Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB) Quality Assurance Guidelines

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Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB) Quality Assurance Guidelines

I. Purpose:
   A. To establish quality assurance (QA) guidelines for the conduct of low-dose rate transperineal interstitial permanent prostate brachytherapy (TIPPB) multi institutional cooperative group studies.

II. Background
   A. Preliminary reports of the success of TIPPB in controlling early stage prostate cancer with few complications have heightened the interest of the medical community. Controlled, prospective multi-institutional trials to validate and investigate the efficacy of this procedure have become a goal of the cooperative groups. The Quality Assurance Review Center (QARC) Radiological Physics Center (RPC), and the Image-Guided Therapy Center (ITC) have expanded their missions to insure the scientific soundness of these trials. They perform this function through (1) individual and institutional credentialing, (2) establishment of procedural standards, and (3) centralized quality assurance review of case submissions.
   B. A partial list of references that describe the procedure and appropriate quality assurance for prostate implantation are listed at the end of this document.

III. Credentialing
   A. General: Brachytherapy, by its nature, is dependent upon the skill of the brachytherapist and the expertise of the support staff. Credentialing therefore needs to address the qualifications and efforts of the implant team as well as the type and quality of available equipment. Since these procedures require a team effort, the institution, the radiation oncologist, and radiation physicist are credentialed as a team.
   B. RTOG Protocols

Institutions wishing to enter patients onto RTOG protocols must be credentialed prior to participating in the study. The treatment team is required to submit four items. All materials must be submitted to the RPC. Forms and reference cases are available on the RPC website (http://rpc.mdanderson.org).

1. Brachytherapy Facility Questionnaire
2. Knowledge Assessment Form
3. Calculation of two reference cases.
4. Data for the most recent prostate implant performed by the radiation oncologist and physicist using the technique proposed for the RTOG protocol.
RTOG requires that the prostate team must have performed at least 10 transrectal ultrasound (TRUS) guided prostate implants. At the bottom of the RTOG Knowledge Assessment Form you will be asked to attest to this by your signature.

The complete package is to be submitted to:

Attention: Irene Harris  
Radiological Physics Center  
1515 Holcombe Blvd. – Box 547  
Houston, TX 77030  

Allow at least 4 weeks for review and approval. Incomplete submissions will take longer.

For any questions contact the RPC at (713) 792-3226.

C. ACOSOG Protocol Z0070

Institutions wishing to enter patients onto the American College of Surgeons Oncology Group (ACOSOG) Protocol Z0070 (A Randomized Trial of Radical Prostatectomy versus Brachytherapy for Patients with T1c or T2a N0 M0 Prostate Cancer) must be credentialed prior to participating in the study. The treatment team is required to submit five items. Forms and reference cases are available on the QARC website (http://www.QARC.org).

1. Brachytherapy Facility Questionnaire

2. Calculation of two Prostate Implant Reference Cases

3. A case list of 15 prostate permanent seed implants which must have been performed over the past 12 months. Use Z0070 Radiation Therapy Skill Verification Form.

4. Data for the 3 most recent cases performed by the physician/physicist team

Note that a criterion for participation is that the prostate team must have performed at least 15 transrectal ultrasound (TRUS) guided prostate implants. At the bottom of the Skill Verification Form you will be asked to attest to this by your signature.

The complete package is to be submitted to the following address:

Physics Division  
Quality Assurance Review Center  
272 West Exchange Street  
Suite 101  
Providence, RI 02903-1025
Allow at least 4 weeks for review and approval. Incomplete submissions will take longer.

For any questions contact QARC at (401) 454-4301.

D. An institution that has been credentialed for one radiation source model does not need to submit the complete package to become credentialed for a second source model. It is only necessary to submit the two reference cases, performed with the new source model. Similarly, changing to a different treatment planning system requires re-credentialing, and only the first two reference cases need to be submitted.

E. Requirements for Digital Data Submission

Institutions that have the capability to submit treatment plans electronically will be expected to transmit data in digital form to the Image-Guided Therapy Center (ITC) in St. Louis (URL: http://3dqa.wustl.edu/)

Institutions wishing to submit treatment planning data in digital form for RTOG or ACOSOG protocols that include permanent prostate brachytherapy implants must be credentialed to do so prior to being allowed to submit such data for patients in this study. This must be accomplished through the TIPPB Reference Cases or, if the TIPPB Reference Cases were accomplished without digital submission, by submitting the TIPPB Reference Cases equivalent digital data set for approval.

Those institutions that intend to submit the treatment planning data electronically must demonstrate capability of digital data exchange with the ITC via a protocol specific (digital) test case as published on RPC’s or QARC’s web site (available at http://rpc.mdanderson.org and www.QARC.org, respectively). Assistance in submitting data in digital format may be obtained from the ITC’s web site (http://itc.wustl.edu). Digital data submitted for either the reference cases or an actual protocol registered case must include the following in accordance with the appropriate (reference case or protocol) requirements:

1. Image Based Digital Data
   a. Patient CT data used for planning
   b. Contours for all protocol required critical normal structures, gross tumor volume(s) (GTV), clinical target volume(s) (CTV) and planning target volume(s) (PTV).

