ACR–ABS–ARS PRACTICE PARAMETER FOR THE PERFORMANCE OF LOW-DOSE-RATE BRACHYTHERAPY

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PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of 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 considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 purpose of this document is to assist practitioners in achieving this objective.

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1 *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (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), the American Brachytherapy Society (ABS), and the American Radium Society (ARS).

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 practice parameter 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 [1].

Low-dose-rate (LDR) brachytherapy has traditionally been used for treating prostate, head and neck, breast, and gynecologic (cervical, vaginal, and endometrial) cancers as well as obstructive bile duct, esophageal, brain, or bronchial lesions [1]. It has been practiced for more than a century with a variety of sources, including radium-226, cesium-137, and, more recently, iridium-192, iodine-125, cesium-131, and palladium-103. LDR brachytherapy can be given as interstitial, intracavitary, intraluminal, and/or plesiotherapy to a wide variety of treatment sites [1].

LDR brachytherapy is accomplished by 1) temporary implants, in which radioactive sources are "afterloaded" for a period of a few hours or days into applicators that are placed temporarily into the patient or 2) permanent implants, in which the radioactive sources are permanently inserted 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/hr at a designated point. Remote afterloading pulse-dose-rate (PDR) brachytherapy is a method that delivers the therapy over a protracted time in periodic (usually hourly) pulses at rates similar to those used for LDR brachytherapy. Brachytherapy can also be administered using remote afterloading, high-dose-rate (HDR) techniques. The use of HDR brachytherapy is covered in the ACR–ABS–ARS Practice Parameter for the Performance of Radionuclide-Based High-Dose-Rate Brachytherapy [2]. Despite different nomenclature, these types of brachytherapy have many common treatment principles. The types of applicators, methods of insertion, and many aspects of treatment planning are similar or even identical for LDR, PDR, and HDR. Because HDR and PDR use very similar software and hardware with a single (usually iridium-192) stepping source, safety and quality assurance methods are similar for the 2 methods of delivery. However, each technique has unique aspects requiring specialized knowledge [3, 4].

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

This practice parameter addresses sealed sources as they are used for LDR brachytherapy. It is recognized that unsealed sources (eg, yttrium-90) are also a form of LDR brachytherapy. Practice parameters for unsealed sources can be found in the ACR–ACNM–ARS–SNMMI Practice Parameter for the Performance of Therapy with Radiopharmaceuticals [5]. For more information on radioembolization, see the ACR–ABS–ACNM–ARS–SIR–SNMMI Practice Parameter for Selective Internal Radiation Therapy (SIRT) or Radioembolization for Treatment of Liver Malignancies [6].

The use of LDR permanent brachytherapy for prostate cancer is covered in a separate ACR–ABS–ASTRO Practice Parameter for Transperineal Permanent Brachytherapy of Prostate Cancer [7].

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. Medical use of radionuclides for therapeutic procedures must adhere to the constraints set forth by these regulatory agencies.[1] 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 practice parameters and technical standards in LDR brachytherapy [8-14].

[1]An agreement state is any state with which the US NRC or the US 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 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. See the ACR–ARS Practice Parameter for Communication: Radiation Oncology [15]. 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–ARS Practice Parameter for Radiation Oncology [16].

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. LDR brachytherapy can also be used as a salvage therapy for re-irradiation of a previously irradiated site where further external-beam radiation therapy would be contraindicated.

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 consultation should be communicated to the referring physician and other treating physicians. See the ACR–ARS Practice Parameter for Communication: Radiation Oncology [15].

C. Informed Consent

Informed consent must be obtained and documented. See the ACR-ARS Practice Parameter on Informed Consent – Radiation Oncology [17].

D. Applicator/Source Insertion

Oncologic practice, including brachytherapy, may require 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

Communication is pivotal in initiating and completing the treatment-planning process. This is initiated with written directive(s) as described in the regulations applicable to each state. This will include treatment site, radionuclide, source strength, total dose to target, and, if applicable, organs-at-risk dose restrictions. The Authorized User (AU) should verify whether NRC 10 CFR35.40 is applicable to their state because this will require preimplant and postimplant directives. Applicator geometry and source positions are defined with localization images or cross-sectional imaging for precise delivery. The specific radionuclides are designated by the radiation oncologist as part of the LDR prescription. Computerized dosimetry is performed by the Qualified Medical Physicist or their 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

Sources are manually or remotely loaded into applicators to deliver the prescribed treatment. Careful attention to the appropriate connection of multiple needles/catheters to the transfer tubes is essential when remote afterloading is used. Assessment of applicator stability before source insertion is essential. 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 verbal and 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 must be consistent with state and federal regulations. The radiation oncologist, the Qualified Medical Physicist, and the radiation safety officer should define the radiation safety guidelines. See the Radiation Safety section of ACR–AAPM Technical Standard for the Performance of Low-Dose-Rate Brachytherapy Physics [18] .

