SWOG
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Policy Memorandum No. 26 **Page 1 of 20 pages**
Subject: Radiation Therapy **Original Release Date:** July 1985
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THE SWOG
RADIATION THERAPY QUALITY ASSURANCE COMMITTEE

A. RADIATION THERAPY (RT) QUALITY ASSURANCE (QA)

One of the requisites of the National Cancer Institutue (NCI) National Clinical Trials Network (NCTN) is that Network Groups must have an RT QA program in place. In February 2003, SWOG arranged to have the Quality Assurance Review Center (QARC) provide RT QA services for all SWOG studies. This arrangement is structured through the NCI, Division of Cancer Therapy Evaluation Program (CTEP). QARC has worked with SWOG to tailor its RT QA program. The components of this program are described below.

QARC was founded in 1980. QARC collects and reviews Radiation Therapy and Diagnostic Imaging Data in support of Cancer Clinical Trials for the Network Groups sponsored by the National Cancer Institute for many of the NCI Network Groups. QARC strives to improve the standards of care in the management of cancer by advancing the quality of clinical trials. QARC is a program affiliated with the University of Massachusetts Medical School.

B. RADIATION THERAPY QA PROGRAM COMPONENTS

I. Protocol Development

The conduct of a quality multi-institutional trial relies substantially on the quality of the protocol document. QARC reviews the protocol to assure that the scientific question asked in the study can be achieved with the RT proposed. QARC ensures that the radiation section is consistent with all sections throughout the document. QARC helps Study Chairs write the radiation section in a clear, concise and technically achievable manner to ensure the implementation of a uniform delivery of radiation across institutions. It is critical that protocols allowing many of the advanced technologies, such as Intensity Modulated Radiation Therapy (IMRT), follow stringent guidelines directed by the NCI. QARC provides the appropriate language and list of materials to be submitted for QA documentation. QARC assists Study Chairs in writing guidelines that can be compatible with a wide variety of capabilities while maintaining a standard to ensure uniformity.

II. Site Credentialing (Benchmarks) and Physics QA

By use of a Radiation Oncology Facility Survey (see Appendix A) questionnaire, QARC learns of all of the responsible clinical and technical contacts at each RT facility. To verify that the facility performs RT that meets community standards and requirements of SWOG studies, QARC requires the completion of benchmarks. The specific benchmark(s) that is required in a study is determined by the prescribed radiation treatment.

The ability of every institution to satisfactorily plan and perform dosimetry (or dosimetric) calculations according to protocol requirements is assessed by benchmark cases. These are sample cases that present typical treatment planning problems encountered in the study. Institutions must demonstrate acceptable planning and calculational methods. SWOG requires a benchmark for certain treatment techniques. These include: Total Body Irradiation (TBI), Stereotactic Radiosurgery (SRS), 3-Dimensional treatment planning and IMRT. The benchmarks allow QARC to evaluate the institution's problem solving approach and methodology. As advanced technologies change the radiation oncology discipline, other benchmarks may be developed. QARC participates in a collaborative effort with the Radiation Therapy Oncology Group (RTOG) and the Radiological Physics Center (RPC) to standardize the benchmarks and avoid duplication for RT departments participating in SWOG and the RTOG.

III. Radiological Physics Center (RPC)

QARC works closely with the RPC at the MD Anderson Cancer Center in Houston. The NCI mandates that all radiation equipment used in the treatment of protocol patients be monitored by the RPC. The RPC monitors radiation therapy facilities with on-site and off-site methods. On-site dosimetry reviews are performed to help institutions resolve problems and to verify the validity of important mechanical and radiation parameters used by the institution for each therapy unit. Routine on-site visits are not practical for the number of participating RT facilities. Therefore, several "off-site dosimetry review" auditing techniques are used. All Network Group RT facilities must participate in the mail-in thermoluminescent dosimetry (TLD) program to verify machine output on a periodic basis. Additionally, the RPC may require comparison of the institution's dosimetry data with RPC "Standard dosimetry" data to identify potential problems in the data used for patient dose calculations; evaluation of reference/or actual patient calculations to verify treatment planning algorithms; and, review of institution's written QA procedures and records.

IV. Data Management and Case Evaluation

Data Acquisition

Once a protocol is activated and as patients are enrolled, SWOG notifies QARC of each registration. The patient is entered into the QARC database and the expected RT date is determined. QARC has adopted a pro-active approach to data collection. At the time each patient is due to begin radiotherapy, a notice is sent to the Clinical Research Associate (CRA) as a reminder that data should be submitted for the Rapid Review (required by protocol) or at the completion of treatment. For patients who had a Rapid Review, summary data should be submitted to QARC at the completion of therapy. Data that is not received will be requested through an interim report to the CRA and the responsible radiation oncologist at each institution two or three times a year. If data remain incomplete for more than six months beyond the completion of therapy, a warning letter is sent to the responsible radiation oncologist with a copy to the Principal Investigator of the registering institution. This advises them that the patient's file will become unevaluable for QA purposes unless all of the required data is submitted to QARC.

