Thank you for participating in this Lung Target Delineation Project being done in conjunction with the SWOG Radiation Oncology Committee. Without your efforts, this project would not be possible.

A few reminders:

- To receive honoraria credit for participation, all 4 cases must be contoured, planned and submitted to QARC twice: once for Phase I and once (several months later, with new instructions) for Phase II.
- Please contour/plan in a manner approximating, as closely as possible, an actual SWOG case submission.
- At the conclusion of the study, you will receive individual feedback, allowing comparison of your contours to other users (anonymously).

Directions:

Participants are to execute the following instructions as specified:

1. Submit contours/treatment plan to QARC (see instructions following the RT section below).
2. Complete the SWOG Lung Target Delineation Study survey. Save the completed survey and send it via e-mail to FLaurie@QARC.org.

Following submission of all required data and electronic survey, you will be asked (after a specified interval to eliminate recency effects) to re-contour and re-plan the same case a second time (Phase II), potentially with modified instructional or imaging data.

At that time, do not reference or utilize the initial plan in any manner or study data may be compromised

Executive Summary of Thoracic Radiotherapy (TRT)

Three-dimensional CT or FDG-PET-CT scan planning is required, using a dose calculation algorithm that takes into account tissue heterogeneity. The target volume will be defined by both imaging and clinical evaluation. The clinical target volume (CTV) for the radiation fields will be the primary tumor, plus *involved* mediastinal, ipsilateral paratracheal lymph nodes (levels 2 and 4), and ipsilateral supraclavicular nodes. The total planned dose will be 54 Gy prescribed to an isodose line that encompasses the planning target volume (PTV) and that satisfies the dose uniformity guidelines *vide infra*. This will be delivered in 30 (thirty), once daily fractions of 1.8 Gy each, to a total dose of 54 Gy to the PTV. The percent of normal lung receiving 20 Gy or more (V20) must be less than 37%.

Data submission

Submission of treatment plans in digital format (DICOM RT format) is required. Instructions for data submission are on the QARC website at www.QARC.org under Digital Data.

NOTE: Submission of plans in RTOG Data Exchange Format is not allowed on this study

Simulation Guidelines

a. A protocol compliant CT-Sim data set is available on the QARC website at www.QARC.org for completion of this study.
b. The included data set may include a multi-phase 4DCT, as well as an un-fused PET/CT dataset.
c. All contouring efforts for this study are to be undertaken on the radiation oncology physician's treatment planning system (TPS) of choice, provided the capacity for DICOM-RT export is present (*vide infra*).
d. For all target volumes/normal structures defined in the TPS, please use the specified ROI designation (bolded, as below), in all capital letters, without spaces (e.g. **GTV_P**, not **gtv _ p**).

Target Volume Definition

a. The definitions of volumes will be in accordance with ICRU Reports #50 and 62.
b. GTV: The primary tumor (**GTV_P**) and clinically positive lymph nodes (**GTV_N**) seen on the pretreatment PET scan (SUV > 3), diagnostic CT scan, and/or treatment planning CT (> 1 cm short axis diameter) will comprise the GTV. The GTV will always be located in the apex of the ipsilateral lung in this particular study. This volume(s) may be disjointed.
c. ITV (if used): The **ITV** includes the envelope that encompasses the tumor motion for a complete respiratory cycle.
d. CTV: The **CTV** is defined to be the GTV plus a 0.5 cm to 1 cm margin as appropriate to account for microscopic tumor extension. The ipsilateral paratracheal lymph nodes (levels 2 and 4) and supraclavicular fossa lymph nodes will be defined as comprising part of the CTV for this protocol. If an ITV approach is used then the ITV plus 0.5 cm to 1 cm is added to the ITV to form the CTV. Elective treatment of the entire mediastinum will not be done. If a uniform margin is used for CTV expansion, please specify **CTV_xxMM**, where xx= the margin expansion in

millimeters, as structure name (e.g. **CTV_05MM** denotes a 5 mm expansion margin); if a non-uniform margin is used, please designate the volume **CTV.**

e. PTV: The PTV margin should account for setup uncertainties and may be individualized. The PTV will comprise the CTV with a minimum 0.5 cm (if daily imaging correction will be used), or a minimum 1.0 cm if daily imaging will not be performed. If a uniform margin is used for PTV expansion, please specify **PTV_xxMM**, where xx= the margin expansion in millimeters, as structure name (e.g. **PTV_05MM** denotes a 5 mm expansion margin); if a non-uniform margin is used, please designate the volume **PTV.**

Organs at Risk to be Defined

The normal anatomy to be outlined on each CT image will include:

- *bilateral lungs (titled **LUNG_L** and **LUNG_R**)*
- *composite lung volume (titled **LUNG_TOTAL**; equivalent to LUNG_L and LUNG_R)*
- *heart (**HEART**)*
  - *The heart should be contoured from its base to apex, beginning at the CT slice where the ascending aorta originates.*
- *skin (**SKIN**)*
  - *The skin should be contoured on each CT slice.*
- *esophagus (**ESOPH**)*
  - *The esophagus should be contoured from the bottom of the cricoid to the level of the carina (for N0-N1) and gastroesophageal junction (for N2).*
- *spinal cord (**CORD**)*
  - *The spinal cord should be contoured on each CT slice.*
- ***bilateral** brachial plexi (**BRAC _L** and **BRAC_R**)*

