Canadian Partnership for Quality Radiotherapy

Technical Quality Control Guidelines

for Canadian Radiation Treatment Centres

A guidance document on behalf of:

Canadian Association of Radiation Oncology

Canadian Organization of Medical Physicists

Canadian Association of Medical Radiation Technologists

Canadian Partnership Against Cancer

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Introduction

The Canadian Partnership for Quality Radiotherapy (CPQR) is an alliance amongst the three key national professional organizations involved in the delivery of radiation treatment in Canada: the Canadian Association of Radiation Oncology (CARO), the Canadian Organization of Medical Physicists (COMP), and the Canadian Association of Medical Radiation Technologists (CAMRT). Financial and strategic backing is provided by the federal government through the Canadian Partnership Against Cancer (CPAC), a national resource for advancing cancer prevention and treatment. The mandate of the CPQR is to support the universal availability of high quality and safe radiotherapy for all Canadians through system performance improvement and the development of consensus-based guidelines and indicators to aid in radiation treatment program development and evaluation.

This document, *Technical Quality Control Guidelines for Canadian Radiation Treatment Centres*, outlines an overall strategy for quality control of radiation treatment equipment and systems. It is supplemented by a series of equipment specific technical quality control (TQC) guidelines that detail performance

objectives and criteria that should be met in order to assure safe operation and an acceptable level of equipment performance. The TQC guidelines replace an earlier set of equipment quality control guidance documents that were produced by COMP under the sponsorship of the Canadian Association of Provincial Cancer Agencies (CAPCA).[1]

The suite of TQC guidelines is part of a larger set of guideline documents created by the CPQR and its partners that include:

- *Quality Assurance Guidelines for Canadian Radiation Treatment Programs*[2] that outlines a benchmark for achievement in the areas of programmatic quality and safety, and details key quality indicators essential to programmatic assessment;
- *National System for Incident Reporting – Radiation Treatment*[3] that provides structure and guidance for reporting radiation treatment incidents nationally and helps users navigate the National System for Incident Reporting – Radiation Therapy (NSIR-RT) database managed by the Canadian Institute of Health Information (CIHI); and
- *Patient Engagement Guidelines for Canadian Radiation Treatment Programs*[4] that outlines overarching elements of patient engagement that are important to ensuring that patients and family members are satisfied with both the process of care and the outcomes of care.

When considered together, these documents address many aspects of quality and safety related to radiation treatment delivery. All TQC guidelines are considered living documents and are reviewed and revised at regular intervals by the CPQR to maintain relevance in the Canadian radiation treatment environment.

Ownership of the CPQR documents resides jointly with the national professional organizations involved in the delivery of radiation treatment in Canada – CARO, COMP, CAMRT, and CPAC. While administration of the TQC guidelines is the responsibility of the CPQR, decisions regarding content changes reside with COMP and are made in close partnership with the CPQR Steering Committee and partners.

The purpose of this document is to present an overarching approach to equipment technical quality control for Canadian radiation treatment facilities. It describes general aspects of a quality control program, including definitions of terms. Detailed testing recommendations, including tests, tolerances and frequencies, are specified in separate, equipment specific, TQC guidelines. The suite of TQC guidelines outline the minimum performance objectives and safety criteria that equipment or technology should meet in order to assure safe operation and an acceptable level of equipment performance. The development of the individual TQC guidelines is spearheaded by expert reviewers and involves broad stakeholder input from the medical physics and radiation oncology community. It is the responsibility of the supervising physicist to ensure that locally available test equipment and procedures are sufficiently sensitive to establish compliance with the criteria specified within the suite of TQC guidelines.

Enquiries regarding specific technical criteria contained within the TQC guidelines (available at cpqr.ca) should be sent to administration@cpqr.ca.

