compliance. To facilitate composite planning, dose to all metastases should be calculated on a single CT scan simultaneously with in-plane resolution of at least 2 x 2 x 3mm. If this is not possible, composite plans should be generated incorporating the dose from each metastasis treated. The composite doses to critical normal tissues will be used to evaluate plan compliance.

Tables 6-6 and 6-7 lists maximum dose limits to a point or volume within several critical organs based on the dose fractionation schema (three or five fractions) assigned based on metastatic tumor location.

If both three and five fraction dose schemes are being used in a given patient, use Table 6-6 for locations being treated with a three fraction regimen. For locations being treated with a five fraction regimen, use Table 6-7. If a given organ has > 1 Gy dose contribution from both the three and five fraction plans, then the three fraction dose constraints in Table 6-6 will be used.

The spinal cord doses are absolute limits, and treatment delivery that exceeds these limits will constitute a major protocol violation. However, some OAR (ie, the esophagus, trachea, bronchi and heart within the lung) may be situated adjacent to the treated GTV/PTV. As such, there is no specified limit as tumors that are immediately adjacent to that organ will not be able to be treated to any of the prescription doses without irradiating a small volume of that organ to the prescribed dose. In such a case, the planning needs to be done so that there is no hot spot within that organ, even if that organ is part of the GTVPTV, i.e., that no part of any OAR receives more than 105% of the prescribed dose In addition, the volume of the OAR in question needs to be minimized, both in length and in the width (i.e., circumference), with efforts made to reduce the dose to the contralateral wall of the organ.

For non-spinal cord organs at risk with known sensitivity to high doses of radiation (including the bowel, esophagus, and stomach) included within a PTV or immediately adjacent to PTVs, a prescription dose at the lower end of acceptable variation should be used. Additionally, every effort should be made to cover the GTV with the prescription dose while ensuring rapid falloff to the organ at risk. Coverage of a section of PTV including or immediately adjacent to the OAR may be as low as 70% of the prescription dose ONLY in this situation. Every effort should be made to cover 100% of the GTV by the prescription dose at the lower end of acceptable variation. Since the tumor and normal tissue may not allow strict avoidance, the larger volume limits will not be scored as protocol Deviations Unacceptable if exceeded.

The total allowable doses over either a three or five fraction treatment regimen based on the schema assigned and are listed in Tables 6-6 and 6-7.

For tumors that are not immediately adjacent to any OAR, centers are encouraged to observe prudent treatment planning principles in avoiding unnecessary radiation exposure to critical normal structures; we expect that the OAR doses will be as low as achievable (ideally, < 6 Gy/fraction).

NOTE: No studies of OAR limits for multiple metastases have been reported in the literature. Thus, organ limits from previously developed protocols, as shown in tables 6-6 and 6-7 below, will be utilized.

Table 6-6 **OAR Dose Limits for 3 fraction SBRT**

Serial Organ	**Volume**	**Volume Dose (Gy)**	**Avoidance Endpoint (Reference)**
Spinal Cord	<0.03 cc	22.5	Myelitis (Timmerman)
	<1.2 cc	13	Myelitis (Timmerman)

Ipsilateral Brachial Plexus	< 0.03 cc	26	Brachial Plexopathy (Timmerman)
	<3 cc	22	Brachial Plexopathy (Timmerman)
Cauda Equina	<0.03 cc	25.5	Neuritis (Timmerman)
	<5 cc	21.9	Neuritis (AAPM TG-101)
Sacral Plexus	<0.03 cc	24	Neuropathy (AAPM TG-101)
	<5 cc	22.5	Neuropathy (AAPM TG-101)
Trachea and Ipsilateral Bronchus*	<0.03 cc	30	Stenosis/Fistula (Z4099)
	<5cc	25.8	Stenosis/Fistula (Timmerman)
Esophagus*	<0.03 cc	27	Stenosis/Fistula (Timmerman 2006 /RTOG 0618)
	<5cc	17.7	Stenosis/Fistula (Z4099)
Heart/Pericardium	<0.03cc	30	Pericarditis (Z4099)
	<15 cc	24	Pericarditis (Z4099)
Great vessels*	<0.03cc	45	Aneurysm (Z4099)
	<10 cc	39	Aneurysm (Z4099)
Skin	<0.03cc	33	Ulceration (Z4099)
	<10cc	31	Ulceration (Timmerman)
Stomach	<0.03cc	30	Ulceration/Fistula (Timmerman)
	<10cc	22.5	Ulceration/Fistula (Timmerman)
Duodenum*	<0.03cc	24	Ulceration (Timmerman 2006)
	<10cc	15	Ulceration (Timmerman 2006)
Bowel*	<0.03 cc	34.5	Ulceration (Timmerman)
	<20cc	24	Colitis/Fistula (Z4099)
Rectum*	<0.03 cc	49.5	Ulceration (Timmerman)

