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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.

Revised 2010 (Resolution 4)*

ACR–ASTRO PRACTICE GUIDELINE FOR THE PERFORMANCE OF LOW-DOSE-RATE BRACHYTHERAPY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiation oncology 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 of 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

This guideline was revised collaboratively by the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO) in cooperation with the American Brachytherapy Society (ABS).

Brachytherapy is the use of radionuclides to treat malignancies or benign conditions by means of a radiation source placed close to or into the tumor or treatment site. This guideline refers only to the use of radionuclide brachytherapy. Brachytherapy alone or combined with external beam therapy plays an important role in the management and treatment of patients with cancer.

Low-dose-rate (LDR) brachytherapy has traditionally been used for treating prostate, head and neck, breast, cervical, and endometrial cancers as well as obstructive esophageal or bronchial lesions. It has been practiced for over a century with a variety of sources including radium-226, cesium-137, and, more recently, iridium-192, iodine-125, and palladium-103. LDR brachytherapy can be given as interstitial, intracavitary, or intraluminal therapy to a wide variety of treatment sites.

LDR brachytherapy is accomplished by 1) temporary implants, i.e., afterloading radioactive sources into applicators that are placed into the patient, or 2) permanent implants, placing the radioactive sources permanently into the cancerous tissue. Source handling and loading into the applicator or tissue can be performed manually or remotely, with source loading performed by a computerized unit. LDR brachytherapy is delivered at dose rates of 4 to 200 cGy per hour at a designated point. Brachytherapy can also be administered using remote afterloading, high-dose-rate (HDR) techniques. The use of HDR brachytherapy is covered in the [ACR–ASTRO Practice Guideline for the Performance of High-Dose-Rate Brachytherapy](#) [1].

The use of brachytherapy requires detailed attention to personnel, equipment, patient and personnel safety, and continuing staff education. Since the practice of radiation oncology occurs in a variety of environments, the judgment of the radiation oncologist and medical physicist should be used to apply these guidelines to individual practices.

This guideline addresses sealed sources as they are used for LDR brachytherapy. Guidelines for unsealed sources can be found in the [ACR–ASTRO Practice Guideline for the Performance of Therapy with Unsealed Radiopharmaceutical Sources](#) [2].

The use of LDR permanent brachytherapy for prostate cancer is covered in a separate [ACR–ASTRO Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer](#) [3].

There is a separate practice guideline referring to the practice of vascular brachytherapy. See the [ACR Practice Guideline for the Performance of Coronary Vascular Brachytherapy \(CVBT\)](#) [4].

The licensing of radioactive sources (radionuclides) and the safety of the general public and health care workers are regulated by the Nuclear Regulatory Commission (NRC) or by agreement states.³ Medical use of radionuclides for therapeutic procedures must adhere to the constraints set forth by these regulatory agencies. Detailed descriptions of NRC licensing and safety issues can be found in the Code of Federal Regulations, Part 20 and Part 35. State requirements for the agreement states are found in the respective state statutes.

A literature search was performed and reviewed to identify published articles regarding guidelines and standards in low-dose-rate brachytherapy.

³An agreement state is any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274.b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

II. PROCESS OF BRACHYTHERAPY

The use of LDR brachytherapy is a complex multistep process involving trained personnel who must work in concert to carry out a variety of interrelated activities. Communication among brachytherapy team members and well-defined procedures are essential for accurate and safe treatment.

A. Clinical Evaluation

The initial evaluation of the patient includes history, physical examination, review of pertinent diagnostic studies and reports, and communication with the referring physician and other physicians involved in the patient's care. The extent of the tumor must be determined and recorded for staging. Staging facilitates treatment decisions, determines the prognosis of the patient, and enables a comparison of treatment results. Clinical evaluation and staging are discussed in the [ACR Practice Guideline for Radiation Oncology](#) [5].

B. Establishing Treatment Goals

LDR brachytherapy is indicated for treatment when the target volume can be well defined and is accessible to source placement. Brachytherapy is commonly used as adjunctive treatment to accompany external beam therapy, increasing the total dose to a specified target volume.

