QUALITY MANAGEMENT FOR INTERSTITIAL IMPLANTS

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The aim of quality management in brachytherapy is to ensure that each individual radioactive source application to the area of interest is:

- administered accurately consistent with the written directives
- within the scope of the institution’s radioactive material license
- safe for the patient, staff and others who may be exposed to radiation during the course of treatment.
Quality Management

- Objectives of federally enforced QMP* are all related to the written directive:
  - Written directive before administration of radiation
  - Identification of the patient before administration of radiation (by more than one way) as the individual named in the written directive
  - Final plan and related calculations in accordance with the written directive
  - Administration of radiation in accordance with the written directive
  - Identification and evaluation of any unintended deviation from the written directive and implementation of appropriative action

(*though the term QMP is dropped in the current Part 35, but the requirements are retained)
Quality Management

- NRC regulatory guide 8.33 (Task DG-8001) contains requirements and recommendations of quality assurance nature to implement the QMP
- NRC website
- The brachytherapy section of the AAPM’s Task Group 40
- For high dose rate (HDR) brachytherapy practice, AAPM’s TG 59
- ABS recommendations for several brachytherapy procedures
Quality Management

Most references deal with the quality assurance program related to

- Radiation safety in brachytherapy, source calibration, safe handling and application of radioisotopes either manually or through remote controlled devices.

- QA of radiation machines, source calibration devices and treatment planning systems.
Quality Management

The other equally important part of brachytherapy quality management program is the procedure-specific quality assurance, defined as

“a set of actions selected to ensure that each important step leading to delivery of a brachytherapy procedure is correctly carried out”
Objectives

Procedure-specific quality management for the temporary interstitial implants

- Implantation Procedure
- Implant Reconstruction
- Treatment planning / Dosimetry
- Source Application and Removal
Quality Management for the Implantation Procedure

1. Template Based Implants Using Rigid Needles

2. Flexible Catheter Implants
1. Control the direction of the needle insertion at the time of implantation
2. Control the geometry of the implant
3. Hold needles in place during the course of treatment
Template Based Implants
Using Rigid Needles

- Prostate Implants
- Gynecological Implants
- Template-based Breast Implants
- Multiple Sites Implants
Prostate Implants

Templates and Needles for temporary LDR / HDR Implants

MUPIT template

Syed-Neblett prostate template
Template Based Implants - QM Implant Procedure

- A check list of items required for the implantation procedure is the first step of a quality management program. This list may vary with the site to be implanted.

- Which template and set of needles are required for the procedure. For example, if the treatment is planned to be given by LDR $^{192}$Ir ribbons, the set of needles required are different from those used for HDR brachytherapy.

- If interstitial hyperthermia is part of the treatment strategy, steel needles need to be implanted and used as antennae for hyperthermia. In such situations, the number of implanted needles will be more than required just for brachytherapy alone.
3-way foley

Gold marker implanter
Contrast solution
Implantation Procedure

- TRUS Transducer
- Rectal needles first
- Urethral needles afterwards
- Template with correct orientation
Implantation Procedure

Transverse

Sagittal
Implantation Procedure
Real-Time HDR prostate implant - Swift (Nucletron)
Real-Time HDR prostate implant - Vitessese (Varian)

For these systems extensive quality assurance of ultrasound imaging system, calibration of the template for one-to-one correspondence with the grid in the US image is required.
Prostate Implant – Procedure QM (summary)

- Determination of the type of implant (LDR or HDR), so that appropriate needles can be chosen for implantation.
- Verification of the template orientation at the time of implantation. The template is in its correct orientation when two holes in the first circle coincide with the 12 o’clock and 6 o’clock positions.
- Implantation of urethral needles at least 5 mm away from urethra.
Prostate Implant - Procedure QM summary

- Verification of the proper functioning of the ultrasound unit, and its calibration with respect to the template (specially, if it is a transducer fixed system).
- Post procedure notes in the patient’s chart by the physician.
- Diagram of the implant with written directives clearly spelling the total dose, dose rate for LDR or dose per fraction for HDR.
- Sending the completed implant loading form to the brachytherapy dosimetry team in radiation oncology.
- Intermediate catheters properly numbered and connected to the needles.
Flexible Catheter Implants

- Breast / Chest Wall Implants
  - Single Channel Breast Implants (Mammosite)
  - Free-hand Planar Breast Implants