Electronic Imaging

Submission of Diagnostic Imaging Data in digital format is preferred over hard copies of films. Digital files must be in DICOM format. These files can be burned to a CD and mailed to QARC. Multiple studies for the same patient may be submitted on one CD; however, please submit only one patient per CD. Individual protocols may use AG Mednet for transmission of images.

RT Objects

QARC is working towards accepting RT objects in an electronic format (DICOM RT objects or RTOG data exchange format). Please contact QARC at 401/454-4301 for further information about submitting data in this format.

Case Evaluations

All patients entered on SWOG studies with RT components undergo an evaluation to determine whether or not the patient's treatment is in accordance with the protocol guidelines. Some studies require an early review performed while the patient is on treatment. This early interventional review is known as a Rapid Review. Studies requiring Rapid Review will also include a Final Review.

Rapid Review

The Rapid Review is an important function that QARC performs for SWOG. This review may be conducted within the first few days of the initiation of therapy or may be required prior to the patient beginning radiation treatment. Data including the staging information, diagnostic imaging, the treatment plans including target volumes and dosimetry arrive at QARC within the time specified by the protocol guidelines. These are assessed by the CRA at QARC to determine that all of the necessary information is included. The dosimetry staff at QARC reviews the treatment plan to ensure that it meets the protocol requirements. QARC Radiation Oncologists will perform a clinical review of the material to ensure that the treatment volumes and treatment plan meet the protocol requirements. When the submitted data meet the protocol requirements, a fax is sent to the treating physician to inform him/her that the planned treatment is according to protocol. A second review while the patient is still under treatment may be required to ensure that the plan has been modified appropriately.

The Rapid Review data will be reviewed by a radiation oncologist and a radiological physicist or dosimetrist within 48 hours of receipt at QARC. An evaluation will include, but not necessarily be limited to, the following:

- Review of the treatment volumes
- Review of the treatment planning and/or Diagnostic Imaging Data
- Review of the computed treatment plans as specified in the protocol

In the event that there is a suggestion of protocol variation, either major or minor, QARC will immediately contact the radiation oncologist at the participating institution.

The aim of the Rapid Review is to ensure that all patients are treated according to the protocol guidelines in a uniform manner to validate protocol analysis.

Final Review

Once the patient has completed treatment, summary data of the complete course is submitted to QARC. These data include copies of the treatment chart, treatment plans, isodoses and dose calculations for subsequent volumes treated after the initial review, e.g., boosts. The complete course of therapy is reviewed by QARC's dosimetry staff. The fraction dose, the total dose, number of fractions, elapsed time, patient position, modality and specified doses for uniformity or normal tissue concerns are compared to the requirements of the protocol. When a sufficient number of completed patients on a protocol or group of related protocols have completed RT and have been reviewed at QARC, a Final Review meeting is scheduled.

The responsible Study Chair(s) are invited to participate in this session. This joint review is a unique aspect of the QARC program. It allows an interaction between clinical and physics staff so that a comprehensive evaluation of the patient's therapy can be completed. Upon completion, a final summary is sent to the responsible radiation oncologist detailing the evaluation of his/her patient. A copy of this summary is sent to the Primary Study Chair and the RT Study Chair. The Final Review verifies that the prescribed treatment was carried out to completion as per protocol. It confirms that treatment was completed as initially described in Rapid Review. The Final Review includes further submission of additional films and isodose distributions or other material as outlined in the protocol.

Final Review materials are to be mailed to QARC at a time specified within the protocol, often no later than 30 days after the last day of radiation therapy. Data are stored in a database at QARC to indicate the level of compliance with the protocol radiotherapy.

Final Review will be carried out by SWOG RT Study Chair in cooperation with the QARC Radiation Oncologist and Dosimetrist. The Final Review form will bear the signature of the QARC Radiation Oncologist and the date of Final Review. The QARC Evaluation Form will be used to indicate the level of compliance with the protocol radiotherapy. QARC will send a report to the RT Study Chair, the radiation oncologist and CRA of the registering institution.

The radiation oncologist may submit the case to the Chair of the RT Committee in case of disagreement.