Abbreviations and Definitions

Abbreviations	
AAPM	American Association of Physicists in Medicine
CAMRT	Canadian Association of Medical Radiation Technologists
CAPCA	Canadian Association of Provincial Cancer Agencies
CARO	Canadian Association of Radiation Oncology
CCPM	Canadian College of Physicists in Medicine
COMP	Canadian Organization of Medical Physicists
CNSC	Canadian Nuclear Safety Commission
CPAC	Canadian Partnership Against Cancer
CPQR	Canadian Partnership for Quality Radiotherapy
QARSAC	Quality Assurance and Radiation Safety Advisory Committee
Definitions	
Expert Reviewer	Medical physicist charged with the development of the technical tests and performance objectives for the equipment or technology outlined in the equipment specific TQC guideline document.
Organization	The hospital, cancer centre, or institution in which the radiation treatment program resides.
Radiation Treatment Facility	The physical location where radiation treatment is administered.
Radiation Treatment Program	The personnel, equipment, information systems, policies and procedures, and activities required for the safe delivery of radiation treatment according to evidence-based and/or best practice guidelines.
Supervising Physicist	A qualified medical physicist; 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 treatment team concerning the operational state of the equipment.
Qualified Medical Physicist	A medical physicist who is certified in radiation oncology physics by the Canadian College of Physicists in Medicine (CCPM) or who holds equivalent certification. Further information on COMP's definition of qualified medical physicist can be found at http://comp-ocpm.ca.

Performance Objectives and Criteria

Objectives and criteria used in the performance evaluation of radiation treatment equipment and technologies fall into several categories:

- **Functionality** – Equipment systems and subsystems for which the criteria of performance are "functional" are either working correctly or not. Such systems are commonly associated with the safety features of the equipment or installation.
- **Reproducibility** – The results of routine quality control tests, for which reproducibility is the criterion, are assessed against the baseline results obtained from the unit during acceptance testing and/or commissioning. Tolerances and action levels should be set for parameters that can be quantified.
- **Accuracy** – Quality control tests which measure accuracy are designed to assess the deviance of a measured parameter from its expected or defined value. An example would be a test quantifying positional accuracy.
- **Characterization and documentation** – In some cases it is necessary to take 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 ionization chamber.
- **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 are defined as follows.

- **Tolerance level** – The tolerance level is used to describe the normal operating range of a system performance parameter. If the difference between the measured value and its expected or defined value is at, or within, the stated tolerance level then no further action is required. The tolerance level will be impacted by the intrinsic variation in the system, as well as the precision of the equipment and process used to measure the given parameter. Statistical methods for analyzing quality control data may be applied to set appropriate tolerance levels (for example, the control limits used in Statistical Process Control [SPC] control charts).[5–6] The TQC guidelines provide recommendations for tolerance levels, based on typical equipment and experience, which may be adapted due to local observations. However, equipment and processes should be selected such that the tolerance levels are less than, or well within, the action levels defined below.

- **Action level** – The action level corresponds to a clinically relevant specification limit. That is, when the performance parameter exceeds its action level, the deviation may pose a clinically significant impact. If the difference between the measured value and its expected or defined value exceeds the action level, then an investigation is required immediately. The investigation should identify whether the deviation is random or systematic through repeat measurement, ideally with independent equipment and/or personnel. 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 shall be restricted to clinical situations in which the identified deviation is of no, or acceptable, clinical significance.

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. A decision may be made to monitor the performance of the parameter in question over a period of time and postpone a decision until the behaviour of the parameter is appropriately characterized. For a problem that is easily and quickly rectifiable, remedial action may be taken as soon as possible. Alternatively, remedial action may be delayed until the next scheduled maintenance period. These options and actions should be described clearly in the facility's quality control policies and procedures.

The decision as to which course of action is most appropriate when tolerance or action levels are exceeded should be made by the supervising physicist in consultation with other clinical and administrative staff in the program.

Acceptance Testing and Commissioning

The purpose of acceptance testing is:[7]

- To ensure the equipment meets vendor specifications;
- To ensure the equipment meets any additional specifications outlined in the tendering process; and
- To familiarize the users with the operation of the equipment.

Strategies for acceptance testing of radiation equipment or technology are beyond the scope of the TQC guidelines; however, they should be consistent with routine quality control objectives and safety criteria. In particular, it is recommended that any new or upgraded system, and its related safety and other sub-systems, should meet the performance objectives described in the TQC guidelines. These tests should be performed by, or under the supervision of, a qualified medical physicist.

