2016 (CSC/BOC)*

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

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 developed collaboratively by the American College of Radiology (ACR) and the American Brachytherapy Society (ABS). Although this document refers to the practice of radiation oncology throughout, it is intended to provide guidance to physicians of any specialty who are delivering, or planning to deliver radiation therapy employing, Electronically-Generated, Low-Energy Radiation Sources (ELS).

ELS refers to equipment utilizing X-ray sources with a peak voltage of up to 120 kVp to deliver a therapeutic radiation dose to clinical targets.

The main advantage in the clinical implementations of ELS over Iridium-192 HDR brachytherapy or megavoltage-electrons is that the emitted energy is lower allowing for much less radiation shielding requirements. Newer ELS devices are typically set on wheels for portability, and are not linked to treatment couches. These devices may be used with short source-to-surface (SSD) collimation, surface applicators, and in some instances, through the use of interstitial or intra-cavitary applicators. Furthermore, since there is no radionuclide in ELS, it is not necessary to address the Nuclear Regulatory Commission (NRC) or state radioactive material license requirements. Depending on the energy level employed, currently, various agreement states and regulations may not include these devices. Users are urged to check their applicable regulations for compliance.

The use of low energy radiation does not mean that ELS is without risk to patients and healthcare personnel or that there should be any reduction in the standard of care or safety measures applicable to 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, equipment, patient and personnel safety.

II. PROCESS OF ELS

The clinical implementation of ELS is a multistep process involving trained clinical personnel who must work in concert to accomplish various interrelated activities. The 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

The initial evaluation of the patient includes a physical examination and medical history, review of pathology, imaging, and other pertinent diagnostic studies and reports. The extent of the tumor must be determined and recorded for staging. Pre-treatment photographs of accessible lesions should be obtained. When treatment involves a body site with functional capacity, pre-treatment functional measurements should be recorded. Clinical staging and pathological staging (when available) should be documented in the permanent clinical record; staging facilitates treatment decisions, influences the prognosis of the patient, and enables a comparison of treatment results.

B. Treatment Goals

The goal of treatment (curative or palliative) should be documented and discussed with the patient and/or authorized caregivers prior to initiation of therapy. Furthermore, treatment options and relative merits and risks should be discussed with the patient and/or authorized representative. Integration of treatment using ELS in conjunction with other treatment modalities such as surgery, and systemic therapy may be necessary so that an adequate course of treatment can be defined.

A summary of the clinical evaluation and treatment goal should be communicated to the referring physician and other physicians involved in the patient's care. Details are contained in the ACR–ASTRO Practice Parameter for Radiation Oncology [1] and the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [2].

C. Informed Consent

Informed consent must be obtained and properly documented, as recommended in the ACR Practice Parameter on Informed Consent – Radiation Oncology [3].

D. Treatment Planning

Treatment planning is a process in which Qualified Medical Physicists or medical dosimetrists, in conjunction with the radiation oncologist, determine the optimal treatment parameters based on the given prescription in order to generate clinically acceptable treatment plans. The treatment planning process includes: treatment technique, applicator selection, and dose distribution to target and surrounding critical structures. These dose distributions may be generated using a treatment planning system (TPS) and a patient image data set (CT or other imaging modality). When devices are not equipped with such a planning tool, the user will 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 machine. A dose calculation at prescription point (or to target) is needed to generate the treatment time needed to deliver the prescribed dose.

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 should be properly documented (revised dose prescription) and approved by the radiation oncologist.

E. Treatment Delivery

With ELS treatment systems, the treatment delivery can be performed in an outpatient treatment room, office-based treatment room or an operating room. The treatment can be performed using a single application or a hypo-fractionated approach.

The treatment delivery consists of four steps:

- Pre-treatment time out
- Treatment setup and verification
- Treatment delivery itself
- Post-treatment quality assurance (QA)

The pre-treatment time out should consist of patient verification using at least two methods (date of birth and patient photo), and verification of the correct plan (treatment area, applicator, energy, and fraction).

The treatment setup should consist of patient and applicator positioning, use of shielding if needed, verification of treatment plan parameters (appropriate target, applicator selection, and its position and orientation).

The treatment delivery itself should be monitored from start to finish. In this phase, both the patient and the treatment unit should be the focus by the treating team. In the event of any patient movement or machine malfunction, a member of the ELS team should be ready to temporarily stop the treatment and apply corrective actions. Before, and during if appropriate, the treatment, the patient should be informed and updated on the treatment time.

