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ACR–AAPM TECHNICAL STANDARD FOR THE PERFORMANCE OF LOW-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 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 treatment in which a radionuclide is used to deliver radiation by interstitial, intracavitary, intraluminal, or surface application. There exist a number of processes and sealed radioactive sources to perform low-dose-rate (LDR) brachytherapy. This document is explicitly not intended to address the use of remote afterloading devices commonly referred to as high-dose-rate (HDR) or pulsed-dose-rate (PDR) systems.

The practice of brachytherapy physics occurs under a variety of settings. The judgment of a Qualified Medical Physicist , in conjunction with a radiation oncologist (authorized user (AU)), should be used to apply these standards to individual practices. Also, radiation safety requirements must 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 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 Physicists 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) [1]. (ACR Resolution 17, adopted in 1996 – revised in 2012, Resolution 42)

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 all 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 because clinical brachytherapy physics involves direct contact with patients and access to 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 the Qualified Medical Physicist.

C. Radiation Therapist

The Radiation Therapist must fulfill applicable 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 because of the uniqueness and relative complexity of each case. As a special procedure, LDR brachytherapy requires a significant time commitment by the Qualified Medical Physicist to develop and maintain high standards for quality procedures, as well as to provide 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 should be done with a well ionization chamber and electrometer or other suitable instrument with a source strength measurement directly traceable to the National Institute of Standards and Technology (NIST) [2]. The AAPM has provided guidelines to verify the source calibration [3,4].

Calibrated survey instruments that are appropriate in energy response and range for the sources used must be available for use at all times [2]. A backup survey meter with current calibration should be readily available in case of primary instrument failure or unavailability.

The facility must have instrumentation to perform periodic sealed-source leak testing or arrange to have this service provided.

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

A computerized treatment planning system for volumetric image reconstruction or processing (computed tomography (CT), ultrasound, magnetic resonance imaging (MRI), etc), applicator reconstruction, and isodose computation should be available to calculate point doses, generate isodose distributions, and compute dose-volume statistics.

Proper maintenance, calibration, quality control, and update of the equipment must be carried out under the supervision of the Qualified Medical Physicist.

IV. QUALITY ASSURANCE PROGRAM

A. Introduction

The Quality Management Program refers to administrative policies, quality assurance (QA), quality control (QC) measures, and consideration of quality improvement (QI) objectives that ensure a consistent and safe fulfillment 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 ensure the accurate delivery of the prescribed dose to the specified volume [5]. The complexity of brachytherapy procedures necessitates that comprehensive quality management include treatment-related devices (planning and imaging systems, applicators, radioactive sources, and delivery systems) and the clinical process [6,7]. The AAPM Task Group 100 report provides suggestions for increasing the effectiveness of quality and safety programs based on formal risk analysis methodology [8]. The Qualified Medical Physicist should work closely with the radiation

oncologist and other members of the brachytherapy team to build consensus and to document the clinical workflow and resources for specific anatomical site 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 that encompass sealed sources and their use and maintain proper written documentation [4]. When these activities relate to radiation safety, they should be carried out in conjunction with the institutional radiation safety officer (RSO).

The Qualified Medical Physicist should institute a documented peer-review mechanism for the review of the brachytherapy physics program by a Qualified Medical Physicist with experience relevant to the scope of the program being reviewed. The review should be performed annually. When reviews are performed on a less frequent schedule, the time between reviews should not exceed 3 years or the next state or Nuclear Regulatory Commission (NRC) inspection [9].

B. Sealed Sources

Because the radiological characteristics of encapsulated sources depend on their physical and chemical form, as well as on the source encapsulation, and the radioactivity distribution within the source, the Qualified Medical Physicist must take these factors into account to properly determine the dose distribution around the source.

Sealed sources with long half-lives (>6 months) must be labeled to distinguish sources that have the same radionuclide and capsule design but different source strengths.

1. Measurement of source strength

   Brachytherapy sources used in radiation oncology must have measurements of their source strength with traceability to national standards. The 1995 AAPM TG 43 report [10], its updated version published in 2004 [11], and supplements [12] should be consulted for dosimetry protocols of specific LDR sources employed for brachytherapy procedures.

