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ACR–ABS–ARS PRACTICE PARAMETER FOR ELECTRONICALLY GENERATED, LOW-ENERGY RADIATION SOURCES (ELS)

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.

[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 developed collaboratively by the American College of Radiology (ACR), American Brachytherapy Society (ABS), and the American Radium Society (ARS). Although this document refers to the practice of radiation oncology throughout, it is intended to provide guidance to physicians of any specialty who deliver radiation therapy using electronically generated, low-energy radiation sources (ELS). The document is intended to provide clinical guidance and does not address issues related to cost of the available devices, coding, reimbursement, or payment policy.

Differences in nomenclature designations for radiation sources and techniques have caused confusion among providers, regulators, and payers. For that reason, the collaborators of this document have chosen to employ the nomenclature that has been utilized by physicians and physicists for over 100 years (ie, defining radiation by its energy range and source). In keeping with that practice, the terminology brachytherapy will be reserved for radionuclides. For purposes of this document, ELS refers to radiation produced artificially by X-ray sources or miniature electron accelerators with a peak voltage of up to 120 kVp to deliver a therapeutic radiation dose to clinical targets, regardless of the source-to-surface distance (SSD). ELS and superficial radiation therapy may be considered synonymously and have appeared in the literature as such [1].

The main advantage in the clinical implementations of ELS over iridium-192 high dose-rate (HDR) brachytherapy or megavoltage-electrons is that the emitted energy is lower, less penetrating and allows for less stringent radiation shielding requirements. Newer ELS devices are typically mobile, and are not fixed to treatment couches, providing greater flexibility for users. These devices may be used with short source-to-surface (SSD) collimation or surface applicators, and in some instances, through the use of intracavitary applicators. Additionally, because no radioactive material is involved in ELS delivery, the regulations promulgated by the US Nuclear Regulatory Commission (NRC) or Agreement States regarding licensure, use, and handling of radioactive substances are not applicable. Most State regulatory agencies have elected to follow the guidance from the Conference of Radiation Control Program Directors (CRCPD) regarding the regulation of ELS. Users are therefore urged to confirm their local applicable regulations for compliance.

Employment of low-energy radiation does not imply that ELS is without risk to patients and health care personnel or that there should be any reduction in the standard of care, process of care, informed consent process or safety measures applicable to all radiation therapy. As in all forms of radiation therapy, ELS requires proper initial and ongoing training of the entire treatment team, with detailed attention to personnel roles, operation of treatment, equipment, patient and personnel safety, and to the quality assurance (QA) program in place.

II. PROCESS OF ELS

The clinical implementation of ELS involves a multistep process beginning with trained personnel of diverse clinical background working in concert to accomplish various interrelated activities. Clinical process mapping should be established through well-defined procedures, documentation, and communication among team members. These components are essential for accurate and safe treatment delivery.

A. Clinical Evaluation

Initial patient evaluation includes a patient and disease appropriate physical examination and medical history, and review of available pathology, imaging, and other pertinent diagnostic studies and reports. The extent of the target lesion must be documented and staged. Pretreatment measurement and photographs of accessible lesions should be obtained. If treatment involves a site with functional capacity, pretreatment functional measurements should be recorded. Clinical staging and pathological staging (when available) should be documented in the permanent clinical record.

B. Treatment Intent

Intent of treatment (curative, adjuvant, or palliative) should be documented and discussed with the patient and/or authorized caregivers prior to initiation of therapy. Treatment options and relative benefits and risks should also be discussed and written informed consent obtained. Integration of treatment using ELS in conjunction with other

treatment modalities, such as surgery, systemic therapy, and additional radiation therapy when considered necessary for disease management, should be discussed.

A summary of the clinical evaluation and treatment goal should be communicated to the referring physician and other providers involved in the patient's care. Details are contained in the ACR–ASTRO Practice Parameter for Radiation Oncology [2] and the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [3].