The last component following the treatment delivery is the post-treatment QA. Prior to removal of the ELS applicator, verification of its position for any possible shift should be evaluated. Reusable items such as the applicator, caps, shielding, and couch top should be cleaned following the manufacturer's recommendation and the universal guidelines for disinfection and sterilization. A post treatment report, as part of the institution quality management program should be generated and signed by both the Qualified Medical Physicist and the radiation oncologist. The purpose of this document is to evaluate and document any treatment deviation and possible reportable event.

F. Treatment Summary

At the conclusion of the course of ELS treatment, a written treatment summary should be generated and provided to the referring physician and any other appropriate healthcare providers. In many instances, a treatment summary may be provided to the patient or authorized caregiver, as recommended in the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [2].

G. Follow-up Evaluation

At the completion of treatment, a follow-up plan should be generated and documented in the patient's chart. The patients should be seen by the radiation oncologist at regular continual intervals. In some cases, direct follow-up is not possible or practical due to the patient's medical condition, patient's choice or any unreasonable travel requirements. In this case, the radiation oncologist should request and review the follow-up documentation provided by other pertinent medical providers.

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 [1] 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, approving the treatment plan, and signing the treatment prescription. The training and experience of the radiation oncologist must also be in compliance with applicable laws and regulations.

B. Qualified Medical Physicist

The Qualified Medical Physicist is responsible for the ELS technical equipment, treatment plan secondary check, radiation safety, and quality assurance of all treatment devices. Depending on the facility personnel, the Qualified Medical Physicist may also be responsible for ELS treatment planning and delivery. For the qualifications of the Qualified Medical Physicist see the ACR–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy [4].

C. Medical Dosimetrist

The medical dosimetrist is responsible for treatment planning. Depending on the site to be treated and facility personnel, this function may be performed by a Qualified Medical Physicist.

D. Radiation Therapist

The radiation therapist is usually responsible for treatment delivery. Depending on the site to be treated and facility personnel, this function may 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 ELS patients 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.

IV. CLINICAL APPLICATIONS

This document has been developed to serve as guidance for facilities currently utilizing ELS devices and/or those which anticipate acquisition of those devices. The scope of the document does not permit an in-depth consideration of each of the devices approved for marketing in the United States nor was that the intent of the authors. The literature cited is limited to available English language sources, and has been selected to review clinical reports, rather than technical/physical material. With regard to non-melanoma cancers of the skin, which have been treated by ELS (superficial and orthovoltage radiation) for over a 100 years, the authors feel that a comparison of end-results is appropriate, since the radiation sources are similar, and only the delivery devices are different. Comparisons to treatment with ELS in other clinical sites have been avoided except in instances where literature regarding clinical outcomes for ELS is available. For many anatomical sites, the authors do not believe that sufficient data or duration of observations are available to compare end-results of ELS in terms of tumor control and/or morbidity with the end-results from other sources of radiation. That being the case, in clinical sites other than non-melanoma skin cancer and select breast cancer, the utilization of ELS should not yet be considered as standard-of-care.

A. Skin

It is estimated that each year over 3 million skin cancers are treated in the United States. Basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) account for the majority of non-melanoma skin cancers (NMSC). [5,6]. Although the mortality rates of BCC and SCC are relatively low, they may require repeated interventions that result in poor cosmesis and negatively affect quality of life; and they are sometimes locally extensive or can metastasize (SCC). The number of all treatment procedures for skin cancers approximately doubled from 1994 to 2006. [7].

Outcome data supports surgery and radiotherapy as equally safe and effective treatments for NMSC [8,9]. Patients referred for radiotherapy have often been selected for having challenging tumor locations, larger tumors, aggressive histopathology, or positive resection margins. Multiple retrospective studies of radiation therapy with long follow-up show recurrence rates following radiation therapy to be less than 5% for T1 and T2 lesions [10]. Petrovich et al, for example, showed 5, 10, and 20 year control rates of 99%, 98% and 98% for 502 tumors of 2 cm or smaller [11]. Superficial or orthovoltage equipment has long been utilized for treatment of skin cancer. These had typically been stationary devices with relatively short source-to-skin distances, and were housed in moderately shielded treatment vaults. Alternatively, skin lesions can be treated with megavoltage electron beams generated by linear accelerators and high-dose-rate isotopic sources. Based on the currently published literature on the available devices, ELS devices have similar dose depth properties, radiation distribution and relative radiobiological effectiveness to Irridum-192 HDR brachytherapy with surface applicators when evaluated in a water equivalent phantom. Similar outcomes are expected in homogeneous tissue whether using HDR brachytherapy with small surface applicators, superficial therapy, orthovoltage, or electron beam therapy. [12]. However, in heterogeneous tissue such as underlying bone, the dose to underlying bone will be much higher with ELS when compared to either Irridum-192 HDR brachytherapy or electron beam treatment [13].

