

Canadian Association of Provincial Cancer Agencies

Standards for Quality Control at Canadian Radiation Treatment Centres

Low Dose Rate Prostate Brachytherapy

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Developed, revised and submitted for approval by THE CANADIAN ORGANIZATION OF MEDICAL PHYSICISTS and THE CANADIAN COLLEGE OF PHYSICISTS IN MEDICINE

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Document development and review process: The quality control documents in this series originated from one of two sources. Some of the source documents were commissioned by CAPCA specifically for the purpose of developing national standards. This is one such document. Others had been previously developed for provincial use by the Physics Professional Affairs Committee of Cancer Care Ontario (formerly the Ontario Cancer Treatment and Research Foundation). The source documents were developed over an extended period of time from 1989 to 2005. Each source document has been reviewed by one or more independent Canadian medical physicists and the reviews accepted by the task group as they became available. The primary and secondary task group reviewers then examined the source document, the external review(s) and any appropriate published literature to propose quality control standards, objectives and criteria to the full task group. The full task group met electronically and, by a consensus approach, developed the present document. The task group gratefully acknowledges the effort contributed by the author(s) of the source document and the reviewer(s) whose work forms the basis of this document. Review, updating and reformatting have been performed and, for any errors or omissions introduced in this process, the task group takes full responsibility.

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Acronyms, Synonyms and Definitions

| | |
|---------------|--|
| AAPM | American Association of Physicists in Medicine |
| ADCL | Accredited Dosimetry Calibration Laboratory |
| Al | Aluminum |
| ANSI | American National Standards Institute |
| BSF | Back-scatter factor |
| CAPCA | Canadian Association of Provincial Cancer Agencies |
| CCO | CancerCare Ontario |
| CCPM | Canadian College of Physicists in Medicine |
| CNSC | Canadian Nuclear Safety Commission (Successor to the Atomic Energy Control Board - AECB) |
| COMP | Canadian Organization of Medical Physics |
| CSA | Canadian Standards Association |
| CTV | Clinical target volume |
| Cu | Copper |
| EPI(D) | Electronic portal imaging (device) |
| Gleason score | A numerical system based on major and minor histological patterns |
| HVL | Half-value layer |
| IAEA | International Atomic Energy Agency |
| ICRU | International Commission on Radiation Units and Measurements |
| IEC | International Electrotechnical Commission (Geneva, Switzerland) |
| IMRT | Intensity modulated radiation therapy |
| INMS-NRCC | Institute for National Measurement Standards of the National Research Council of Canada |
| IPEM | Institution of Physics and Engineering in Medicine |
| IPSM | Institute of Physical Sciences in Medicine |
| ISO | International Organization for Standardization |
| Isocentre | The intersection of the axes of collimator and gantry rotation |
| Linac | Electron linear accelerator |
| MLC | Multileaf collimator |

| | |
|--------------|--|
| MPPAC | Medical Physics Professional Advisory Committee |
| MU | Monitor unit |
| NCRP | National Council on Radiation Protection and Measurements |
| NIST | National Institute of Standards and Technology |
| NRCC | National Research Council of Canada |
| NTD | Normal treatment distance |
| ODI | Optical distance indicator |
| PMMA | Polymethyl methacrylate |
| PDD | Percentage depth dose |
| PSA | Prostate specific antigen |
| PTV | Planning target volume |
| QA | Quality assurance (the program) |
| QC | Quality control (specific tasks) |
| SSD | Source-to-surface distance |
| STP | Standard temperature and pressure |
| TBI | Total body irradiation |
| TG- | Publications of various AAPM Quality Assurance Task Groups |
| TLD | Thermoluminescent dosimeter |
| U | air-kerma strength ($\mu\text{Gy m}^2/\text{h}$) |
| WHO | World Health Organization |
| σ | Standard deviation |
| ϵ_T | Timer/monitor end error |

Frequencies:

| | |
|----------|---|
| Daily: | Once during every treatment day and separated by at least 12 hours. |
| Weekly: | On average once every 7 days and at intervals of between 5 and 9 days |
| Monthly: | On average once every four weeks and at intervals of between 3 and 5 weeks |
| Annually | On average once every 12 months and at intervals of between 10 and 14 months. |

Output:

Output constancy check: a daily instrument reading (corrected for temperature and pressure) taken under reproducible geometrical conditions designed to check that the radiation output (e.g. cGy/MU) values in clinical use are not in error.

