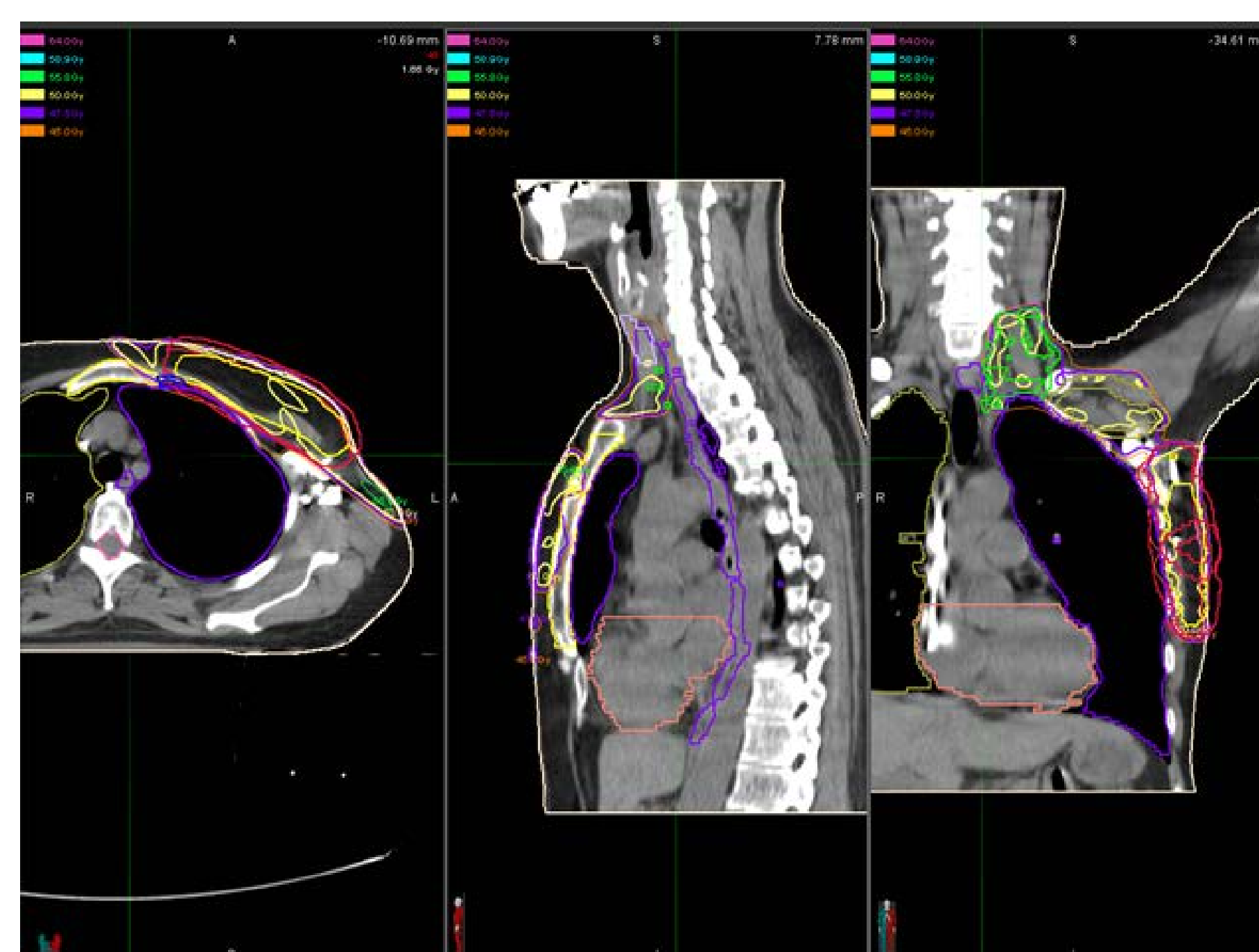


Figure 5: Benchmark for Arm 2/2B

Results:

Presently, 184 institutions have initiated the credentialing process. Of the 184 institutions that have submitted their benchmarks, 3% failed and never resubmitted a benchmark for re-review. The breakdown of credentialed techniques is; 5% IMRT only, 53% 3DCRT only and 42% 3DCRT/IMRT. Of those sites that have been credentialed: 8% of the institutions failed the benchmark for 1A, 10% failed for 2B and 34% failed for 2A at least once, before being credentialed. 9% of the institutions failed 2A twice, 2 institutions failed three or more times and 9% failed 2A when planned using 3D and IMRT at the same institution. An explanation for the higher failure rate for 2A benchmark is due to the addition of the nodal irradiation.

Arm	Sites Failed	# Sites Failed		
		=2	≥2	planned 3D & IMRT
1A	13			
2A	57	5	2	5
2B	10	2		

Table 1: Summation of number of benchmark failures per study arm.

The following are the most common areas of failure for the 1A :

- Lung_IPSI (Lung IPSI re'c 20Gy)
 - PTV_WB_EVAL (Dose to 50% of PTV WB)
 - PTV_EVAL BREAST (Volume of PTV WB EVAL rec'd 62 Gy)
- The following are the most common areas of failure for the 2A :
- PTV_Axilla (Dose to 95%)
 - PTV_Axilla (Max point dose w/in PTV_Axilla)
 - PTV_EVAL_Breast (Max dose w/in PTV WB)
 - Lung_IPSI (Lung IPSI re'c 20Gy)
 - PTV_EVAL_BREAST (Dose to 50% of PTV WB)
 - PTV_EVAL BREAST (Volume of PTV WB EVAL rec'd 62 Gy)

The following are the most common areas of failure for the 2B :

- PTV_EVAL_CHSTWLL (Dose to 95%)
- PTV_SCL (Dose to 95%)

Conclusions:

Currently 166 institutions have been credentialed for this study. The protocol has accrued 40 patients which have all been pre-treatment reviews where 6 of them had to be re-submitted for a re-review due to volume contouring.

Support:

Work supported by PHS grant CA10953 awarded by NCI, DHHS

Figure 1: IROC Houston on-line Facility Questionnaire