- Head & Neck Implants
  - Planar Implants
  - Gold Button/Button Technique
  - Loop technique/Arch Technique

- Multiple Site Implants
Flexible Catheter Implants

-QM implantation procedure

Several sites are easily accessible from at least two sides for freehand flexible catheter implants. General considerations for such implants are:

- Availability of sterile sharp ‘angled’ needles (trocars)
- Buttons
  - plastic buttons of different colors
  - metallic buttons to be used as stoppers
  - gold buttons for shielding
- Appropriate catheters, sterile rulers and marking pens
- Ensure the patency of the catheters to be implanted
Breast single channel (Mammosite) -QM implantation procedure

Catheter entry

Proper contrast and volume of fluid

MAMMOSITE APPLICATOR WITH BABY Ng TUBE
Multi-channel Implant - QM implantation procedure

Marking the implant planes and needle entry & exit points

Proper interplane separation

Different color catheters or different color buttons for each plane
Multi-channel Implant - QM implantation procedure
Free-hand Breast Implants - QM implantation procedure

- Marking entry and exit points of the trocars on the breast
- Inter-digitating needles in the neighboring planes
- Inter-planar distances and inter-catheter distances should follow Paris or Manchester system rules for LDR implants for $^{192}$Ir wires and ribbons, respectively. For HDR implants, this spacing is desirable.
- Catheters secured by the buttons at both ends, so that the unintended movement of catheters is no more than 2 mm.
- Different color catheters for each plane (or at least different color button)
- Flexible metallic or plastic stylets inserted into the implanted catheters to ensure patancy of the catheters
- Single plane chest wall implants require careful spacing to avoid hot and cold spots in the implant.
H & N implants - QM of Implantation Procedure
H & N implants - QM of Implantation Procedure

Arch Technique

• Tonsillar pillars
• Soft palate
H & N implants - QM of Implantation Procedure
H & N implants - QM of Implantation Procedure

Plastic & Gold Button Technique: Base of Tongue
H & N implants - QM of Implantation Procedure

Plastic & Gold Button Technique: Tonsillar fossa
Before implantation, marks on skin for proper catheter separation
Different color buttons for different planes of an implant
Different color catheters for different implants, in the case of multiple-site implants
Each catheter secured in its place with a metallic button securing catheter position within~2 mm
Distal end blocked to ensure source ribbon/wire does not go through.
The intraoral plastic button(s) which serve as a spacer to allow the $^{192}$Ir sources to project beyond the mucosa should be used whenever necessary
The loop applications are for LDR implants and should not be used for HDR applications
For LDR implants, measurement of the implanted catheter length to determine the number of seeds for each catheter
For HDR implants, measurement of catheter length parameter
Clear diagram of the color coded implant for brachytherapy dosimetry team
Multiple Sites Implants

- Multiple site implants in close proximity are usually mixed implants, i.e., template based implant and a free hand flexible catheter implant or an intracavitary application. Examples for the former are vulvar implants, breast and axillary lymph node implants, whereas interstitial-intracavitary cervical and some extensive maxillary implants fall in the later category.
- Additional considerations about the possible overlap of two implants needs to be taken into account.
- Extent of flexible implant in the presence of a rigid implant requires clear demarcation of the boundaries of each implant at least externally before the start of the implantation process.
- If there is any intracavitary application within or close to the rigid needle implant, securing of the intracavitary applicator in place within 2 mm is required.
Practical considerations of Implant Reconstruction

- Template based rigid needle implants
  - Prostate implants
- Flexible catheter Implants
  - Breast Implants
  - Head and Neck implants
Templates and Rigid needles
- QM Reconstruction

Reconstruction of Applicator Geometry

Orthogonal Films  Stereo-shift Films  CT images
Templates and Rigid needles - QM Reconstruction
Templates and Rigid needles - QM Reconstruction
Templates and Rigid needles
- QM Reconstruction
Templates and Rigid needles
- QM Reconstruction
Templates and Rigid needles
- QM Reconstruction
Templates and Rigid needles - QM Reconstruction

Auto-detection of rigid catheters require manual verification
Templates and Rigid needles
- QM Reconstruction

- Film-based dosimetry
- CT/MRI/US-based 3D planning
Prostate Implants - QM Implant Reconstruction (summary)