C. Informed Consent

Informed consent must be obtained and properly documented, as recommended in the ACR Practice Parameter on Informed Consent – Radiation Oncology [4].

D. Treatment Planning

Treatment planning is the process in which a qualified medical physicist or medical dosimetrist, in conjunction with the radiation oncologist, determine the optimal treatment parameters based on the disease status and intent in order to generate a clinically optimum treatment plan. The treatment-planning process includes selection of treatment technique, applicator and dose distribution to the target lesion and surrounding critical structures, or organs at risk (OARs). Dose distributions may be generated from an appropriate patient image data set (CT or other imaging modality) with a computer-based treatment-planning system (TPS). When facilities are not equipped with such a planning tool, the user must rely on water phantom–generated isodose graphs provided by the manufacturer and confirmed by the qualified medical physicist at the time of commissioning the treatment device. Source replacement for any currently available device requires recommissioning and recalibration [5]. A dose calculation at a specific prescription point or target volume is required to generate the treatment time needed to deliver the prescribed dose.

Prior to treatment delivery, an independent check of the treatment plan must be performed using a secondary TPS or measured data acquired during the commissioning process prior to treatment delivery. Any subsequent revision of the plan must be properly documented as a revised dose prescription and approved by the radiation oncologist.

E. Treatment Delivery

Except for intraoperative radiation therapy (IORT), treatments using ELS systems can often be performed in an outpatient treatment room or office-based treatment room. Depending on treatment site, intent, and plan, treatment may be performed using a single application or a hypofractionated approach.

Treatment delivery consists of 4 steps:

- Pretreatment time-out
- Treatment setup and verification
- Treatment delivery itself
- Posttreatment QA

The pretreatment time-out should be performed immediately prior to treatment and should consist of patient verification using at least 2 methods, such as date of birth and patient photo, and verification of the correct plan, including treatment site, applicator size, energy level (if adjustable), total planned dose, and dose per fraction.

The treatment setup should consist of patient and applicator positioning, placement of shielding if needed, and verification of treatment plan parameters as noted above.

Treatment delivery should be monitored throughout. Both the patient and the treatment device should be monitored by the treating team. In the event of any patient movement or machine malfunction, a member of the ELS team should be ready to pause the treatment and apply appropriate corrective actions. When possible, patient anxiety may be diminished if they are kept aware of remaining treatment time with, analgesics and antianxiolytics used only as needed.

The final component of treatment is posttreatment QA. Prior to removal of the ELS applicator, verification of its position for any possible shift should be confirmed. Reusable items such as the applicator, caps, shielding, and

couch top should be cleaned or sterilized following the manufacturer's recommendation, universal guidelines, and local facility or jurisdictional policies for disinfection and sterilization. Posttreatment documentation as part of the facility quality management program should be generated and signed by both the qualified medical physicist and the radiation oncologist. Any noted reportable event should be communicated to the appropriate radiation safety professional for timely action, as required.

F. Treatment Summary

At the completion of the course of ELS treatment, a written treatment summary should be generated and provided to the referring physician and any other appropriate health care providers. Many facilities will routinely provide a treatment summary to the patient, and in all instances, this should be provided if requested. See the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [3].

G. Follow-up Evaluation

At the completion of treatment, the follow-up plan should be outlined to the patient and appropriate caregiver(s), including posttreatment care of the treatment site, scheduling of follow-up visits, and contact information in the event of any adverse reactions or concerns. Necessary medications should be provided or prescribed. The follow-up plan should be documented in the patient's chart, with a copy for the patient or caregiver(s). Following treatment, patients should be seen by the radiation oncologist as necessary and appropriate for the treatment site, intent, and management of posttreatment morbidity. If direct follow-up is not feasible because of the patient's medical condition, choice, or any unreasonable travel requirements, the radiation oncologist should request and review the follow-up documentation provided by other pertinent medical providers. The follow-up plan should be provided to the referring physician and any other health care providers directly involved in the patient's care.