Data Transfer/Institutional Performance

Details of the RT delivered to each protocol patient and the agreement of the treatment to the protocol requirements are stored in the QARC database. These treatment data are transferred to SWOG for use in the study analysis. Additionally, data to determine an institution's compliance with the data submission guidelines and the protocol requirements are used by SWOG to assess institutional performance.

C. QUALITY CONTROL SUBCOMMITTEE

The function of the Quality Control Subcommittee (QCS) is to ensure the highest standards of radiation therapy in compliance with protocol treatment. The QCS is the responsibility of the Chair of the RT Committee. The QCS develops guidelines to ensure this standard of radiation therapy in protocol design and quality assurance of radiation therapy. The QCS oversees the performance of QARC. QARC reports institutional performance on an annual basis to the QCS. This committee meets in conjunction with the SWOG Meetings.

I. Functions of the Quality Control Subcommittee

1) Develop, implement and periodically review guidelines for evaluation of eligibility for membership in the Group. These evaluation criteria will apply both to new applicants as well as to the ongoing evaluation of performance of member institutions and individuals.

2) Review institutions and individuals according to these guidelines and submit a report on such reviews to the Chair of the RT Committee.

3) Review for the Statistical Center, the progress of ongoing clinical trials in terms of satisfactory quality of radiation therapy data.

4) Report the Subcommittee's findings to the Chair of the RT Committee prior to the Committee meeting at the semi-annual meeting of SWOG, to allow discussion and to initiate steps to maintain the scientific quality of cooperative trials.

5) Review new protocols with the aim of a clear definition of radiotherapy aspects and inclusion of quality control measures as proposed by the QCS.

6) Develop guidelines and procedures for Rapid Review of radiation therapy data and treatment plans, including a mechanism to correct apparent deficiencies in cooperation with the Director of the QARC.

7) Develop workshops at Group meetings to assist institutions and radiation therapists in compliance with protocol treatment. This activity should be integrated into the educational efforts of the RT Committee.

II. Membership of the Quality Control Subcommittee

The Chair of the QCS will be appointed by the Chair of the RT Committee. The Statistical Center, Operations Office and RPC will appoint a representative as a member of the QCS. Staff from QARC including the Director, Director of Operations, Senior Physicist and SWOG CRA will regularly attend the meetings of the QCS. Other members of the QCS will be appointed by the Chair of the QCS.

Quality Control Subcommittee appointments will follow the term of the RT Committee Chair.

III. Meetings

Meetings of the QCS will be held at each semi-annual Group meeting, or as called by the Chair.

IV. Procedures

Decisions of the QCS will be made by majority vote of members present. Such decisions or recommendations will be in the form of a report to the Chair of the RT Committee.

D. POLICY/GUIDELINES FOR RADIATION THERAPY PARTICIPATION IN GROUP PROTOCOLS

Minimum RT Requirements:

- The treating radiation oncologist must be a radiation oncologist on staff at an RT facility that is a site approved by SWOG. The **registering** physician, whether a medical or radiation oncologist, must be a member of SWOG. A radiation oncologist must be board eligible to be a Group member. Treating radiation oncologists who are not members of SWOG do not need board certification as long as they treat the patient at an approved RT facility.

- Megavoltage Equipment (^{60}CO, 2 MV X-ray or greater).

- Minimum SSD, SAD, TSD or TAD: 80 cm.

- Capability of obtaining field length of 30 cm at 80 or 100 cm.

- Simulation equipment.

- Provision must be available for individual field shaping, i.e., cerrobend blocks or individually cut lead blocks.

- Adequate equipment and personnel capable of treating all fields each treatment day on each patient.

Physics Support:

- Equipment and personnel for calibration and periodic quality control procedures as prescribed by the RPC. This includes a radiological physicist.

- Computed multiportal isodose summations.

- Computed multiple point calculations on irregular field treatments, i.e., means of measuring changes in SSD, provisions for off-axis calculation of TAR or % depth dose, etc.

General:

- Equipment and personnel for copying of portal and localization films.

- Clerical assistance to provide copies of pertinent data to the RT Committee, QARC, RPC, Statistical Center and Operations Office as required.

NOTE: Many protocols will require benchmarks that are in excess of the minimum requirements.

E. EVALUATION PROCESS FOR NEW APPLICANTS

Individual radiation oncologists desiring to become Group members must be recommended for membership. Investigators at full Group and NCORP institutions are recommended by the Principal Investigator; Affiliate investigators are nominated by the Principal Investigator from the full Group institution with which they will affiliate. The current curriculum vitae must accompany the nomination letter. Radiation oncologists must be board eligible in order to become approved for membership in SWOG. Nominations are submitted to the Operations Office which in turn are submitted to the Group's membership reviewer. Final recommendations are reported to the Board of Governors at each semi-annual Group meeting for endorsement and approval. An institution desiring the approval of its radiotherapy facility must complete the questionnaire (see Appendix B) containing vital information regarding the RT facility. These questionnaires will be reviewed by the Chair of the RT Committee. Specific approval for the institution to participate in stereotactic radiosurgery protocols will be based on satisfactory performance on the standardized QARC Benchmark.