- A set of radiographs in the OR to ensure that the implant is in the correct place
- Foley balloon filled with diluted (50%) contrast solution
- To view the implant position with respect to a full bladder position, diluted (20%) hypaque solution is injected directly into the bladder (that’s why 3 way Foley)
- For CT based planning 2 mm transverse slices are desirable to identify the distal ends of the needle tips accurately
- If auto-detection feature is used, individual catheter tips need to be verified manually
Numbering of all the implanted channels on a printed diagram of the template

For film based reconstruction, loading each channel with a uniquely defined dummy train and the loaded dummy’s identification marked against the channel in which it is loaded

For CT based reconstruction, no need to load dummy trains in steel needles, but auto – detection needs manual verification

All dummy markers should truly represent the source wire, with the cold tip or leader of the same size as that of the source train.

The patient should be positioned in a reproducible position (we use 3 point set up) so that when radiographs or scout films are taken before each fraction, the patient is in the same position as for the planning radiographs or CT.

It is extremely important to ensure patient immobilization during the entire procedure of localization films, because identification of various channels and calculation points may require data entry from different sets of films.

Treatment planning system should be periodically checked to ensure it is consistent in reconstruction.
Flexible catheter (Mammosite) - QM Reconstruction
Localization of Mammosite catheter by inserting dummy wire through the HDR port right up to the tip of the applicator.

Either orthogonal films or CT scan can be performed after ensuring that the balloon is inflated with the planned amount of fluid (20% contrast).

Without CT, however, the dose to the skin cannot be accurately assessed nor can the trapped air be visualized, two problems that would lead to aborting the procedure.

On the other hand, radiographic or CT scout view verification of the size of the balloon before each treatment, to assure that it hasn’t leaked, should be a routine QA procedure.
Head & Neck Implants - QM Implant Reconstruction
Head & Neck Implants - QM Implant Reconstruction
Head & Neck Implants - QM

Implant Reconstruction (summary)

- Mark catheters from superior to inferior starting at the shallow plane.
- If the implantation is carried out in sagittal planes, start from the left side plane, numbering catheters from anterior to posterior.
- If there are multiple implants in close proximity, catheters should be marked continuously without separating them.
- Numbering should be done for the corresponding flexible stylets as well, because catheters and their corresponding stylets will generally be of different sizes.
- Patients usually are in pain (or sometimes even disoriented); carefully positioning them on the table with a head rest and possibly a masking tape to stabilize their head may be useful. Immobilization is essential because several films may be required and the patient’s position reproducibility is crucial.
- Dummy ribbons should be loaded and their position in the catheters noted on the diagram.
- Orthogonal films or variable angle oblique films are preferable.
- For CT based planning, the dummy ribbons are generally not required, but in some cases artifacts due to the dental fillings or gold buttons (used for providing shielding), may obscure the catheter’s distal end, necessitating the need to use dummy ribbons.
Even though most free-hand catheters are implanted without the aid of any well defined geometrical pattern, their numbering should follow a very consistent order to avoid any kind of confusion for treatment planning and source loading.

It is imperative that a preplan is carried out in such cases and guidelines from classical systems like Manchester, Paris or Quimby be taken.

Once the implant is complete, a diagram closely resembling the implant may be drawn showing different catheters in at least two planes, e.g., transverse and coronal or sagittal planes.
Templates and Rigid needles

- QM Planning & Dosimetry
Templates and Rigid needles
– QM Planning & Dosimetry

Optimization Strategy ????

Center cooler

Center hot?
Templates and Rigid needles – Planning & Dosimetry

- Optimization by constraints (OC)
  - Requires dose points inside and outside the volume

- Geometric Optimization (GO)
  - Allows dwell positions themselves as dose points

- Combination of OC and GO (GO! OC!)