   The Qualified Medical Physicist must establish acceptable limits of accuracy for source strength measurements as well as a course of action if the source strength does not fall within these limits.

   All sources containing radionuclides with a half-life greater than 6 months should have their source strength measured upon receipt. Autoradiographs must be performed on these sources prior to initial use to verify the uniformity of radioactivity spatial distribution for each source.

   For sources containing radionuclides with a half-life of less than 6 months, a random sample of sources from each manufacturer’s lot number should have their source strength measured upon receipt. The quantities of sources to be assayed are described in the AAPM Report 98 [3].

   Source strength should be specified in terms of air kerma strength, not apparent activity, for all clinical aspects of the procedure, such as source ordering, source strength assays, and treatment planning [3]. The current source strengths of new sources must be entered into the treatment-planning system. An additional qualified individual should perform a check of the entered values.

2. Instrumentation

   For direct measurement of source strengths, a well ionization chamber with known axial response and an electrometer, as applicable, are recommended. The constancy of the well ionization chamber and electrometer must be verified upon receipt, after repair, before and after mailing for calibration, and prior to each use. For source calibrations, the well ionization chamber and electrometer must be calibrated at least every 2 years [4].

An uncalibrated well ionization chamber may be used in conjunction with a source whose strength has been determined by an Accredited Dosimetry Calibration Laboratory (ADCL) or NIST by the replacement method to provide relative response for verifying source strength, describing batch variation, and confirming source identity according to strength. The sensitivity, linearity (if appropriate), and reproducibility of the instrument must be documented at least annually [3,13].

3. Brachytherapy applicators and templates

   The Qualified Medical Physicist must determine the source location, the coincidence of dummy and active sources, and the location of shields for intracavitary applicators prior to initial use. Such applicators should be radiographically inspected annually and physically inspected prior to each use. For appropriate interstitial applicators, the coincidence of dummy and active sources must be verified prior to initial use.

   Prior to first use, and periodically thereafter, needle-guiding templates should be checked for alignment and scaling between physical needle positions and the superimposed electronic grid generated by the ultrasound and treatment planning system [14].

4. Radiation safety

   Radiation safety practices must be consistent with the institution's radioactive material license, license amendments, and existing regulations [2]. Nevertheless, the Qualified Medical Physicist in conjunction with the RSO should be responsible for developing, overseeing, and documenting radiation safety procedures, including, but not limited to, the following:
   a. Written procedures for ordering, receiving, returning, and/or disposing of radioactive materials and for performing patient and room surveys following source removal
   b. Procedures for the safe handling, preparing, cleaning, sterilizing, and sorting of sources
   c. Policies for personnel monitoring of radiation exposure
   d. An inventory control program sufficient to identify the locations of all sealed sources at any time
   e. Emergency procedures for leaking sources and loss of or dislodging of sources
   f. Leak tests of inventoried long half-lived sources
   g. Ensuring the security of all radioactive sealed sources, including procedures for the interdepartmental transport and retrieval of sources prior to and subsequent to implantation
   h. Documentation and reporting of medical events in accordance with state or federal regulations
   i. Determining and evaluating unsafe and risky procedures
   j. Patients should be provided with written release instructions for radiation protection including, but not limited to, potential limitations on patient contact with minors and pregnant women. These instructions must be consistent with guidance of the ACR–ABS Practice Parameter for the Performance of Low-Dose-Rate Brachytherapy [15].

C. Treatment Planning and Dosimetry

Brachytherapy treatment planning should include, at a minimum, the determination of the appropriate isodose distribution. A consistent means of specifying and documenting administered activity must be in place. Treatment-planning specifications should include, at a minimum, a description of technique and applicator, radionuclide, source strength(s), anatomical description of target volume, dose-to-target volume, dose to reference points, and the dose distribution. In the planning process, image-based volumetric computerized treatment-planning algorithms that provide a means to conform the dose distribution to the target and minimize the dose to organs at risk (OARs) should be used. The time-dose pattern, anatomical description of the target volume, dose to the target volume, and volumetric dose statistics should be determined if 3-D patient imaging information is used. Prior and/or planned external beam and brachytherapy doses that overlap with the current LDR plan should be considered during the LDR planning to target volumes, and OARs should also be documented with every treatment plan.

