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NRG ONCOLOGY PROTOCOL DEVELOPMENT TEMPLATE FOR RADIATION THERAPY

DISEASE SITE: Head and Neck
SUB-COMPONENT: SBRT

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Underlined highlighted texts are either instructions or suggestions to be deleted or replaced by PIs with regular texts without highlight.

Regular highlighted texts are examples to be selected (remove highlight), deleted or replaced by PIs with regular texts.

5.2 Radiation Therapy

Notes 1,2,...: The note(s) included at this point in the protocol should be designed to emphasize special information that the study chair does not want the investigator to overlook. An example might be a statement that IGRT is required for the study.

For credentialing requirements, please refer to section 8 of the protocol.

Radiation Therapy Schema

Schema at the beginning of the protocol should be followed.

5.2.1 Treatment Technology

List allowed Treatment Modalities (including energy): photons, protons.
Required Capabilities: IMRT, IGRT, etc.

This protocol requires photon treatment. Proton therapy is not allowed. IMRT techniques including static field and helical IMRT (Tomotherapy) and VMAT are allowed. ViewRay and CyberKnife are allowed. Photon beams with energies of 6-10 MV are allowed. The photon energy of 6 MV is preferred. All patients are required to have daily IGRT. Minimum field size should be greater than the field size of the smallest field used for beam commissioning. Beam shaping for treatment delivery shall be via conical collimator, iris or multi-leaf collimator (MLC). Treatment shall be delivered using treatment machine commissioned and equipped to deliver SBRT.

5.2.2 Immobilization and Simulation

Immobilization

Proper immobilization is critical for this protocol. Patient setup reproducibility must be achieved using appropriate clinical devices. Patients will be treated supine and must have a secure head and neck immobilization (e.g. aquaplast mask) made prior to the treatment planning CT scan. Intraoral immobilization devices may be utilized for tongue position control or immobilization and should be considered when the targets involve the pharyngeal axis.

Simulation Imaging

This subsection should include information about the extent of CT imaging, the resolution of the

scan information including the slice thickness, and details of the allowed use of contrast agents and the handling of tissue densities when contrast is used.

The treatment planning CT scan should be performed with IV contrast unless contraindicated, obtained in the immobilization device and in the treatment position with a slice thickness of ≤ 1.5 mm. Additional CT reconstruction with small field of view can be acquired for better contouring. Metal artifact reduction technique in CT scanner can be used for cases with dental filling or other high- density objects. For patients in whom contrast is contraindicated, PET/CT and MRI based imaging should be used to guide tumor and normal organ volume definition. Recommended MRI slice thickness is ≤ 1.5 mm.

5.2.3 Imaging for Structure Definition, Image Registration/Fusion and Follow-up

Please indicate “Not applicable” if it does not apply to your protocol. Please do not delete this subsection.

In addition to the planning CT, adjunct imaging can be registered to the planning CT data set to aid in target delineation. While not mandatory, we strongly recommend obtaining and fusing an FDG PET/CT as well as accompanying diagnostic contrast enhanced CT images. Contrast enhanced MRI can also be extremely valuable and is strongly encouraged for tumors near the skull base.

5.2.4 Definition of Target Volumes and Margins

Note: All structures must be named for digital RT data submission as listed in the table below. The structures marked as “Required” in the table must be contoured and submitted with the treatment plan. Structures marked as “Required when applicable” must be contoured and submitted when applicable.

Resubmission of data may be required if labeling of structures does not conform to the standard DICOM name listed. Capital letters, spacing and use of underscores must be applied exactly as indicated.

Entries in the first column of the list below will be entered and edited by the QA Staff. The PIs are required to specify the information in the second, third columns. The detailed specifications have to include crucial items such as boundary definitions and margins.

| Standard Name | Description | Validation <u>Required/Required when applicable/Optional</u> |
|-----------------|----------------------|---|
| GTV_4000 | GTV to receive 40 Gy | Required |
| PTV_4000 | PTV to receive 40 Gy | Required |

| | | |
|---------------|----------------|--------------------------|
| PTV_Eval_4000 | PTV minus OARs | Required when applicable |
| | | |

Detailed Specifications

Target volumes: The definitions of volumes will be in accordance with the 1999 ICRU Report #62.

