Canadian Association of Provincial Cancer Agencies

Standards for Quality Control at Canadian Radiation Treatment Centres

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Kilovoltage X-ray Radiotherapy Machines

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Developed, revised and approved by THE CANADIAN ORGANIZATION OF MEDICAL PHYSICS 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 the present. 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.

Table of Contents

Acronyms, Definitions and Symbols

AAPM	American Association of Physicists in Medicine
ADCL	Accredited Dosimetry Calibration Laboratory
Al	Aluminum
AMFPI	Active Matrix Flat Panel Imaging Devices
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
CT	Computed Tomography
CTV	Clinical target volume
Cu	Copper
EPI(D)	Electronic portal imaging (device)
FWHM	Full width at half maximum
Gleason score	A numerical system based on major and minor histological patterns
Gy	Gray, unit of absorbed dose (1J/kg)
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
mMLC	mini- or micro-Multileaf Collimator
MPPAC	Medical Physics Professional Advisory Committee
MRI	Magnetic Resonance Imaging
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
SRS	Stereotactic radiosurgery
SRT	Stereotactic radiotherapy
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 (μGy m^2/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 grossly 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 protocols 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 use with conventional radiotherapy kilovoltage radiotherapy units. It is based on a report originally prepared for the Medical Physics Professional Advisory Committee of Cancer Care Ontario.

A quality control program on 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 on 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 the locally available equipment and procedures are sufficiently sensitive to establish compliance or otherwise with the objectives and criteria specified here. There are many publications dealing with the performance, specifications and quality control of radiation therapy kilovoltage radiotherapy units that have been consulted in the preparation of this document (AAPM 2001; IPEM 1999; Van Dyk, 1999). These publications have extensive reference lists. Some have detailed descriptions of how to conduct the various quality control tests.

Radiation safety activities are beyond the scope of this report. However, such activities may be integrated into routine quality control programs of kilovoltage equipment (Belanger and Papin, 2003; Bushong, 2001; NCRP 49; NCRP 127; Roessler, 1998; Safety Code 20A).

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 (AAPM, 2001; IPEM, 1999). 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. Examples are isocentre diameter and reference dosimetry (cGy/MU).

4. Characterization and documentation. In some cases it is necessary to make measurements to characterize 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 which 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.

It is recognized that older equipment, which either was not designed to or is currently unable to meet the standards described here, is still providing a useful service to patients in many centres. In such cases, the equipment may fail to meet all action level requirements and the use of such equipment must be restricted to clinical situations in which the identified inadequate performance is of no or acceptable and understood clinical significance.

System Description

Kilovoltage radiotherapy units, although eclipsed first by cobalt-60 irradiators and then by linear accelerators, remain useful in the mix of energies available to a radiotherapy program. Low energy x-ray beams have application in the treatment of skin lesions and shallow tumours. The quality assurance program for the kilovoltage units must match the rigor of that for the most-modern irradiators and is every bit as important in order to safely deliver an accurate dose to the patient for those lesions they are appropriate to treat.

Application of kilovoltage radiotherapy is divided into two categories based on the chosen tube voltage. The lower energy range (the "kilovoltage" range; x-ray tube potentials of 30 or 40 to 100 kV and tube currents of a few mA) is used to irradiate surface lesions. Filtration of up to 6 mm of Al is added to remove the very low energy photons and 'harden the beam'. Applicator cones, attached directly to the tube-housing head, are the usual method by which the irradiation area is defined. Variable collimators are also available on some units and require additional quality control tasks over those performed for applicators. Irradiation is performed at short SSD (e.g. less than 20 cm) and the lesion depth must be less than a few millimetres. Hence, the use of the 'kilovoltage' region is selected when surface-to-shallow lesions are treated. In so doing, tissue greater than that at a moderate depth is spared when treating surface lesions.