- Inverse planning?
Templates and Rigid needles
- Planning & Dosimetry
Dose distribution
Templates and Rigid needles
– Planning & Dosimetry
Templates and Rigid needles
- Planning & Dosimetry
Templates and Rigid needles

- Planning & Dosimetry

- **Cumulative DVH**
  - It is basically the summation of voxels over dose
  - Often limited to a specific anatomical structure
  - Slope of the volume vs dose curve is an indication of dose uniformity
  - It can be used to determine that part of the target volume that is underdosed or that part of an organ that is overdosed
Templates and Rigid needles – Planning & Dosimetry

Differential volume dose histogram

$^{192}$Ir point source, 1000 cGy at 1 cm in tissue

"Natural" volume dose histogram

$^{192}$Ir point source, 1000 cGy at 1 cm in tissue

Differential and “Natural” DVH - Comparison for a Point source
Templates and Rigid needles
- Planning & Dosimetry

“Natural” DVH for Prostate
Prostate implant - QM planning and Evaluation

- Loading of channels per the delineated target volume or according to the gold seeds previously implanted into the prostate.
- Activity per seed in the central six needles is half of that used for the outer needles for LDR implants, dose rate about 65cGy per hour.
- For HDR implants, catheter length parameter, i.e., the distance from the indexer to the tip of the needles should be measured for all channels and entered into the planning system. This should be within 1mm for all channels.
- For HDR implants, geometrical optimization works very well, but for further urethral dose reduction, central six needles’ dwell time should be decreased to about one-third of the original dwell time.
- Dose to the bladder points and rectal points should be calculated and be less than the prescribed dose and urethral dose also should be controlled. At our center, no point in urethra gets more than 110% of prescribed dose.
- For TURP and re-irradiation cases, the dose to urethra should further be reduced by reducing the dwell time in the central six needles (producing a hollow cylinder or doughnut shaped distribution).
- Dwell positions for HDR implants should remain within the target volume.
- The dose prescription and dose limitation to organs at risk will however take precedence over the above suggestions.
- Dose evaluation for LDR or HDR prostate implants should be carried out and reported as per the ABS and ICRU 58 guidelines.
The smallest-volume isodose surface covering the entire target volume is taken to be the planned target dose (PTD).

Though high dose gradients exist around the source dwell positions, the total volume of the hyper dose sleeve (200% PTD) should be restricted to less than 10% of the treatment volume.

Using the ‘natural’ DVH, evaluation of the dose distribution between the catheters and in the treated volume is evaluated and the effect of dose optimization is assessed.

Since attempts are made to make the dose distribution in the target volume homogeneous, it should approach Manchester system type loading. The mg-hrs required from Paterson Parker tables for the reference isodose surface volume can be compared with the actual mg.hrs used after appropriate conversions from the planned total air kerma strength for manual calculation. In our center for prostate implants, these values matched within 5% for more than 97% of the cases, in fact for 68% of the treatment plans the mg-hrs were within 2%.
Single channel (Mammosite) - QM Planning & Dosimetry
**Single channel (Mammosite) - QM Planning & Dosimetry**

- First dwell position about 0.3 -0.5 cm from the distal end
- 6-8 dwell positions of 0.5 cm each
- Maximum dwell time in the center
- Other dwell times are low and are adjusted for better coverage
Multi-channel - QM Planning & Dosimetry
Head & Neck - QM Planning & Dosimetry
Head & Neck - QM Planning & Dosimetry
Treatment planning of flexible catheters is in general more difficult as there can be more than one simultaneous implant and each one requires different type of planning. For example, for tongue implants, the most distal source needs to be loaded above the mucosa for LDR implants, and with much higher dwell time for HDR implants. Whereas, for neck implant dwell times near the skin should be reduced and dwell positions kept at least 5 mm from the skin.

A composite plan for multiple implants always should be made for dosimetry and evaluation. For HDR treatments, if required, different plans can be exported separately to the treatment machine.

For HDR treatments, all catheter length parameters should be measured individually, at both the entrance to the skin and exit (or most distal) ends. The length of the catheter within the tissue as obtained by radiographic or CT means should be compared with these measurements. Both should agree within 2 mm.

Dose prescription in these implants is volume based; the target volume is either delineated on the CT slices or taken from the surgical markers. Effective interaction between physicist and radiation oncologist forms the basis of an effective treatment plan.

Plan evaluation should be carried out in all the transverse and sagittal planes to check for any hot or cold spots and any overlapping of loaded catheters. Natural DVH's are of great help in picking up the right isodose surface and for evaluating the plan using its dose uniformity and quality indices.
Quality Management of Treatment Planning and Evaluation

- Treatment planning for interstitial implants should be carried out on planning systems, which use ICWG formulism adopted in AAPM’s TG 43 report.
- Source strength should be specified as air kerma strength of the source to be used, with proper corrections for the source anisotropy along its axis.
- The planning system should be thoroughly tested before its clinical implementation.
- Also, periodic performance re-evaluation should be carried out by using reproducible catheter placement in a simple geometrical pattern.
- Post implant dose calculations should be performed after localization of the catheters or needles with respect to the target volume and the organs at risk.
- Dose distribution should be obtained in multiple planes after volume dose calculations.
Quality Management of Treatment Planning and Evaluation

- Treatment planning should be performed by a dosimetrist or a medical physicist and should be reviewed with the attending radiation oncologist before the start of an HDR fraction or during the first half of an LDR treatment.