Setup margin (SM): Daily IGRT is a requirement for this trial, therefore, the SM will be 0.3 cm in all directions.

GTV_4000: The GTV represents clinically or radiographically areas grossly involved with tumor and will be designated as GTV_4000. These volumes are defined based on physical exam and review of available imaging. FDG-PET may assist in GTV identification but specific GTV border delineation should not rely exclusively on PET signal given the known variable association between gross tumor extent and PET signal cutoff. Grossly Positive Nodes must be included in the GTV. Recommended GTV contouring inclusion criteria are as follows: greater than 1.5 cm in long axis and/or > 1 cm in short axis, a cluster of 3 or more borderline size nodes, radiographic evidence of extra-nodal extension (ENE), a node of any size with evidence of necrosis, or a node with a standard uptake value (SUV) above 4 on PET/CT. A patient who underwent aggressive biopsy or subtotal resection (and meets eligibility criteria as defined in section 3.2.3) with a biopsy/resection bed in association with the radiographically visible gross target disease must include the entire biopsy bed/resection bed in the GTV. This residual tumor + biopsy/resection bed GTV must have its largest maximum dimension <7.5 cm to meet eligibility criteria.

PTV_4000: The PTV will be equal to the GTV+SM. SM is defined in the section above. A margin of 3 mm around the GTV is required in all directions to define PTV. When expansion of a GTV results in a PTV that extends beyond the patient's body surface, the PTV should be constrained to at least 3 mm from within the external contour. The use of tissue equivalent bolus material is indicated in situations where the disease is at or just under the skin surface. The PTV should align with the skin surface when bolus is used.

PTV_Eval_4000: The simple isotropic expansion of GTV to PTV can result in a dosimetric challenge when PTV overlaps with a critical OARs (spinal cord, brainstem, optic structures, brachial plexus, carotid artery, esophagus) and their associated PRVs, hence PTV_Eval_4000 can be created that is equal to PTV volume minus impinging OARs and can be used for dosimetric evaluation.

5.2.5 Definition of Critical Structures and Margins

Note: All structures must be named for digital RT data submission as listed in the table below. The structures marked as “Required” in the table must be contoured and submitted with the treatment plan. Structures marked as “Required when applicable” must be contoured and submitted when applicable.

Resubmission of data may be required if labeling of structures does not conform to the standard DICOM name listed. Capital letters, spacing and use of underscores must be applied exactly as indicated.

Entries in the first column of the list below will be entered and edited by the QA Staff. The PIs are required to specify the information in the second, third columns. The detailed specifications have to include crucial items such as boundary definitions and margins.

| OAR Standard Name | Description | Validation |
|-------------------|--|------------|
| SpinalCord | Spinal Cord | Required |
| SpinalCord_PRV05 | PRV=5mm expansion around Spinal Cord | Required |
| BrainStem | Brain Stem | Required |
| BrainStem_PRV03 | PRV=3mm expansion around Brain Stem | Required |
| Parotid_R | Right Parotid Gland | Required |
| Parotid_L | Left Parotid Gland | Required |
| Larynx_GS | Glottic and Supraglottic Larynx | Required |
| GlnD_Submand_R | Right Submandibular Gland | Required |
| GlnD_Submand_L | Left Submandibular Gland | Required |
| Pharynx | Uninvolved posterior pharyngeal wall plus adjacent constrictor muscles | Required |
| Cavity_Oral | Oral Cavity | Required |
| Lips | Lips | Required |

