12 Credentialing

Prior to patient registration, participating physicians and sites must meet all the following credentialing requirements.

12.1 Surgeon Credentialing

All surgeons' credentialing will be conducted by the study chair or designee.

12.1.1 Thoracic Surgery Credentialing

Participating surgeons must complete and submit the Z4099 Surgeon Credentialing Checklist available on the Z4099 page of www.acosog.org prior to registering a patient. Surgeons must meet one of the following criteria:

1. Membership in General Thoracic Surgery Club. Criteria for membership include:
    - Surgeons who have obtained specialty certification in thoracic surgery by the American Board of Thoracic Surgery or the Royal College of Surgeons, or other official certifying organization;
    - Surgeons who have been in practice for a minimum of two years beyond the completion of formal training in thoracic surgery, and devote at least 50% of their practice to general thoracic surgery;
    - Surgeons whose list of all operations performed in the year prior to application has been certified by the chief(s) of surgery at their institution(s).
2. Board-certified cardiothoracic surgeon with $\geq$ 50% of surgery practice devoted to general thoracic surgery.

NOTE: Surgeons who do not meet the above criteria must submit the following for review by the study chair:

- Case list of operative experience for the previous year
- Operative and pathology reports for five sublobar resection procedures done during the previous year

12.1.1 Brachytherapy Credentialing for Surgeons

Sites who would like the option of using brachytherapy must complete and submit the brachytherapy portion of the Z4099 Surgeon Credentialing Checklist for each surgeon participating in the study. The checklist is available on the Z4099 page of http://www.acosog.org prior to registering a patient. Each physician must meet one of the following criteria. Documentation specified for each criterion must accompany the checklist.

1. Enrolled a patient in ACOSOG Z4032 study. NOTE: If treatment planning or personnel have changed since participation in Z4032, then brachytherapy credentialing must be repeated.
2. Attended an ACOSOG Brachytherapy Workshop. Include emailed documentation from ACOSOG of attendance.
3. Viewed the training video on seed placement and successfully completed the quiz available on the Z4099 page of www.acosog.org. No documentation is necessary - the test results will be sent to the study chair for approval.
4. Observed a SR + brachytherapy case by an approved surgeon. Include written documentation of participation.

12.1.2 Surgeon Credentialing Submission Instructions

The Z4099 Surgeon Credentialing Checklist and all required supporting documents will be submitted via Fax or email to:

ACOSOG Site Coordinator

Phone: 507-284-9565

Fax: 507-293-1150

Email: rstacosogsite@mayo.edu

Credentialing materials will be routed to and reviewed by the Study Chair. The surgeon will be contacted if additional information is needed. Once credentialing requirements have been met, ACOSOG will notify the surgeon.

12.2 Radiation Oncology/Site Credentialing

12.2.1 Brachytherapy Credentialing for Radiation Oncology Departments

Credentialing for radiation oncology departments that intend to use brachytherapy on this study includes completion of a questionnaire and two test cases before patients may be treated. The questionnaire and information about the test cases are available at http://atc.wustl.edu.

The questionnaire requires information regarding personnel, the implant technique to be used, the treatment planning system, and quality assurance procedures.

The first test case is a calculation for a single seed of the same model that will be used for the site's patients. The questionnaire and first test case will be submitted via hardcopy to ITC. See submission instructions below.

For the second test case a post-implant CT scan of an actual implant will be downloaded from http://atc.wustl.edu and a treatment plan performed following the instructions on the website. The second test case will be submitted digitally to ITC.

Approval of the test cases will apply to the treatment planning system and seed model that were used. A change in either the planning system or the seed model will require resubmission of the questionnaire and the first test case. A change in planning system will also require resubmission digitally of the second test case.

The completed questionnaire and test cases will be reviewed by the radiation oncology co-chair(s) or designee. The co-chair will contact the site if additional information is needed. Once credentialing requirements have been met, the co-chair will notify the ACOSOG Site Coordinator, who will notify the site.

NOTE: If the institution has participated in Z4032 and successfully submitted digitally one or more cases, only the questionnaire and first test case need to be submitted. If the treatment planning system, brachytherapy source or personnel has changed since participation in Z4032, then the second test case must be submitted as well.

The questionnaire and first test case will be submitted as hard copies. The second test case must be submitted digitally in DICOM RT format. Submission by either CD or SFTP is supported. See Site Credentialing Submission Instructions (Section 12.2.3).

12.2.2 SBRT Credentialing for Radiation Oncology Departments

Credentialing for stereotactic body radiation therapy and heterogeneity corrections by the Radiological Physics Center (RPC) is necessary prior to enrolling patients on this study.