Output Measurement: a determination of the absorbed dose to water (cGy) at a reference point in the photon beam for a chosen field size and beam quality.

Introduction

Patients receiving treatment in a Canadian cancer centre have a reasonable expectation that the quality of their treatment is independent of their geographic location or the centre they are attending. Insofar as medical physicists contribute to treatment quality, this expectation will be more closely met through the harmonisation of quality control standards across the country. The Canadian Association of Provincial Cancer Agencies (CAPCA) has initiated the process of standardisation of treatment quality in Canada through its draft document “Standards for Quality Assurance at Canadian Radiation Treatment Centres”. This present document is an appendix to the CAPCA document and is concerned with quality control standards for low dose rate (LDR) prostate brachytherapy. This document was specially commissioned for this quality control series.

A quality control program for equipment used to deliver radiotherapy in a Canadian cancer centre must be carried out by, or under the direct supervision of, a qualified medical physicist. Here, a qualified medical physicist is one who is certified in Radiation Oncology Physics by the Canadian College of Physicists in Medicine or who holds equivalent certification. This individual, known as the supervising physicist, is responsible for ensuring compliance with the local quality control protocol, maintaining appropriate documentation, taking appropriate remedial actions and communicating with other members of the radiation therapy team concerning the operational state of the equipment. Depending on local circumstances and organisational structure, one physicist may supervise quality control for all equipment or the responsibilities may be dispersed. However, the supervising physicist for a particular piece of equipment must have a direct line of communication to the Quality Assurance Committee for the Radiation Treatment Program.

This document contains specific performance objectives and criteria that the equipment should meet in order to assure an acceptable level of treatment quality. However, it does not recommend how the tests should be carried out. It is the responsibility of the supervising physicist to ensure that locally available test equipment and procedures are sufficiently sensitive to establish compliance or otherwise with the objectives and criteria specified here. There are several other publications dealing with the performance, specifications and quality control of LDR prostate brachytherapy (Nath 1995; Yu 1999; Nag 2000; Williamson 1998). Most of these publications have extensive reference lists. Some have detailed descriptions indicating how to conduct the various quality control tests.

Radiation safety activities are beyond the scope of this report. However, such activities may be combined with routine quality control programs for equipment.

A successful quality assurance program is critically dependent upon adequately trained staff and a culture of continuous quality improvement. Educational opportunities to be offered to quality control staff must include new staff orientation, in-house continuing education, conference participation and manufacturer’s courses as appropriate. All such

educational activities must be documented as part of the quality assurance program. Continuous quality improvement embodies the concepts of documentation, monitoring, review and feedback.

The standards promoted in this document are based on the experience of the authors and reviewers and are broadly consistent with recommendations from other jurisdictions (Nath 1995; Yu 1999; Nag 2000; Williamson 1998). Although this document has undergone extensive review it is possible that errors and inaccuracies remain. It is hoped that the users of these standards will contribute to their further development through the identification of shortcomings and advances in knowledge that could be incorporated in future versions.

Performance Objectives and Criteria

Objectives and criteria for the evaluation of the performance of radiotherapy equipment fall into several categories.

1. **Functionality.** Equipment systems and sub-systems for which the criterion of performance is “Functional” are either working correctly or not. Such systems are commonly associated with the safety features of the equipment or installation. Operating a facility which has failed a test of functionality has the potential to expose patients and staff to hazardous conditions.
2. **Reproducibility.** The results of routine quality control tests, for which reproducibility is the criterion, are assessed against the results obtained at installation from the accepted unit. Tolerances and action levels may be set for parameters that can be quantified.
3. **Accuracy.** Accuracy is the deviation of the measured value of a parameter from its expected or defined value. An example is template positional accuracy.
4. **Characterisation and documentation.** In some cases it is necessary to make measurements to characterise the performance of a piece of equipment before it can be used clinically. An example is the measurement of the ion collection efficiency of an ionisation chamber.
5. **Completeness.** The use of this term is restricted to the periodic review of quality control procedures, analysis and documentation.

