Revised 2015 (Resolution 50)*

ACR–AAPM TECHNICAL STANDARD FOR THE PERFORMANCE OF HIGH-DOSE-RATE BRACHYTHERAPY PHYSICS

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 the guidance in this document 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 this document is to assist practitioners in achieving this objective.

[1] Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This standard was revised collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

Brachytherapy is a method of treatment in which a sealed radioactive source(s) is (are) used to deliver radiation by interstitial, intracavitary, intraluminal, or surface application. The extremely high source strength (or activity) of the high-dose-rate (HDR) source(s), typically iridium-192 in the range of 148 to 481 GBq (4 to 13 Curies) or cobalt-60 in the range of 66 to 82 GBq (1.8 to 2.2 Curies), permits delivery of the prescribed dose in terms of minutes. This procedure is usually carried out on an outpatient basis.

Since the practice of HDR brachytherapy physics occurs under a variety of settings, the judgment of a Qualified Medical Physicist (QMP), in conjunction with a radiation oncologist, should be used to apply these standards to individual practices. Also, radiation safety requirements must be in compliance with appropriate federal and state regulations.

Although a number of reference documents are recommended for suggested reading, 3 documents represent the basis from which much of this technical standard evolved: American Association of Physicists in Medicine (AAPM Code of Practice for Brachytherapy Physics [1], the AAPM Task Group Report on High-Dose-Rate Brachytherapy Treatment Delivery [2], and the AAPM Report on Comprehensive Quality Assurance in Radiation Oncology [3].

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 American College of Radiology (ACR) considers certification, 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 strongly 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 by the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [4]

The appropriate subfield of medical physics for this standard is Therapeutic Medical Physics (including medical physics certification categories of Radiological Physics, Therapeutic Radiological Physics, and Radiation Oncology Physics).

In addition, the Qualified Medical Physicist must meet any qualifications imposed by the state and/or local radiation control agency to practice radiation oncology physics and/or to provide oversight of the establishment and conduct of the physics quality management program.

Where required, the Qualified Medical Physicist must have a license to practice therapeutic medical physics. Similarly, depending on the bylaws of the relevant hospital/institution, the credentials and delineated privileges for the Qualified Medical Physicist should be confirmed through the medical staff membership process in the appropriate category since clinical brachytherapy physics involves direct contact with patients and their hospital records.

In the case of HDR brachytherapy, the Qualified Medical Physicist is recognized as an Authorized Medical Physicist (AMP) by federal and state regulatory authorities. The Qualified Medical Physicist should be an

Authorized Medical Physicist in accordance with applicable US Nuclear Regulatory Commission or Agreement State requirements.

B. Medical Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended. The Medical Dosimetrist activities should be performed under the supervision of a Qualified Medical Physicist involved with the HDR procedure.

C. Radiation Therapist

The radiation therapist must fulfill state licensing requirements and should have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy.

III. RESOURCES

A. Personnel Requirements

Active brachytherapy programs require additional physics and support personnel beyond that required for external beam therapy due to the uniqueness and relative complexity of each case. As a special procedure, HDR brachytherapy requires significant time commitment by the Qualified Medical Physicist to develop and maintain high standards for quality procedures and to provide documentation to comply with regulatory agencies. Consequently, these nonclinical aspects should be included when budgeting personnel requirements.

B. Equipment Needs

Each facility must have instrumentation to independently verify the source strength or activity provided by the manufacturer. This must be done with a well ionization chamber and electrometer or other suitable instrument(s) with a calibration performed by an accredited dosimetry calibration laboratory (ADCL) traceable to the National Institute of Standards and Technology (NIST) or by a calibration laboratory accredited by the AAPM. The chamber calibration must be performed every 2 years and after any servicing that may have affected the systems' calibration [5,6].

Calibrated survey instruments that are appropriate in energy response and range for the sources used must be available for use at all times [5,6]. A backup survey meter should be readily available in case of primary instrument failure. The primary survey instrument must have a current calibration certificate traceable to NIST, and the backup survey instrument may be calibrated by intercomparison with the primary survey instrument, at least annually.

