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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 considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 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 831 N.W.2d 826 (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 delivering therapeutic radiation 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 16400 U to 53500 U (4 to 13 Curies) or cobalt-60 in the range of 22800 U to 27900 U (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, 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, three documents represent the basis from which much of this technical standard evolved: 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, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [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). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

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.

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 because practice of clinical brachytherapy physics involves direct contact with patients and access of their hospital records.

Regulatory agencies may define requirements for an Authorized Medical Physicist for practice covered in this Technical Standard. It is assumed in this Technical Standard that the Qualified Medical Physicist meets all requirements of an Authorized Medical Physicist within the relevant jurisdiction(s) of their practice.

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 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, as well as providing documentation to comply with regulatory agencies. Consequently, these commitments should be included when budgeting personnel requirements.

B. Equipment Needs

Each facility must have access to instrumentation to independently verify the source strength 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 and electrometer 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 with valid calibration should be readily available in case of primary instrument failure or being sent out for calibration. The primary survey instrument must have a current calibration certificate, 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.

Appropriate local shielding, storage facilities, and transportation containers, must be available. In particular, storage containers for emergency use and an emergency kit, including long handle forceps must be available inside the treatment suite.

When applicable, a computerized treatment planning system (TPS) that allows outlining of anatomy and applicators, based on 3-D image data sets (computed tomography (CT), ultrasound (US), magnetic resonance imaging (MRI), etc), creation, optimization and evaluation of 3-D dose distributions, must be available.

Proper maintenance, calibration, quality control (QC), 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, 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 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.

QC 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 [2]. 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 HDR program. The review should be performed within 3 years [9].

A. HDR Sealed Sources

Because 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. Measurement of HDR source(s) strength

   HDR brachytherapy source strength must be measured with direct or secondary traceability to national standards. The 1995 AAPM Task Group 43 Report [10], the updated version published in 2004 [11], and its supplements, Supplement 2 from 2017 [12], together with the AAPM Task Group 138 Report [13], 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 ±5% of that reported by the manufacturer [3,5]. Although ±5% is the maximum discrepancy allowed, good practice and proper instrument maintenance typically insures a ±3% of discrepancy [14]. We recommend addressing the source of larger discrepancies (>±3%) by cross calibration with different instruments (electrometer, re-entrant ionization chamber, cables) or contacting the source manufacturer.

   All HDR source(s) must be calibrated at the institution prior to their first clinical use. The source strength measurement report should include the source type, serial number of the source, source strength from the manufacturer, the date the measurement for calibration was performed, the equipment used in the calibration, the dosimetry protocol used to determine the source strength, the discrepancy between the measured source strength and the manufacturer's value, and the name of the Qualified Medical Physicist responsible for the calibration. The appropriate source strength must be entered in the treatment-planning computer. An additional qualified individual should perform an independent verification of the parameters entered in to the treatment console and/or TPS.

2. Instrumentation

   The constancy of the ionization chamber and electrometer used for calibrating the HDR source(s) should 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 [11,15].

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. 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 and manufacturer recommendations.

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 introduction of a new applicator in a clinic should be a team effort since elements of the treatment and patient care specific for that applicator are responsibility of the whole team. This includes but is not limited to: physician, physicist, dosimetrist, therapist, nurse, surgeon, radiation safety officer, sterilization staff, etc. The team needs to discuss timing, communication, and workflow for applicator implantation, simulation, and treatment in a patient-centric manner. The Qualified Medical Physicist should inform the team about the particular features, constraints, and requirements regarding the applicator and its intended clinical use. This information is often included in the Instructions For Use (IFU) documentation provided by the manufacturer. The authorized user (AU) and the Qualified Medical Physicist need proficiency in applicator functionality and its use in all clinical scenarios, including emergency situations. Applicators should be imaged in a phantom or water bath using the intended imaging modality prior to use in a patient. A phantom-based end-to-end dry run test using the applicator, transfer tubes, and active HDR source should also be considered. While is it typical for a vendor representative to be present for the first use of a new applicator in the clinic, this should not be a replacement for all required tests and preparations prior to clinical use. In some cases, the Qualified Medical Physicist may not have access to the applicator prior to implantation (e.g. sterile disposable applicators). In this case, one should use a checklist, including: visual and haptic check applicator integrity, correct device size/model and auxiliary components, package integrity, lot number and expiration date. If possible one should assemble and check the functionality of the applicator on a sterilize field prior to its insertion. For all applicators, the Qualified Medical Physicist should be aware of the manufacturer specified lifetime as required by state (or NRC) regulations. The applicators and transfer tubes should be visually inspected prior to each use and annually through radiographic analysis. A correct and accurate specification of the total treatment length (applicator plus transfer tube) is essential for correct treatment delivery. The Qualified Medical Physicist should oversee measurement, confirmation, and recording of this length. When images are acquired for planning, the use of wire and dummy markers is encouraged when appropriate, in order to further ensure a correct delineation of the applicator and dwell positions.

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 (RSO), should be responsible for developing, overseeing, and documenting radiation safety procedures. These include but are not limited to: written procedures regarding ordering, securing, receiving, returning, and/or disposing of HDR radioactive materials and for performing patient surveys preceding and following source removal [1]:

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. Procedures for checking the safety interlock of the treatment room door
f. Participation in training of professional and technical staff regarding HDR at least annually
g. Presence and proper functioning of the in-room monitor and remote alarm, their backup battery, and the portable survey instrument
h. Assuring visibility at all times of the remote alarm outside of the treatment room

i. Assuring the security of the HDR unit
j. 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 as soon as possible and ensure a confirmation of the receipt of the source from the manufacturer is received to assure its safe delivery.
k. Policies for personnel monitoring of radiation exposure.