The Chair will provide approval or disapproval (pending further information) for each facility. Notices of approval or disapproval are provided to the RPC, Operations Office and the RT facility. Once approved, registrations to protocols containing RT are then accepted. At each semi-annual Group meeting, the list of facilities that have been granted approval within the last six months is circulated to the RT Committee members.

Institutions may participate in radiation therapy-containing protocols approved for their institution, as long as the facility has been reviewed and approved by the RT Committee.

F. EVALUATION OF PARTICIPATION IN GROUP RT STUDIES

I. The performance of all institutions will be rated as to their adherence to protocol treatment plans and information reporting requirements.

II. Data regarding therapy at Group, NCORP and Affiliate facilities will be evaluated individually.

III. Radiation oncologists will be responsible for the submission of their RT data to the Study Chair through the Principal Investigator of the sponsoring member institution.

IV. Patients must receive their RT at one of the SWOG-approved RT facilities. No patient will be allowed to register on a study in which RT may be given unless the patient's planned course of RT is to be at a Group-approved RT facility.

V. If compliance with the submission requirements of materials for Rapid Review (QARC review) and after completion of radiotherapy drops below 90% over a two-year window period, the Group Chair will be notified and action will be taken consistent with the current Group policy on Institutional Performance Review (see Policy No. 33). It is recommended that a warning letter be sent to the poorly-performing institution. If compliance has not improved after six months, the institution will be put on probation. If the deficiencies are not corrected by the next Group meeting, the institution will be suspended relative to its radiation therapy participation in protocols for a period of six months, following which the institution returns to probationary status for a further six months. If performance is still not adequate, participation in studies containing RT will be subject to review by the QCS.

VI. Institutions and individuals may appeal decisions by the QSC through the Chair of the RT Committee and the Group Chair.

VII. Benchmarks might be required from time to time and compliance with these will be required for continued participation.

G. GUIDELINES FOR PREPARATION AND APPROVAL OF GROUP PROTOCOLS INVOLVING RT

The RT section of the protocol must indicate in detail the following (see sample protocol in Appendix C):

- Equipment and beam factors acceptable under the protocol.
- Target volume described in anatomic terms, including diagrams where appropriate.
- Dose distribution in the target volume and how the dose distribution will be determined.
- Total dose to be delivered, including dose variations permissible under the protocol across the target volume and acceptable interruptions of treatment.
- Dose fractionation and frequency of treatment.
- Prescribed changes in portal size must include description of the anatomic area to be covered in a boost dose and how this will be determined as well as prescribed changes in fractionation.
- Treatment planning, i.e., simulator and/or portal films, points of computer calculation of dose, etc.
- Necessary material to be submitted for Rapid and Final Review of the protocol treatment, as well as dates for mailing.
- Material to be submitted to the QARC must be specifically identified: e.g., copies of simulator and/or portal films, dose calculations including computer calculations, patient contours or description of measurement, staging information, demographic information, radiotherapy treatment records or any other information which may be needed.
- All protocols must include appropriate informed consent information outlining the radiation therapy, including the expected side effects and complications. Other statements as may be desirable or required by Federal, State, or local authorities or the local Clinical Investigation Review Committee should be added.
- All protocol proposals must be submitted by the Study Chair to the Operations Office for review and distribution to the Chair of the RT Committee, the Statistical Center and to the RPC (All protocols containing radiation therapy must have an RT Study Chair assigned who is responsible for the radiation aspects of the protocol.)
- A copy of each reviewer's critique will be forwarded to the authors, the Chair of the disease oriented committee and the Operations Office.
- After a suitable review period, the protocol critiques will be returned to the author by the Operations Office for appropriate revision.

- To be acceptable, the radiation therapy portion of a protocol should follow the format of the sample protocol which forms Appendix C of these guidelines. The Operations Office will inform the Statistical Center when patients may be entered on a new protocol.

H. QUALITY CONTROL REVIEW OF RADIOTHERAPY PROTOCOL TREATMENT IN GROUP STUDIES

The treating radiation oncologist should be consulted prior to patient registry on all those protocols which contain radiotherapy as a mode of treatment.