- All patient dose calculations should be verified by the brachytherapy physicist by reviewing that no gross errors have occurred and by performing an independent dose calculation to at least one critical point.
Quality Assurance of Source Application and Removal

- Prostate implants
- Gynecological implants
- Head and Neck implants
Gold Markers

Needles and marker seeds

Gold Markers

Needles Shifted after 1st. fraction
Needle movement
Needle or Catheter Movements and Possible Corrections
HDR Treatment
SKIN REACTION
HDR Treatment
HDR (Mammosite) Treatment

- Skin reaction at 7 weeks post treatment
HDR (Mammosite) Treatment
HDR (Mammosite) Treatment
Quality Assurance of Source Application and Removal
Quality Assurance of Source Application and Removal - LDR

- Based on the treatment plan, $^{192}$Ir source ribbons of proper strength and size are ordered and received in the department.
- The number of sources and their strengths are compared with the user’s order and logged.
- All sources are stored in the hot lab, with radioactive material sign posted on its door. When opening the package, it should be determined that there is no contamination due to damage during shipping. Exposure at 1 meter and at surface along with wipe test of outer container be noted and logged.
- Ribbons should be transported to the patient’s room in a cart after calibration, with proper labeling of radioactive material after calibration as per AAPM’s TG 56.
- Loading should be carried out by the authorized user and physics staff using long handle forceps. Radiation survey with a calibrated meter should be done after the sources are loaded and secured in respective channels as per the plan. The time of source loading and survey results are noted down in the patient’s chart.
A “Caution: Radiation Area” sign is posted on the patient’s door with the type of sources and radiation dose at 1 meter, at bed side and at the door noted on the radiation label.

Emergency phone numbers of the radiation safety officer (RSO) and the physician should also be on the label.

After the completion of treatment, all sources should be removed using long forceps and placed in shielded container.

A radiation survey should be carried out and its results noted down. When satisfied that all sources have been removed and secured in the container, all radiation labels from the door and room are removed.

Sources are removed from the container and stored in the hot lab for later shipment to the supplier.
Quality Assurance of Source Application and Removal - HDR

- All HDR applications should be done after a proper treatment day QA
- New source calibration, and periodic source calibration as per the radioactive materials license must be carried out. Differences up to 5% from the manufacturer’s calibration certificate are generally acceptable, but it is good practice to check with the manufacturer if the difference is more 3%.
- Authorized user and medical physicist or RSO must be present for all HDR treatments
- Authorized user should verify that correct source transfer tubes are used
- The treatment plan should be compared with that from the treatment planning system by checking the dwell times in each channel and total treatment time.
- The implanted needles or catheters should be connected by one person to their respective numbers on the afterloader turret and verified by a second.
- Emergency kit should be available in the treatment room, and two radiation survey meters (at least one of them being ionization chamber type with high range (500 R) should be available at the console.
Once the treatment is finished, the physicist surveys the patient and again reading at the afterloader surface and at a distance (some states require at 20 cm, NRC requirement is at 1 m) from the afterloader surface is noted.

Before any HDR fraction, the patient with template & needles is either scanned or radiographed to ensure that the applicator is in the right position. Mammosite patients should be radiographed (or scouted) to ensure that the balloon is intact.

For MammoSite applicator, it is mandatory to ensure that the luer lock is firmly connected. Also, all MammoSite patients, endobronchials and endoesophageals should be treated in the scanning position, i.e., supine on a treatment table or a gurney.

All source transfer tubes should be as far off the patient as possible to reduce any contact dose to other areas of the patient.

HDR fractionated treatments should be at least 6 hours apart.

For any treatment plans with more than the number of available channels on an older treatment planning system that requires the division into two separate plans should be checked very carefully by the authorized user, physicist, and therapist, to ensure planned channel is connected with the treatment channel.