	<3.5 cc	45	Proctitis/Fistula (Timmerman)
	< 20 cc	27.5	Proctitis/Fistula (Timmerman)
Bladder	0.03cc	33	Cystitis/Fistula (Timmerman)
	<15 cc	16.8	Cystitis/Fistula (AAPM TG-101)
Ureter	<0.03 cc	40	Stenosis (Timmerman)
Penile bulb	< 3cc	25	Impotence (Timmerman)
Femoral heads	<10 cc	24	Necrosis (Timmerman)
Bile duct	< 0.03 cc	36	Stenosis (Timmerman)
Renal hilum/vascular trunk	<15 cc	19.5	Malignant Hypertension (Timmerman)
Rib	< 0.03 cc	50	Pain or Fracture (Timmerman
	<5 cc	40	Pain or Fracture (Timmerman
Parallel Organ	**Volume**	**Volume Dose (Gy)**	**Avoidance Endpoint (Reference)**
Lung (total)	<15% lung volume	20	Pneumonitis/Lung Function (RTOG 0618)
	< 37% lung volume	11	Pneumonitis (Timmerman)
	1500 cc	10.5	Basic Lung Function (Z4099)
	1000 cc	11.4	Pneumonitis (Z4099)
Ipsilateral kidney	<130 cc	12.3	Nephritis (Timmerman 2006)
Total Kidney	<200cc	15	Basic Renal Function (Timmerman)
Liver	<700 cc	17.1	Liver function (Timmerman 2006/Z4099)

*NOTE: Avoid circumferential irradiation.

Table 6-7 **OAR Dose Limits for 5 fraction SBRT**

Serial Organ	**Volume**	**Volume Dose (Gy)**	**Avoidance Endpoint**
Spinal Cord	<0.03 cc	28	Myelitis (Timmerman)
	<0.35 cc	22	Myelitis (Timmerman)
	<1.2 cc	15.6	Myelitis (Timmerman)

Ipsilateral Brachial Plexus	< 0.03 cc	32	Brachial Plexopathy (RTOG 0813)
	<3 cc	30	Brachial Plexopathy (RTOG 0813)
Cauda Equina	<0.03 cc	32	Neuritis (AAPM TG-101)
	<5 cc	30	Neuritis (AAPM TG-101)
Sacral Plexus	<0.03 cc	32	Neuropathy (AAPM TG-101)
	<5 cc	30	Neuropathy (AAPM TG-101)
Trachea and Ipsilateral Bronchus*	<0.03cc	40	Stenosis/Fistula (Timmerman)
	<5cc	32	Stenosis/Fistula (RTOG 0813)
Esophagus*	<0.03cc	35	Stenosis/Fistula (Timmerman)
	<5 cc	27.5	Stenosis/Fistula (RTOG 0813)
Heart/Pericardium	<0.03 cc	38	Pericarditis (Timmerman)
	<15 cc	32	Pericarditis (RTOG 0813)
Great vessels*	<0.03 cc	53	Aneurysm (Timmerman)
	<10 cc	47	Aneurysm (RTOG 0813)
Skin	< 0.03cc	38.5	Ulceration (Timmerman)
	< 10cc	36.5	Ulceration (Timmerman)
Stomach	< 0.5cc	35	Ulceration/Fistula (Timmerman)
	< 5cc	26.5	Ulceration/Fistula (Timmerman)
Duodenum*	< 0.5 cc	30	Ulceration (RTOG 1112)
	< 5 cc	18.3	Ulceration (Timmerman 2006)
Bowel*	< 0.03 cc	40	Ulceration (Timmerman)
	<20 cc	28.5	Colitis/Fistula (Timmerman)
Rectum*	<0.03 cc	55	Ulceration (Timmerman)
	<3.5 cc	50	Proctitis/Fistula (Timmerman)
	<20 cc	32.5	Proctitis/Fistula (Timmerman

Bladder	< 0.03	38	Cystitis/Fistula (Timmerman)
	<15 cc	20	Cystitis/Fistula (Timmerman)
Ureter	< 0.03 cc	45	Stenosis (Timmerman)
Penile Bulb	<3 cc	30	Impotence (Timmerman)
Femoral head	<10 cc	30	Necrosis (Timmerman)
Bile Duct	<0.03 cc	41	Stenosis (Timmerman)
Renal hilum/Vascular Trunk	<15 cc	23	Malignant Hypertension (Timmerman)
Rib	<0.03 cc	57	Pain or Fracture (Timmerman)
	<5 cc	45	Pain or Fracture (Timmerman)
Parallel Organ	**Volume**	**Volume Dose (Gy)**	**Avoidance Endpoint**
Lung (total)	< 37% lung volume	13.5	Pneumonitis (Timmerman)
	< 1500 cc	12.5	Basic Lung Function (RTOG 0813)
	< 1000 cc	13.5	Pneumonitis (RTOG 0813)
Total Kidney	< 200cc	18	Basic Renal Function (Timmerman)
Liver	<700 cc	21	Liver Function (Timmerman)

*__NOTE__: Avoid circumferential irradiation.

6.5.5 Rib/Chest wall Dose Constraints

Recent reports have highlighted that the rib and chest wall in proximity to the treated lesion may represent an organ at risk for complication. Tumor location, particularly when located peripherally, will enhance the potential risk for chest wall toxicity. While target coverage should not be compromised to limit dose to the rib/chest wall, every effort should be made to minimize dose to this OAR.

6.6 Documentation Requirements (6/30/14)

6.6.1 Treatment Interruptions

In general, treatment interruptions should be avoided by preventative medical measures and nutritional, psychological, and emotional counseling. Treatment breaks, including indications, must be clearly documented on the treatment record.

6.6.2 The "NRG-BR001 Datasheet" is available in the Forms section of the website: http://www.rtog.org/ClinicalTrials/ProtocolTable/StudyDetails.aspx?study=1311
Sites will record dose-volume values for all required structures on this datasheet. The datasheet must be completed and submitted with the digital RT data via TRIAD for review.

6.6.3 In addition to IGRT credentialing (see Section 5.1), it is recommended that IGRT images in the treatment position for every fraction (and a table of subsequent 'shifts') for each patient be submitted for subsequent future evaluation.