| | | |
|-----------------|--|---|
| Esophagus_S | Upper Cervical Esophagus | Required |
| Bone_Mandible | Mandible | Required |
| Joint_TM_R | Right Temporomandibular Joint | Required |
| Joint_TM_L | Left Temporomandibular Joint | Required |
| A_Carotid_R | Right Carotid Artery | Required |
| A_Carotid_L | Left Carotid Artery | Required |
| External | Patient body contour | Required |
| Skin | Inner ring of all tissue within 3mm patient body contour | Required |
| E-PTV_4000 | External minus PTV | Required |
| Eye_R | Right Globe | Required for targets near* the skull base |
| Eye_L | Left Globe | Required for targets near* the skull base |
| Lens_R | Right Lens | Required for targets near* the skull base |
| Lens_L | Left Lens | Required for targets near* the skull base |
| GlnD_Lacrimal_R | Right Lacrimal Gland | Required for targets near* the skull base |
| GlnD_Lacrimal_L | Left Lacrimal Gland | Required for targets near* the skull base |
| OpticNrv_R | Right Optic Nerve | Required for targets near* the skull base |
| OpticNrv_L | Left Optic Nerve | Required for targets near* the skull base |
| OpticChiasm | Optic Chiasm | Required for targets near* the skull base |
| Cochlea_R | Right Cochlea | Required for targets near* the skull base |
| Cochlea_L | Left Cochlea | Required for targets near* the skull base |
| Brain | Whole Brain | Required for targets near* the skull base |
| Lobe_Temporal_R | Right Temporal Lobe | Required for targets near* the skull base |

| | | |
|-----------------|-----------------------|--|
| Lobe_Temporal_L | Left Temporal Lobe | Required for targets near* the skull base |
| BrachialPlex_R | Right Brachial Plexus | Required for targets below cricoid cartilage |
| BrachialPlex_L | Left Brachial Plexus | Required for targets below cricoid cartilage |

*Near is defined as any point on the contour coming within 5 mm of the base of the skull.

Detailed Specifications

SpinalCord: The cord begins at the cranial-cervical junction (i.e., the top of the C1 vertebral body). Superior to this is brainstem and inferior to this is cord. The inferior border of the spinal cord volume will be defined at approximately T3-4 (ie, 2-3 cm below the lowest slice level that has PTV on it). The spinal cord shall be defined based on the treatment planning CT scan.

SpinalCord_PRV05: Planning Risk Volume (PRV) spinal cord defined as SpinalCord + 5 mm in all directions.

BrainStem: The inferior most portion of the brainstem is at the cranial-cervical junction where it meets the spinal cord. For the purposes of this study, the superior most portion of the brainstem is approximately at the level of the top of the posterior clinoid. The brainstem shall be defined based on the treatment planning CT scan.

BrainStem_PRV03: Planning Risk Volume (PRV) brainstem defined as Brainstem + 3 mm in all directions.

Parotid_R and Parotid_L: Parotid glands will be defined in their entirety (superficial and deep lobes) based on the treatment planning CT scan.

Larynx_GS: This will be defined as the glottic and supraglottic larynx, including the tip of the epiglottis, the epiglottis, the aryepiglottic folds, arytenoids, false cords, and true cords, up to but not including the medial border of the thyroid cartilage, and including the cricoid cartilage to the inferior edge of the arytenoid cartilage, but not the hypopharynx.

Gland_Submand_R and Gland_Submand_L: Submandibular glands will be defined in their entirety based on treatment planning CT scans.

Pharynx: This will be defined as the pharyngeal wall plus adjacent constrictor muscles deemed not to require treatment (external to PTVs). This extends from the superior constrictor region (level of the inferior pterygoid plates) to the cricopharyngeal inlet (level of the posterior cricoid cartilage).

Cavity_Oral: The oral cavity will be defined as a composite structure posterior to lips consisting of the anterior 1/2 to 2/3 of the oral tongue/floor of mouth, buccal mucosa, and superiorly the palate, and inferiorly to the plane containing the tip of the mandible.

Esophagus_S: This will be defined as the cervical or superior (S) esophagus, a tubular structure that starts at the bottom of pharynx (cricopharyngeal inlet) and extends to the thoracic inlet.

