ATC-AstraZeneca IMRT Credentialing and Quality Assurance Guidelines

I. Purpose

This document establishes credentialing requirements and quality assurance (QA) guidelines for institutions planning to participate in ATC-AstraZeneca supported protocols allowing intensity modulated radiation therapy (IMRT) and that require digital data submissions.

II. Credentialing Requirements for Participating Institutions

A. The following items are required before you can enter cases on each ATC supported protocols allowing IMRT:

1. Submit a completed IMRT Facility Questionnaire ((*http://atc.wustl.edu*) specific to the IMRT protocol

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2. Contact the ITC (itc@castor.wustl.edu) and request an SFTP account for digital data submission (unless your institution already has been issued a SFTP account for a different protocol).

3. Submit and successfully complete a protocol specific Dry-Run test showing digital data submission capability

4. Submit a successful IMRT Benchmark (*http://atc.wustl.edu*). If institution has previously been credentialed via the RPC IMRT phantom experiment or the QARC benchmark they will be grandfathered.

B. Facility Questionnaire: The IMRT Questionnaire may be obtained at *http://atc.wustl.edu*. The Questionnaire provides information regarding the IMRT treatment planning, treatment equipment, and in-house QA procedures.

1. IMRT Computer planning system: Documentation of IMRT system to be used. To

participate in ATC supported protocols allowing IMRT, the institution's planning system must have the capability of digital data exchange with the ATC for all digital data required by the specific protocol. This digital data must comply with one of two formats:

- RTOG Specification for Tape/Network Format for Exchange of Treatment planning Data, Version 3.20, or later; or
- DICOM 3.0 in compliance with the ATC's DICOM 3.0 Conformance Statement.

2. IMRT Treatment Verification Procedures: Documentation of the IMRT planning and delivery process as well as the routine QA tests performed to insure proper functioning. The method used to conduct a check of the dose and monitor unit calculations performed by the IMRT planning system must be provided.

C. Dry Run (Benchmark) Test: A complete patient data set as specified by the treatment protocol is to be submitted to the ITC to demonstrate compliance with technical requirements (see Dry Run Guidelines at http://itc.wustl.edu/). **A separate dry run test MUST be performed for each IMRT planning system used.**

1. No port films are required for the Dry Run test, as the patient's treatment is not required to be per protocol. However, if you plan on submitting your treatment verification images in digital format, you must prove that you have a compliant method of submitting these images as part of the Dry Run test.
2. **NOTE:** There is no requirement that the patient whose data is used for the Dry Run test be treated according to the protocol. This test set can be from a data set for a patient who was previously seen and/or treated (in some other fashion). The only requirement is that the CT scan be close to protocol compliant and the tumor/target volumes and critical normal structure contours be defined in compliance with the protocol and that protocol compliant treatment plans be generated and the appropriate data submitted to the ITC. Any protocol immobilization device requirement is waived for this test data set. All patient identifying data for the Dry Run test data should be removed before submission to protect patient confidentiality.

D. IMRT Benchmark Test: This IMRT benchmark has been accepted by all of the NCI funded cooperative groups and Quality Assurance Offices as a minimum standard for an institution to be credentialed for use of IMRT in clinical trials. The benchmark is not site specific, i.e. it applies to IMRT treatment of all disease sites. The benchmark should be submitted to the ITC, (http://atc.wustl.edu).

IV. Protocol Requirements

A. Protocols permitting IMRT treatment delivery must be written using the nomenclature defined in the NCI IMRT Working Group Report (IMRT Collaborative Working Group: Intensity modulated radiation therapy: current status and issues of interest. Int. J. Radiat. Oncol. Biol. Phys. 51:880-914, 2001) and the International Commission on Radiation Units and Measurements (ICRU) Reports 50 and 62 for specifying the volumes of known

tumor, i.e., Gross Tumor Volume (GTV), the volumes of suspected microscopic spread, i.e., Clinical Target Volume (CTV), and the marginal volumes necessary to account for setup variations and organ and patient motion, i.e., Planning Target Volume (PTV).

B. The protocol must provide a clear definition of the GTV, CTV, and margins used to create the PTV.

C. The protocol must provide a clear definition of the prescription dose and dose heterogeneity allowed throughout the PTV.

D. The protocol must require that a volumetric treatment planning CT study be used to define the GTV.

E. The protocol must clearly define the organs-at-risk that are required to be contoured and provide clear guidelines for contouring each organ-at-risk defined in the study. Dose constraints for each organ-at-risk in the irradiated volume should be defined if these constraints are known from previous studies. This should include a definition of major and minor deviation for each organ at risk.

F. The protocol must require that specific procedures be in place to insure correct, reproducible positioning of the patient. As a minimum, orthogonal (AP and lateral) DRRs and corresponding orthogonal portal images (film or electronic) are to be required.

G. The treatment machine monitor units generated using the IMRT planning system must be independently checked prior to the patient's first treatment. Measurements can suffice for a check as long as the plan's fluence distributions can be recomputed for a phantom geometry.

V. Protocol Data to be Submitted and Quality Assessment Parameters

A. Patient Data Submission: The following information is to be submitted to the ITC for each protocol patient at times specified in the protocol:

1. DDSI Form: Digital Data Submission Information Form (obtain from ATC website).

2. Digital dosimetry and imaging data.
   a. Protocol compliant images (e.g. CT or MRI scan series);

   b. Protocol compliant contours using required standard names (standard structure names can be found on the ATC website) for all GTV, CTV and PTVs, and for all specified critical normal structures. They must be contoured on all slices in which each structure exists or as defined by the protocol and include skin on ALL CT cuts;

   c. Volumetric 3-D dose distribution (**with** heterogeneity corrections) data in absolute dose for each fraction group used to deliver a protocol compliant dose. Note, a Fraction Group represents the beams and doses for a concurrently treated set of

beams;

d. DVH's computed **with** heterogeneity correction for the total dose of all dose distributions submitted for item c (summed fraction groups from item c) for all PTVs and all specified critical normal structures. A DVH of all "unspecified tissue" must also be provided.

f. Any corrections to previously submitted digital data should be discussed with the ITC prior to such submission.