B. Treatment Planning and Dosimetry

Treatment planning for all HDR procedures 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 documentation should include a description of technique and applicator, source strength(s), the anatomical description of target, and dose-to-target volume and/or dose-to-reference point. Isodose distributions in three orthogonal planes containing the points or volume of interest should also be included when possible. Except for HDR procedures with well-defined applicator and treatment volume geometries, such as vaginal cylinders, 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. Orientation of applicators and activation of dwell positions should be checked. Contours of targets and organs at risk (OARs) as well as Dose Volume Histogram (DVH) parameters for targets (e.g. D90, D95, V100, V150, etc) and OARS (e.g. D1cc, D2cc) should be checked and confirmed with the treating attending physician. Prior external beam and brachytherapy doses to target volumes should also be documented appropriately.

The Qualified Medical Physicist should independently verify the source strength displayed by the treatment console computer. In addition, the correct date and time at the treatment console computer should be verified.

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

1. Image-guided HDR procedures

Volumetric imaging is increasingly used in HDR brachytherapy, through different modalities: CT, MRI, US, positron emission tomography (PET). Although one can claim that in the modern era some form of imaging (mostly US) is used for guiding the applicator insertion, it was only in the last decade that most HDR brachytherapy procedures had become 3-D image-based, either through single- or multi-imaging modalities. In cervical cancer, Groupe Européen de Curiethérapie (GEC)-European Society for Radiotherapy and Oncology (ESTRO) has published guidelines for image-based HDR of the cervix [14,16-21], thus creating the basis for the transition from 2-D, point-based treatment, to 3-D, volume-based ones. In lieu of similar guidelines in the United States, Qualified Medical Physicists involved in the image-based HDR for the cervix may consult the GEC ESTRO guidelines for a successful implementation of the image-guided radiation therapy (IGRT) program.

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 [22-24].

The position of intracavitary, intraluminal, interstitial, and surface applications 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.

Whether using a CT-based plan or a template, applicator-based plan, one should insure the accurate treatment delivery by confirming the applicator size/type and reproducing its placement through geometrical measurements. If multiple markers are placed at the vaginal vault prior to the planning CT, fluoroscopy or scout CT can be used, when available, to confirm placement by reproducing the placement of the cylinder relative to markers. Without markers, the only purpose for imaging is to document applicator placement.

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 [5,10,11,25]. 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 [25-27]. Heterogeneity corrections have only recently been made available to the brachytherapy community. The AAPM Task Group 186 Report [25] 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 [28] 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 [29]. 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 a 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, treatment time
e. Volumetric dose coverage of the target and dose constraints of tissue/OARs

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 total dwell time, the point-dose verification to specific points in the dose distributions, etc. This plan verification step should be completed prior to treatment initiation. Target-dose deviations greater than 5% should be investigated and resolved prior to treatment.

C. 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 AU and an Authorized Medical Physicist in accordance with state and federal regulations.

2. 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 individual from the HDR brachytherapy team to assure that the correct source treatment channel is connected to the correct catheter/applicator. Lastly, prior to each treatment, a dummy wire check should be done to ascertain that all catheters/applicators are unobstructed.

3. Documentation
All patient specific documents created or used in patient treatment should be either uploaded to the patient's Electronic Medical Record or otherwise available for audit by regulators and other parties who may need access to the information. These documents may include:
   a. An HDR treatment plan which displays pertinent information regarding the case. This may include the source, source strength, a description or visualization of the loading pattern used, dose prescription, activated dwell positions, DVH data, and isodose curves.
   b. Independent verification of treatment time/dose (secondary dose calculation)
   c. Survey information (pre- and post- patient treatment)
   d. Checklist that are utilized by the treatment team
   e. Other required documentation such as verification of time outs, confirmation of completion of treatment delivery, etc.

4. Pre- and Posttreatment survey

A pretreatment survey should be conducted and compared to posttreatment survey.
After the source has been retracted at the end of the delivery, a posttreatment 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 posttreatment survey must be documented as part of the treatment record and should be done under the supervision of the Qualified Medical Physicist.

D. New Procedures

Any new HDR treatment delivery methodology should be discussed with the AU and Qualified Medical Physicist prior to patient treatment. The AU and Qualified Medical Physicist should agree upon the new process including use of imaging modalities, patient transport procedures, validation and QA steps, etc. Basic standards of practice and prudent courses of action should be determined ahead of time. As discussed in section 4, Brachytherapy Applicators, the Qualified Medical Physicist should oversee the commissioning and quality assurance of any new devices and evaluate intended imaging modalities with device compatibility. Any modifications to an existing process (such as using an existing applicator in a different way or site) should be evaluated by the treatment team ahead of time.

V. DOCUMENTATION

The Qualified Medical Physicist is responsible for maintaining proper, complete, and accurate records required by regulatory agencies and accrediting institutions. This may include documentation of the performance of daily QA, source strength verification, applicator commissioning reports, treatment planning annuals, and more. The documents should record the results and frequency of these tests. These records should also be available to individuals performing internal audits (eg, radiation safety committee) or external audits (accrediting bodies or peer review).

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*As of May 2015, all practice parameters and technical standards that are collaborative with only the American Association of Physics in Medicine are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 54, 2015). The effective date is the first day of the month following a 60-day period that begins on the date the document was approved.

Development Chronology for this Technical Standard
2000 (Resolution 18)
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