For quantities that can be measured, tolerance and action levels may be defined.

- i. **Tolerance Level.** For a performance parameter that can be measured, a tolerance level is defined. If the difference between the measured value and its expected or defined value is at or below the stated tolerance level then no further action is required as regards that performance parameter.
- ii **Action Level.** If the difference between the measured value and its expected or defined value exceeds the action level then a response is required immediately. The ideal response is to bring the system back to a state of functioning that meets all tolerance levels. If this is not immediately possible, then the use of the equipment must be restricted to clinical situations in which the identified inadequate performance is of no or acceptable and understood clinical significance. The decision concerning the most appropriate response is made by the supervising physicist in conjunction with the users of the equipment and others as appropriate. If the difference between the measured value and its expected or defined value lies between the tolerance and action levels, several courses of action are open. For a problem that is easily and quickly rectifiable, remedial action should be taken at once. An alternative course of action is to delay remedial action

until the next scheduled maintenance period. Finally, the decision may be made to monitor the performance of the parameter in question over a period of time and to postpone a decision until the behaviour of the parameter is confirmed. Once again, this will be a decision made by the supervising physicist in consultation with the users of the equipment and others as appropriate.

Documentation of equipment performance is essential and is discussed later. However, at the conclusion of a series of quality control tests it is essential to inform the users of the equipment of its status. If performance is within tolerance verbal communication with the users is sufficient. If one or more parameters fails to meet Action Level criteria, and immediate remedial action is not possible, then the users of the equipment must be informed in writing of the conditions under which the equipment may be used. Compliance with Action Levels but failure to meet Tolerance Levels for one or more parameters may be communicated verbally or in writing depending on the parameters and personnel involved. The judgement of those involved will be required to make this decision.

System Description

Brachytherapy is a procedure in which sealed radionuclide sources are placed in close proximity to or inside the tumor. New brachytherapy modalities for prostate cancer have appeared in Canada and elsewhere over the last few years: ultrasound guided transperineal interstitial permanent prostate brachytherapy (TIPPB) and high dose-rate (HDR) brachytherapy. In prostate brachytherapy, three radionuclides are currently used: ^{125}I , ^{103}Pd and ^{192}Ir . ^{192}Ir is used for HDR brachytherapy. QC procedures are similar to those of other HDR procedures and can be found in the CAPCA document “Brachytherapy Remote Afterloaders” available on this website. ^{125}I and ^{103}Pd are used for permanent implants and are the radionuclides of interest here.

TIPPB was first proposed by Holm and colleagues (1981; 1983). The procedure consists of using a transrectal ultrasound probe to first define the prostate contours in 5 mm thick transaxial images for dosimetric planning and then, some weeks later, delivering radioactive seeds (sources 0.8 mm in diameter \times 4.5 mm in length) into the prostate gland. In both steps, the patient is placed in the lithotomy position. Needles containing the seeds are inserted through the perineum and into the prostate under the guidance of the transrectal ultrasound probe. The needles are prepared for the procedure in one of three ways: manual loading on site, purchased pre-loaded needles and seed loading devices. Some customization of the Quality Control standards presented here may be necessary to accommodate the particular method of needle loading in use.

TIPPB has become a very popular treatment alternative for low risk prostate cancer patients due to the pioneering work of the Seattle group (Holm 1981). This treatment option is offered to patients having early localized prostate cancer (Stage $< \text{T2c}$, Gleason score < 7 and PSA < 10). Biochemical disease-free survival rates have now been reported for this procedure for follow-up periods of up to 12 years (Holm 1983; Blasko 1987; Ragde 1998; Beyer 1997; Wallner 1996; Storey 1999; Ragde 2000; Peschel 2003; Merrick 2003).