"Orthovoltage" therapy refers to radiation therapy obtained with x-ray tube potentials in the 100 to 300 kV range, although 200-300 kV may be the more practical specification. This deeper radiotherapy tool requires beam currents of up to 20 mA and applied filtration equivalent to HVL values of 1 to 4 mm Cu. Coned applicators or movable diaphragms are used to define these beams. While coned applicators may be constructed mostly of metal (e.g. Cu), they have a clear plastic end to aid in viewing the target region. Hence attention must be given to the competence of the plastic portion. SSD values of approximately 50 cm are chosen (although a range of 30-50 may be required in practise). The depth dose distribution in this range is dependent, of course, on kV, HVL, SSD and field size. Maximum dose occurs close to the skin, with 90% of the dose being delivered within a tissue depth (water depth) of 2 cm.

Kilovoltage radiotherapy units continue to be successfully used for superficial therapy. Their simpler design, unique range of application and their traditional-type of technology set them apart from the higher energy devices. On commencing a revised radiotherapy quality assurance program for the kilovoltage units, it may be necessary for physicists to begin the evaluation of a basic level (i.e. the acceptance/commissioning-test level) in order to obtain baseline information on which to build the on-going quality assurance program. Such a re-vitalised QA program may even include the requirement to obtain lost documentation for the unit.

Acceptance Testing and Commissioning

Radiotherapy units that are newly acquired or substantially upgraded require 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 familiarise 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 and/or provincial regulations and it is the supervising physicist or designate's responsibility to be familiar with these requirements and to demonstrate compliance. Decommissioning of radiotherapy equipment and facilities may also be regulated by provincial and/or federal authorities.

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 standards for kilovoltage radiotherapy unit acceptance testing should be consistent with routine quality control objectives and criteria. In particular, there is no reason why a new or upgraded kilovoltage unit, and its associated safety systems, should not meet the Tolerance Levels detailed later in this document (Table 1). Optical, mechanical, electrical and radiographic accuracy and safety tests must be included. Several of these tests are based on an existing HARP (Healing Arts Radiation Protection) document, the X-ray Safety Code (20A), Reg. 543 (Healing Arts Radiation Protection Act, Ontario, 1990) and publications of Van Dyk (1999), the AAPM (2001)and IPEM(1999). The 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 kilovoltage radiotherapy unit 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 kilovoltage unit. A qualified medical physicist must judge the extent of testing required.

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.

Clearly, all of the tests listed in Table 1 must be performed at this time with the intended local test equipment and protocols if meaningful baselines are to be established.

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, within defined tolerances, over the life of the unit. Thus, quality control tests typically are periodic repetitions, partial or full, of acceptance and commissioning tests. For kilovoltage radiotherapy units, tests are required for optical, mechanical, radiographic and safety systems.

The minimum standards for the quality control tasks of kilovoltage radiotherapy units 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 document, TG-61' (AAPM, 2001) and the IPEM document, Report 81 (IPEM, 1999). The Tolerance Level is typically set at 50-75% of the Action Level.

The tests should 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. Documented evidence supporting this decision is essential. It is unlikely that a frequency of less than half that 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 are recommended by the manufacturer of the equipment and 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.

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 the piece of equipment. Such standards are based on documents such as this. In addition to the specification of standards, the protocol should provide sufficient detail concerning the test equipment and procedures to be followed that there could be no residual 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.

It is also necessary to maintain appropriate records of education, training, skills and experience of those involved with any aspect of the quality control program.

The documentation may be in any form of type of medium according to institutional policies.