1. Imaging
    a. Image-guided applicator/source localization: Image-guided procedures are the standard of care. Imaging modalities such as fluoroscopy, MRI, CT, and ultrasound are used to achieve high-quality delivery of brachytherapy [16-21]. 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 imaging modality prior to its clinical use [14,22-24].
    b. Localization images: The position of all intracavitary, intraluminal, and interstitial implants must be verified before treatment, as applicable, with appropriate medical imaging modalities. It is preferred that images be acquired 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 should be approved by the responsible radiation oncologists.

2. Computerized planning system

    Computerized planning systems must undergo rigorous acceptance tests and commissioning to ensure that the dose-calculation algorithm properly converts the source strength and dosimetry parameters into the appropriate absorbed dose distribution, including dose-volume statistics, if available, and to ensure that hardware and software were installed properly [2,10-12,25]. Correction for decay of source strength must be made regularly to reflect change in source strength. The handling of image data and their use in dose calculations must also be verified for accuracy in comparison (where appropriate) with well-established methods of dose calculation (eg, nomograms or lookup tables). Model-based treatment planning system algorithms and the use of material heterogeneity corrections have increased the accuracy and complexity of brachytherapy dose calculations [25-27]. These new approaches need to be implemented with great care because current prescription and outcome data are based on the TG-43 formalism [12]. 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 and documented to ensure the accuracy of dose-calculation algorithms, software changes, hardware changes, and source data files [28,29]. All training should be documented.

3. Treatment plan and review

    For each brachytherapy procedure, a treatment plan and dosimetry report pertinent to the plan should be reviewed and completed by the Qualified Medical Physicist. The report should include, but is not limited to, the following items:

    a. Patient name, ID, and treatment site
    b. Prescribed dose
    c. Description of the source, the implant technique, and the source distribution pattern used
    d. Total source strength, dose rate, and implant duration
    e. Isodose distributions in appropriate planes
    f. Dose-volume indices used to evaluate coverage of the target and the quality of the treatment plan along with dose constraints of tissue/OARs.

    The treatment plan should be independently reviewed by the AU and a Qualified Medical Physicist or a designate not directly involved with generating the treatment plan [30]. This review may include, but is not limited to, ensuring that the:

    a. Planned dose conforms to the prescription
    a. Applicator type, implant geometry and applicator reconstruction, and source position(s) are reasonable
    b. Radionuclide, source configuration and strength, source calculation model, date of implant, and implant duration are correct
    c. Volumetric dose coverage of the target and dose constraints of tissue/OARs are satisfactory

4. Independent dose calculation

   To validate the treatment plan, an additional dose calculation using an independent method from the treatment-planning system should be used. This validation should be consistent with the prescription, source position(s), and source strength. Consistency with prior practice, when applicable, should be checked using the target volume and total source strength to generate regression fits to dosimetric indices. This plan validation step should be completed prior to treatment initiation. There may be instances in which treatment plan validation may not fit with the implant workflow and may need to be delayed (ie, prostate seed implants, intraoperative implants, etc) until source placement is complete.

D. Clinical Medical Physics Management

1. Source loading and placement

   The Qualified Medical Physicist or Medical Dosimetrist must be available for consultation during applicator placement and loading. The prescribed loading of applicators must be independently confirmed and documented.

2. Source removal and radiation safety review

   For a temporary implant, the Qualified Medical Physicist or Medical Dosimetrist must be available for consultation during source and applicator removal. The Qualified Medical Physicist, in conjunction with the RSO, should be responsible for developing, overseeing, and documenting the process/procedure for radiation safety review at the time of source removal.

E. New Procedures

In conjunction with the medical director and/or the appropriate AU, 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 clinical initiation. New devices and applicators must be evaluated with respect to integrity, suitability for use with the radioactive sources, and effects on dose distributions. This evaluation must be prepared as a written report and distributed in accordance with institutional policy.

V. DOCUMENTATION

The Qualified Medical Physicist is responsible for maintaining complete and accurate records required by regulatory agencies and accrediting bodies. Records documenting the results and frequency of QA checks, QC measures, corrective actions**.**

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