III. QUALIFICATIONS OF PERSONNEL

The qualifications and responsibilities of the qualified personnel performing these therapeutic procedures should be in accordance with the ACR–ASTRO Practice Parameter for Radiation Oncology [2] and must be in compliance with the applicable laws and regulations.

A. Radiation Oncologist

The radiation oncologist is responsible for evaluating the patient for appropriateness of ELS treatment, obtaining informed consent, developing and signing the treatment prescription, approving the treatment plan, confirming the accuracy of patient setup, monitoring the course of therapy and ordering any changes necessary, managing acute treatment-related morbidity, establishing a follow-up plan at the completion of therapy, and seeing the patient in posttherapy follow-up as necessary and appropriate. All activities of the radiation oncologist must be documented in the clinical record as appropriate. The training and experience of the radiation oncologist must also be in compliance with applicable laws and regulations, and privileges of the radiation oncologist within the facility must be appropriate for the planned procedure.

B. Qualified Medical Physicist

The qualified medical physicist is responsible for the commissioning and calibration of the ELS device, for the primary or secondary review of the treatment plan as appropriate for the facility, for all aspects of patient and staff, radiation safety, and for QA of all related treatment devices. Depending on the facility personnel, the qualified medical physicist may also be responsible for ELS treatment planning and delivery. The qualifications of the qualified medical physicist are defined in the following documentation: ACR–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External-Beam Therapy [6] or the ACR–AAPM Technical Standard for the Performance of High-Dose-Rate Brachytherapy Physics [7].

C. Medical Dosimetrist

The medical dosimetrist is responsible for calculations required for treatment delivery as developed by the radiation oncologist's treatment prescription. Depending on the site to be treated and facility personnel, this function may be performed by a qualified medical physicist.

D. Radiation Therapist

In the majority of facilities, the radiation therapist is responsible for actual treatment delivery. Depending on the site to be treated and facility personnel and the type of procedure, this function may also be performed by a radiation oncologist, qualified medical physicist, or medical dosimetrist, pursuant to state regulations.

E. Oncology Nurse

Individuals involved in the nursing care of patients undergoing ELS should have appropriate nursing credentials and experience in the care of radiation therapy patients. The nurse must fulfill the scope of practice and meet the appropriate state's licensing requirements. Oncology nursing certification is encouraged.

F. Support Services

Where appropriate, patients and caregivers should be provided access to nutritional, social service, and financial counseling services.

IV. CLINICAL APPLICATIONS

This document is intended to serve as guidance for facilities currently utilizing ELS devices and/or those that anticipate acquisition of those devices. It is not intended as a resource in device acquisition, nor does its scope allow for comparison of the various devices or applicators currently available or their specifications; these details should be the purview of the individual users and the designated purpose of the devices. The literature cited is limited to available English-language sources and has been selected to review clinical reports. Although some technical and physical data are cited, the scope of the document does not permit an in-depth review of that literature. For greater details on related topics, readers are referred to consensus documents developed by various organizations and individual literature manuscripts [8].

ELS devices providing superficial (up to 120 kVp) and orthovoltage (generally between 120 and 300 kVp) radiation have been available for over a century. The size of the devices, lack of mobility, and limited depth of penetration of the available sources effectively limited their utility, which, in the case of superficial devices, was limited to benign and malignant skin diseases. Orthovoltage devices were employed for deeper tumors, but the limitations of dose delivery render any comparisons to historical data with these devices of little value. Alternatively, comparison of superficial radiation ELS treatment results with the more recently available devices and historical data is appropriate. The poor dose deposition characteristics of orthovoltage radiation devices has rendered them effectively obsolete for clinical use, but superficial radiation ELS devices have remained in the armamentarium since they were first introduced in the early 1900s. With primary indications for cutaneous lesions, the devices were employed mainly by radiation oncologists and dermatologists. Indications for superficial radiation in the benign dermatoses waned with the availability of many topical and systemic products, and in the 1980s, the use of ELS for nonmelanoma skin cancers (NMSCs) by dermatologists was largely displaced by the introduction and rapid acceptance of Mohs microsurgery [8].