For intermediate and high-risk patients (PSA > 10 and/or Gleason score > 6 and/or stage $> \text{T2c}$), HDR brachytherapy is more commonly used, mainly as a boost strategy. From a radiobiological point of view the use of a higher radiation dose rate may be an advantage for higher-grade prostate cancer. HDR brachytherapy uses a remote afterloader to guide a single, tiny (1mm diameter \times 3 mm length), highly radioactive source of Iridium-192 at the end of a thin, flexible stainless steel cable. The afterloader directs the cable through the catheters or applicators that are placed in the patient, under ultrasound guidance as for TIPPB, by the brachytherapy physician to treat the tumor. The source travels through each catheter in steps, stopping for planned time intervals at predetermined locations called dwell positions. So far, the 5-year results from phase I/II studies reported in the literature show promising PSA control and negative biopsy results in patients with intermediate and high risk prostate cancer (Martinez 2000).

A prostate brachytherapy program, whether it involves permanent seed implants or high dose rate temporary implants, requires the competencies of multiple health professionals to be efficient and productive. From the physicist’s point of view, there is a

convergence of many technologies into a single procedure. AAPM task groups 43 (Nath 1995) and 64 (Yu 1999), as well as the ABS guideline (Nag 2000), are reference documents for these procedures. Three areas are of importance for all implants: imaging, dosimetry and radiation protection.

Prostate brachytherapy is based first on the use of ultrasound as a real-time guidance device. Conventional x-ray films or fluoroscopy can also be used to visualize the seeds or the catheters after they have been implanted. Such verification can be made in the operating room or the brachytherapy suite. Finally, CT-scans (and less commonly, MRI scans) are used for TIPPB post-plan QA and for HDR planning purposes. Several commercial vendors offer dedicated treatment planning systems with image capture software and DICOM import/export capabilities. For all prostate brachytherapy programs, a calibrated well chamber and hand-held radiation monitor must be available at all times. Other personal dosimeters, such as ring and wrist dosimeters, can also be used.

Acceptance Testing and Commissioning

Low dose rate prostate brachytherapy equipment that is newly acquired or substantially upgraded requires acceptance testing before being put into clinical service. Acceptance tests have three purposes:

- to ensure that the unit meets stated specifications,
- to establish baseline parameters for the future quality control program,
- to familiarize the customer with operation of the unit.

In addition, acceptance testing of the equipment and facility will include establishing compliance with applicable radiation safety codes. These are included in federal regulations and it is the supervising physicist or designate's responsibility to be familiar with these requirements and to demonstrate compliance. Decommissioning of brachytherapy equipment and facilities may also be regulated by provincial and/or federal authorities.

All imaging modalities and treatment planning systems that are used in prostate brachytherapy and that are newly acquired or substantially upgraded require acceptance testing before being put into clinical service. Acceptance tests are customarily described in a document prepared by the vendor, although the purchaser may wish to specify additional tests. The document is signed by the purchaser upon satisfactory completion of testing, before which formal purchase of the unit should not be completed.

The dosimetric description of the sources should be made according to AAPM task Group 43 recommendations (Nath 1995, Rivard 2004). The AAPM and the Radiological Physics Center (RPC) jointly maintain a registry of low-energy brachytherapy seed designs that meet the AAPM dosimetric prerequisites. Peer reviewed articles giving dosimetric parameters of each of these seeds can be found in the registry (http://rpc.mdanderson.org/rpc/htm/Home_htm/Low-energy.htm), along with a description of the AAPM prerequisites. The medical physicist should regularly carry out a thorough search of the scientific literature for any new assessment of a seed's dosimetric parameters and its potential impact on clinical dosimetry.

Any new or upgraded treatment planning system and/or new seed model should be validated against known test cases and also by hand calculation. Potentially helpful in this regard are the test cases used by the RPC for credentialing participants in clinical trials research having an LDR prostate brachytherapy component, and available on the web (http://rpc.mdanderson.org/rpc/Documents/Prostate%20Brachytherapy%20QA_facility%20v_4.pdf). Before using a seed model clinically for the first time, a well chamber should be sent to an accredited dosimetry calibration laboratory (ADCL) for calibration. Alternatively, a single seed can be sent to an ADCL for measurement of its air kerma strength, and this value used to obtain a calibration factor for the well chamber. Compliance with applicable radiation safety codes must be ensured for each radionuclide, source type and activity range to be used.