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

Table 1: Quality Control Tests

Designator	Test	Performance	
		Tolerance	Action
Daily			
DK1	Patient monitoring audio-visual devices	Functional	
DK2	Door closing mechanism and interlock	Functional	
DK3	Couch movement and brakes	Functional	
DK4	Unit motions and motion stops	Functional	
DK5	Interlocks for added filters/kV-filter choice	Functional	
DK6	Beam status indicators	Functional	
DK7	Beam-off at key-off test	Functional	
DK8	Emergency off test	Functional	
DK9	kV and mA indicators	Functional	
DK10	Backup timer/ monitor unit channel check	1%	2%
DK11	Dosimetric test: output check	3%	5%
Monthly			
MK1	Mechanical stability and safety	Functional	
MK2	Cone selection and competency	Functional	
MK3	Physical distance indicators	2	3
MK4	Accuracy of head tilt and rotation readouts	1^{o}	1.5^{o}
MK5	Light/x-ray field coincidence	2	3
MK6	Light field size	2	3
MK7	X-ray field size indicator	2	3
MK8	X-ray field uniformity / filter integrity	5%	8%
MK9	Timer and End Effect Error	Characterize	+/-0.05min
MK10	Output linearity		1%
MK11	Output reproducibility	Characterize	<.03 CoV
MK12	Beam quality	10%	15%
MK13	Output Calibration Verification	2%	3%
MK14	Timer Accuracy Verification	2%	3%
MK15	Records	Complete	
Annually			
AK1	Reference Dosimetry	1%	2%
AK2	Alignment of focal spots	0.5	1
AK3	kVp measurement	5%	10%
AK4	Focal spot size	Reproducible	
AK5	Independent quality control review;	Complete	

Tolerance and Action Levels are specified in millimetres unless otherwise stated.

Notes

Daily Tests

DK1	Functional check of the operability of patient monitoring audio-visual devices.
DK2	Functional check of the operability of door-closing mechanisms and interlock(s).
DK3	Functional check of couch motion and brakes (where applicable)
DK4	Functional check of unit motions and motion stops
DK5	Functional check of interlocks for added filters, correct placement of filters and the matching of filters with kV value.
DK6	Functional check of the beam status indicators.
DK7	Functional check of beam-off at key-off
DK8	Functional check of emergency off button
DK9	Functional check of kV and mA indicators
DK10	Quantitative verification of correct operation of back-up timer
DK11	Quantitative dosimetric test: output reproducibility test at the chosen energy and filter combinations.

Monthly Tests

MK1	Verification that the unit and accessories are firmly anchored and may be used without endangering patients or staff.
MK2	Verification of the integrity of the cones and cone indicators.
MK3	Verification of the distance indicator.
MK4	Verification the angle readouts
MK5	Performance parameters refer to agreement at each edge. This test does not apply to all machine designs.
MK6	Geometric test to verify the light field sizes (where applicable).
MK7	Confirmation of radiation field size when a variable collimation system is provided. At least two field sizes must be checked.
MK8	Using a film, the flatness and symmetry of the X-ray beam must be assessed for the largest cone.
MK9	Timer and end-effect error measurement may be performed in conjunction with MK10.
MK10	Output linearity measurement for a standard SSD and field size and a dose range of 10-1000cGy.
MK11	Output reproducibility verification with the criterion being specified as the coefficient of variation of 10 readings under the same exposure conditions.
MK12	The Half Value Layer of any clinically used beams is measured. The HVLs measured in mm Al or Cu as appropriate are compared with the values obtained at commissioning. These tolerances acknowledge measurement uncertainty.

MK13	Using a high quality dosimetry system calibrated against the local secondary standard the calibration of all clinically used beams is checked.
MK14	The accuracy of the timer must be checked against a stop watch over a range of doses of 10-1000cGy.
MK15	Documentation relating to the daily quality control checks, preventive maintenance, service calls and subsequent checks must be complete, legible and the operator identified.

Annual tests

AK1	Using a high quality dosimetry system calibrated against the local secondary standard all beams and cones in use are recalibrated.
AK2	Focal spot – quantitative measurement, assessed relative to acceptance test value where applicable
AK3	kV quantitative measurement can be performed at the primary of the transformer.
AK4	Using a pin hole or resolution tool.
AK5	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.

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