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ACR–ABS PRACTICE PARAMETER FOR THE PERFORMANCE OF RADIONUCLIDE-BASED HIGH-DOSE-RATE BRACHYTHERAPY

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiation oncology 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, ___ 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

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the American Brachytherapy Society (ABS).

Brachytherapy is a radiation therapy method in which radionuclide sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application. This practice parameter 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 [1]. High-dose-rate (HDR) brachytherapy uses radionuclides such as iridium-192 at dose rates of 20 cGy per minute (12 Gy per hour) or more to a designated target point or volume. High-dose-rate (HDR) brachytherapy is indicated for treating malignant or benign tumors where the treatment volume or targeted points are defined and accessible.

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[2]. 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 practice parameters and technical 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 inter-related activities. Communication among brachytherapy team members and well-defined procedures are essential for accurate and safe treatment. See the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [2].

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–ASTRO Practice Parameter for Radiation Oncology [3] and the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [2].

B. Establishing Treatment Goals

The goals of therapy should be documented. 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 evaluation should be communicated to the referring physician and other physicians involved in the patient's care.

[2]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).

C. Informed Consent

Informed consent must be obtained and documented. See the ACR Practice Parameter on Informed Consent – Radiation Oncology [4].

D. Applicator Insertion

Oncologic practice, including brachytherapy, may require 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 who is a licensed authorized user of radionuclides for medical purposes [5].

Each type of brachytherapy procedure has unique characteristics. The brachytherapy team should operate according to an established procedural system that has been developed by the radiation oncologist and brachytherapy team members. This systematic approach to applicator and 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 brachytherapy process.

E. Image Acquisition

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

F. Treatment Planning

The radiation oncologist (authorized user) must provide a signed and dated written directive (WD) to the planner (ie, Qualified Medical Physicist, certified medical dosimetrist, or the authorized user) with at least the treatment site, the radionuclide used, the dose per fraction, the total number of fractions, and the planned total dose [6]. Using treatment-planning software and 2-D or 3-D images, applicator geometry, source dwell position(s), targets, organs at risk, dose points, etc, are created. Computer-planning techniques to shape the dose distribution are widely available but should be used correctly to properly optimize the dosimetry. An independent check of the dosimetry plan must be performed prior to treatment delivery (See section V.). Once the authorized user has reviewed the plan and final adjustment to the WD (prescription) parameters (total dose, dose per fraction, number of fractions, dose constraints, etc) has been made, the plan must be saved and locked to prevent any unintended changes.

G. Treatment Delivery

“Time Out”: Verification of patient identity is required prior to treatment delivery. A “time out” should be performed and documented in the medical record prior to treatment delivery. At a minimum, the “time out” should include patient identity, treatment site, laterality if applicable, dose per fraction, and fraction number.

Prior to each treatment, the Qualified Medical Physicist or radiation oncologist should verify that the HDR afterloader transfer tubes are appropriately connected to each applicator channel. The Qualified Medical Physicist should verify all treatment parameters at the HDR treatment console prior to source delivery, including the correspondence between planned source strength and afterloader source strength with appropriate corrections for source decay. In a multifraction treatment regimen using indwelling needles or catheters, where interfraction movement is possible, it is important to verify that the applicator is stable with regards to the target and organs at

risk before delivery of subsequent fractions. In any single-fraction treatment it is also important to verify applicator positioning prior to treatment.

Radiation safety measures are mandatory for HDR procedures to ensure exposure is confined to the patient and that the source is properly delivered and returned to the radiation safe location within the afterloader. The radiation oncologist and the Qualified Medical Physicist must be in the immediate vicinity at all times while HDR brachytherapy is being administered. The patient must be continuously monitored by video or audio means during treatment and the proper functioning of equipment directly supervised by the qualified personnel. Treatment delivery must be documented for each fraction and subject to detailed scrutiny as described in the patient and personnel safety section (See section VI.). At the end of each treatment, the patient and the room must be surveyed to confirm the source has been safely retracted into the afterloading device. The radiation survey results should be recorded and maintained per regulatory requirements.

H. Treatment Summary

At the conclusion of the course of treatment, a written treatment summary should be generated, which includes a description of the brachytherapy technique, dose per fraction, number of fractions, total brachytherapy dose, and total dose of external beam therapy, if given. There should also be a brief outline of the clinical course, acute toxicities or procedure complications, if any, and a plan for patient follow-up care. See the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [2].

I. Follow-up Evaluation

Patients treated with HDR brachytherapy should be evaluated at regular intervals for disease status, procedure-related side effects, and radiation complications. Information about the patient's clinical status should be communicated to the primary, referring, and other appropriate physician.