The standards for acceptance testing of prostate brachytherapy systems should be consistent with routine quality control objectives and criteria applied subsequently. In

particular, there is no reason why a new or upgraded system, and its associated safety systems, should not meet the Tolerance Levels detailed later in this document (Table 1). Tests on all functional systems and sub-systems of the equipment must be included. These tests should be performed by, or under the supervision of, a qualified medical physicist.

Adherence to these standards (Table 1) must be demonstrated and documented, in or outside of the vendor's acceptance testing protocol, before a new LDR prostate brachytherapy system or major upgrade is accepted, and put into clinical service. Also, an appropriate subset of acceptance tests must be performed after any repair or preventive maintenance interventions on the equipment. The extent of testing required must be judged by a qualified medical physicist.

Commissioning generally refers to the acquisition of additional measured data from a unit after most acceptance testing is completed, with two purposes:

- for subsequent operating/performance calculations, for example, involving radiation dose,
- to establish baseline parameters for the future quality control program.

It is essential that all of the tests listed in Table 1 be performed at commissioning with the intended local test equipment and protocols so that meaningful baseline values are established for QC.

Quality Control of Equipment

The purpose of a quality control program is to assure that operational standards for a unit that were considered acceptable at time of purchase continue to be maintained, as closely as possible, over the life of the unit. Thus, quality control tests typically are periodic repetitions, partial or full, of acceptance and commissioning tests. For LDR prostate brachytherapy, tests are required for mechanical, radiological and safety systems.

The minimum standards for LDR prostate brachytherapy quality control are listed in Table 1. These standards consist of a series of tests to be performed, along with their minimum frequency. The tests are derived from the published literature and, in particular, the standards laid out in the AAPM documents, TG-43 (Nath 1995) and TG-64 (Yu 1999). The Tolerance Level is typically set at 50-75% of the Action Level.

The tests must be performed by a qualified medical physicist, or a suitably trained individual working under the supervision of a qualified medical physicist. Independent verification of the results of quality control tests is an essential component of any quality control program. To ensure redundancy and adequate monitoring, a second qualified medical physicist must independently verify the implementation, analysis and interpretation of the quality control tests at least annually. This independent check must be documented.

Daily tests must be scheduled prior to patient treatments. For other tests, testing at less than the minimum frequency is permissible only if experience has established that the parameters of interest are highly stable. Documentary evidence supporting this decision is essential. It is unlikely that frequencies of less than half those specified here could be justified.

In the event that the equipment does not meet the stated performance objectives and criteria, an adjustment or repair should be effected. If it is not possible to restore the equipment to full performance immediately, then the use of the equipment must be restricted to clinical situations in which the identified inadequate performance is of no or acceptable and understood clinical significance. The decision on the most appropriate response is made by the supervising physicist in conjunction with the users of the equipment and others as appropriate.

Preventive maintenance schedules and interventions recommended by the manufacturer of the equipment should be adhered to diligently. Following preventive maintenance or repair, the appropriate quality control tests selected from those listed in Table 1 must be performed before the unit is returned to clinical service. The extent of testing required must be judged by a qualified medical physicist. Frequently, equipment repairs and quality control testing are performed by different individuals. In such cases, good communication and reporting between the various staff involved are essential.

As pointed out previously, radiation safety activities are beyond the scope of this report. However, such activities must be integrated into routine quality control programs for equipment, e.g. room surveys after an implant procedure.

Documentation

Appropriate documentation is an essential component of a quality assurance program. All documents associated with the program should contain, as a minimum, the following information:

1. the name of the institution
2. the name of the originating department
3. the name(s) of the document's author(s)
4. the name of the individual(s) or group who approved the document for clinical use
5. the date of first issue
6. the number and date of the current revision

Further guidelines on the design of appropriate documentation may be found elsewhere (ISO 1994, Quality 2000)

Documents for use in a quality control program may be conveniently separated into two major categories: protocols and records. The protocols must be included in the Policy and Procedure Manual of the Radiation Treatment Quality Assurance Committee.

