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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.

Revised 2010 (Resolution 3)\*

## **ACR–ASTRO PRACTICE GUIDELINE FOR THE PERFORMANCE OF HIGH-DOSE-RATE BRACHYTHERAPY**

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### **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 or X-ray sources (electronic brachytherapy) 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 radionuclides for brachytherapy. Brachytherapy alone or combined with external beam therapy plays an important role in the management and treatment of patients with cancer. Such treatment can be given as interstitial, intracavitary, or intraluminal therapy. High-dose-rate (HDR) brachytherapy uses radionuclides such as iridium-192 at dose rates of 20 or more cGy per minute to a designated target point or volume. HDR brachytherapy is indicated for treating tumors or lesions where the treatment volume or targeted points are defined and accessible.

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) [1].

The use of brachytherapy requires detailed attention to personnel, equipment, patient and personnel safety, and continuing staff education.

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.<sup>3</sup> 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 and regulations.

A literature search was performed and reviewed to identify published articles regarding guidelines and standards in HDR brachytherapy.

## II. PROCESS OF BRACHYTHERAPY

The use of HDR 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. See the [ACR Practice Guideline for Radiation Oncology](#) and the [ACR Practice Guideline for Communication: Radiation Oncology](#) [2-3].

### B. Establishing Treatment Goals

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

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<sup>3</sup>An 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).

summary of the evaluation should be communicated to the referring physician.

### C. Informed Consent

Informed consent must be obtained and documented as logistically feasible. See the [ACR Practice Guideline on Informed Consent – Radiation Oncology](#) [4].

### D. Applicator Insertion

Oncologic practice, including brachytherapy, commonly requires the interaction of multiple specialists. The choice and placement of afterloading applicators and 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 option, and insertion techniques. Standard orders or care guidelines may enhance the systematic approach to the insertion process.

### E. Image Acquisition

In most, but not all, applications images should be obtained of the implanted regions. In certain instances, clinical assessments without images may suffice for verifying applicator position. These images may be either film based (2D) or scan based (3D). The authorized user should select the optimal imaging studies for treatment planning. The purpose of these images is to acquire special images of the implant applicator, the treatment target, and, insofar as possible, the surrounding normal tissue. It is desirable to have 3D spatial information so that the relationship of the target and surrounding critical organs can be displayed and that the relationship of the applied dose to the target and to the normal critical structures can be determined. To help minimize imaging artifacts and localization uncertainties, computed tomography (CT) or magnetic resonance imaging (MRI) slice thicknesses on the order of 1 mm should be used.

### F. Treatment Planning

HDR 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 source positions, the planned total dose, the dose per fraction, and the total number of fractions. Applicator geometry and source dwell positions are defined with localization images or CT scans. Organ at

risk points or volumes should be defined (i.e., urinary bladder catheter balloon, rectal catheter or contrast, fiducial marker or retractor, or vaginal packing). Computerized dosimetry is performed by the medical physicist or his or her designee and approved by the radiation oncologist before the treatment is delivered. Optimization techniques to shape the dose distribution are widely available but should be used carefully to avoid areas of over or under-dosages. An independent check of the dosimetry plan should be performed prior to treatment delivery (see section V).

#### G. Treatment Delivery

Prior to each treatment, the medical physicist or radiation oncologist should verify the proper connection of each applicator to the planned delivery channel. The medical physicist should verify all treatment parameters at the HDR console prior to treatment, including the correspondence between planned source strength and afterloader source strength with appropriate corrections for decay and source changes. In a multifraction treatment regimen using indwelling needles or catheters, where interfraction movement is possible, a means of verifying accurate positioning of the applicators before subsequent fractions are delivered is important for accurate treatment delivery, optimal tumor control, and patient safety.

HDR treatment is delivered by remote afterloading of high-activity radioactive sources or miniature X-ray tubes [5]. Radiation safety considerations are essential for HDR procedures. The radiation oncologist and the medical physicist must be in the immediate vicinity at all times while HDR brachytherapy is being administered, and the patient and the functioning of equipment must be continuously monitored by video or audio means and/or direct observation. Treatment delivery must be subject to detailed scrutiny as described in the patient and personnel safety section (see section V). At the end of each treatment, the patient and the room must be surveyed to ensure that the source has been retracted into the afterloading device.

#### H. 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, acute side effects, clinical course, and patient disposition. See the [ACR Practice Guideline for Communication: Radiation Oncology](#) [3].

#### I. Follow-up Evaluation

Patients treated with HDR brachytherapy should be evaluated at regular intervals for response and early and late effects on normal tissues.

