Amended 2006 (Res. 16g)*

ACR TECHNICAL STANDARD FOR THE PERFORMANCE OF BRACHYTHERAPY PHYSICS: REMOTELY LOADED HDR SOURCES

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Brachytherapy is a method of treatment in which sealed radioactive sources are used to deliver radiation by interstitial, intracavitary, intraluminal, or surface application. This standard has been developed by the American College of Radiology (ACR) to outline a standard of physics practice related to one area of this modality: the use of remotely loaded high-dose-rate (HDR) brachytherapy sources. The extremely high activity or strength of the HDR source, typically iridium -192 in the range of 4-10 Curies permits delivery of the prescribed dose in several minutes. This procedure is usually carried out on an inpatient/outpatient basis.

However, since the practice of HDR brachytherapy physics occurs under a variety of settings, the judgment of a Qualified Medical Physicist, in conjunction with a physician, should be used to apply these standards to individual practices. Finally, radiation safety requirements shall be in compliance with appropriate federal and state regulations.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The ACR considers certification and continuing education and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics, and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this standard are Therapeutic Radiological Physics and Radiological Physics.

A Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

Where required, the medical physicist shall have a license to practice therapeutic radiological physics. In addition, the credentials and delineated privileges for the Qualified Medical Physicist should be confirmed through the medical staff membership process in the appropriate category if available, since clinical brachytherapy physics involves direct contact with patients and their hospital records.

A. Qualified Medical Physicist should institute a documented peer-review mechanism for reviewing the brachytherapy physics program. The review should be performed on a yearly basis.

B. Medical Dosimetrist

When a medical dosimetrist is available to the brachytherapy service, this individual should be certified. The Medical Dosimetry Certification Board is recommended.

III. RESOURCES

A. Personnel Requirements

Beyond that required for external beam irradiation, active brachytherapy programs require additional physics and support personnel due to the uniqueness and relative complexity of each case.

B. Equipment Needs

Each facility should have instrumentation to independently verify the source strength or activity provided by the manufacturer. This should be done with a well ionization chamber, with calibration traceable to the National Institute of Standards and Technology (NIST).

Calibrated survey instruments that are appropriate in energy response and range for the sources used shall be available. A backup meter should be readily available in case of primary instrument failure.

The facility shall have instrumentation to perform periodic sealed-source leak testing or arrange to have this service provided in compliance with applicable federal or state regulations.

Appropriately shielded treatment rooms, storage containers for emergency use, and manipulation devices for emergency use shall also be available.

A computerized planning system shall be available to calculate point doses and to generate isodose distributions.

Proper maintenance, calibration, and updating of this equipment shall be carried out under the supervision of a Qualified Medical Physicist.

IV. QUALITY ASSURANCE PROGRAM

Quality assurance (QA) in radiation oncology may be defined as those administrative policies, quality improvement (QI) procedures, and quality control (QC) measurements that ensure a consistent and safe fulfillment of the dose prescription. The medical physicist is responsible for maintaining the scientific records regarding appropriate description of the source, calibration of the source, and the current stated activity or strength of the source in order to assure accurate delivery of the prescribed dose to the specified volume.

Quality control for sealed sources includes maintaining an ongoing review for adherence to regulatory and licensing requirements. Accordingly, the medical physicist shall develop, implement, supervise, and review the policies and procedures for use of the HDR source and maintain proper written documentation. When these activities relate to radiation safety, they should be carried out in compliance with the guidelines established by the institutional radiation safety program.

A. HDR Sealed Sources

Since the radiation characteristics of the encapsulated source depend on the source encapsulation and the distribution of the activity or strength within the source, it is incumbent on the medical physicist to obtain the following information and to evaluate its effect on clinical dosimetry: physical and chemical form, source encapsulation, and uniformity characteristics of radionuclide distribution within the source.

1. Calibration of HDR sources

   HDR brachytherapy sources used in radiation oncology shall have calibrations with direct or secondary traceability to national standards.

   Each institution shall have the ability to independently measure source strength or activity and compare it to the source strength or activity provided by the manufacturer. The medical physicist shall establish acceptability limits for such measurements as well as a course of action if the source strength or activity does not fall within these limits.

   All HDR sources shall be calibrated prior to their first clinical use. Written documentation of the calibration indicating strength or activity, date of calibration, and the name of the medical physicist responsible for the calibration should reside at the treatment delivery unit. This strength or activity value should also be entered in the treatment-planning computer.

2. Instrumentation

   For direct calibration of sources, a well ionization chamber with NIST-traceable calibration and known axial response is recommended. The constancy of the chamber shall be checked with a long-lived sealed source upon receipt, after repair, and prior to each use. The well ionization chamber shall be calibrated at least every 2 years.

   The sensitivity, linearity, and reproducibility of the instrument shall be documented annually.

3. Treatment delivery unit

   Computer-controlled HDR treatments are to be carried out with a high degree of precision and accuracy. The medical physicist should establish a quality control program to assure that the intended accuracy and precision are met and maintained. Autoradiographs or other suitable method approved by the medical physicist shall be performed on the HDR sources prior to initial use to determine that the source moves to the intended dwell positions in the applicator and to determine the discrete step-size spacing between dwell positions. The desired mechanical accuracy and precision is 1 mm or less. Accuracy of the source dwell time must also be determined. The program shall be consistent with regulatory requirements. Minimally, the QC testing should demonstrate that the HDR source can execute the treatment plan with a high degree of fidelity.