The quality control protocol contains the standards, or performance objectives and criteria, to be applied to a piece of equipment. Such standards are based on documents such as this one. In addition to the specification of standards, the protocol should provide sufficient detail concerning the test equipment and procedures to be followed that there can be no ambiguity in the interpretation of the test results.

The quality control record contains the results of the tests, the date(s) on which they were performed and the signatures and qualifications of the tester and the supervising physicist. When the number of tests to be performed on a particular occasion is limited and the test procedure is simple it may be advantageous to combine the protocol and record into a single document.

In addition to the protocol and record, it is essential to have a means of documenting any corrective action that takes place, together with any subsequent tests. Deviations from the locally approved protocol, such as those resulting from clinical pressure to access the equipment, must, of course, also be documented.

Finally, all documentation related to the quality control program must be retained for at least ten years.

Table 1: Quality Control Tests – LDR Prostate Brachytherapy.

| Designator | Test | Performance | |
|-------------|---|------------------------|--------|
| | | Tolerance | Action |
| Daily | | | |
| DPB1 | Radiation monitor | Functional | |
| DPB2 | Source strength verification (Well chamber) | 3% | 5% |
| DPB3 | US system/probe | Functional | |
| DPB4 | Source inventory | Complete | |
| DPB5 | Records | Complete | |
| | | | |
| | OR planning and seed loading devices | | |
| DPB6 | Console displays (treatment status indicator, date, time) | Functional | |
| DPB7 | Printer operation, Paper supply | Functional | |
| DPB8 | System self-test | Functional | |
| DPB9 | Delivery interrupt | Functional | |
| DPB10 | Power failure recovery | Functional | |
| DPB11 | Data transfer from Planning Computer | Functional | |
| DPB12 | Seed loading devices | Functional | |
| DPB13 | Communication between all systems | Functional | |
| DPB14 | Emergency seed loading kit (if applicable) | Functional/ Sterilized | |
| DPB15 | Online source strength verification | 8% | 15% |
| Annually | | | |
| APB1 | Ultrasound positional accuracy | 1 | 2 |
| APB2 | Ultrasound volumetric accuracy | 5% | 10% |
| APB3 | Stepper positional accuracy | 1 mm | 2 mm |
| APB4 | Template positional accuracy | 1 mm | 2 mm |
| APB5 | Source parameters and TPS dose calculation verification | 2% | 3% |
| APB6 | Emergency seed handling procedures review | Complete | |
| APB7 | Independent quality control review | Complete | |
| | | | |
| | OR planning and seed loading devices | | |
| APB8 | Online source strength measurements device calibration/verification | 3% | 5% |
| APB9 | Source positional accuracy (loading devices) | 2 | 3 |
| Bi-annually | | | |
| BPB1 | Well-chamber calibration | 1% | 2% |

Tolerances and action levels are specified in millimetres unless otherwise stated

N.B.: RADIATION SAFETY RELATED TESTS HAVE NOT BEEN INCLUDED IN THIS LIST BUT MUST BE PART OF A COMPREHENSIVE QA PROGRAM. SPECIFIC LICENSE REQUIREMENTS AND APPLICABLE SAFETY CODES MUST BE FOLLOWED. FOR EXAMPLE, CNSC ANNUAL DOCUMENTATION AND REPORT FOR MANUAL AND AFTERLOADING BRACHYTHERAPY MUST BE PERFORMED.

N.B.: THE QA OF ANY IMAGING DEVICES USED (C-ARM, CT SCANNER, MRI AND SO ON) MUST BE PERFORMED ACCORDING TO THE DEVICES' PROTOCOL.

Notes

Any maintenance on the ultrasound, computer, seed loading devices and so on should be followed by a thorough QA testing involving the daily and/or annual QA appropriate to the situation.

Daily Tests

- DPB2 10% of the seeds should be tested at a minimum. A secondary device can also be used as part of a seed loader (e.g. Isolader from Mentor or SeedSelectron from Nucletron) for which more than 10% and up to 100% of the seeds can be measured. Validation studies of the Isolader (Morrier et al., 2004) and SeedSelectron (Rivard et al., 2005) have been published.
- DPB5 Documentation relating to the daily quality control checks, preventive maintenance, service calls and subsequent checks must be complete and legible. The operator(s) must be identified.
- DPB6-15 The configuration of these tests will depend on the equipment selected and the clinical workflow (OR pre-planning/live planning with or without a seed loading device). Safety is the concern and tests should be designed accordingly. As a minimum, manufacturer's recommendations and applicable regulations must be followed.