The goal of treatment (curative, palliative, or to establish local tumor control) should be documented as clearly as possible. Treatment options and their relative merits and risks should be discussed with the patient. Integration of brachytherapy with external beam or other therapies is necessary to define the intended course of treatment. A summary of the consultation should be communicated to the referring physician. See the [ACR Practice Guideline for Communication: Radiation Oncology](#) [6].

C. Informed Consent

Informed consent must be obtained and documented as logistically feasible. See the [ACR Practice Guideline on Informed Consent – Radiation Oncology](#) [7].

D. Applicator/Source Insertion

Oncologic practice, including brachytherapy, commonly requires the interaction of multiple specialists. The choice and placement of afterloading applicators and the loading and unloading of radioactive sources are the responsibility of the radiation oncologist.

Each type of brachytherapy procedure has its own set of unique characteristics. The brachytherapy team should operate according to an established system of procedural

steps that have been developed by the radiation oncologist and brachytherapy team members. This systematic approach to applicator or source insertion should include a description of preimplantation procedures, sedation or anesthesia needs, applicator options, and insertion techniques. Standard orders or care guidelines may enhance the systematic approach to the insertion process.

E. Treatment Planning

LDR brachytherapy is administered according to the written, signed, and dated prescription of the radiation oncologist. Before treatment, the final prescription must designate the treatment site, the radionuclide used, the number of sources, the planned total dose, and the dose rate at designated points. Applicator geometry and source positions are defined with localization images or cross-sectional imaging. The specific radionuclides are designated by the radiation oncologist, as part of the LDR prescription. Computerized dosimetry is performed by the medical physicist or his/her designee and approved by the radiation oncologist. Independent verification of brachytherapy parameters (by another person or another method) is done pretreatment (see section V).

F. Treatment Delivery

LDR sources are manually or remotely loaded into applicators to deliver the prescribed treatment. If treatment modification is required, such modification must be documented. Treatment delivery must be subject to detailed scrutiny as described in the patient and personnel safety section (see section V).

G. Radiation Safety Considerations

Patients should be provided with written descriptions of the radiation protection guidelines, including, but not limited to, discussion of potential limitations on patient contact with minors and pregnant women.

Safety considerations should be consistent with state and federal regulations. The radiation oncologist, the medical physicist, and the radiation safety officer should define the radiation safety guidelines.

H. Patient Evaluation during Temporary Implants

The radiation oncologist evaluates patients on a regular basis during their brachytherapy treatment. Applicator and source placement, medical condition, and radiation safety issues should be addressed during the course of therapy. The patient's progress through therapy is documented in the hospital chart. At the end of treatment, the patient and room must be surveyed to ensure that all radiation sources have been retrieved.

I. Treatment Summary

At the conclusion of the course of treatment, a written summary of the treatment delivery parameters should be generated, including the total dose of brachytherapy and the total dose of external beam therapy if given, treatment technique, treatment volume, any acute side effects, clinical course, and patient disposition.

J. Follow-Up Evaluation

Patients treated with brachytherapy should be evaluated after treatment at regular intervals by the radiation oncologist for response and early and late effects on normal tissues. See the [ACR Practice Guideline for Radiation Oncology](#) [5].

III. QUALIFICATIONS OF PERSONNEL

The brachytherapy team includes the physician, medical physicist, dosimetrist, radiation therapist, nurse, and radiation safety officer. Qualifications of the brachytherapy team include the credentials listed below:

A. Radiation Oncologist

Certification in Radiology by the American Board of Radiology of a physician who confines his/her professional practice to radiation oncology. Alternatively, certification in Radiation Oncology or Therapeutic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec may be considered proof of adequate physician qualifications.

or

Satisfactory completion of a residency program in radiation oncology approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA).

B. 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 and 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 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 for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Therapeutic Radiological Physics and Radiological Physics.

A Qualified Medical Physicist should meet the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#) [8]. (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

The Qualified Medical Physicist should be an Authorized Medical Physicist in accordance with applicable U.S. Nuclear Regulatory Commission or Agreement State requirements.