With the widespread availability of linear accelerator–based electron beam therapy in the 1970s and 1980s, ELS devices were also generally abandoned by radiation oncologists. Introduction of the more mobile devices in the late 1990s and early 2000s, with low-energy radiation generated by small or miniaturized X-ray tubes, and introduction of a variety of applicators for noncutaneous deep sites renewed interest in the modality. As noted, confusion regarding nomenclature has prompted several organizations to develop position papers and surveys regarding definitions and utilization [8-10]. Numerous reports have essentially confirmed a long-understood doctrine of radiation therapy: regardless of the source of radiation, devices with similar dose deposition, dose rate, and relative biological effectiveness (RBE) characteristics will provide similar outcomes related to morbidity and short- and long-term disease control. Consideration of these issues becomes increasingly important in evaluation of a literature base that is populated almost entirely by manuscripts describing techniques and outcomes employing a single device

or set of applicators. Although the comparison of those outcomes to historical data is based on therapies using similarly designed applicators and even similar dose rates, differences in source energy range and in the spectrum of produced radiation may result in significant different dose distributions and depths of penetration. Differences in any measurable outcomes will therefore be determined by the thoughtful comparisons of radiation characteristics, appropriate selection of indications, skill, and experience of the providers, selection of applicators, treatment planning decision making, and quality control.

A. Skin

It is estimated that each year over 5 million skin cancers are treated in the United States. Basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) account for the majority of NMSCs [5,11,12]. Although the mortality rates of BCC and SCC are relatively low, they do represent the most common site of multiplicity and can require repeated interventions that may result in poor cosmesis, functional impairment depending on location of the lesions, and, if extensive, may negatively affect quality of life and potentially survival.

Decades of outcome data support surgery and radiotherapy as equally safe and effective treatments for NMSC when patients have been selected for therapy appropriately [13-15]. Patients referred for radiation therapy have often been selected because of tumor locations, suggesting poor functional and/or cosmetic results with surgery, large or deep tumors, aggressive histopathology, positive resection margins, underlying comorbidity, or patient preference. Multiple retrospective studies of radiation therapy with long follow-up demonstrate recurrence rates following adequate radiation therapy to be less than 5% for T1 and T2 lesions [16]. Petrovich et al reported 5-, 10-, and 20-year control rates of 99%, 98%, and 98%, respectively, for 502 tumors that were 2 cm or smaller [11].

As noted above, surgical management had largely supplanted ELS radiation therapy for smaller NMSCs in the late 1990s/early 2000s, with dermatologists increasingly moving toward the use of Mohs micrographic techniques. Radiation oncologists had often elected to employ linear accelerator-generated electron beams, which had preferable dose deposition characteristics to ELS, except for the most superficial of lesions. Iridium-192–based HDR afterloaders deployed within existing shielded rooms and with trained staff are now widely available in the radiation oncology community. The development of cutaneous applicators for skin cancer treatment has led to a greater utilization of these HDR devices in the radiation oncology armamentarium. Despite the utilization of applicators of similar design, the comparison of outcomes with patients treated with ELS devices may be problematic because of the differences in source energy spectrum, radiation quality and beam characteristics. However, if considering carefully selected patients, similar outcomes are expected whether using HDR brachytherapy with small surface applicators, ELS, orthovoltage, or electron beam therapy [12,17,18].

Because modern ELS applicators and cones will typically obscure the cutaneous target lesion during treatment setup, extreme care must be taken with applicator or cone placement. Consideration must also be given to tissue heterogeneities. Underlying bone may receive a higher absorbed dose from ELS than from HDR brachytherapy. Dose deposition in high-density tissue is generally affected in a different manner by radiation beams of different qualities [20]. The impact of tissue heterogeneity on the variation of absorption of radiation in the ELS energy range would seem to amplify the need for consensus-driven nomenclature of the different radiation sources.