III. QUALIFICATIONS OF PERSONNEL

The HDR brachytherapy team includes the physician(s), Qualified Medical Physicist, dosimetrist, radiation therapist, nurse, and radiation safety officer. High-dose-rate brachytherapy requires close coordination between all members of the team as it is given in relatively large doses per fraction in a short period of time. Errors in treatment leading to radiation misadministration can happen quickly with serious consequences. Communication among team members and well-defined procedures for performing HDR brachytherapy are thus essential for accurate and safe treatment. Qualifications of the brachytherapy team include the credentials listed below.

A. Radiation Oncologist who also meet the requirements of the Authorized User [5]

Certification in Radiology 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, or certification in Radiology by the American Board of Radiology of a physician who confines his/her professional practice to radiation oncology.

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

For the qualifications of the Qualified Medical Physicists, see the ACR–AAPM Technical Standard for the Performance of High-Dose-Rate Brachytherapy Physics [7].

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

The nurse must fulfill state licensing requirements.

IV. PATIENT SELECTION CRITERIA

A. Cervical Cancer

Brachytherapy is an essential modality in the definitive treatment of cervical cancer. Brachytherapy is usually done in conjunction with external beam irradiation, and often chemotherapy is administered as well. International randomized trials have concluded that HDR brachytherapy is equivalent to low-dose-rate (LDR) brachytherapy for local control, survival, and toxicity. Treatment planning is an integral part of cervical cancer brachytherapy because of the need for high curative doses to the cervix and paracervical tumor and the close proximity of the normal pelvic organs. It is most commonly delivered with intracavitary applicators and may also be delivered with interstitial devices. Brachytherapy is used postoperatively in some patients following hysterectomy [8-13].

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 low risk of morbidity. Brachytherapy is also used for patients with recurrent endometrial carcinoma and, in this setting, application is sometimes interstitial rather than intracavitary. Definitive irradiation requiring brachytherapy may be considered for patients with medically inoperable endometrial carcinoma [14-18].

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 extent of residual disease following external beam irradiation, brachytherapy may be either intracavitary or interstitial [19,20].

D. Bile Duct

Postoperative radiation may be helpful in patients with positive margins or positive nodes. Intraluminal or interstitial 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

High-dose-rate intraluminal brachytherapy has been used in the treatment of esophageal cancer, both for palliation and as a component of a definitive regimen [24]. In the definitive setting, HDR brachytherapy has most commonly been used in combination with external beam radiation therapy, though brachytherapy alone may be adequate in the subset of cancers confined to the mucosal layer of the esophagus [25-27]. The improvement in local control with the addition of HDR brachytherapy must be balanced against the risk for treatment-related morbidity in each individual case.

F. Bronchus/Trachea

High-dose-rate brachytherapy has been used to treat malignancies involving the central lung, bronchus, and trachea. In definitive cases, it can be used alone or in conjunction with external beam radiotherapy [28-31]. High-dose-rate brachytherapy also has a well-established role in the palliation of primary and recurrent endobronchial lesions [32].

G. Prostate

High-dose-rate brachytherapy may be used in combination with external beam radiation therapy for the treatment of prostate cancer in any risk group. It may also serve as the sole treatment for low-risk and intermediate-risk disease [33-41]. In addition, HDR brachytherapy may be used to salvage local recurrence of disease after definitive external beam radiation therapy [42,43]. There is a separate ACR–ABS Practice Parameter for Transperineal Permanent Brachytherapy of Prostate Cancer [44].

H. Breast

High-dose-rate brachytherapy can be used as a boost to the tumor bed after conventional external beam radiation therapy, and it can also be used for delivering accelerated partial breast irradiation (APBI) as the sole postoperative radiation treatment. This approach treats a limited volume of breast tissue around the lumpectomy site over a short duration of time (typically 10 treatments delivered twice daily over 5 treatment days). Applicator insertion techniques include multicatheter interstitial tubes stabilized with buttons and various single-entry intracavitary devices (balloon catheters and other multichannel devices). Additionally, HDR brachytherapy can be noninvasively targeted to the lumpectomy bed utilizing superficially placed applicators positioned according to mammographic image guidance. APBI is used for selected patients with early breast cancer. The role of radionuclide-based intraoperative therapy in treating early-stage disease is being evaluated in clinical trials [45]. In this approach, radiation therapy is administered to the tumor bed at the time of the lumpectomy procedure. Further information related to patient selection and indications is available from ASTRO and ACR documents [46,47].