Target Dose Prescription Guidelines

a. Prescribed Dose and Fractionation: The total dose to the PTV will be 54 Gy given in 30 fractions. The patient will be treated with one fraction per day.

b. Prescription Specifications: The entire PTV shall receive at least 93% of the protocol dose and a contiguous volume of no more than 2 cc within the PTV shall exceed

120% of the protocol dose. The MTD will be quoted as the PTV minimum target dose. The maximum and minimum point doses *(within the PTV)* will be reported.

c. Tissue Heterogeneity Corrections: All radiation doses will be calculated with inhomogeneity corrections that take into account the density differences within the irradiated volume (i.e., air in the lung and bone).

Treatment Planning

a. Intensity Modulated Radiation Therapy (IMRT):

1. IMRT mock-planning must be performed using an approved dose calculation algorithm. Approved algorithms include: convolution superposition, collapsed cone convolution, and Monte Carlo.
2. IMRT treatment planning systems used must have the capacity to export DICOM 3.0 format.
3. The total planned dose will be 54 Gy prescribed to an isodose line that encompasses the planning target volume (PTV) and that satisfies the dose uniformity guidelines *vide infra*. This will planned in 30 (thirty), once daily fractions of 1.8 Gy each, to a total dose of 54 Gy to the PTV.

b. *Dose Constraints for OAR's:* The following dose constraints shall be used for planning:

Highest priority = Cord (50 Gy)

2nd highest priority= Lungs total, defined as the total lung volume minus the CTV (V20 $\leq$ 37% total or mean lung dose $\leq$ 20 Gy)

3rd highest priority= Ispilateral brachial plexus (< 60 Gy)

4th highest priority= Esophagus (mean dose < 36 Gy)

5th highest priority= Heart ($\leq$ 1/3 may receive up to 60 Gy, $\leq$ 2/3 may receive up to 45 Gy, & the whole heart may receive up to 40 Gy

Definitions of Deviations in Protocol Performance for dose, uniformity, and volume:

Dose

1. Compliant: ≥ 99% of the PTV receives ≥ 93% of the protocol dose, and a contiguous volume of no more than 2cc inside PTV exceeds 120% of the protocol dose.

2. Minor deviation: Between 95% and 99% of the PTV receives 93% of the protocol dose or a contiguous volume of more than 2cc inside the PTV exceeds 120-125% of the protocol dose.
3. Major deviation: More than 1 cm^3 of tissue outside the PTV receives ≥ 120% of the protocol dose, or less than 95% of the PTV receives 93% of the protocol dose, or a contiguous volume of more than 2cc inside the PTV exceeds 125% of the protocol dose. Doses in this region are not acceptable.

Volume

1. Minor Deviation: Omni-directional margins >0.5 cm greater than specified, margins less than specified, or field(s) <1 cm greater than specified.
2. Major Deviation: GTV not encompassed fully by ITV, CTV or PTV, fields transect tumor or specified target volume(s), or fields are more >1 cm greater than specified.

Critical Organ

1. Minor Deviation: Major Deviation: The maximum dose to organ(s) at risk exceeds the limits specified (vide supra) by < 5%.
2. Major Deviation: The maximum dose to organ(s) at risk exceeds the limits specified by ≥ 5%.

Review

The data shall be sent to:

Quality Assurance Review Center
640 George Washington Highway, Suite 201
Lincoln, RI 02865
Phone: 401/ 753-7600
Fax: 401/ 753-7601
Web: http:\\www.qarc.org

Institutions are required to submit the treatment plan in digital format. An institution's treatment planning system must have the capability of exporting data in DICOM 3.0 in compliance with the Advanced Technology Consortium's (ATC) DICOM 3.0 Conformance Statement. A list of commercial systems that are known to have this capability is on the ATC Website at: (http://atc.wustl.edu/credentialing/atc_compliant_tps.html).

NOTE: Submission of plans in RTOG Data Exchange Format is not allowed on this study.

The digital data may be sent electronically to QARC via ftp or on by courier on CD. Instructions for digital submissions may be found on the QARC Website - www.qarc.org, under Digital Data, RT Treatment Planning.

Digital data submission shall include:

- Target volumes and normal structures (as above)
- Beam geometry
- DVHs for the total treatment for all PTV's and for any normal structures in these volumes. If IMRT is used, a DVH shall also be submitted for a category of tissue called "unspecified tissue," which is defined as tissue contained within the skin, but which is not otherwise identified by containment within any other structure.
- Treatment planning system summary report that includes the monitor unit calculations, beam parameters, calculation algorithm, and volume of interest dose statistics.

All questions regarding this protocol should be directed to:

Charles R. Thomas, Jr., M.D.
Oregon Health and Science University
Department of Radiation Medicine
M/C KPV 4
3181 SW Sam Jackson Pk Rd
Portland, OR 97239-3098
Phone: 503/494-8758
Fax: 503/346-0237
Email: thomasch@ohsu.edu