Radiation Therapy Quality Control will commence when a patient is randomized to receive RT as part of their protocol treatment, or when a patient is entered in a non-randomized study involving RT. Prior to randomization or entry of a patient in a non-randomized study, the participating radiation oncologist is strongly recommended to consult with the RT Study Chair regarding any aspects of the protocol which may be unclear. If the RT Study Chair is not available, the Chair of the RT Committee is prepared to assist in protocol compliance prior to treatment.

The Statistical Center will immediately inform QARC of the registration, the arm to which the patient has been randomized, and other important information, e.g., the expected start date of radiation therapy.

All information has to be sent to QARC and labeled with the case number, patient's name and any other pertinent information which may be necessary.

If insufficient data has been received for Rapid Review, QARC will contact the radiation oncologist at the participating institution.

I. MISSING INFORMATION

While complete information is usually required for Rapid or Final Review, it is realized that occasionally certain records may not be available. In such a case, the radiation oncologist must document the reason why this information will not be forthcoming and this must be sent to QARC so that it becomes part of the documentation for the Final Review. Cases with incomplete data at the time of Final Review will be considered unevaluable if no explanatory documentation is received at QARC.

J. CRITERIA FOR EVALUATION

Radiotherapy Deviations - Deviation criteria are defined within the specific protocol guidelines.

APPENDIX A

QARC
QUALITY ASSURANCE REVIEW CENTER

Please return by Fax: 401- 454-4683
Radiation Oncology Facility Survey
Version Date: 2-27-2004

The Quality Assurance Review Center (QARC) is a Data and Review Center, providing radiotherapy quality assurance and diagnostic imaging data management programs for several NCI supported Network Groups and international pharmaceutical companies. QARC is an established research resource for clinical investigators around the world.

In an effort to maintain up-to-date records, please complete the Radiation Facility information below. Your time is appreciated.

Submit Survey to:

QARC

Attn: Maryann Bishop-Jodoin

272 West Exchange St., Suite 101

Providence, RI 02903-1025

For questions regarding this form contact MJodoin@QARC.org

Individual Completing Survey:

Name: _____

Phone: _____

Email: _____

Name of Radiation Oncology Facility: _____

Address: _____

_____

_____ **Country:** _____

Phone: _____ **Fax:** _____

Is this Facility also known by any other name? If so, please provide: _____

_____

Mailing Address (if different from above): _____

_____

_____

_____

Name of Registering/ Referring Institution(s): _____

_____

Responsible Radiation Oncologist:

Name: _____ **Email:** _____

Facility: _____

Address: _____

_____

Phone: _____ Fax: _____

Radiotherapy Coordinator- Primary Contact in Radiation Oncology (The person within RT who will triage questions):

Name: _____ **Email:** _____

Facility: _____

Address: _____

_____

Phone: _____ Fax: _____

Other Radiation Oncologists Who May Be Treating Patients:

Name: _____ **Email:** _____

Name: _____ **Email:** _____

Name: _____ **Email:** _____

Name: _____ **Email:** _____

Physicist Responsible for Protocol Compliance:

Name: _____ **Email:** _____

Facility: _____

Address: _____

_____

Phone: _____ Fax: _____

Person Responsible for Protocol Patients Dosimetry:

Name: _____ **Email:** _____

Facility: _____

Address: _____

_____

Phone: _____ Fax: _____

Does this site participate in the Radiological Physics Center's (RPC) Thermoluminescent Dosimetry (TLD) survey program (required)?

Yes _____ No _____ Date of last survey: _____

APPENDIX B

SWOG

DATE: _____

Return to: Paul Okunieff, M.D.
Univ of Florida Shands Cancer Ctr
2033 Mowry Rd, Ste 145
PO Box 103633
Gainesville FL 32610-3633
Phone: 352-273-8010
FAX: 352-273-8109

I. RADIATION THERAPY DEPARTMENT DATA:

Name of hospital, office or clinic	Street address
Therapeutic radiologist-in-charge	City, State and Zip
Member Institution for Affiliates and indicate if AFFILIATE or NCORP (**Please indicate one.**)	(Area code) Phone number
Name of Radiation Therapy Contact Person	Phone # for Contact person if different from above
FAX number	email address for contact person

II. CLINICAL PERSONNEL: Indicate whether full-time or part-time

A. Radiation Oncologists: Indicate how much time spent at member institution, AFFILIATE institution.

_____

_____

_____

B. Technologists: Indicate whether certified RTT

_____

_____

_____

C. Radiological Physicists and Dosimetrists:

_____

_____

_____

D. Other: (Including Data Managers & Nurse Oncologists)

_____

_____

_____

III. PATIENT CASELOAD:

A. Please give most recent annual statistics and indicate year from which these data are derived:

Year: _____

Total patients treated: _____
(give number)

IV. FACILITIES:

Total square footage _____

V. EQUIPMENT:

Please provide the following information for treatment machines, dosimetry computer, simulator, etc.