The selection of applicator or cone size, total dose, number of fractions, dose per fraction, and depth of dose-point calculation with any of the platforms described will vary with the area, depth, and location of the skin lesion as well as treatment intent and other patient-specific factors. For example, the development of skin erythema or desquamation reaction might warrant consideration for early termination of radiation treatment. Contemporary treatment planning may include ultrasound of the target lesion for precise measurement of thickness [20]. Standard fractions (2-3 Gy per fraction to a total dose equi-effective dose at 2 Gy per fraction [EQD_2] 60-70 Gy) have been used for external-beam radiation modalities such as ELS, orthovoltage, and electron-beam therapy, in cases in which cosmesis, functional, and normal tissue tolerance are primary concerns [12,18-21]. Because of the previously stated dosimetric similarities between ELS and HDR brachytherapy, for superficial targets, treatment of small superficial NMSCs using surface applicators or cones, dose hypofractionation schedules, such as 35 to 42 Gy in 5 to 10 fractions and 42 Gy in 6 fractions, are t often used with a typical depth prescription of 3 mm [12,20,22] if cosmesis or functional maintenance are not of primary concern [18].

Early empirical observations of the effect of ELS and orthovoltage radiation on delay of wound healing and diminution of fibroblastic activity suggested that the modalities might be beneficial for postresection management of benign keloids. Decades of small anecdotal and retrospective reports have confirmed the efficacy of ELS therapy following keloid resection to prevent recurrence [23-25]. In the absence of randomized prospective trials, empirical observations generally recommend initiation of radiation immediately following lesion resection, or within 72 hours of resection. Bandages should be removed to ensure that all suture-related skin disruption is included in the treatment field. Some authors have suggested that kVp should vary based on the body part treated, but in general, any devices that operate between 50 and 120 kVp seem adequate [26]. Recommended treatment courses vary between 1 and 3 fractions administered without break, with total doses between 13 and 18 Gy. There have been reports that single-fraction courses at the HDR may predispose patients to hyperpigmentation, but responses with up to 95% freedom from recurrence have been reported. The adjuvant use of steroid injections does not appear to add benefit [27].

Based on available historical and contemporary literature, the use of ELS in appropriately selected NMSCs and keloids is considered to be appropriate for inclusion in the standard clinical armamentarium.

B. Breast

Significant data, including those from randomized clinical trials with long-term follow-up, has confirmed that patients with early-stage breast cancer may achieve comparable outcomes when appropriately selected and managed by either modified radical mastectomy or breast conservation therapy with excision followed by radiation, with or without hormonal therapy or chemotherapy as indicated. Surgical and radiation oncology techniques and outcomes for those primary procedures are beyond the scope or intent of this document. An increased understanding of the risk factors associated with in-breast tumor recurrences (IBTR) at the site of primary disease or immediately adjacent to the primary excision has increased interest in a variety of radiation-related interventions to reduce that risk. Early interest had centered on local-field boost therapy employing a variety of external-beam techniques most often with conventional fractionation and protraction, but availability of single- and multiple-channel applicators for HDR brachytherapy prompted interest in shortening the course of either primary or boost radiation. Primary radiation could be administered by intraoperative radiation therapy (IORT) as a single treatment, or over 5 days, through applicators placed during or shortly after surgery. Consideration of the risks, benefits, and outcomes of partial breast irradiation or accelerated partial breast irradiation (APBI) has been adequately discussed elsewhere and is also beyond the scope and intent of this document.