For sealed sources that will be used clinically for a period exceeding 6 months, the facility must have instrumentation to perform leak tests or arrange to have this service provided at intervals not to exceed 6 months.

Appropriately local shielding, storage facilities, transportation containers, storage containers for emergency use, and manipulation devices must also be available.

A computerized treatment-planning system for volumetric image guidance (CT, ultrasound, etc), applicator reconstruction, and dose computation must be available to calculate point doses, to generate isodose distributions, and to compute dose-volume statistics.

Proper maintenance, calibration, quality control, and update of all HDR equipment must be carried out by a Qualified Medical Physicist or under the supervision of a Qualified Medical Physicist and must meet all applicable federal, state, and local regulations.

IV. QUALITY ASSURANCE PROGRAM

Quality assurance (QA) refers to administrative policies, quality control (QC) measures, and consideration of quality improvement objectives that ensure a consistent and safe fulfilment of the treatment prescription. The Qualified Medical Physicist is responsible for a QA program that maintains the scientific records regarding appropriate description, calibration, and the current source strength in order to assure accurate delivery of the prescribed dose to the specified volume [7]. The complexity of brachytherapy procedures necessitates that comprehensive QA include treatment-related devices (eg, planning and imaging systems, applicators, radioactive source(s), and delivery system(s)) and the clinical process [8]. The Qualified Medical Physicist should work closely with the radiation oncologist and other members of the brachytherapy team to build consensus and document the clinical workflow and resources for specific anatomical sites and treatment modality combinations.

Quality control for brachytherapy sources includes maintaining an ongoing review for adherence to regulatory and licensing requirements. Accordingly, the Qualified Medical Physicist must develop, implement, supervise, and review the policies and procedures for use of the HDR source(s) and maintain proper written documentation [9]. When these activities relate to radiation safety, they should be carried out in compliance with the guidelines established by the institutional radiation safety program.

The Qualified Medical Physicist should institute a documented peer-review mechanism for reviewing the brachytherapy physics program. The review should preferably be performed by a Qualified Medical Physicist that is independent of the program under review. The review should be performed annually. When reviews are performed on a less frequent basis, the time between reviews should not exceed 3 years [10].

A. HDR Sealed Sources

Since the radiation characteristics of the encapsulated source depend on its physical and chemical form, as well as the source encapsulation and the distribution of the activity within the source, the Qualified Medical Physicist must take these factors into account to properly determine the radiation distribution around the source.

1. Calibration of HDR source(s)

   HDR brachytherapy sources must have calibrations with direct or secondary traceability to national standards. The 1995 AAPM Task Group 43 Report [11], the updated version published in 2004 [12], and its supplement [13], together with the AAPM Task Group 138 Report [14], should be consulted for dosimetry protocols of specific HDR source(s) employed for the brachytherapy procedures.

   The Qualified Medical Physicist must determine that the measured source strength is accurate to within ±3% of that reported by the manufacturer and establish a course of action if the source strength does not fall within these limits.

   All HDR source(s) must be calibrated at the institution prior to their first clinical use. Written documentation of the calibration indicating the source type, serial number of the source, source strength, the date of calibration, the equipment used in the calibration, the dosimetry protocol, and the name of the Qualified Medical Physicist responsible for the calibration should reside at the treatment-delivery unit. The appropriate source strength must be entered in the treatment-planning computer. An additional qualified individual should perform a second check of the calibration.

2. Instrumentation

   The constancy of the ionization chamber and electrometer used for calibrating the HDR source(s) must be checked upon receipt, after repair, and prior to each use. The ionization chamber and electrometer must be calibrated at least every 2 years at an ADCL facility. The sensitivity, linearity, and reproducibility of the instrument must be documented at least annually.