I. Head and Neck

Low-dose-rate 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 [48-59]. Tumors in the head and neck affect important anatomic structures; therefore, careful attention to the preservation of normal tissue structure and function is needed. Multifraction regimens that avoid large doses per fraction have been recommended [60]. Computer-based dose optimization, advances in radiation safety, and improved nursing care are important reasons why LDR brachytherapy is being supplanted by HDR brachytherapy, especially in head and neck brachytherapy where nursing care is so important to patient comfort and quality outcomes [36,61-66]. Interstitial, intracavitary, and surface applications and intraoperative techniques are applicable techniques. Head and neck brachytherapy may be applied as a single modality or as a boost treatment in combination with external beam radiation therapy. It may be used in any sites in the head and neck as primary curative treatment, as salvage therapy, or for re-irradiation [67].

J. Soft-Tissue Sarcoma

High-dose-rate brachytherapy has a role in the treatment of soft-tissue sarcoma, typically as part of a multidisciplinary management plan with surgery as the primary intervention. It can be a part of definitive therapy [68-76], postoperative adjuvant therapy [77-79], intraoperative radiotherapy [69,80-82], and palliative treatment.

K. Pediatric Tumors

High-dose-rate brachytherapy can be useful in managing pediatric tumors. There are potential long-term consequences of irradiation in the pediatric patient, which should be a primary consideration in treatment

planning along with local disease control. There are major advantages to brachytherapy for avoiding irradiation to normal tissue and growth centers.

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. [83,84]. Both interstitial and plesiotherapy (surface applicators) techniques can be used. High-dose-rate brachytherapy can be used in combination with surgery for keloids.

M. Intraoperative Brachytherapy

High-dose-rate brachytherapy catheters or and other devices can be inserted at the time of open or laparoscopic surgery. Such devices can be left in place for postoperative simulation dosimetry and fractionated treatment delivery in a brachytherapy suite or shielded room. The advantages of the fractionated approach are time allocation for wound healing, obtaining simulation imaging, achieving good dosimetry, and the dose fractionation for normal tissue tolerance. Alternatively, in a shielded OR (operating room) applicators can be inserted after maximum tumor resection, and a single HDR fraction can be given to the surgical margin 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 that conform to various tumor bed configurations. These techniques may be used in a variety of tumor types and body sites [85,86].

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 [87,88] or for unresectable, inoperable, and recurrent disease. For anal cancers, HDR brachytherapy can be used as a boost after external beam radiotherapy [89] or as definitive treatment in selected cases. Both interstitial and intracavitary techniques have been used.

O. Other Indications

The list of indications above is not comprehensive or exclusive. Brachytherapy can be applied and radiation accurately delivered to any site where there is localized disease. The indication may be curative or palliative. The individual radiation oncologist may find HDR brachytherapy beneficial in a variety of other tumor types and specific clinical situations (eg, penis, bladder, urethra, vulva, central nervous system, ocular).

V. EQUIPMENT

High-dose-rate brachytherapy treatment is delivered with computerized robotic devices (remote afterloading devices) for reasons of radiation safety and precision of treatment delivery. They consist of a tiny but powerful radiation source attached to the end of a fine cable, a radiation safe container, a motor drive, and sophisticated computer equipment for reliable execution of complex radiation treatment plans (ie, instructions for where and how long the radiation source should be deployed.) Equipment manufacturers offer a wide range of applicators for interstitial, intracavitary, intraluminal, and superficial brachytherapy. The radiation source must be changed (usually quarterly and sometimes more often) to account for radioactive decay, and a maintenance contract is essential to ensure the equipment functions safely and correctly. A schedule of updating and replacing the applicator should be implemented to address issues of wear and aging equipment. Computerized treatment planning is accomplished with specialized hardware and highly technical software compatible with the respective HDR brachytherapy system being used.

Periodic scheduled preventive maintenance is essential. The Qualified 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–AAPM Technical Standard for the Performance of Low-Dose-Rate Brachytherapy Physics.) [89,90].

VI. PATIENT AND PERSONNEL SAFETY

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

A. Patient Protection Measures Should Include the following:

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 Qualified 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 the following:

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, Qualified 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 Parameter for Continuing Medical Education (CME) [91].

VIII. DOCUMENTATION

Reporting should be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [2].

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–ASTRO Practice Parameter for Radiation Oncology [3]. 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–ASTRO Practice Parameter for Radiation Oncology [3] 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 website (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 allows relative sparing of adjacent critical structures. Coordination between the radiation oncologist and treatment planning staff and effective quality assurance procedures are important components of successful HDR brachytherapy programs.

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**As of May 2010, all radiation oncology collaborative parameters are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 8, 2010). The effective date is displayed below:

Development Chronology for this Practice Parameter
1996 (Resolution 15)
Revised 2000 (Resolution 23)
Revised 2005 (Resolution 15)
Amended 2006 (Resolution 16g, 36)
Revised 2010 (Resolution 3)
Amended 2014 (Resolution 39)
Revised 2015 (CSC/BOC)