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 medical record. Before and after the procedure, a survey to assess for background and stray sources, respectively, should be conducted. See the Patient and Personnel Section ACR-ABS-ARS Practice Parameter for the Performance of Radionuclide-Based High-Dose Rate Brachytherapy [2]

I. Treatment Summary
At the conclusion of the course of treatment, a written treatment summary, which includes a description of the brachytherapy technique, total brachytherapy dose, and the total dose of external-beam therapy, if given, should be generated. Parameters such as the actual number of sources, source strength(s), and treatment duration (for temporary implants) may also be documented. The summary should include that the written directive was followed and/or whether modifications were made during the course of the implant. 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–ARS Practice Parameter for Communication: Radiation Oncology [15].

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–ARS Practice Parameter for Radiation Oncology [16]. Patients treated with LDR/PDR 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 physicians.

III. QUALIFICATIONS OF PERSONNEL

The brachytherapy team includes the physician, Qualified 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 Radiation Oncology or Therapeutic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada (RCPSC), or the Collège des Médecins du Québec or certification in Radiology by the ABR of a physician who confines their professional practice to radiation oncology, or

Satisfactory completion of a residency program in radiation oncology approved by the ACGME, the RCPSC, the Collège des Médecins du Québec, or the American Osteopathic Association. The designation of AU-eligible certificates; not every completing ACGME-accredited resident will be United States AU-eligible, and most Canadian residents are not, because they do not have AU preceptors.

B. Qualified Medical Physicist

For the qualifications of the Qualified Medical Physicist, see the ACR–AAPM Technical Standard for the Performance of Low-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 certification in radiation therapy.

E. Nurse

The nurse must fulfill state licensing requirements.

Continuing Education Program

Continuing medical education (CME) 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:

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

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) [19].

The educational program should include patient safety procedures, especially the urgent removal and handling of sources in the event of a medical emergency. Nursing staff must be trained in the safe handling of sources and in the performance of surveys for such occasions.

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of continuing quality improvement (CQI) as described in the ACR–ARS Practice Parameter for Radiation Oncology [16]. 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–ARS Practice Parameter for Radiation Oncology [16] for a detailed description of CQI Committee functions.

IV. PATIENT SELECTION CRITERIA

The use of brachytherapy is integral to the treatment of many malignancies, especially gynecologic, eye, head and neck, sarcomas, bronchus and trachea, central nervous system, gastrointestinal, and genitourinary malignancies [8-12, 20-22]. LDR prostate brachytherapy is discussed in the ACR–ABS–ASTRO Practice Parameter for Transperineal Permanent Brachytherapy of Prostate Cancer [7]. Patient selection and eligibility criteria should follow disease site-specific stages and criteria and focus on tumor location, size, and type. 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 ACR-ABS-ARS Practice Parameter for the Performance of Radionuclide-Based High-Dose Rate Brachytherapy [2]. LDR brachytherapy remains an appropriate method of dose delivery in clinical situations in which brachytherapy is indicated [18, 23]. PDR brachytherapy is another method of brachytherapy delivery that employs equipment similar to that used for HDR but with a lower activity source that has similar shielding requirements to LDR; treatment is delivered in periodic pulses usually over 1 or

more days.

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 Qualified 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–AAPM Technical Standard for the Performance of Low-Dose-Rate Brachytherapy Physics [18]).

VI. PATIENT AND PERSONNEL SAFETY

Patient protection measures include those related to medical safety and radiation protection (for further information, see the ACR–AAPM Technical Standard for the Performance of Low-Dose-Rate Brachytherapy Physics [18]).

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 as well as in brachytherapy-specific quality management procedures
   3. Charting systems and forms for dose specification, definition, and delivery of treatment parameters as well as recording and summation of brachytherapy and external-beam therapy treatment [24]
   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) pertinent brachytherapy parameters to be used in each procedure (eg, source model, radionuclide, source strength, dose rate, total dose, and treatment duration) before LDR brachytherapy

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. Appropriate safety equipment for use of sealed sources

VII. DOCUMENTATION

Reporting should be in accordance with the ACR–ARS Practice Parameter for Communication: Radiation Oncology [15].

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

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 *ACR Position Statement on Quality Control and Improvement, Safety, Infection Control and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

IX. 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 allows relative sparing of adjacent critical structures. Coordination between the radiation oncologist and treatment-planning staff as well as clearly defined quality assurance and radiation safety procedures are important components of successful LDR brachytherapy programs.

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*Practice parameters and technical standards that are collaborative with only radiation oncology societies (ACR Resolution 8, 2010) or are collaborative with the American Association of Physics in Medicine (ACR Resolution 54, 2015) are approved by the ACR Council Steering Committee (CSC) and the ACR Board of Chancellors (BOC) and will not go through the ACR Council. The effective date for these CSC/BOC documents is the first day of the month following a 60-day period that begins on the date the document was approved.

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