Bone_Mandible: This includes the entire bony structure of the mandible from TMJ through the symphysis. It is recognized that for oral cavity cancers, this may overlap with PTVs.

A_Carotid_R and A_Carotid_L: This will include the carotid artery at the same level of the PTV plus an additional 2cm cranial and caudal to the level of the PTV. When the PTV is located above the carotid bifurcation, only the internal carotid artery (not the external branch) should be contoured.

Skin: This will be defined as an inner ring of tissue comprising the external skin and the tissue 3mm underneath it.

E-PTV_4000: This will be defined as tissue located within external contour of the patient outside of PTV.

Lobe_Temporal_R and Lobe_Temporal_L: The temporal lobe is bounded by the sylvian fissure cranially, the base of the middle cranial fossa caudally, the temporal bone anteriorly, the tentorium of the cerebellum and incisura preoccipitalis posteriorly, the temporal bone laterally and the cavernous and sphenoid sinus and sylvian fissure medially.

BrachialPlex_R and BrachialPlex_L: The defined ipsilateral brachial plexus originates from the spinal nerves exiting the neuroforamine on the involved side from around C5 to T2. However, for the purposes of this protocol, only the major trunks of the brachial plexus will be contoured using the subclavian and axillary vessels as a surrogate for identifying the location of the brachial plexus. This neurovascular complex will be contoured starting proximally at the bifurcation of the brachiocephalic trunk into the jugular/subclavian veins (or carotid/subclavian arteries) and following along the route of the subclavian vein to the axillary vein ending after the neurovascular structures cross the second rib.

5.2.6 Dose Prescription

Note: The information provided in this section can be used for adjusting the dose constraints for treatment planning purposes. This table together with the planning priority table should be used during dose optimization. It is important to remember that ideal plans might not be achievable in all cases. Thus, the Compliance Criteria table could be different than the information given here. Cases will be scored using the Compliance Criteria table.

The prescribed dose of 40 Gy will be delivered over 5 fractions using 8 Gy per fraction.

Treatments will typically be delivered over 10-15 days with a minimum of 40 hours in between

fractions and a maximum of 5 days in between fractions. The recommended fractionation is every other weekday (e.g. Monday, Wednesday, Friday, Monday and Wednesday). However, twice weekly treatment (e.g. Mondays and Thursdays) is also acceptable.

| Target Standard Name | Dose (Gy) | Fraction Size (Gy) | # of fractions | Frequency | Dose specification technique |
|----------------------|-----------|--------------------|----------------|-------------------------------------|------------------------------|
| PTV_4000 | 40 | 8.0 | 5 | every other weekday or twice weekly | Covering 95% of PTV |

5.2.7 Compliance criteria

The compliance criteria listed here will be used to score each case. Given the limitations inherent in the treatment planning process, the numbers given in this section can be different than the prescription table. The Per Protocol and Variation Acceptable categories are both considered to be acceptable. The Per Protocol cases can be viewed as ideal plans, and the Variation Acceptable category can include more challenging plans that do not fall at or near the ideal results. A final category, called Deviation Unacceptable, results when cases do not meet the requirements for either Per Protocol or Variation Acceptable. Plans falling in this category are considered to be suboptimal, and additional treatment planning optimization is recommended.

VxGy [cc], VxGy [%], Vx%[cc], Vx%[%]: Volume [cc or %] receiving Dose [Gy, or %]
 CVxGy[cc], CVxGy[%], CVx%[cc], CVx%[%]: Complement Volume [cc or %] receiving Dose [Gy, or %]
 Dxcc[Gy], Dxcc[%], Dx%[Gy], Dx%[%]: Dose [Gy or %] to Volume [cc or % of total volume]
 DCxcc[Gy], DCxcc[%], DCx%[Gy], DCx%[%]: Dose [Gy or %] to Complement Volume [cc or % of total volume]
 Minimum dose is defined to D99%[Gy] or D99%[%]
 Maximum dose is defined as D0.03cc[Gy] or D0.03cc[%]
 Mean[Gy] or Mean[%]: Mean dose in Gy or %
 R100%: Ratio of 100% isodose volume over structure volume [SBRT only]
 R50%: Ratio of 50% isodose volume over structure volume [SBRT only]