Type of Equipment	Manufacturer/Model	Year of Acquisition	Special Features (if any)

VI. RADIATION PROTECTION:

1. Please name the designated Radiation Safety Officer for your department.

_____

2. Name the individual who performs regular calibration of your therapeutic radiologic equipment and give the frequency of these services.

_____

_____

APPENDIX C

SAMPLE PROTOCOL

The following information should be collected at registration:

The radiotherapy facility name, radiation oncologist name and the planned start date for radiotherapy must be provided at the time of registration.

TREATMENT - EXAMPLE (S0222)

Radiation Therapy Treatment Guidelines are inserted into Section 7.0 (Treatment Plan). The following is an example of the type of information included and the format used.

7.4 Chest Radiation Therapy

Chemotherapy should be given prior to the daily radiation. Radiotherapy is strongly recommended to begin within 1 - 3 hours of TPZ infusion. Day 1 of radiation therapy must be a Monday, Tuesday or Wednesday, but no later in the week. Refer to Section 12.1 for Radiation Therapy Review.

3D conformal treatment planning is required for this study. Centers must demonstrate their ability to do 3-dimensional CT planning by successfully completing benchmark material through the Quality Assurance Review Center (QARC). An approved 3D benchmark must be either already on file at QARC or the benchmark material must be submitted by the time the final submission of the radiation forms. The benchmark material can be obtained from the QARC website (www.QARC.org). It is only necessary to complete the 3D benchmark once to be approved for any of the protocols that QARC monitors, unless the 3D treatment planning system has changed.

NOTE: Intensity Modulated Radiation Therapy (IMRT) is not allowed on this protocol.

NOTE: G-CSF will not be allowed during radiation therapy. Epogen use will be left up to the discretion of the treating physician.

a. Equipment

1. All fields must be simulated by a standard radiotherapy approved-use simulator.

   Treatment planning for this protocol requires CT simulation for the boost, and also the initial fields in order to meet protocol requirements for normal tissue doses, dose volume histograms, etc. CT information can be transferred to the treatment planning system using either a dedicated CT simulator or a CT in which a flat tabletop is utilized.

2. Only linear accelerators generating photons with peak energy ≥ 4 MeV will be used.

3. The calibration of therapy machines used in this protocol will be verified by the Radiological Physics Center (RPC).

b. Target Dose

1. Prescription Point: The prescription point is at or near the isocenter.

2. Dose Definition: Dose is specified in cGy to muscle.

3. Prescribed Dose and Fractionation:

Initial fields: The total dose to the prescription point will be 4,500 cGy given in 25 fractions. The patient will be treated with one fraction per day, except holidays, with all fields treated per day. 180 cGy will be delivered to the isocenter.

Boost fields: The total boost dose will be 1,600 cGy given in 8 fractions. The patient will be treated with one fraction per day, except holidays, with all fields treated per day. 200 cGy will be delivered to the isocenter. (See Section 7.5)

4. Treatment Technique: The initial fields may be treated by either AP/PA or any other field arrangement that covers the target volume described below. The use of IMRT is not allowed in this study.

5. Tissue Heterogeneity: No corrections are to be made for tissue heterogeneities.

6. DOSE UNIFORMITY: THE DOSE VARIATION IN THE TARGET VOLUME WILL BE +7% AND -5% OF THE PRESCRIPTION POINT DOSE. THIS APPLIES TO ALL PHOTON TREATMENT TECHNIQUES. WEDGES, COMPENSATORS AND OTHER METHODS OF GENERATING A UNIFORM DOSE DISTRIBUTION ARE ENCOURAGED.

7. Isodose Plans: A hard copy of the isodose distribution for the composite plan will be submitted. Isodose distributions will be displayed, if possible, in axial, sagittal and coronal planes through the prescription point. If sagittal and coronal planes are not available, then a minimum of three axial distributions must be submitted. The three planes shall be the central plane through the prescription point, a plane 2 cm inferior to the superior field border and a plane 2 cm superior to the inferior field border. The prescription point and the outlines of the target volume and critical organs should be shown. Isodose values must be clearly labeled. The effects of shielding blocks should be included.