3. Color hardcopy isodose distribution for the axial, sagittal and coronal planes through the isocenter for the total dose plan must be submitted. They may be as hardcopy, or as electronic files of screen dumps, such as jpg files. These dose distributions must include:

   a. A reasonable number of isodose lines which can be used to determine that the digital dose and anatomy data are properly aligned relative to each other. The prescription dose for the high-dose PTV should be displayed. If the hard copy isodose lines are in percentage, the conversion factor to absolute dose (Gy or cGy) for all delivered fractions must be indicated.

   b. The above isodoses shall be superimposed over the treatment planning CT images or reconstructed planes of the planning CT images and must be in color.

4. Treatment prescription and verification images:

   a. DMLC and SMLC IMRT treatments require:

      - Digital or hardcopy (hard copy films will be digitized) treatment prescription and verification images shall be submitted. At least one orthogonal pair (AP and lateral) setup DRR, simulation field, and portal image shall be submitted. Where geometrically possible, Beam's Eye View DRRs and portal images for each field shall be submitted. Acceptable formats shall be specified in the protocol.

   b. Serial or helical tomotherapy treatments require:

      - As specified in protocol

VI. QA Review

A. Time Line Definitions for Quality Assurance Review

1. Rapid review of cases: The first case from each radiation oncology facility will

undergo *Rapid Review*. In this process, the case will be planned, electronically submitted to the ITC, reviewed, and approved prior to the start of treatment. Additional patients may not be enrolled until approval for the rapid review case is received. Allow 3 business days for the results of the rapid review process. Cases that are submitted on a Friday will not be processed until the following Monday. The rapid review process will not start until all required data are received by the ITC. Cases that do not meet contouring and quality assurance criteria will not be approved and corrections will need to be made to obtain approval for accrual and treatment. If corrections or additional documentation is requested, the subsequent submission of the case will not be given priority review over other Rapid Review cases.

2. Timely review of cases: Following rapid review, there will be a *Timely Review* of the subsequent 4 cases submitted. Each of these cases may proceed to treatment following planning without waiting for review and approval. The treatment plan must be electronically submitted to the ITC within one week. These cases will be reviewed in a timely manner (5 business days) for the results with feedback given to the submitting radiation oncology facility. Corrections and resubmission of data will be requested for cases that do not meet contouring and quality assurance criteria. Once the Rapid Review case and the first 4 Timely Review cases have been submitted, all 5 cases will be re-evaluated together. This process will occur for each radiation oncology facility participating in the study. Feedback regarding this re-evaluation of treatment guideline compliance will be forwarded to the radiation oncology facility. During the period of timely review, the radiation oncology facility will be permitted to continue accrual. If the review of cases 4 and 5 demonstrates a treatment plan that is unacceptable, the radiation oncology facility will be required to repeat the rapid review and timely review process. Additional patients may not be enrolled until approval for the rapid review case is received.

3. Regular QA Review for remaining cases: Each additional case review will be done within 10 business days of the receipt of all required data. Corrections and resubmission of data will be requested for cases that do not meet contouring and quality assurance criteria. If protocol non-compliance is documented, the radiation oncology facility may be required to repeat the timely review process (4 cases) if the facility is to continue participating in the trial.

B. Quality Assurance of the CT Scan Data and Digital Planning Data Format

1. ITC personnel will review the CT scan data set to ensure protocol compliance with regard to both inter-slice spacing as well as the superior/inferior extents of the scan region.
2. ITC personnel will review the format of the digital treatment planning data submitted for compliance with the appropriate data exchange specification version. Deviations from compliance will be noted and, depending upon the severity of the deviation, may require a complete resubmission of the digital data set.

C. Quality Assurance of Target Volumes and Organs at Risk Volumes

1. The ITC will facilitate the review of the GTV, CTV, and PTV by the Radiation Therapy PI of the study or his/her designees.
2. The ITC will facilitate the review of all designated critical structures contours by the Radiation Therapy PI of the study or his/her designees.

D. Quality Assurance of Dose Distribution

1. The ITC will compare the electronic isodose distributions with the "hardcopies" submitted to verify correct interpretation and conversion of the digital patient and dose data.
2. ITC personnel will calculate DVH's for the sum of all dose distributions submitted (each submitted distribution is for one set of concurrently treated beams) and may compare them with the digitally submitted dose-volume histograms for the PTV, designated critical structures, and unspecified tissue.
   a. There should be reasonable agreement between an individual participating institution's DVH computations and those of the ITC. Therefore, any discrepancy between the submitting institution's DVHs and those computed by the ITC in excess of $\pm$5% (or 3 cc for small structures) in total volume will need to be resolved prior to successfully completing the Dry Run Test

E. Criteria for QA Assessment of Treatment Plan

1. In general, the plan assessment criteria will vary among groups and QA centers and protocols. However, each protocol must have established criteria for evaluating the submitted treatment plan. An overall score will be assigned to each plan. The items typically involved in the scoring are the coverage and overdose of each PTV and the level of specified organ(s)-at-risk sparing. The largest variation encountered (None, Minor or Major) is typically the overall score assigned to the plan.

2. No credentialing plan (dry run) will be approved that results in a Major Variation. Plans with No Variation or Minor Variations will be approved (assuming no other significant areas of protocol non-compliance).