Normalization of Dose:

The plan is normalized such that 95% of the PTV_4000 volume receives prescription dose of 40 Gy. The treatment plan should be initially normalized such that 100% corresponds to the maximum dose within the PTV. For this SBRT approach, the recommended isodose prescription line chosen should be between 80%-90% but may range from 75-95%. As a result, a hotspot will exist within the PTV that is equal to the prescription dose divided by the prescription isodose line (i.e., $40\text{Gy}/0.75 = 53.3\text{ Gy}$ when 40 Gy is prescribed to the 75% isodose). The preferred location of global maximum dose should be inside the GTV. Doses higher than the prescription isodose (i.e., hotspots) should be manipulated to occur within the target and away from critical structures.

Any dose > 105% of the prescription dose should occur within the PTV and not within the normal tissues outside the PTV.

Note: Deviation Unacceptable occurs when dose limits for Variation Acceptable are not met

Target Volume Constraints and Critical Normal Structure Constrains and Compliance Criteria

| Name of Structure | Dosimetric parameter | Per Protocol | Variation Acceptable* | Notes (Please remove this column when notes are not needed) |
|--------------------------------------|----------------------|--------------|-----------------------|---|
| GTV_4000 | V40Gy[%] | ≥99 | ≥90 | Required for all cases |
| PTV_4000 or PTV_Eval_4000 | V40Gy[%] | ≥ 95 | ≥90 | |
| | D95%[Gy] | ≥40 | >34 and <45 | |
| | D0.03cc[Gy] | ≤ 50 | ≤54 | |
| SpinalCord | D0.03cc[Gy] | ≤8 | <10 | |
| SpinalCord_PRV05 | D0.03cc[Gy] | ≤10 | <12 | |
| BrainStem | D0.03cc[Gy] | ≤10 | <12 | |
| BrainStem_PRV03 | D0.03cc[Gy] | ≤12 | <14 | |
| | D0.03cc[Gy] | ≤42 | <44 | |
| | D50%[Gy] | ≤32 | <34 | |
| Esophagus_S | D0.03cc[Gy] | ≤25 | <30 | Required when treating lesions near skull base |
| Skin | D0.03cc[Gy] | ≤30 | <35 | |
| OpticNrv and OpticNrv_L, OpticChiasm | D0.03cc[Gy] | ≤8 | <10 | |
| BrachialPlex_R and BrachialPlex_L | D0.03cc[Gy] | ≤10 | <12 | |

| | | | | |
|--|--|--|--|----------|
| | | | | low neck |
|--|--|--|--|----------|

*Per Protocol range is excluded from Variation Acceptable range.

Recommended Dose Spillage Criteria, Not for Plan Score

- Conformity:** Acceptable isodose distributions should be as conformal as possible. To this end, the ratio of prescription isodose volume to PTV should be as close to 1 as possible.
 Conformity Index (CI) = Ratio of the prescription isodose volume to the PTV volume.
 The prescription isodose volume will be converted to contour for calculation of this ratio and labeled as V40Gy. [Note: These criteria will not be required in treating very small tumors < 2.5 cm axial GTV dimension or < 1.5 cm craniocaudal GTV dimension].
- Dose fall-off:** Guidelines for the ratio of the 50% prescription isodose volume to the PTV volume (R50%) and for the maximum dose at 2 cm (D2cm) of the PTV are given in Table below. The 50% isodose volume may be elongated deliberately in order to avoid OAR thereby making it difficult to meet the guidelines in Table below. This is acceptable as long as normal tissue constraints are met.

