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The American College of Radiology will periodically define new practice guidelines 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 guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline 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, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines 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 guideline and technical standard by those entities not providing these services is not authorized.

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ACR TECHNICAL STANDARD FOR THE PERFORMANCE OF BRACHYTHERAPY PHYSICS: INTRAVASCULAR APPLICATIONS USING CATHETER-BASED SYSTEMS (IVBT)

PREAMBLE

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

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

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Brachytherapy is a method of treatment in which sealed radioactive sources are used to deliver radiation by interstitial, intracavitary, surface, or, more recently, by intravascular brachytherapy (IVBT) application. This standard has been developed by the American College of Radiology (ACR) to outline a standard of medical physics practice related to one area of this modality: the use of radioactive sources for intravascular irradiation. At the present time, various methods exist to deliver the ionizing radiation from the brachytherapy source to peripheral or cardiac vessels. Broadly speaking, intravascular radiation delivery ensues from catheter-based systems deploying either gamma or beta emitters or from implanted radioactive stents. Dosimetric considerations differ between the catheter-based systems delivering a single acute exposure within several minutes versus the permanently implanted radioactive stent that should have an associated effective treatment time.

This procedure is usually carried out in the cardiac catheterization laboratory or interventional radiology setting using a team approach. Minimally, the team responsible for the intravascular radiation delivery consists of a radiation oncologist, an interventional

cardiologist or interventional radiologist, and a medical physicist. The main techniques include use of manually loaded sources, remotely loaded sources, radioactive stent placement, and, possibly, radioactive liquid balloons.

Since the practice of IVBT physics occurs under a variety of settings, the judgment of a Qualified Medical Physicist should be used to apply these standards to individual practices. The focus of this standard is on intravascular brachytherapy delivered using catheter-based systems. Information regarding the performance of coronary vascular brachytherapy is covered in the [ACR Practice Guideline for the Performance of Coronary Vascular Brachytherapy](#). No companion clinical performance guideline exists at present for peripheral brachytherapy. Finally, radiation safety requirements must be in compliance with appropriate federal and state regulations.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The ACR considers certification and continuing education and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more of the subfields in medical physics and to be a Qualified Medical Physicist.

The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR) or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfield(s) of medical physics for this guideline are Therapeutic Radiological Physics and Radiological Physics.

A Qualified Medical Physicist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

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

In the absence of a facility-wide peer-review program, a mechanism for medical physicist peer review must be put into place. It is recognized that the peer-review process for the medical physicist in solo practice may present a

difficult situation; however, the medical physicist should institute a documented peer-review mechanism for the review of the brachytherapy physics program.

III. RESOURCES

A. Personnel Requirements

Medical physicists and their support personnel should be staffed at levels that permit effective and safe use of the IVBT source and source train. Active brachytherapy programs require additional physics and support personnel due to the uniqueness and relative complexity of each case.

When a medical dosimetrist is available to assist the medical physicist in the IVBT brachytherapy service, this individual should be certified. Certification by the Medical Dosimetry Certification Board is recommended.

B. Equipment Needs

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

Radiation survey instruments that are appropriate in energy response and range for the sources used must be available. A backup 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.

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

Additionally, two independent precision timer systems are required for measuring the source and source train dwell time associated with the dose prescribed in the written directive.

Proper maintenance, calibration, and updating of this equipment must be carried out under the supervision of the medical physicist.

IV. QUALITY MANAGEMENT PROGRAM

A. Introduction

Quality management (QM) in radiation oncology may be defined as those administrative policies, quality improvement (QI) procedures, and quality control (QC)

measurements that ensure a consistent and safe fulfillment of the dose prescription. The medical physicist is responsible for maintaining the scientific records regarding appropriate description of the source, calibration of the source, and the current stated activity of the source to assure accurate delivery of the prescribed dose to the specified volume.

Quality control for sealed sources primarily entails maintaining an ongoing review for adherence to regulatory and licensing requirements. Accordingly, the medical physicist shall develop, implement, supervise, and review the policies and procedures that encompass use of the IVBT source and maintain proper written documentation. When these activities relate to radiation safety, they should be carried out in conjunction with the institution's radiation safety officer.

B. IVBT Sealed Sources

Since the radiation characteristics of an encapsulated source depend on the source encapsulation and the distribution of the activity within the source, it is incumbent on the medical physicist to obtain the following information: physical and chemical form, source encapsulation, and uniformity characteristics of radionuclide distribution within the source and the source train.