Annual Tests

- APB1-4 Transverse and longitudinal positional accuracy, as well as volume accuracy, can be measured using specially designed phantoms, e.g. CIRS brachytherapy phantom model 45. Information about ultrasound verification procedures (e.g. use of ethylene glycol-water mixture and water temperature) for prostate can be found in Goldstein et al (2002). A simple prostate implant template verification set-up is also described in Mutic et al (2000). In addition various manufacturers also have their own recommendations.
- APB5 Peer reviewed articles giving dosimetric parameters of each of these seeds can be found in the registry:
(<http://rpc.mdanderson.org/rpc/htm/Home.htm/Low-energy.htm>).
The source data are usually based on Monte Carlo calculations *and* on experimental measurements, the combination being referred to as a consensus dataset (Chan 2004). Validation of the parameters in the TPS can be performed in two ways: 1) a simple 1D hand calculation for a single source compared to the TPS or 2) a simple geometry involving a

few seeds which can be reproduced in the TPS and in independent software (EXCEL, MATLAB or another commercial TPS). Tolerance and action levels refer to agreement between the TPS and an independent calculation

- APB6 The configuration of these tests will depend on the design of the facility and equipment. Review of the emergency procedures for seed/needle loading if a seed loading device is normally used and fails. Emergency procedures if a seed should drop on the floor, stick in a needle or be found in the urine bag should be reviewed.
- APB7 To ensure redundancy and adequate monitoring, a second qualified medical physicist must independently verify the implementation, analysis and interpretation of the quality control tests at least annually.
- APB8, 9 These measurements have been discussed in various publications including Yu, 1999 and Rivard, 2005

Bi-annual Tests

- BPB1 The well chamber should be sent to an accredited dosimetry calibration laboratory once every two years. A calibrated source, of each seed model used, could also be acquired from the manufacturer each year for verification purposes.

References and Bibliography

Blasko, J.C., Radge, H., and Schumacher, D. (1987) "Transperineal Percutaneous Iodine-125 Implantation for Prostatic Carcinoma Using Transrectal Ultrasound and Template Guidance". *Endocurietherapy/Hyperthermia Oncol* **3**, 131-139.

Chan G.H., Nath R., Williamson J.F. (2004). "On the development of consensus values of reference dosimetry parameters for interstitial brachytherapy sources." *Med Phys* **31**, 1040-1045.

Goldstein, et al. (2002) "Design of Quality Assurance for Sonographic Prostate Brachytherapy Needle Guides" *J Ultrasound Med* **21**, 947-954

Grimm, P.D., Blasko, J.C., Sylvester, J.E., Meier, R.M. and Cavanagh W. (2001) "10-year biochemical (prostate-specific antigen) control of prostate cancer with ¹²⁵I brachytherapy." *Int J Radiat Oncol Biol Phys* **51**, 31-40.

Holm, H.H. and Gammelgaard, J. (1981) "Ultrasonically guided precise needle placement in the prostate and the seminal vesicles." *J Urol* **125**, 385-387

Holm, H.H., Pedersen, J.F., Hansen, H. and Stroyer, I. (1983) "Transperineal I-125 iodine seed implantation in prostatic cancer guided by transrectal ultrasonography." *J. Urol* **130**, 283-286

ISO 9001 1994 BS EN ISO 9001: (1994) Quality Systems. Model for Quality Assurance in Design, Development, Production, Installation and Servicing (British Standards Institute, London).