2. Treatment Planning Digital Data
   a. 3D dose matrix
   b. Dose-volume histograms for all contoured volumes in absolute dose.

3. Hard Copy Supporting Documentation
   a. Copy of physician’s prescription.
   b. Copy of the pre-implant TRUS study with prostate volume drawn, if
required by the protocol.

c. Axial, sagittal and coronal hard copy isodoses superimposed on the CT (in absolute dose).
d. Protocol specific Digital Data Submission Reporting form available from the ITC web site.

Those institutions that intend to submit electronically should contact Mr. William Harms at (314) 747-5412 or Mr. Bill Straube at (314-362-9762) to establish an ftp account for their facility on the ITC’s ftp server (castor.wustl.edu).

F. Equipment

1. Imaging: If ultrasound, fluoroscopy, CT or MRI is used to perform prostate implants, the institution is asked to explain how the imaging capability of the equipment was determined and what regularly scheduled procedures are in place to insure that the equipment continues to meet stated specifications.

2. Treatment Planning: Information pertaining to the system used for pre and post implant planning and evaluation is listed on the Facility Questionnaire. Capabilities and the use of the system in the conduct of the procedure should be detailed, as well as the routine QA tests performed to insure the proper functioning of the treatment planning system (TPS).

The TPS must be able to perform structure-based analysis from axial image sets. This shall include isodose display and generation of Dose-Volume Histograms (DVHs).

The calculation grid should be set no larger than (2mm x 2mm x the axial slice width). The goal is for the TPS to be capable of transmitting data to the ITC electronically.

The method of conducting a check of the calculations performed by the TPS must be provided.

3. Sources: The Facility Questionnaire queries the type, form and range of nominal strengths for sources used for prostate implantation. Additionally, the procedures used to insure the receipt and implantation of the proper sources (e.g., assay and handling procedures) must be provided. Assay procedures and regular quality control of the assay equipment will be addressed.

Unless specified otherwise in the protocol, either Iodine-125 or Palladium-103 seeds that comply with the AAPM specification may be used. The sources must be received and inventoried in accordance with state and federal regulations. At least 10% of the sources will be assayed in such a manner that direct traceability to either the NIST or an ADCL is maintained. Corrected NIST 1999 standards will be used. Agreement of the average measured source strength shall agree with that indicated in the vendor’s calibration certificate to within ±5%. No measured source strengths should fall outside ±10% of that indicated in the vendor’s calibration certificate.
4. Specific equipment standards
   a. Ultrasound (Frequencies, axial and lateral resolution, low contrast detectability, noise)
   b. Fluoroscopy (Resolution, contrast, noise, dose)
   c. CT (Resolution, contrast, noise, dose)
   d. MRI (Resolution, contrast, noise)
   e. Assay equipment
      (1) NIST-traceable calibration every 2 years either by an ADCL, or by use of a NIST or ADCL calibrated source.
      (2) Sensitivity sufficient to distinguish differences of one part in 100.
      (3) If the assay is to be used for calibration of sources as opposed to quality assurance (i.e., the assay source strength is used for planning, as opposed to that stated by the manufacturer), the system must meet the qualifications for a dose calibrator (e.g., linearity and reproducibility).

G. Written Procedures
   1. The institution should have a written protocol outlining the normal conduct of the implant procedure. This protocol should address, as a minimum, order, receipt, inventory, handling and disposal of radioactive sources; patient selection, scheduling, and flow; procedural conduct and record keeping.

IV. Procedural Standards

A. Treatment Volumes.

   The Clinical Target Volume is to be specified by protocol. Typically it is the pre-implant TRUS definition of the prostate.

   The Planning Target Volume is to be specified by protocol as an enlargement of the CTV by a specified amount in the lateral, anterior, posterior, cranial, and caudal directions.

   The Evaluation Target Volume (ETV) is the post implant CT definition of the prostate.

B. Preplanning should be performed individually on a treatment planning system or, if permitted by the specific protocol, via a standard, published implant rules (a nomogram with distribution rules, for instance). Prior to the beginning of the implant procedure, each member of the implant team must have access to the following written information: patient demographic data, disease specifics, size and location of the CTV and PTV, the type, strength, and number of sources that will be implanted and their planned location, the targeted dosimetric result of the implant, e.g., the reference dose and the design intent to deliver at least this dose to the PTV.
C. A method of independently checking the results of the pre-plan is required prior to performing the implant. Comparison with similar, previous implants via an institutionally developed gland size versus total air kerma strength curve is acceptable.

D. Post-Implant Dosimetric Analysis.

1. **Post-Implant CT scan for Treatment Planning:** A CT scan will be performed according to protocol following the implant. The patient will be scanned in a supine position. The use of contrast and catheterization will be specified in the protocol. The maximum CT slice thickness shall be no greater than 5 mm and may be specified to be smaller in the protocol. Abutting slices will be acquired from 2 cm cephalad to the base of the gland to 2 cm caudad to the apex. All of the seeds used in the implant should be encompassed in the scan. The ETV shall be determined from this scan, as shall specified normal tissues, such as the urethra and the rectum. The CT scan will be used to create a post-implant treatment plan (post plan).

