1996 (Res. 13)
Revised 2000 (Res. 24)
Revised 2005 (Res. 16)
Amended 2006 (Res. 16g,36)
Effective 10/01/05

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

PREAMBLE

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

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

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Brachytherapy is the use of radioactive isotopes to treat malignancies or benign conditions by means of a radioactive source placed close to or into the tumor or treatment site. 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 as treatment for prostate, head and neck, breast, cervical, and endometrial cancers as well as obstructive esophageal or bronchial lesions. LDR therapy has been used since the late 1800s with a variety of sources including radium-226, cesium-137, and, more recently, iridium-192, iodine-125, and palladium-103. Such treatment can be given as interstitial, intracavitary, or intraluminal therapy to a wide variety of treatment sites. This guideline does not apply to intravascular brachytherapy.

LDR brachytherapy is accomplished by 1) temporary implants, after-loading radioactive sources into applicators that are placed into the patient, or 2) permanent implants, placing the isotope permanently into the cancerous tissue. Source handling can be manual, with source loading into the applicator or tissue by hand, or remote, with source loading performed by a computerized unit. LDR brachytherapy is delivered at dose rates of 4-200 cGy per hour at a designated point.

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 Practice Guideline for the Performance of Therapy with Unsealed Radiopharmaceutical Sources.

The licensing of radioactive sources and the safety of the general public and health care workers are regulated by the Nuclear Regulatory Commission (NRC) or by agreement states.[1] Medical use of isotopes 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.

II. PROCESS OF BRACHYTHERAPY

The use of LDR brachytherapy is a complex 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. This will facilitate treatment decisions, determine the prognosis of the patient, and enable a comparison of treatment results.

B. Establishing Treatment Goals

LDR brachytherapy is indicated for treatment where 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 therapy should be defined. A summary of the consultation should be communicated to the referring physician.

C. Informed Consent

Informed consent must be obtained and documented.

D. Applicator/Source Insertion

Oncologic practice, including brachytherapy, commonly requires the interaction of multiple specialists. The choice and placement of after-loading 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 steps, sedation or anesthesia procedures, the specific applicators used, and the 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 loading, the prescription must designate the treatment site, the isotope, the number of sources, the planned dose, and the dose rate to designated points. Applicator geometry and isotope positions are defined with simulation radiographs. The specific isotope positions 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

[1] 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).

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 of 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, 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.

III. QUALIFICATIONS OF PERSONNEL

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

A. Radiation Oncologist

Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency program or an American Osteopathic Association (AOA) approved residency program in radiation oncology.

or

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 Le College des Medecins du Quebec may be considered proof of adequate physician qualifications.

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 that certification and continuing education in the appropriate subfield(s) 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) 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.

The continuing education of a Qualified Medical Physicist should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME). 2006 (Res. 16g)

C. Radiation Therapist

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

D. Medical Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended.

E. Nurse

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

IV. EQUIPMENT

LDR brachytherapy requires a variety of applicators to be used with manual or remote LDR applicators. After-loading 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 physicist supervising the quality improvement program is responsible for documenting the maintenance and repair of manual equipment, remote after-loading units, and applicators. (See the ACR Technical Standard for the Performance of Brachytherapy Physics: Remotely Loaded HDR Sources.)

V. 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 training of staff in emergency procedures in case of equipment malfunction.
3. Charting systems and forms for prescription, definition and delivery of treatment parameters, and recording and summation of brachytherapy and external beam therapy treatment.
4. A physics program for ensuring accurate dose delivery to the patient.
5. A system for the radiation oncologist and physicist to verify independently (by another person or another method) all brachytherapy parameters to be used in each procedure (source, isotope and activity, dose rate, total dose, treatment duration, etc.) prior to institution of 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.

VI. 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 initially and for retraining must cover the following:

A. The safe operation of LDR applicators, sources, and manual or remote after-loading 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).

VII. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology.

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

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. 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 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 Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described in the ACR Practice Guidelines and Technical Standards book by the Guidelines and Standards Committee of the Radiation Oncology Commission.