1. Calibration of IVBT sources

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

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

2. Instrumentation

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

3. Treatment delivery unit

IVBT treatments are to be carried out with a high degree of mechanical precision and accuracy. The medical physicist should establish a QC program to assure the intended accuracy and precision consistent with the specifications of the manufacturer. The program must be consistent with regulatory requirements.

4. Brachytherapy catheters

The medical physicist shall observe that the source and source train can travel to intended locations in the treatment catheters and, if applicable by design, the coincidence of dummy markers and the active source and source train.

5. Radiation safety

Radiation safety practices are dictated by the institution's radioactive material license, license amendments, and existing regulations. Nevertheless, the medical physicist should be providing oversight for developing and documenting radiation safety procedures, including, but not limited to, those listed below:

- a. Written procedures regarding ordering, receiving, returning, and/or disposing of IVBT radioactive materials and for performing patient surveys following source removal.
- b. An inventory control program sufficient to locate and identify the IVBT device and all sealed sources at any time.
- c. Emergency procedures for removal or retrieval of the IVBT source from the patient.
- d. Procedures for assuring audio and visual communication between the patient, IVBT team members, ancillary staff, and the operator of the treatment delivery unit.
- e. Training of professional and technical staff regarding IVBT.

C. Treatment Planning and Dosimetry

A consistent means of specifying and documenting absorbed dose must be in place. Dose specification should include the device and the source type, anatomic description of target, diameter and length of vessel injury, and dose to the reference point. (For a more complete description of anatomic treatment volume for coronary arteries, see the [ACR Practice Guideline for the Performance of Coronary Vascular Brachytherapy](#).) For catheter-based approved systems, dose prescription

options include specifying the dose at a fixed distance from the center of the catheter or at a fixed distance into the arterial wall.

The source strength must be checked regularly and corrections made to compensate for a decay of 2% or more.

1. Patient dose and calculation

Dose depends on the geometry of the vessel. The size of the vessel diameter must be determined either by intravascular ultrasound (IVUS) or by the interventional radiologist or interventional cardiologist using arteriogram and the size of the angioplasty balloon. Treatment times are determined from the cross sectional geometry of the vessel, the activity of the sources, and the source train length. The treatment time is prescribed by a radiation oncologist following consultation with the medical physicist and interventional radiologist or interventional cardiologist, and should be verified.

2. Timing of the treatment

For devices that have a built-in timer, the proper operation of the timer should be checked before use in the patient. For devices without a timer, a primary treatment timekeeper shall be used, and a backup timing system should be employed if the primary system fails.

3. Positioning of catheter and sources in catheter

The interventional radiologist or interventional cardiologist is responsible for placing the radiopaque markers in the correct location to indicate the treatment area along the catheter. When the sources move into the treatment position, they can be located under fluoroscopy. The radiation oncologist or the medical physicist needs to verify the correct position of the sources.

D. Clinical Quality Management

1. Source loading, placement, and treatment

The medical physicist and radiation oncologist shall be available for consultation during applicator placement, particularly if more than one vessel segment is to be treated. Prior to treatment, the prescribed loading of applicators shall be independently confirmed. Only physicians or other appropriately trained personnel should apply, adjust, or remove brachytherapy applicators.

The interventional cardiologist or interventional radiologist, a radiation oncologist, and a medical physicist should all be physically present during the treatment. The role of the interventional cardiologist or interventional radiologist is to manage and monitor the patient; the radiation oncologist treats the patient; and the medical physicist is in charge of radiation safety, dosimetry, and documentation.

2. Physics chart check protocol

The medical physicist shall develop a chart check protocol for reviewing treatment delivery to ensure accuracy of calculations and fulfillment of the physician's written prescription.

3. Dosimetry report

A written dosimetry report shall be completed by the medical physicist and signed by the radiation oncologist for each brachytherapy procedure. The report should include:

- a. Description of the sources.
- b. Description of the technique and source pattern used.
- c. Dose rate and total time of implant.
- d. Total source strength.
- e. Prescribed dose.

E. New Procedures

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

V. DOCUMENTATION

The medical physicist is responsible for maintaining complete and accurate records required by regulatory agencies or accrediting bodies. Records documenting the frequency of performance of the QM program, including QI procedures and the result of QC measurements, are important, both for retrospective analysis of trends and for 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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