3. Treatment-delivery unit

   Computer-controlled HDR treatments are to be carried out with a high degree of precision and accuracy. The Qualified Medical Physicist should establish a QC program to assure that the intended accuracy and precision are met and maintained. Autoradiographs or another suitable method approved by the Qualified Medical Physicist must be performed on the HDR source(s) before the first use of the afterloader on a given day 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 are 1 mm or less [5]. Accuracy and linearity of the source dwell time must also be determined. The program must be consistent with regulatory requirements.

   The QC testing should demonstrate that the HDR source(s) can execute the treatment plan with a high and predetermined degree of fidelity.

4. Brachytherapy applicators

   The Qualified Medical Physicist must determine that the source can travel accurately to intended locations in the applicators and must determine the coincidence of the dwell positions of the dummy markers and the active source. The location of shields for intracavitary applicators must be checked prior to use. Applicators and transfer tubes should be 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 must be verified prior to initial use. All brachytherapy applicators and transfer tubes should include visual and radiographic inspection annually or as required per state regulations. In addition, the Qualified Medical Physicist should follow the manufacturer's recommendations for replacement of any applicators or transfer tubes should they reach their expected lifetimes.

5. Radiation safety

   Radiation safety practices must be consistent with the institution's radioactive material license, license amendments, and existing regulations [5,6]. The Qualified Medical Physicist, in conjunction with the radiation safety officer, should be responsible for developing, overseeing, and documenting radiation safety procedures including, but not limited to, the following: Written procedures regarding ordering, receiving, returning, and/or disposing of HDR radioactive materials and for performing patient surveys preceding and following source removal
   a. An inventory control program to locate and identify the HDR source(s) at any time
   b. Emergency procedures for retrieving the HDR source(s) from the patient
   c. Checking the functionality of the backup battery of the HDR unit
   d. Procedures for checking the safety interlocks 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 at least annually
   g. Presence and proper functioning of the in-room radiation monitors and its backup battery, the warning light, and the portable survey instrument

h. Assuring the security of the HDR unit
i. After each source change, the old source must be placed inside the vendor-supplied container, with proper paperwork and shipping label attached, sealed, and locked up securely inside the treatment room or appropriately secure hot lab room. The user should arrange for pickup of the container to return to the vendor within 24 hours of source change and ensure a confirmation of the receipt of the source from the manufacturer is received within days to assure its safe delivery.

Treatment Planning and Dosimetry

Treatment planning for all implants should include, at a minimum, the determination of the appropriate dose distribution. A consistent means of specifying and documenting absorbed dose must be in place. Treatment-planning specifications should include, at a minimum, a description of technique and applicator, source strength(s), the anatomical description of target volume, dose-to-target volume, and dose-to-reference and/or tolerance points. Isodose distributions in orthogonal planes containing the points of interest should also be included. Except for HDR procedures with well-defined applicator and treatment volume geometries, such as vaginal cylinders for endometrial cancer, imaged-based volumetric computerized treatment-planning algorithms that provide a means to conform the dose distribution to the target and minimize the dose to tissue at risk should be used. The time-dose pattern, anatomical description of the target volume, dose-to-target volume, and volumetric dose statistics should be determined if 3-D patient imaging information is used. Prior external beam and brachytherapy doses to target volumes should also be documented with every treatment plan.

A Qualified Medical Physicist should check the source activity before each treatment to ensure that the computer updated activity is correct. In addition, any manufacturer recommendations concerning adjustments based on "daylight savings time" should be followed.

Mathematical corrections for decay of source strength or activity should be made at intervals consistent with 1% physical decay (typically daily for iridum-192) [5].

1. Image-guided HDR procedures
   a. Image-guided applicator/source localization: Image-guided procedures are becoming more prevalent. Three-dimensional image-based brachytherapy has been shown to improve local control and overall survival and significantly reduce toxicity. There are a number of uses of various imaging modalities to achieve high-quality delivery of brachytherapy [6-12,16,17,20-23]. For cervical cancer, MRI-based treatment planning with applicators in situ has been shown to be superior to the conventional film-based methodology, both in delineation of targets and organs at risk as well as in dose planning.