Martinez, A.A., Kestin, L.L., Stromberg, J.S., Gonzalez, J.A., Wallace, M., Gustafson, G.S., Edmundson, G.K., Spencer, W and Vicini, F.A. (2000) "Interim report of image-guided conformal high-dose-rate brachytherapy for patients with unfavorable prostate cancer: the William Beaumont phase II dose-escalating trial." *Int J Radiat Oncol Biol Phys* **47**, 343-352

Merrick, G.S., Butler, W.M., Galbreath, R.W., Lief, J.H. (2001) "Five-year biochemical outcome following permanent interstitial brachytherapy for clinical T1-T3 prostate cancer". *Int J Radiat Oncol Biol Phys* **51**, 41-48.

Merrick, G.S., Wallner, K.E. and Butler, W.M. (2003) "Permanent interstitial brachytherapy for the management of carcinoma of the prostate gland" *J Urol* **169**, 1643-1652

Morrier J, Varfalvy N, Chretien M, Beaulieu L. (2004). "Evaluation of an automatic needle-loading system". *J Appl Clin Med Phys*. **5**, 82-90.

Mutic, S., Low, D.A., Nussbaum, G.H. et al. (2000) "A simple technique for alignment of perineal needle template to ultrasound image grid for permanent prostate implants." *Med*

Phys **27**, 141 - 143

Nag, S., Bice, W., DeWyngaert et al. (2000) "The American Brachytherapy society recommendations for permanent prostate brachytherapy postimplant dosimetric analysis." Int J Radiat Oncol Biol Phys **46**, 221-230.

Nath, R., Anderson, L.L., Luxton, G., et al. (1995) "Dosimetry of interstitial brachytherapy sources: recommendation of the AAPM Radiation Therapy Committee Task Group No. 43. Med. Phys **22**, 209-234.

Peschel, R.E. and Colberg, J.W. (2003) "Surgery, brachytherapy and external beam radiotherapy for early stage prostate cancer" Lancet Oncology **4**, 233-241

Quality Management Systems – Requirements, Ed 1, (2000), (International Organization for Standardization, Geneva)

Ragde, H., Elgamal, A.A., Snow, P.B., Brandt, J., Bartolucci, A.A., Nadir, B.S. and Korb, L.J. (1998) "Ten-year disease free survival after transperineal sonography-guided iodine-125 brachytherapy with or without 45-gray external beam irradiation in the treatment of patients with clinically localized, low to high Gleason grade prostate carcinoma". Cancer **83**, 989-1001

Ragde, H., Korb, L.J., Elgamal, A.A., Grado, G.L. and Nadir, B.S. (2000) "Modern prostate brachytherapy. Prostate specific antigen results in 219 patients with up to 12 years of observed follow-up." Cancer **89**, 135-41

Rivard M.J., Coursey B.M., DeWerd L.A., Hanson W.F., Huq M.S., Ibbott G.S., Mitch M.G., Nath R., Williamson J.F. (2004) "Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculations." Med Phys **31**, 633-674.

Rivard M.J., Evans DA, Kay I. (2005). "A technical evaluation of the Nucletron FIRST system: conformance of a remote afterloading brachytherapy seed implantation system to manufacturer specifications and AAPM Task Group report recommendations." J Appl Clin Med Phys. 6, 22-50.

Storey, M., et al. (1999) "Transperineal 125-Iodine Implantation for treatment of clinically localized prostate cancer: 5-year tumor control and morbidity" Int J Radiat Oncol Biol Phys **43**, 565-70

Van Dyk, J. ed. (1999) The Modern Technology of Radiation Oncology. Medical Physics Publishing, Madison, Wisconsin.

Wallner, J., Roy and Harrison, L. (1996) "Tumor control and morbidity following transperineal iodine 125 implantation for stage T1/T2 prostatic carcinoma". J Clin Oncol **14**, 449-453.

Williamson, J., Coursey, B.M., DeWerd, L.A., Hanson, W.F. and Nath, R. (1998) "Dosimetric prerequisites for routine clinical use of new low energy photon interstitial brachytherapy sources: Recommendations of the American Association of Physicists in Medicine Radiation Therapy Committee". Med Phys **25**, 2269-2270

Yu, Y., Anderson, L.L., Li, Z. et al. (1999) "Permanent prostate seed implant brachytherapy: Report of the American Association of Physicists in Medicine Task Group No. 64." Med Phys **26**, 2054-2076.