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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

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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 care¹. 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

Brachytherapy is a method of treatment in which a radiation source(s) is used to deliver radiation by interstitial, intracavitary, intraluminal, or surface application. This standard, developed initially by the American College of Radiology (ACR) for the performance of low-dose-rate (LDR) brachytherapy physics, was revised collaboratively by ACR and the American Association of Physicists in Medicine (AAPM). There exist a number of processes and sealed radioactive sources to perform LDR brachytherapy treatment. This document is not intended to explicitly address the use of remote afterloading devices commonly referred to as high-dose-rate (HDR) or pulsed-dose-rate (PDR) systems.

Since the practice of 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.

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 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 \(CME\)](#) [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 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.

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 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, LDR brachytherapy requires a 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 non-clinical aspects should be included when budgeting personnel requirements.

B. Equipment Needs

Each facility must have instrumentation to independently verify the source strength and activity provided by the manufacturer. This must be done with a well ionization chamber and electrometer or other suitable instrument with a calibration directly traceable to the National Institute of Standards and Technology (NIST) [2,3]. At a minimum, the facility must have an indirectly traceable verification of the source manufacturer's calibration by way of a source strength comparison [4].

Calibrated survey instruments that are appropriate in energy response and range for the sources used must be available for use at all times [2,3]. A backup survey meter should be readily available in case of primary instrument failure.

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 guidance (CT, ultrasound, etc), applicator reconstruction, and isodose 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 the equipment must be carried out under the supervision of the Qualified Medical Physicist.

IV. QUALITY ASSURANCE PROGRAM

A. Introduction

Quality assurance (QA) refers to administrative policies, 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 scientific records regarding appropriate description, calibration, and the current source strength in order to assure the accurate delivery of the prescribed dose to the specified volume [5]. The complexity of brachytherapy procedures necessitates that comprehensive QA include treatment-related devices (planning and imaging systems, applicators, radioactive sources, and delivery systems) and the clinical process [6]. The Qualified Medical Physicist should work closely with the radiation oncologist and other members of the brachytherapy team to build consensus and document of 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 [7]. When these activities relate to radiation safety, they should be carried out in conjunction with the institutional radiation safety officer.

The Qualified Medical Physicist should institute a documented peer-review mechanism for reviewing the brachytherapy physics program. The review should ideally 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 schedule, the time between reviews should not exceed 3 years or the next state/NRC inspection [8].

B. Sealed Sources

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

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

1. Calibration of sources

Brachytherapy sources used in radiation oncology must have calibrations with direct or secondary traceability to national standards. The 1995 AAPM TG 43 report [9] and its updated version published in 2004 [10] and subsequent addendums should be consulted for dosimetry protocols of specific LDR sources employed for the 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 be calibrated 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 be calibrated upon receipt. The quantities of sources to be assayed are described in the AAPM Report 98 [4].

For all clinical aspects of the procedure, source strength should be specified in terms of air-kerma strength, not apparent activity [4]. The current source strengths of new sources must be entered in the treatment-planning computer. An additional qualified individual should perform a check of the calibration and the entered values.

2. Instrumentation

For direct calibration of sources, a well ionization chamber and electrometer with NIST-traceable calibration and known axial response are recommended. The constancy of the well ionization chamber and electrometer must be checked with a long-lived sealed source upon receipt, after repair, and prior to each use (or weekly). For direct calibration of sources, the well ionization chamber and the associated electrometer must be calibrated at least every 2 years [7].

For verifying source strength, describing batch variation, and confirming source identity according to strength, an uncalibrated well ionization chamber may be used in conjunction with a NIST-traceable calibrated source by the replacement method to provide relative response. The sensitivity, linearity (if appropriate), and reproducibility of the instrument must be documented at least annually [4,11].

3. Brachytherapy applicators

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.

4. Radiation safety

Radiation safety practices must be consistent with the institution's radioactive material license, license amendments, and existing regulations [2,3]. Nevertheless, 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:

- 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. An inventory control program sufficient to identify the locations of all sealed sources at any time
- d. Emergency procedures for leaking sources and loss of or dislodging of sources
- e. Leak tests of inventoried long half-lived sources
- f. Assuring the security of all radioactive sealed sources. This includes procedures for the interinstitutional transport and retrieval of sources prior to and subsequent to implantation.
- g. Documentation and reporting of medical events in accordance with state or federal regulations

C. Treatment Planning and Dosimetry

Treatment planning for all implants should include, at a minimum, the determination of the appropriate isodose 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), anatomical description of target volume, dose-to-target volume, dose to reference and/or tolerance points, and the dose distribution. In the planning process, 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 the 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.

Corrections for decay of source strength must be made regularly to reflect change in source strength.

1. Imaging

- a. Image-guided applicator/source localization: Image-guided procedures are becoming the standard of care. There are a number of uses of various imaging modalities to achieve high-quality delivery of brachytherapy [12-16]. 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 [17-20].

- b. Localization images: The position of all intracavitary, intraluminal, and interstitial implants must be verified before treatment with appropriate medical imaging modalities. It is preferred that images should 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 calibration and conversion factors into the appropriate absorbed dose distribution, including dose-volume statistics, if available, and that hardware and software were installed properly [2,9,10,21]. 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 treatment planning system algorithms and the use of heterogeneity corrections have increased the complexity of the dose calculations that may be employed in brachytherapy [21-23]. 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 [24]. All training should be documented.

3. Treatment 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 [25]. Treatment 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, 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
- f. Final dosimetry report
- g. Dosimetry report treatment plan

4. Independent dose calculation

An additional dose calculation using an independent method from the treatment-planning system should be used to validate the dose calculation results of the computerized planning systems. This validation should be consistent with the written prescription, source positions, and source strength. This plan verification step should be completed prior to treatment initiation. There may be instances where final plan verification may not be consistent 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. Prior to placement, the prescribed loading of applicators must be independently confirmed and documented.

2. Medical physics consultation

The Qualified Medical Physicist must develop and implement a program for review and analysis of patient status, including changes in the physics aspects of the treatment regime, consultation on and participation in patient setup and treatment modifications, and review of patient-specific treatment and technical notes.

3. Dosimetry report

A written dosimetry report must be completed by the Qualified Medical Physicist for each brachytherapy procedure. The report should include, but is not limited to, the following items:

- a. Description of the sources
- b. Total source strength
- c. Description of the technique and source pattern used
- d. Dose rate and implant duration
- e. Prescribed dose, which should include any dose-volume indices used to evaluate the quality of the treatment
- f. Isodose distributions in appropriate planes
- g. Evidence of an independent review of the dose calculation

The report should be signed by the Qualified Medical Physicist and the responsible radiation oncologist. The Qualified Medical Physicist should follow recommended reporting methods for specific implant anatomical sites and radionuclides when provided [26,27].

4. 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 radiation safety officer, 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 physician, 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 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, and QI objectives 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.

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