2. **Post-Implant Treatment Plan:** On the above CT scan, a credentialed individual shall draw the prostate (ETV), and all other normal tissues specified in the protocol, such as rectum, urethra, and bladder. The implanted sources shall be identified and the dose distribution calculated on a grid not to exceed 2mm x 2mm x CT slice thickness.

3. **Reporting:** Guidelines established by the American Brachytherapy Society (IJROBP 46:221, 2000) are to be followed. DVH-based analysis must be used in the post-plan evaluation. The following values shall be reported. $V_n$ is the percentage of the prostate (ETV) that received at least n% of the prescription dose. $D_m$ is the minimum dose received by m% of the ETV.
   - **Coverage.** $V_{100}$, $V_{90}$, $V_{80}$, $D_{90}$.
   - **Uniformity.** $V_{150}$, $V_{200}$.
   - **Urethra.** The maximum dose to the urethra and volume of urethra (in cm$^3$) that received more than 200% of the prescription dose. The average dose to the urethra may also be required as specified in the protocol.
   - **Rectum.** The maximum dose to the rectum and the volume of the rectum (in cm$^3$) that received more than 100% of the prescription dose. The average dose to the rectum may also be required as specified in the protocol.
V. Data to be Submitted to the ITC electronically, or to QARC, if electronic submission is not possible and is permitted by the protocol.

A. Copy of the pre-implant TRUS study with the prostate volume drawn, if required by the protocol.

B. Copy of the physician's prescription.


D. Copy of the post-implant treatment plan, which will consist of the following. These data shall be submitted electronically to ITC or, if permitted by the protocol, by hardcopy to QARC if electronic submission is not possible.

1. A copy of the CT scan used to create the post-implant treatment plan (post plan) with no isodoses or structures delineated. For hard copy submissions the images shall be scaled such that the maximum width of the prostate measures at least 4 cm.

2. Hard copy of the CT scan used to create the post-implant treatment plan (post plan) with isodoses and structures superimposed. Structures will include the ETV and normal tissues specified by the protocol, such as the urethra and rectum. Images shall be scaled such that the maximum width of the prostate measures at least 4 cm.

3. For those submitted electronically, there shall be at least three transverse cuts (one each near the superior and inferior periphery of the ETV and one near the center) in such a fashion as to be able to determine the extent of the isodose surface and its relationship to the target and surrounding anatomy. Isodose contours may be normalized to some value (e.g., the reference dose) or displayed in dose, but will include at least the following values with relation to the prescription (reference) dose: 200%, 150%, 100%, 90%, 80%, and 50%.

4. For those cases submitted by hard copy, copies showing the prostate (ETV) and specified normal tissues and isodose contours superimposed on the CT slices will be provided for all slices on which the prostate (ETV) and/or specified normal tissues are drawn. Isodose contours may be in dose (Gy) or normalized to some value (e.g., the reference dose). The isodose contours will include at least the following values with relation to the prescription (reference) dose: 200%, 150%, 100%, 90%, 80%, and 50%. Color or another method must clearly indicate the values of particular contours.

5. For electronic submissions the seed localization information must be submitted in an ITC approved digital format.

6. Dose volume histogram for the ETV (Prostate).

7. Dose volume histograms of normal tissues specified in the protocol, such as rectum and urethra.
VI. Centralized Quality Assurance Review

A. Quality Assurance of Digital Data Format and Volumetric-Image Scan Data (for cases submitted electronically to ITC)

1. The format of the digital TPV data submitted will be reviewed for compliance with the appropriate 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.

2. The volumetric image data set is reviewed to ensure protocol compliance with regard to both interslice spacing as well as the superior/inferior extents of the scan region.

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

1. The contours of the prostate (ETV), and designated organs at risk (e.g. urethra, rectum) will be reviewed. For some cooperative groups, after an institution has demonstrated compliance with the protocol, future cases may be spot checked only.

C. Quality Assurance of the Dose Distribution

For cases submitted electronically to ITC

1. The digital dose distribution will be displayed as isodoses overlaid on selected slices of the image data set and compared with hardcopy isodose distributions for the plans submitted in order to verify correct interpretation and conversion of the digital patient and dose data.

2. The ITC will calculate DVH's for the dose distributions submitted. They may be compared with the digitally submitted DVHs for the ETV and designated organs at risk.

For cases submitted by hardcopy to QARC

1. Hard copy showing the prostate (ETV) with isodose contours superimposed on the CT slices will be reviewed for all slices on which the prostate (ETV) and/or specified normal tissues are drawn. Isodose contours may be in dose (Gy) or normalized to some value (e.g., the reference dose). The isodose contours will include at least the following values with relation to the prescription (reference) dose: 200%, 150%, 100%, 90%, 80%, and 50%. Color or another method must clearly indicate the values of particular contours.

2. Dose volume histograms of the prostate (ETV) and specified normal tissues will be reviewed. The volume of each organ must be stated.

D. Evaluation criteria shall be as specified in the protocol.
VII. References