### III. QUALIFICATIONS OF PERSONNEL

The HDR brachytherapy team includes the physician(s), medical physicist, dosimetrist, radiation therapist, nurse, and radiation safety officer. HDR brachytherapy requires extensive interaction between all members of the team. Because treatment is given with such a highly active source over a short duration, the consequences of error and possible misadministration are potentially serious with HDR brachytherapy. Communication among team members and well-defined procedures for performing HDR brachytherapy are essential for accurate and safe treatment. 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 \(CME\)](#) [6]. (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

#### A. Cervical Cancer

Brachytherapy is essential in the definitive treatment of cervical cancer. This is combined with external beam irradiation and often chemotherapy. International randomized trials have concluded that HDR brachytherapy is equivalent to LDR brachytherapy for local control, survival, and toxicity. Treatment planning is an integral part of cervical cancer brachytherapy due to the close proximity of the normal pelvic organs and the need for significant doses to be delivered to the cervix and paracervical tissues to achieve cure. Brachytherapy is used postoperatively in some patients following hysterectomy [7-14].

#### B. Endometrial Cancer

Vaginal brachytherapy, with or without external beam, is frequently used following surgical staging in the treatment of patients with early endometrial carcinoma. Vaginal brachytherapy is an effective means of reducing the risk of a vaginal recurrence with a very low risk of morbidity. Brachytherapy is also used for patients with recurrent endometrial carcinoma, and in this setting is sometimes interstitial rather than intracavitary. Definitive irradiation requiring brachytherapy is used infrequently

for patients with medically inoperable endometrial carcinoma [15-18].

#### C. Vaginal Cancer

Brachytherapy is used alone or in combination with external beam irradiation in the curative treatment of cancers of the vagina. Depending on the bulk of residual disease following external beam irradiation, brachytherapy may be either intracavitary or interstitial [19-20].

#### D. Bile Duct

Following surgery with radiation may be helpful in patients with positive margins or positive nodes. Brachytherapy can be used as a boost following external beam to areas of close or positive margin. External beam irradiation plus brachytherapy can be effective palliation for patients with unresectable disease. There is confirming data that radiation can provide long term local control and that dose escalation with brachytherapy may be important in better outcomes. Intraluminal brachytherapy alone can be used to palliate biliary obstruction along with percutaneous drainage [21-23].

#### E. Esophagus

HDR brachytherapy has been used in the treatment of esophageal cancer, in the palliation of advanced disease, and in the definitive treatment of superficial cancer [24-25]. HDR brachytherapy has also been used as a boost treatment following external beam radiation therapy (or combined external beam radiation therapy and chemotherapy). The improvement in local control must be balanced by the potential morbidities, with respect to esophageal HDR brachytherapy [26-27].

#### F. Bronchus/Trachea

HDR brachytherapy has been used in treating malignancies involving the lung, bronchus, and trachea. In some cases it can be used in conjunction with external beam radiotherapy in definitive cases [28-29], and in the definitive treatment of primary tracheal carcinomas [30]. More commonly, HDR brachytherapy has a well-established role in the palliation of primary and recurrent endobronchial lesions [31-34].

#### G. Prostate

HDR brachytherapy may be used in combination with external beam radiation therapy in the treatment of prostate cancer in any risk group. It may also be administered as the sole treatment for low risk and some intermediate risk patients [35-47]. There is a separate [ACR-ASTRO Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer](#) [48].

## H. Breast

HDR brachytherapy can be used as a lumpectomy bed boost, but is more commonly used as a technique for administering accelerated partial breast irradiation (APBI) as the sole radiation treatment following breast conserving surgery. This approach treats a limited volume of tissue around the lumpectomy cavity over a shortened time period (typically 10 treatments delivered twice daily over 5 treatment days). Techniques include multicatheter interstitial implants (placed free-hand or with utilization of templates) and intracavitary devices (balloon catheters and other similar devices). APBI is appropriate for selected patients with early breast cancer. Further information related to patient selection and indications is available from ASTRO and ACR documents [49-50].

## I. Head and Neck

LDR brachytherapy has long played an important role in the treatment of head and neck malignancies. The same operative techniques may be used for HDR brachytherapy [51-62]. Tumors in the head and neck affect important structures; therefore, careful attention to dose principles that preserve tissue function are needed, particularly, multifraction regimens that avoid large doses per fraction [63-66]. Computer-based dose optimization, advances in radiation safety, and improved nursing care are important reasons why LDR brachytherapy is being supplanted by HDR brachytherapy [67-75]. Interstitial, intracavitary, surface applications (plesiotherapy), and intraoperative techniques are all used in head and neck HDR brachytherapy. Depending on the clinical circumstances, it may be applied as a single modality or as a boost treatment in combination with external beam radiation therapy. HDR brachytherapy may be used in many sites in the head and neck, particularly in the lip and oral cavity, the oropharynx, and the nasopharynx, and in the treatment of cancers of various histologies. It may also be used for re-irradiation in the event of tumor recurrence after external beam radiation therapy [76].