Primary and boost radiation breast techniques employing ELS devices have employed 50 to 100 kVp photons using mobile X-ray generators and cones or mini-X-ray sources inserted through single applicators in a manner used by HDR brachytherapy. ELS in breast cancer has generally been accomplished with devices using low-kilovotage X-rays, but with different dose rates and physical spectrums that may render data related to the outcomes not interchangeable [28]. Recently, the long-term outcomes of a randomized trial of a risk-adapted IORT trial versus external-beam radiation (TARGIT-A) was published [29]. This trial included 2,298 women randomized to IORT at the time of the original lumpectomy versus whole-breast external-beam radiation. If postoperative pathologic evaluation demonstrated high-risk features (ie, positive margins), additional external-beam radiation was delivered in the IORT arm (approximately 20% of the patients were found to have these high-risk features). The 1,140 women in the IORT arm were treated with 50 kV X-rays at the center of a spherical applicator over a 20- to 30-minute interval. Applicator size ranged from 1.5 to 5 cm, with a surface dose calculation of 20 Gy and a fall-off to 5 to 7 Gy at 1 cm. Median follow-up was 8.6 years. The trial was designed as a local recurrence noninferiority study and did meet this end point, with local recurrence rates of 2.11% in the IORT arm versus 0.95% in the external-beam arm. Previously published society consensus statements raised concern over ELS as a standard option in breast cancer, although no such consensus statements have been available subsequent to publication of the TARGIT data [29].

C. Other sites

Low dose rate (LDR) and HDR brachytherapy has been routinely utilized in the adjuvant settings of cervical, uterine, and vaginal cancers, to deliver high doses of radiation to target volumes that are in close proximity to normal pelvic organs. Brachytherapy with or without external-beam radiation is an accepted standard of care in these diseases and, depending on site involvement, disease stage, and patient-related factors, may be primary

monotherapy or combined with surgery with or without systemic therapy. Vaginal brachytherapy may also be used to palliate tumor-related symptoms. The use of intravaginal ELS as an alternative to HDR or LDR brachytherapy has been reported to include comparisons of different radiation sources [31]. Logistical advantages of ELS in this setting include lower radiation dose to personnel and reduced room-shielding needs [32], but the impact of the higher surface doses and lower depth doses delivered with ELS are of some concern.

A recent report of pooled data from 5 centers included 51 patients with resected glioblastoma treated with IORT doses of 10 to 40 Gy at the applicator surface. With a median follow-up of 18 months, median overall survival was 18 months. Based on their observations of safety and efficacy, the authors suggested initiation of prospective clinical trials utilizing IORT for this disease [34].

Anecdotal reports have appeared, suggesting the use of ELS intraoperatively following the resection of solitary brain metastases, postoperative rectal cancer, and postoperative and recurrent cancers of the head and neck [26,33,35]. In addition, a phase I/II study is underway to evaluate the use of ELS in the treatment of glioblastoma multiform directly after gross tumor resection with single IORT doses of 27 to 30 Gy [36]. Although treatments have been generally well tolerated, long-term local control rates and overall survival data are unavailable, and ELS cannot be considered a standard treatment in this setting.

V. EQUIPMENT SPECIFICATIONS

There are currently several FDA-approved and commercially available devices that utilize ELS. The kilovoltage (kVp) energy level of the marketed devices (kV) varies from 50 to 100 kVp with a tube current of 0.04 to 10 mA. The ELS devices are designed to deliver low-energy radiation at a high-dose rate to small tissue areas or volumes, using either surface contact or short SSD techniques. In the event of system failure or malfunction, the devices are designed to save the treatment data to the permanent electronic storage.

The applicators generally used with ELS devices vary in size and shape (conical, cylindrical, spherical, needle, and flat) to properly adapt to the treatment site (Section IV). Depending on the intended use, some of the applicators are designed for multiple patient use and can be sterilized.