4. Brachytherapy applicators

   The medical physicist shall determine that the source can travel accurately to intended locations in the applicators and shall determine the coincidence of dummy markers and the active source. The location of shields for intracavitary applicators shall be checked prior to initial use. Such applicators should be radiographically inspected annually and physically inspected prior to each use. For appropriate interstitial applicators, esophageal applicators, and pulmonary catheters the coincidence of dummy markers and the active source dwell positions shall be verified prior to initial use.

5. Radiation safety

   Radiation safety practices shall be consistent with the institution's radioactive material license, license amendments, and existing regulations. The medical physicist should be responsible for developing, overseeing, and documenting radiation safety procedures, including, but not limited to, those listed below:

   a. Written procedures regarding ordering, receiving, returning, and/or disposing of HDR radioactive materials and for the performance of patient surveys following source removal.
   b. An inventory control program sufficient to locate and identify the HDR source and all sealed sources at any time.
   c. Emergency procedures for retrieving the HDR source from the patient.
   d. Procedures for checking the safety interlock and the audio and visual communications between the patient and operator of the treatment delivery unit.
   e. Participation in training of professional and technical staff regarding HDR.
   f. Presence and proper functioning of the in-room monitors, the warning light, and the portable survey instrument.

B. Treatment Planning and Dosimetry

All implants should be planned, at least to the extent of determining an appropriate source distribution. A consistent means of specifying and documenting absorbed doses shall be in place. This specification may be based on traditional systems of brachytherapy dosimetry. It should include a description of technique and applicator, source strength or activity, anatomical description of target volume, dose to target volume, dose to reference and/or tolerance points, and the time-dose pattern. Prior external beam and brachytherapy doses to target volumes should also be documented with each implant's dosimetry.

Corrections for decay of source strength or activity should be made each day of use for Ir-192.

1. Localization - dosimetry images

   The position of all intracavitary, intraluminal, and interstitial implants should be verified before treatment with appropriate medical imaging modalities. The medical physicist, dosimetry personnel, or responsible radiation oncologist should be present during the localization of the applicators.

2. Computerized planning systems

   Computerized planning systems shall undergo rigorous acceptance tests and commissioning to ensure that the dose calculation algorithm properly converts the source calibration and conversion factors into the appropriate absorbed dose distribution, and to ensure that the hardware and software were installed properly. In-service training should be given and documented for new users and, when appropriate, following major software releases.

   Periodic tests shall be implemented to ensure the continued accuracy of dose calculation algorithms; to ensure that software changes, including editing of source data files, were implemented correctly and have not corrupted the source data; and to ensure that any hardware changes were installed properly.

3. Patient dose calculation

   An additional and independent method should be used to validate the dose calculation results of the computerized planning systems. This validation should be consistent with the written prescription and completed before the dose is delivered.

   Furthermore, the source positions entered into the treatment planning systems should be verified by a method approved by the medical physicist. This method may be as simple as superimposing the source dwell positions and resulting isodose distributions on the appropriate medical image.

   The final treatment plan must be reviewed and signed by a medical physicist prior to the implementation.

C. Clinical Medical Physics Management

1. Routine clinical practice

   The medical physicist or medical dosimetrist shall be available during the image acquisition phase of the HDR planning, whereby dummy markers are used to delineate HDR dwell positions that may be activated for dose delivery. Appropriately trained personnel shall be present at the HDR console during the treatment of the patient.

   A medical physicist must be in the immediate vicinity at all times while HDR brachytherapy is being administered.

2. Medical physics consultation

   The medical physicist shall develop and implement a program for review and analysis of patient status including changes to the physics aspects of the treatment regime, consultation on and participation in patient setup and treatment modifications, and reviews of patient-specific treatment and technical notes.

3. Dosimetry report

   For each brachytherapy procedure a dosimetrist or medical physicist shall complete a written dosimetry report. The report should include:

   a. Description of the sources.
   b. Description of the technique and source pattern used.
   c. Absorbed dose rate and total time of implant or delivered dose.
   d. Total number of dwell positions.
   e. Prescribed dose.
   f. Isodose distributions in appropriate planes or other expressions of dose at various points delineated by physicians.
   g. Evidence of independent validation of dose calculations.

   The report will be signed by the medical physicist and the responsible radiation oncologist.

D. New Procedures

In conjunction with the physician-authorized user, the medical physicist shall define basic standards of practice and develop a reasonably prudent course of action to determine the quality and safety of any new procedures prior to initiation. New devices/applicators shall be evaluated with respect to integrity, suitability for use with the HDR radioactive sources, and effects on dose distributions. A written report of the evaluation shall be distributed in accordance with institutional policy.

V. DOCUMENTATION

The medical physicist is responsible for maintaining proper, complete, and accurate records required by regulatory agencies or accrediting bodies. Records documenting the frequency of performance of the quality maintenance program, including quality integration procedures and results of quality control measurements, are important, both in retrospective analysis of trends and in documenting current status. It is recommended that a mechanism be established to review these records with the medical director and administration on a documented, periodic basis.

ACKNOWLEDGEMENTS

This standard was revised according to the process described in the ACR Practice Guidelines and Technical Standards book by the Guidelines and Standards Committee of the Commission on Medical Physics.

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*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Standard
2000 (Resolution 18)
Revised 2005 (Resolution 18)
Amended 2006 (Resolution 16g)