      As the prescription in MRI-based or CT-based treatment planning has migrated away from the conventional prescription point approach to one which is based on volume coverage, the accuracy in contouring, image reconstruction, and dose optimization is a new concept for radiation oncologists and Qualified Medical Physicists in HDR brachytherapy. Groupe Européen de Curiethérapie (GEC)-European Society for Radiotherapy and Oncology (ESTRO) has published guidelines for image-based HDR of the cervix [20,24]. In lieu of similar guidelines in the United States, Qualified Medical Physicists involved in the image-based HDR for cervix may want to consult the GEC ESTRO guidelines for a successful implementation of the IGRT program. The ACR–ASTRO Practice Parameter for Image-Guided Radiation Therapy (IGRT) [25] and its updated version also contain relevant information on the image guidance, which should be consulted.

      The Qualified Medical Physicist must ensure the spatial resolution, fidelity, applicator compatibility, and appropriate use of each imaging modality. Also, the Qualified Medical Physicist must ensure that proper acceptance testing and commissioning as well as a documented QA program is in place for each system prior to its clinical use [26-28].

The position of all intracavitary, intraluminal, and interstitial implants must be verified before treatment. Images, when acquired, should be with the patient in the treatment position. The responsible radiation oncologist should be present with the Qualified Medical Physicist or dosimetry personnel during applicator localization. Prior to treatment initiation, the localization images, when acquired, should be approved by the responsible radiation oncologists.

MRI-based HDR planning for the prostate has also become more popular recently. However, this is an emerging modality and is not mature enough for this collaborative committee to provide recommendations at the present time.

2. Computerized planning systems

Computerized planning systems must 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 including dose-volume statistics, if available, and that hardware and software were installed properly [5,11,12,29]. The handling of image data and their use in dose calculations must also be verified for accuracy in comparison (where appropriate) to well-established methods of dose calculation. Model-based dose algorithms and the use of heterogeneity corrections have increased the complexity of the dose calculations that may be employed in brachytherapy [29-31]. Heterogeneity corrections have only recently been made available to the brachytherapy community. The AAPM Task Group 186 Report [29] has raised the major issues in dose calculations that are not addressed by current guidance documents, which are water-based (the Task Group 43 Report and its updates and supplements). The Qualified Medical Physicist should consult the AAPM Working Group on Model-Based Dose Calculation Algorithms in Brachytherapy for appropriate implementation of the recommendations to improve the accuracy in dose calculations, especially in image-based HDR dose planning.

These new approaches need to be implemented with great care. All users must receive proper training. An in-service program should be given for new users and, when appropriate, provided to all users following software releases. A written treatment-planning system QA program must be implemented to ensure the accuracy of dose-calculation algorithms, software changes, hardware changes, and source data files [32]. All training should be documented.

3. Plan review

The treatment plan should be independently reviewed by the radiation oncologist and a Qualified Medical Physicist or dosimetrist not directly involved with the generation of the treatment plan. The plan review may include, but not be limited to, the following:

a. Patient demographic information
b. Plan dose/prescription conforms to the written directive
c. Applicator type, applicator size, implant geometry and applicator reconstruction, and source positions
d. Radionuclide, source configuration and strength, date of implant, implant duration
e. Volumetric dose coverage of the target and dose constraints of tissue/organs at risk

4. Independent dose calculation

An independent method from the treatment-planning system should be used to validate the dose calculation results of the computerized planning systems, such as the point-dose verification to specific points in the dose distributions. This validation should be consistent with the written prescription, source

positions, and source strength. This plan verification step should be completed prior to treatment initiations. Target-dose deviations greater than 5% should be investigated and resolved prior to treatment.

B. Clinical Medical Physics Management

1. Routine clinical practice

The Qualified Medical Physicist or medical dosimetrist must be available during the image acquisition phase of the HDR planning to ensure that all information necessary for planning is properly acquired (eg, dummy marker placement/labels). Personnel (physician, Qualified Medical Physicist, dosimetrist, and/or therapist) present at the HDR console during the treatment of the patient must, at a minimum, be trained in emergency procedures and operation of the afterloader. Though training provided by the manufacturer is preferred, in-house training provided by an individual having received prior manufacturer training is sufficient.