Commissioning generally refers to the process of preparing the equipment for clinical service.[7] It involves the acquisition of additional measured data after most acceptance testing is completed, with two main purposes:

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

It is essential that all of the tests listed in the relevant tables of the equipment specific TQC guidelines be performed at commissioning with the intended local test equipment and protocols so that appropriate baseline values are established for quality control. Commissioning activities must be performed by, or

under the supervision of, a qualified medical physicist. All commissioning data should be independently double checked. In addition, the use of external audits is recommended when commissioning new equipment or specialized techniques. Examples of audits include the Imaging and Radiation Oncology Core (IROC) dosimetry blocks/anthropomorphic phantoms,[8] or having colleagues from another institution perform measurements on the equipment with independent measurement devices and processes.

An appropriate subset of acceptance or commissioning tests shall be performed after any hardware or software upgrade on the equipment. The extent of testing required shall be judged by a qualified medical physicist.

Quality Control of Equipment

The purpose of a quality control program is to assure that operational standards that were considered acceptable at time of purchase continue to be maintained, as closely as possible, over the life of the equipment. Thus, quality control tests typically are periodic repetitions, partial or full, of acceptance and commissioning tests. Tests shall 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 shall independently verify the implementation, analysis, and interpretation of the quality control tests at least annually. This independent check shall be documented.

Ideally, daily tests shall be scheduled prior to patient treatments. Testing at less than the frequency recommended in the TQC guidelines is considered acceptable only if experience has established that the parameters of interest are highly stable. Documentary evidence supporting this decision is required.

In the event that the equipment does not meet the stated performance objectives and criteria, an adjustment or repair is needed. An appropriate subset of acceptance, commissioning or routine quality control tests shall be performed after any repair of the equipment. The extent of testing required shall be judged by a qualified medical physicist. Developing prospective strategies for testing following common servicing is highly recommended. If it is not possible to restore the equipment to full performance immediately, then the use of the equipment shall be restricted to clinical situations in which the identified inadequate performance is of no, or acceptable and understood, clinical significance. The decision as to the most appropriate response shall be made by the supervising physicist in conjunction with the users of the equipment and others as appropriate. Any restrictions on clinical operations must be clearly communicated to the users of the equipment and others as appropriate. Furthermore, the use of the restricted operation must be inhibited by means of hardware locks and/or software administration settings, if possible, in order to prevent inadvertent use.

Preventive maintenance schedules and interventions recommended by the manufacturer of the equipment shall be adhered to. Frequently, equipment repairs and quality control testing are performed

by different individuals. Good communication and reporting between the various staff involved are essential.

Radiation safety activities, such as those outlined by regulators[9] and the CPQR's *Quality Assurance Guidelines for Canadian Radiation Treatment Programs*[2] shall be integrated into routine quality control programs for equipment. The TQC guidelines include testing of the facility's radiation safety systems, as applicable.

Documentation

Appropriate documentation is a required component of a quality assurance program. All policies and procedures associated with quality control testing of equipment should contain the following information:

- The name of the institution;
- The name of the originating department;
- The name(s) of the document author(s);
- The name of the individual(s) or group(s) who approved the document for clinical use;
- The date of first issue; and
- The number and date of the current revision.

The International Organization for Standardization provides further guidelines on the design of appropriate documentation.[10–12]

Documents for use in a quality control program should be separated into two major categories: protocols and records. The quality control protocol should provide sufficient detail concerning the test equipment and procedures to be followed so that there is no ambiguity in the interpretation of the test results. They should also clearly define actions to be taken if tests fall outside of action levels. The quality control record contains the results of the tests, the date(s) on which they were performed and the name of the tester and the supervising physicist, as appropriate.

In addition to the protocol and record, facilities must document any corrective action or servicing that takes place, together with the results of any subsequent testing. Deviations from the locally approved protocol, such as those resulting from clinical pressure to access the equipment shall be documented as well.

All documentation related to the quality control program must be retained for at least ten years, unless otherwise specified by federal or provincial regulations. For example, federal regulations for Class II prescribed equipment (e.g., linear accelerators, high dose rate brachytherapy remote afterloaders) require records to be maintained for three years after the expiry or revocation of the associated licence.[9]

Equipment Specific Technical Quality Control Guidelines

The detailed performance objectives and safety criteria for radiation treatment equipment are itemized in a series of equipment specific TQC guideline documents. These guidelines are separated from this overarching document due to independent generation dates and review cycles. Each equipment specific TQC guideline contains a brief system description and the tables of recommended tests, frequencies, and performance objectives.

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