8. Dose Volume Histograms: Dose volume histograms of the total treatment (initial and boost fields) are required for the following:

Target Volume
Esophagus
Spinal Cord
Left Lung
Right Lung
Right and Left Lung

Calculations must be submitted regarding the total lung volume minus the primary tumor and involved lymph node volume (expressed in %) receiving more than 2,000 cGy. Calculations must also be submitted for the length (in cm) of the esophagus receiving > 4,500 cGy (LET45) and the volume (expressed in %) of the esophagus receiving > 4,500 cGy (V45).

c. Normal Tissue Tolerances

1. Maximum spinal cord dose is 5,000 cGy to any point during the entire course of radiation (initial plus boost fields). A posterior spinal cord shield will not be an acceptable technique. Oblique or lateral field arrangements with custom shielding are recommended to limit spinal cord dose.

2. The entire heart may not receive more than 3,000 cGy. Up to 50% of the cardiac silhouette may receive up to 5,000 cGy. Every effort should be made to prevent radiation to the entire left ventricle.

3. All efforts should be made to minimize the volume of radiated normal lung tissue. It is recommended that the calculated total lung volume (TLV), i.e. the right and left lung minus the gross tumor volume, receiving greater than 2,000 cGy be 35% or less. If your treatment planning system is unable to calculate the lung volume minus the gross tumor volume, indicate what the treatment system is able to calculate, i.e. lung volume including the gross tumor volume.

d. Treatment Interruptions/Delays

Please see Section 8.4 for Radiotherapy Interruptions/Delays.

e. Target Volumes

The target volume will be defined by both CT scan and clinical evaluation. The initial radiation fields will be delivered to a volume that includes (at a minimum) the primary tumor, ipsilateral hilar nodes and the ipsilateral mediastinal nodes according to the location of the primary.

For upper or middle lobe primary tumors, include the ipsilateral paratracheal lymph nodes up to the level of the superior head of the clavicle or 2 cm above the primary tumor or lymph nodes greater than 1 cm in maximum diameter, whichever level is higher. Include the subcarinal nodes to at least 3 cm below the carina or 2 cm below the primary or mediastinal lymph nodes 1 cm or larger in diameter, whichever level is lower.

For lower lobe primary tumors, include the inferior ipsilateral mediastinal nodes to the level 2 cm below the primary lesion. Include the subcarinal nodes to at least 3 cm below the carina, the ipsilateral hilar nodes, and the ipsilateral mediastinal lymph nodes to the level of the superior head of the clavicle.

For any location of primary tumor, always include ipsilateral mediastinal nodes 2 cm above or below any known mediastinal disease or primary tumor, and all mediastinal nodes ≥ 1 cm on CT scan. The target volume will be treated with a minimum of 1.5 cm - 2 cm radial margin. Treatment of the contralateral uninvolved mediastinal lymph nodes within the levels defined above is at the discretion of the treating radiation oncologist.

Unless involved with tumor or within 1.5 to 2 cm of known tumor, the supraclavicular, contralateral hilar and inferior mediastinal lymph node regions are not to be treated. In the presence of atelectasis and/or pneumonia that obscures tumor volume, determination of the field margin will be left to the judgment of the treating radiation oncologist.

7.5 **Boost Therapy**

Radiotherapy Boost

There will be no break (other than the weekend) between induction radiation and the boost radiation. RT will be continued for an additional 1,600 cGy with 200 cGy fractions, daily except weekends. Dose will be prescribed to the central axis at isocenter.
The prestudy CT scan (preferably a CT scan done for simulation purposes with a flat tabletop) should be used to plan the radiation boost volume. The boost volume will include the primary tumor, known involved lymph nodes measuring ≥ 1 cm on initial CT plus a 1.5 - 2 cm margin. Angled oblique and/or lateral fields may be used and must cover the target volume as defined here. Field orientation should be selected to minimize the volume of radiated lung outside of the target volume.

It is recommended that no more than 35% of total lung volume (excluding the gross tumor volume, i.e., primary tumor and lymph nodes greater than 1 cm in diameter) receives more than 2,000 cGy (initial and boost fields combined).

SUBMISSION OF RT RECORDS – EXAMPLE (S0222)

Section 12.0 (Discipline Review) must outline requirements for the submission of radiation therapy records/films. The following is an example of the type of information included and the format used. A separate radiation therapy flow sheet is no longer required.

12.1 Radiation Therapy Review

All patients registered to this study will undergo radiation therapy review by the Quality Assurance Review Center (QARC). QARC will review the materials from the first day of treatment. The purpose of rapid review is to verify that the radiotherapy will be given according to the protocol. The Radiation Therapy Study Chair will assess the adherence to the protocol by reviewing the complete documentation of the administration of all radiotherapy.