All participating institutions must use the AAA, superposition/convolution or Monte Carlo based dose calculation algorithms. Institutions wishing to submit IMRT plans must also be credentialed for intensity modulated radiotherapy (IMRT) prior to enrolling patients on this study. Instructions for completing these requirements or determining if they already have been met are available on the RPC web site at http://rpc.mdanderson.org/rpc. Select "Credentialing" and "Credentialing Status Inquiry".

SBRT credentialing includes the steps outlined below. Centers previously credentialed for some of the technologies/procedures involved may not have to be re-credentialed. However, institutions not using superposition/convolution algorithms that were previously credentialed to use Clarkson or pencil beam algorithms for SBRT on RTOG 0236 will be required to be re-credentialed for heterogeneity corrections. In addition, institutions that have changed the technology/procedures previously credentialed (i.e., fundamentally change methods like changing from tracking to abdominal compression for motion control) must be re-credentialed with their new systems. Institutions that have changed from standard IMRT to Tomotherapy, CyberKnife® or volume arc IMRT delivery will require re-credentialing.

SBRT Credentialing Process

1. **Obtain SFTP Account.** A Secure FTP (SFTP) account with username and password can be obtained by contacting the ITC at (314) 747-5415 or itc@wustl.edu. Guidelines for digital submission are available at http://atc.wustl.edu.
2. **Complete Facility Questionnaire.** Each participating institution must complete a Facility Questionnaire available on http://atc.wustl.edu. Information in a previous Facility Questionnaire can be extended to meet this requirement by simply adding data that is specific to this SBRT protocol. All questions in the Facility Questionnaire pertaining to IMRT (if this treatment modality is to be used), heterogeneity corrections, respiratory movement control, and IGRT must be answered.
3. **Complete Knowledge Assessment.** Each participating institution must complete a Knowledge Assessment questionnaire available at http://atc.wustl.edu. This questionnaire verifies the investigator's knowledge of the protocol. NOTE: Questions pertaining to brachytherapy also are included in the assessment.
4. **Perform IGRT Verification Study.** Each institution must perform a verification study demonstrating their ability to reproducibly register daily IGRT information with a planning CT dataset (i.e., the gross tumor volume falls within the CT simulation defined PTV). The patient used for this verification procedure must have a target in the lung that is similar to the lesions that will be treated for patients entered on this study. The information submitted must include three (3) IGRT datasets (from three (3) different fractions) for a single anonymized patient and must employ the method that will be used for respiratory control for patients entered from a particular institution. This information with a spreadsheet (the spreadsheet is available on the ATC web site, http://atc.wustl.edu) will be reviewed by the Medical Physics Co-Chair.
5. **Irradiate Phantom.** Each participating institution must irradiate a standardized phantom provided by RPC. Instructions for requesting and irradiating the phantom are available at the RPC web site, http://rpc.mdanderson.org/rpc/ by selecting "Credentialing" and "ACOSOG." The phantom simulates a lung tumor within lung tissue equivalent material.

   This trial allows IMRT techniques (including CyberKnife® and Tomotherapy), and the phantom irradiation requirements vary according to the combination of delivery technique and respiratory control methodology. In general, institutions using conformal techniques and abdominal compression for respiratory motion control together with the recommended margins will irradiate the stationary version of the phantom. The exception is for institutions intending to use either tracking or gating techniques when lesions do not remain within the stated margins. These institutions will be required to irradiate the moving phantom for credentialing. Additionally, institutions using CyberKnife® or Tomotherapy delivery will be required to irradiate the moving phantom for all methods of respiratory control. The RPC will provide assistance to help the institution determine the appropriate phantom irradiation technique.

The credentialing materials will be reviewed by the study team. The site will be contacted if additional information is needed. Once credentialing requirements have been met, RTOG will notify the ACOSOG Site Coordinator, who will notify the site.

12.2.3 Site Credentialing Submission Instructions

Brachytherapy: The questionnaire and first test case will be submitted as hard copies. The second test case must be submitted digitally in DICOM RT format.

SBRT: The treatment planning CT, treatment plan (CT files, dose files, plan files, and structure files) and other required materials must be submitted digitally as DICOM RT. The irradiated phantom will be submitted to ITC as well. Forms and questionnaires may be submitted electronically (if available) or as hard copies.

All submissions via CD or hard copy should be submitted to:

Image-guided Therapy QA Center

4511 Forest Park Ave, Suite 200

St. Louis, MO 63108

Phone: (314) 747-5415

Fax: (314) 747-5423

Email: itc@wustl.edu

An SFTP account (username and password) can be obtained by contacting the ITC at (314) 747-5415 or itc@wustl.edu. Guidelines for digital submission are available at http://atc.wustl.edu.

Sites must notify ITC via e-mail when digital data are submitted. The e-mail must include the study number and a description of the datasets being submitted (e.g., Z4099 radiation oncology brachytherapy credentialing, Z4099 SBRT credentialing, phantom, etc.).