C. Medical Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended.

D. Radiation Therapist

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

E. Nurse

State licensure as a registered nurse or practical nurse is recommended.

IV. PATIENT SELECTION CRITERIA

The use of brachytherapy is integral to the treatment of many malignancies, especially gynecologic, head and neck, sarcomas, bronchus and trachea, CNS, gastrointestinal and genitourinary malignancies. LDR prostate brachytherapy is discussed in the [ACR–ASTRO Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer](#) [4]. Temporary and permanent techniques can be used, depending on the clinical presentation as well as the experience, preference, and expertise of the treating physician.

In recent years, HDR brachytherapy has become more commonly used in many locales, and details of brachytherapy indications are included in the HDR practice guideline reference. LDR brachytherapy remains an appropriate method of dose delivery in clinical situations where brachytherapy is indicated [9-26].

V. EQUIPMENT

LDR brachytherapy requires a variety of applicators to be used with manual or remote LDR applicators. Afterloading LDR units, applicators, treatment-planning computers and software, and procedure and treatment aids should be appropriately selected for the clinical applications. Regular inspection, maintenance, and repair

of this equipment are mandatory. The medical physicist supervising the quality improvement program is responsible for documenting the maintenance and repair of manual equipment, remote afterloading units, and applicators. (See the [ACR Technical Standard for the Performance of High-Dose-Rate Brachytherapy Physics](#) [27].)

VI. PATIENT AND PERSONNEL SAFETY

Patient protection measures include those related to medical safety and radiation protection.

A. Patient Protection Measures Should Include:

1. A radiation exposure-monitoring program, as required by the NRC or appropriate state agencies.
2. Annual (re)training of staff in emergency procedures in case of equipment malfunction, and brachytherapy-specific quality management procedures.
3. Charting systems and forms for dose specification, definition and delivery of treatment parameters, and recording and summation of brachytherapy and external beam therapy treatment [22].
4. A physics quality assurance program for ensuring accurate dose delivery to the patient.
5. A system for the radiation oncologist and medical physicist to verify independently (by another person or another method) pertinent brachytherapy parameters to be used in each procedure (e.g., source model, radionuclide, source strength, dose rate, total dose, and treatment duration) prior to LDR brachytherapy.

B. Personnel Safety Measures Should Include:

1. A radiation exposure-monitoring program, as required by the NRC or appropriate state agencies.
2. Routine leak testing of all sealed sources, as required by regulatory agencies.
3. Appropriate safety equipment for use of sealed sources.

VII. EDUCATIONAL PROGRAM

Continuing medical education programs should include radiation oncologists, medical physicists, dosimetrists, nurses, and radiation therapy staff. Radiation safety programs should also include hospital-based personnel who will be involved with brachytherapy patients. Educational programs used for both initial training and retraining must cover the following:

- A. The safe operation of LDR applicators, sources, and manual or remote afterloading equipment, as appropriate to the individual's responsibilities.

B. Treatment techniques and new developments in radiation oncology and brachytherapy.

The program should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#) [8].

VIII. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Guideline for Communication: Radiation Oncology](#) [6]. There should be documentation of parameters such as the actual number of sources, source strength(s), treatment duration (for temporary implants), and total dose after the implant has been completed.

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of continuing quality improvement (CQI) as described in the [ACR Practice Guideline for Radiation Oncology](#) [5]. It is the responsibility of the Director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions. The Director will designate appropriate personnel to constitute the CQI Committee that will review LDR brachytherapy as part of the CQI meeting agenda. Refer to the [ACR Practice Guideline for Radiation Oncology](#) [5] for a detailed description of CQI Committee functions.

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web page (<http://www.acr.org/guidelines>).

X. SUMMARY

LDR brachytherapy is an important modality in the treatment of a variety of malignancies. The use of LDR brachytherapy allows high doses of radiation to be given to defined target volumes and relative sparing of adjacent critical structures. Coordination between the radiation oncologist and treatment planning staff, and clearly defined quality assurance and radiation safety procedures are important components of successful LDR brachytherapy programs.

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