| PTV Volume (cc) | Recommended CI | Recommended ratio of the 50% prescription isodose volume to the PTV volume (R50%) | Recommended maximum dose (Gy) at 2cm from the PTV in any direction (D2cm) |
|---------------------------------|----------------|---|---|
| PTV volume (cc)* < 25 | ≤ 1.5 | < 7.5 | < 26 |
| $25 \leq$ PTV volume (cc) < 50 | ≤ 1.5 | < 6.5 | < 31 |
| $50 \leq$ PTV volume (cc) < 75 | ≤ 1.5 | < 5.7 | < 34 |
| $75 \leq$ PTV volume (cc) < 100 | ≤ 1.5 | < 5.5 | < 36 |
| $100 \leq$ PTV volume (cc) | ≤ 1.5 | < 5.3 | < 37 |

Note *: These criteria will not be required in treating very small tumors (< 2.5 cm axial GTV dimension or < 1.5 cm craniocaudal GTV dimension).

Recommended dose acceptance criteria for other normal tissue, but not to be used for plan score.

| Structure | Recommended dose acceptance criteria |
|--|---|
| E-PTV_4000 | $D1cc[\%] \leq 105$ |
| Bone_Mandible, Joint_TMJ_R and Joint_TMJ_L | $D0.03cc[Gy] \leq 42$ |
| Cavity_Oral | $Mean[Gy] \leq 25$ |
| GlnD_Submand_R and GlnD_Submand_L | $Mean[Gy] \leq 25$ |
| Larynx_GS* | $Mean[Gy] \leq 20$ |
| Pharynx | $Mean[Gy] \leq 20$ |
| Parotid_R and Parotid_L | $Mean[Gy] \leq 15$ |
| Eye_R and Eye_L* | $Mean[Gy] \leq 10$ $D0.03cc[Gy] \leq 42$ |
| Cochlea_R and Cochlea_L | $D0.03cc[Gy] \leq 42$ |
| Lobe_Temporal_R and Lobe_Temporal_L* | $Mean[Gy] \leq 10$ $D0.03cc[Gy] \leq 42$ |

*These structures are considered critical and recommended acceptance criteria should be strictly observed.

Delivery Compliance criteria

| | Per Protocol | Variation Acceptable | Notes (Please remove this column when notes are not needed) |
|---|--------------|----------------------|--|
| Start date (X days/weeks after X) (Please remove this row when the start date is not specified in the protocol.) | | | |

| | | | |
|--------------------------------|------------|--|--|
| Overall Treatment time | 10-15 days | | |
| Minimum time between fractions | 40 hours | | |
| Maximum time between fractions | 5 days | | |
| Interruptions | | | |

5.2.8 Treatment Planning Priorities and Instructions

It is recognized that a portion of the PTV that is close to the skin or critical OARs (e.g. spinal cord, brainstem, optic structures, brachial plexus, carotid artery) may receive significantly less than the prescription dose. This is acceptable in these regions even if cold spots exist within the GTV, as meeting constraints of certain critical OARs must take precedence over tumor coverage. A minimum of 90% of the GTV for the case to be scored as a Variation Acceptable, and a minimum of 85% of the PTV must be covered by the prescription dose for the plan to be scored as Variation Acceptable. Patients with skin involvement, or with PTVs so close to the skin that tissue equivalent bolus must be utilized to ensure adequate dose are ineligible for registration on this protocol.

- Critical Structure and Target priorities must be listed in order of decreasing importance:

1. SpinalCord
2. BrainStem
3. OpticNrv_R and OpticNrv_L, OpticChiasm
4. BrachialPlex_R and BrachialPlex_L
5. Ipsilateral Carotid Artery
6. Skin
7. Esophagus_S
8. PTV_4000 and GTV_4000
9. Larynx_GS
10. Eye_R and Eye_L
11. Lobe_Temporal_R and Lobe_Temporal_L
12. Pharynx
13. Cavity_Oral
14. Bone_Mandible and Joint_TMJ_R and Joint_TMJ_L
15. Parotid_R and Parotid_L
16. GlnD_Submand_R and GlnD_Submand_L
17. Cochlea_R and Cochlea_L

- Required dose calculation algorithms
(Convolution/Superposition, Monte Carlo, etc...)