Source replacement for any currently available device requires recommissioning and recalibration [5]. It is the responsibility of the qualified medical director, as defined in the ACR–ASTRO Practice Parameter for Radiation Oncology [2] to identify problems, see that actions are taken, and evaluate the effectiveness of the actions. The director will designate appropriate personnel to constitute the Continuous Quality Improvement (CQI) Committee that will review ELS as part of the CQI meeting agenda. Refer to the ACR–ASTRO Practice Parameter for Radiation Oncology [2] for a detailed description of CQI Committee functions.

VI. PATIENT AND PERSONNEL SAFETY

Institutions using these ELS devices must have a radiation protection program in place to ensure radiation safety for both patients and staff as detailed in Section VI. These safety measures should include:

1. A radiation exposure–monitoring program as required by appropriate regulatory agencies, such as state agencies, or guidance documents, such as NCRP Report 127 “Operational Radiation Safety Program” or the CRCPD’s SSR’s (Sec. D.1101 and Sec. D.1201) [37].
2. Only personnel necessary to the procedure may remain in the treatment room during ELS treatment delivery.
3. Use of appropriate localized shielding around the treatment site and portable shielding for personnel.
4. Use of a calibrated survey meter to verify adequate shielding of personnel necessary to remain in the room during ELS treatment delivery.
5. Establishment of safe operating procedures, including those covered under guidance document CRCPD SSR (Sec. X.11.h) [38].
6. Establishment of safety precautions recommended in guidance document CRCPD SSR (Sec. X.11.i) [38].
7. Establishment of a culture of safety (see the ACR–ASTRO Practice Parameter for Radiation Oncology) [2].
8. ELS safety processes should be part of a CQI program (see the ACR–ASTRO Practice Parameter for Radiation Oncology) [2].

VII. EDUCATIONAL PROGRAM

CME programs directed to ELS indications and procedures should be available for all members of the treatment team and, where appropriate, should include operating room personnel. Prior to initiation of any ELS program, all involved personnel should be trained in safe and appropriate use of the ELS equipment, including safe operations and emergency procedures. The training must be provided by the manufacturer (application specialist) or a designated qualified individual. Educational programs used for both initial training and periodic (at least on an annual basis) retraining must cover:

1. The safe operation, including emergency procedures, of ELS sources as appropriate to the individual's responsibilities.
2. The radiation oncologist must have CME of alternative treatment techniques, in addition to new developments in ELS-based radiation oncology.

The educational program should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [39].

VIII. DOCUMENTATION

Reporting should also be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [3].

Successful ELS implementation requires documentation of all elements of the ELS process as detailed above: clinical evaluations, goals of therapy, informed consent, treatment planning, treatment delivery, and follow-up care. Likewise, regulatory and safety measures established for the protection of both patients and personnel, as delineated above, must be documented in the medical record.

IX. 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 Improvement, Safety, Infection Control, and Patient Education appearing under the heading *ACR Position Statement on Quality Control & 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).

X. SUMMARY

This collaborative practice parameter has been commissioned and created by the ACR, ABS, and ARS to bring the best practices of the previous standard of therapeutic radiation to a modality that has gained utility within and outside the traditional radiation oncology milieu.

The document defines this form of therapy as ELS, related to traditional radiation oncology metrics of beam energy, SSD, and radiation source.

As with all of radiation oncology a professional standard of evaluation, treatment goals, robust informed consent process, quality treatment-planning process, safe and well-documented treatment delivery, appropriate documentation, QA, and patient follow-up are essential, as are the appropriate qualifications of all involved personnel.

ELS has emerged as a potential alternative to linear accelerator and HDR afterloader brachytherapy-based radiation therapy for uncomplicated superficial cutaneous lesions and for selected other treatment sites. This form of radiation therapy is best performed within the scope of practice of the specialty of radiation oncology and in radiation oncology clinics. For other specialists and locations, it remains critical that all elements of these practice parameters are observed to ensure the quality of care and safety of patients and personnel.

Future directions will need to include outcome analysis from the registries and the development of uniform clinical pathways based on evidence and best practices.

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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
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