NOTE: An approved 3D benchmark must be on file at QARC. The benchmark material can be obtained from the QARC website (www.QARC.org).

a. Rapid Review: **Within three days of the start of radiotherapy**, the following data must be submitted for rapid review:

- Copies of the planning CT and/or the diagnostic imaging utilized in defining the Gross Target Volume (GTV).
- Copies of simulator films and or digitally reconstructed radiographs (DRRs) for each field. The target volume and involved lymph nodes should be drawn.
- The RT-1 Dosimetry Summary Form, one for each target volume.
- Copies of worksheets and/or printouts used for calculation of monitor units.
- Color copies of isodose distributions to demonstrate that the dose variation is within protocol guidelines. The target volume and prescription point must be clearly shown. Refer to Section 7.4b.7 for additional information regarding isodose distributions.
- DVHs for the total treatment for the structures indicated in Section 7.4b.8.

- BEV's of portals showing collimator, beam aperture, target volume and critical structures.

- Documentation of the maximum dose to the spinal cord. This may be obtained from a composite DVH, appropriate isodose distribution or point dose calculation.

- Copies of verification (portal) films (or hard copy of real time portal images) for each field.
- Photographs of the patient in the treatment position.

- **S0222** Checklist for Submission of Radiation Oncology Quality Assurance Materials. This form is available on the QARC website at www.qarc.org.

NOTE: Black and white copies of color documentation are not acceptable.

b. Final Review: **Within 30 days of the completion of radiotherapy**, the following data must be submitted:

- Copies of additional simulation films and verification (portal) films for any major field modifications made subsequent to the initial reporting of data for on-treatment review.

- An RT-1 Dosimetry Summary Form if changes have been made subsequent to submission of on-treatment data.

- An RT-2 Radiotherapy Total Dose Record Form.

- Copies of calculations and isodoses performed subsequent to the submission of the on-treatment data.

- Copies of verification (portal) films (or hard copy of real time portal images) for each field.

- A copy of the patient's radiotherapy record including the prescription and daily and cumulative doses to all required areas and dose specification points.

- **S0222** Checklist for Submission of Radiation Oncology Quality Assurance Materials. This form is available on the QARC website at www.qarc.org.

- Lung Carcinoma Radiation Therapy Form (Form #50644). A copy of this form should also be submitted to the Data Operations Center in Seattle.

c. Data from Sections 12.1a - b should be sent to:

Quality Assurance Review Center
272 West Exchange Street, Suite 101
Providence, RI 02903-1025
Phone: 401/454-4301
Fax: 401/454-4683

d. Questions regarding the dose calculations or documentation should be directed to:

SWOG Protocol Dosimetrist
Quality Assurance Review Center
272 West Exchange Street, Suite 101
Providence, RI 02903-1025
Phone: 401/454-4301
Fax: 401/454-4683

e. Questions regarding radiotherapy should be directed to:

Quynh-Thu X. Le, M.D.
Stanford Medical Center
Department of Radiation Oncology
875 Blake Wilbur Drive, R. CC-G228
MC 5847
Stanford, CA 94305-5847
Phone: 650/498-5032
Fax: 650/725-8231
E-mail: qle@reyes.stanford.edu

12.2 Definitions of Deviations in Protocol Performance:

Prescription Dose

Minor Deviation: The dose to the prescription point (for tumor and critical normal tissues) differs from that in the protocol by between 6% and 10%.

Major Deviation: The dose to the prescription point differs from that in the protocol by more than 10%.

Dose Uniformity

Minor Deviation: The variation of dose within the target volume exceeds +7% and –5% of the dose to isocenter.

Volume

Minor Deviation: Margins less than specified or fields excessively large as deemed by the study.

Major Deviation: Transection of tumor or potentially tumor bearing area.

OTHER PROTOCOL INFORMATION

Standard RT Expectations

The RT Study Chair will be provided with a list of standard RT expectations. From this list, the items required for submission for a given protocol should be selected and explicitly listed in Section 12.1-12.2. If the study requires an item which is not on the standard expectation list, the RT Study Chair should contact the Data Operations Center in Seattle and request the creation of a new expectation report. This new item should also be listed in Section 12.0.

Change in Radiotherapy Plans

If a patient never receives the planned radiotherapy, if the patient receives radiotherapy at a non-SWOG approved radiotherapy facility, if the patients will not complete the planned radiotherapy course or if there will be a delay of > 14 days in the completion of radiotherapy, the change in Radiotherapy Plans Form should be completed and submitted to the Data Operations Center in Seattle.

Dosage Modifications

Instructions for radiotherapy modifications or interruptions/delays should be included in Section 8.0.

RT Forms

Attach appropriate RT forms to the protocol in the Master Forms (Section 18.0).

Informed Consent Information for Radiation Therapy

Paragraphs detailing radiotherapy procedure and toxicities for inclusion in the study consent form should be written in lay language.