## J. Soft Tissue Sarcoma

HDR brachytherapy has a role in the treatment of soft tissue sarcoma because of the high doses of radiation which are required to obtain tumor control. It plays an important role in the multidisciplinary management of soft tissue sarcoma. It can be a part of definitive therapy [77-80], postoperative adjuvant therapy [81-83], intraoperative radiotherapy [79,84-86], and palliative treatment [87].

## K. Pediatric Tumors

In selected cases, HDR brachytherapy can be useful in managing pediatric tumors.

## L. Skin

Although skin cancer can be treated using a variety of radiotherapy techniques, HDR brachytherapy offers unique dosimetric properties that may be useful for treating skin cancer over irregularly shaped and difficult to access skin surfaces. [88-91]. Both interstitial and plesiotherapy (surface applicators) techniques can be used. HDR brachytherapy can be used in combination with surgery for keloids [92].

## M. Intraoperative Brachytherapy

HDR brachytherapy can be used intraoperatively for delivering a single high dose of radiation after maximal tumor resection and while the “tumor bed” is accessible and normal tissues can be displaced or shielded from the site of treatment. Special intraoperative applicators have been developed which conform to a wide variety of size and shape of tumor bed and which can be inserted with flexibility and precision. A shielded operating room is required for intraoperative HDR brachytherapy. In the absence of a shielded operating room, intraoperatively placed catheters may be used for postoperative fractionated HDR brachytherapy delivered in a shielded treatment room. These techniques may be used in a variety of tumor types and body sites [93-94].

## N. Anorectal

Interstitial, intraluminal, or intraoperative HDR brachytherapy may be used in the treatment of anal and rectal cancers. This modality can be part of a preoperative approach for resectable or locally advanced rectal cancers [95-98] or for unresectable, inoperable, and recurrent disease [99-105]. For anal cancers, HDR brachytherapy can be used as a boost after external beam radiotherapy [106-109], or as definitive treatment in carefully selected cases.

## O. Other Indications

The list of indications above is not meant to be comprehensive. The individual radiation oncologist may find HDR brachytherapy beneficial in a variety of other tumor types and specific clinical situations (e.g., penis, bladder, urethra, central nervous system, ocular).

## V. EQUIPMENT

HDR brachytherapy treatment is delivered with computerized, remotely afterloaded devices that contain a radioactive source or a miniaturized X-ray tube. Equipment manufacturers offer applicators for interstitial, intracavitary, contact (plesiotherapy), and intraluminal treatment that are used with the treatment units. An applicator replacement schedule should be implemented to avoid damage caused by repetitive use. Computerized

treatment planning is accomplished with specialized hardware and software compatible with the respective HDR brachytherapy system being used.

Periodic scheduled preventive maintenance is essential. The medical physicist supervising the quality improvement program is responsible for documenting the maintenance and repair of remote afterloading units, applicators, and other equipment. (See the [ACR Technical Standard for the Performance of Low-Dose-Rate Brachytherapy Physics](#). [106-110].)

## 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 in brachytherapy-specific quality management procedures.
3. Charting systems for dose specification, definition and delivery of treatment parameters, and recording and summation of HDR brachytherapy and external beam therapy treatment.
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) all brachytherapy parameters to be used in each procedure (source model, radionuclide source strength (activity), total dose, treatment duration, etc.) prior to HDR brachytherapy treatment delivery.
6. Routine leak testing of all sealed sources as required by regulatory agencies.
7. Use of a hand-held radiation survey meter when initially entering the room after a source run.

### 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. Use of a hand-held radiation survey meter when initially entering the room after a source run.
4. 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, including emergency procedures, of HDR applicators and HDR remote afterloading equipment and sources 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 \(CME\)](#) [6].

## VIII. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Guideline for Communication: Radiation Oncology](#) [3].

## 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](#) [2]. 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 HDR brachytherapy as part of the CQI meeting agenda. Refer to the [ACR Practice Guideline for Radiation Oncology](#) [2] 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 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

HDR brachytherapy is an important modality in the treatment of a variety of different malignancies. Its use 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 procedures are important components of successful HDR brachytherapy programs.

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\*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

#### Development Chronology for this Guideline

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