Principal Reviewer: Beth A. Erickson, MD

ACR Guidelines and Standards Committee
Laurie E. Gaspar, MD, MBA, Chair
E. Brian Butler, MD
Nancy A. Ellerbroek, MD

Beth A. Erickson, MD
Cassandra S. Foens, MD
Song K. Kang, MD
Peter M. Mauch, MD
Tariq A. Mian, PhD
Seth A. Rosenthal, MD
Anthony H. Russell, MD
Oscar E. Streeter, Jr., MD
Vipul V. Thakkar, MD
Frank A. Vicini, MD

Steven A. Leibel, MD, Chair, Commission

REFERENCES/LITERATURE REVIEW

1. Blasko JC, Mate T, Sylvester JE, et al. Brachytherapy for carcinoma of the prostate: techniques, patient selection, and clinical outcomes. *Seminars in Radiation Oncology* 2002;12:81-94.
2. Brenner DJ. Radiation biology in brachytherapy. *J Surg Oncol* 1997;65:66-70.
3. Chadha M. Gynecologic brachytherapy-II: intravaginal brachytherapy for carcinoma of the endometrium. *Seminars in Radiation Oncology* 2002;12:53-61.
4. Collaborative Ocular Melanoma Study Group. Collaborative ocular melanoma study (COMS) randomized trial of I-125 brachytherapy for medium choroidal melanoma: visual acuity after 3 years. COMS Report No. 16. *Opthalmology* 2001;180:348-366.
5. Gaspar LE, Nag S, Herskovic A, et al. American Brachytherapy Society (ABS) consensus guidelines for brachytherapy of esophageal cancer. *Int J Radiation Oncology Biol Phys* 1997;38:127-132.
6. Grimm PD, Blasko JC, Sylvester JE, et al. 10-year biochemical (prostate-specific antigen) control of prostate cancer with 125 I brachytherapy. I*nt J Radiation Oncology Biol Phys* 2001;51:31-40.
7. Gupta AK, Vicini FA, Frazier AJ, et al. Iridium-192 transperineal interstitial brachytherapy for locally advanced or recurrent gynecological malignancies. *Int J Radiation Oncology Biol Phys* 1999;43:1055-1060.
8. Katz A, Eifel PJ. Quantification of intracavitary brachytherapy parameters and correlation with outcome in patients with carcinoma of the cervix. *Int J Radiation Oncol Biol Phys* 2000;48:1417-1425.
9. Mazeron JJ, Noel G, Simon JM. Head and neck brachytherapy. *Seminars in Radiation Oncology* 2002;12:95-108.
10. Morganti AG, Trodella L, Valentini V, et al. Combined modality treatment in unresectable extrahepatic biliary carcinoma. *Int J Radiation Oncology Biol Phys* 2000;46:913-919.
11. Nag S, Chao C, Erickson B, et al. The American Brachytherapy Society recommendations for low-dose-rate brachytherapy for carcinoma of the cervix. *Int J Radiation Oncology Biol Phys* 2002;52:33-48.
12. Nag S, Quivey JM, Earle JD, et al. The American Brachytherapy Society recommendations for brachytherapy of uveal melanomas. *Int J Radiation Oncology Biol Phys* 2003;56:544-555.
13. Nath R, Anderson LL, Meli JA, et al. Code of practice for brachytherapy physics: report of the AAPM Radiation Therapy Committee Task Group No. 56. American Association of Physicists in Medicine. *Med Phys* 1997;24:1557-1598.
14. Potters L. Permanent prostate brachytherapy: lessons learned, lessons to learn. *Oncology* 2000;14:981-991.
15. Potters L, Cao Y, Calugaru E, et al. A comprehensive review of CT-based dosimetry parameters and biochemical control in patients treated with permanent prostate brachytherapy. *Int J Radiation Oncology Biol Phys* 2001;50:605-614.
16. Quon H, Harrison LB. Brachytherapy in the treatment of head and neck cancer. *Oncology* 2002;16:1379-1393.
17. Syed AM, Puthawala AA, Abdelaziz NN, et al. Long term results of low-dose-rate interstitial-intracavitary brachytherapy in the treatment of carcinoma of the cervix. *Int J Radiation Oncology Biol Phys* 2002;54:67-78.
18. Takamura A, Saito H, Kamada T, et al. Intraluminal low-dose-rate 192 IR brachytherapy combined with external beam radiotherapy and biliary stenting for unresectable extrahepatic bile duct carcinoma. *Int J Radiation Oncology Biol Phys* 2003;57:1357-1365.
19. Vicini FA, Kini VR, Edmundson G, et al. A comprehensive review of prostate cancer brachytherapy: defining an optimal technique. *Int J Radiation Oncology Biol Phys* 1999;44:483-491.