Acceptable choices of algorithm are listed at
<http://rpc.mdanderson.org/RPC/home.htm>

For Convolution/Superposition type algorithms, dose should be reported as computed inherently

by the given algorithm. For Monte Carlo or Grid Based Boltzmann Solver algorithms, conversion of Dm (dose-to-medium) to Dw (dose-to-water) should be avoided. Dm, computed inherently by these algorithms, should be reported. These principles hold for Pencil Beam type algorithms and for homogeneous dose calculations when allowed for a clinical trial (e.g., conical collimators in stereotactic radiosurgery).

- Primary dataset for dose calculation

The primary dataset for dose calculation must be a treatment planning CT. In the case in which contrast is present during the treatment planning CT, the density of the contrast should be overridden to a representative background electron density.

-Dose matrix resolution

Dose grid size should be ≤ 2 mm in all directions. In presence of small targets or targets in close proximity to critical OARs, dose grid size of 1 mm is strongly recommended.

-List treatment planning recommendations and give link to FAQs

5.2.9 Patient specific QA

- Describe technique and give Gamma pass rate recommendation

Any patient-specific QA that needs to be acquired should follow institutional guidelines and AAPM task group report recommendations.

For IMRT/VMAT plans, patient specific QA is highly recommended. The recommended patient specific QA criteria is for 90% of the comparison points to pass a $\pm 3\%/2\text{mm}$ Gamma Index analysis.

5.2.10 Treatment Localization/IGRT

Image-guided radiation therapy (IGRT) is radiation therapy using imaging to facilitate accuracy and precision throughout its entire process. In this section we use the terminology IGRT to focus on image-guidance at the time of radiation delivery to ensure its adherence to the planned treatment, with computer assisted process, i.e. image handling together with calculation of shift and rotations (if available) must be determined with computer assistance.

The following information should be provided for localization guidance

* Will simple isocenter localization technique be used at beginning of treatment and weekly thereafter?

* Are all IGRT techniques included?

* Is IGRT tied to margin reduction?

* The time points of imaging (e.g. before, mid, after treatment)? This should be decided based on immobilization, treatment margin, etc.

* Allowed image guidance methods: 2D x-ray, 3D-xray, electromagnetic localization, optical surface imaging, other

Image registration techniques: fiducial markers, bone as surrogate, soft tissue, other

* Give recommendations for correcting (e.g. correcting for linear shifts less than 1 mm is not recommended)

* Other

At beginning of treatment for every fraction, capability should exist to define the positions of targets within the patient anatomy according to 3-D coordinate system. By doing that, the patient could be set up for each delivery with the intention of directing the radiation toward an isocenter or target. Angular as well as translational couch corrections are strongly recommended. The following techniques are acceptable for image-guided radiation delivery, although cone-beam CT is strongly recommended:

- a) Cone-Beam CT device mounted on the linear accelerator. The CT images can be generated by using either MV treatment beam or kV auxiliary equipment attached to the accelerator. Before delivering radiation, on-board imaging might be obtained at every fraction on the treatment unit for verifying the isocenter of treatment fields.
- b) Fan-Beam CT device equipped to the helical beam delivery accelerator, which uses the MV beam to acquire helical CT images for localization.
- c) Diagnostic CT device sharing the treatment couch with the linear accelerator.
- d) kV x-ray devices mounted on wall or floor that produce orthogonal or near-orthogonal projection views of a patient in the treatment position.

The accuracy of localization should be ≤ 1.5 mm during the treatment. Any shifts made to align the pretreatment IGRT imaging ≥ 3 mm requires repeat imaging and confirmation of alignment prior to the administration of SBRT.

5.2.11 Case Review

The Principal Investigators, XXX, MD will perform ongoing remote RT Quality Assurance Review after cases enrolled have been received at IROC Philadelphia-RT.