Administration of HDR brachytherapy must be supervised by an authorized user and a Qualified Medical Physicist in accordance with state and federal regulation.

2. Medical physics consultation

The Qualified Medical Physicist must 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. Dose delivery quality assurance

The Qualified Medical Physicist must develop a process to assure that the technical aspects of the HDR treatment are correct for the specific patient prior to each treatment. For multifraction HDR, such a process should include validation that parameters used for treatment of the first fraction are appropriately corrected for source activity and remain valid for the remaining treatment fractions if a new plan is not created. Imaging techniques that monitor the constancy of the HDR applicator/catheters relative to the target tissues and tissues at risk should be considered for use as documentation in the validation process. Additionally, all multicatheter/applicator treatments should include a procedure performed by a second person to assure that the correct source treatment channel is connected to the correct catheter/applicator. Lastly, prior to each treatment, a “dry run” with the dummy wire should be done to ascertain that all catheters/applicators are unobstructed to permit activation of all dwell positions in all catheters/applicators that contribute to the dose distribution. A pretreatment survey should be conducted and compared to post-treatment survey.

4. Quality management report

A quality management report for each HDR brachytherapy case should be generated. This can be in a form of a checklist completed by the Qualified Medical Physicist. This will ensure that all required steps established by the facility (prior to, during, and after the procedure) have been completed. This report should include any other known dose to the target or its vicinity from prior external beam treatment or brachytherapy. Independent check results should also be documented in this report. Any unintended deviation from the written directive for treatment should be evaluated to determine if it should be considered a reportable event. The findings should be documented in the quality management report and, if applicable, used for action as defined by the facility’s policies and procedures and in accordance with state and federal regulations. The quality management report should be signed by the Qualified Medical Physicist and the Authorized User.

The quality management report should include, but not be limited to, the following items:

a. Description of the source
b. Updated source strength for the treatment
c. Description of the technique and source pattern used
d. Dose delivered, dwell positions, and total number of dwell positions
e. Delivered dwell time at each position, and total dwell time
f. Reference position (eg, distance to farthest dwell) for each applicator channel
g. Step size between dwell positions
h. Prescribed dose
i. Isodose distributions in 3 orthogonal planes through the implant or other appropriate planes or other expressions of dose at various points delineated by physicians, specified with or without heterogeneity correction
j. Relevant dose volume statistics (DVH)
k. Evidence of independent validation of dose calculations

The report must be signed by the Qualified Medical Physicist and the responsible radiation oncologist.

5. Post-treatment survey

After the source has been retracted at the end of the delivery, a post-treatment radiation survey of the patient, transfer tube(s), and the HDR unit must be completed with a calibrated survey meter to ensure that the source is indeed retracted inside the HDR unit. The post-treatment survey must be documented as part of the treatment record and should be done under the supervision of the Qualified Medical Physicist.

C. New Procedures

In conjunction with the physician-authorized user, the Qualified Medical Physicist must define basic standards of practice and develop a prudent course of action to determine the quality and safety of any new procedures prior to initiation. New devices and/or applicators must be evaluated with respect to integrity, suitability for use with the HDR radioactive sources and intended imaging modality(ies), and effects on dose distributions. This evaluation must be prepared as a written report and must be distributed in accordance with institutional policy.

V. DOCUMENTATION

The Qualified Medical Physicist is responsible for maintaining proper, complete, and accurate records required by regulatory agencies and accrediting bodies. Records documenting the results and frequency of QA checks and QC 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 technical standard was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (http://www.acr.org/guidelines) by the Committee on Practice Parameters and Technical Standards – Medical Physics of the ACR Commission on Medical Physics in collaboration with the AAPM.

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*Practice parameters and technical 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 practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Technical Standard
2000 (Resolution 18)
Revised 2005 (Resolution 18)
Amended 2006 (Resolution 16g)
Revised 2010 (Resolution 6)
Revised 2015 (Resolution 50)