The selection of the total dose, number of fractions and dose per fraction, with any of the platforms just described, may vary with the size, extent, and location of the skin lesion as well as treatment intent and other patient-specific factors. Standard fractions (2 to 3 Gy per fraction to a total dose of equi-effective dose at 2 Gy per fraction [EQD_2] 60 to 70 Gy) have been used for external beam radiation modalities such as orthovoltage and electron beam therapy in cases where cosmesis, functional, and normal tissue tolerance are primary concerns [14]. Because of the previously stated dosimetric similarities between ELS and HDR brachytherapy, treatment of small superficial targets using surface applicators, dose hypo-fractionation schedules, such as 35 to 42 Gy in 5 to 10 fractions and 42 Gy in 6 fractions, are typically used with a typical depth prescription of 3 mm [15].

B. Breast

Early breast cancer may be treated with comparable outcomes by mastectomy or by lumpectomy and post-operative whole breast radiation therapy (WBRT). Whole breast radiation therapy is commonly accompanied by a tumor bed boost dose because the majority local recurrences occur in or near the primary site of the disease. Most local recurrences are prevented by radiation therapy. It was in this context that ELS was first applied in treatment of breast cancer. A favorable 5-year local recurrence rate of 1.73% was reported using intraoperative ELS as a boost [16].

It also may be unnecessary to irradiate the whole breast in early breast cancer [17]. ELS has been studied as a form of partial breast irradiation. A "risk-adapted" comparison of WBRT to a single dose of 20 Gy intraoperative radiation therapy (IORT) using ELS, was administered with the initial lumpectomy or separately during a second operative procedure to introduce the radiation applicator. Additional external beam radiation therapy was given for adverse features in 22% of IORT cases based upon pathological findings of cases treated the initial lumpectomy. In the patients treated with IORT in the "pre-pathology" arm the recurrence rate was 2.1%. There was lower in mortality in the IORT arm due to fewer non-breast cancer deaths in the IORT arm compared to WBRT. Intraoperative radiation therapy for breast cancer is the subject of much interest and discussion: it is the subject of ongoing studies including a registry trial [18].

C. Other sites

Radionuclide-based brachytherapy has been commonly utilized in the management of gynecologic malignancies, including cervical, uterine, and vaginal cancers, to deliver radiotherapy to target volumes that are in close proximity to normal pelvic organs. Brachytherapy is a standard treatment utilized with or without external beam radiotherapy, for definitive treatment of selected cases of gross disease, or after surgery to reduce the risk of local recurrence. Vaginal brachytherapy may also be used to palliate tumor-related symptoms. The use of intra-vaginal ELS as an alternative to conventional brachytherapy has been reported in three citations, to approximately 72 patients. [1-3]. The stated advantages are primarily the portability and low shielding requirements, making it possible to deliver the treatment in the operating room [19]. Given the variation in patient selection and ELS prescription dose/fractionation regimens utilized it is not yet possible to draw conclusions regarding the efficacy or toxicity of ELS as a substitute for traditional brachytherapy.

Despite the relatively low shielding requirements of ELS, there are only a few reports of IORT with ELS, for cancers other than breast. One study reported 42 patients who underwent definitive resection for locally advanced or recurrent rectal cancer treated with ELS IORT of 5 Gy prescribed to a 1 cm depth. There were no complications attributed to IORT and local control in the 34 evaluable patients, after a mean follow up of 22 months was 68% [20]. The authors considered these results favorably but it is difficult to find a true comparison group.

ELS have also been used intraoperatively following the resection of solitary brain metastases. Weil et al [21] reported on 23 solitary brain metastases resected and then treated with ELS IORT 14 Gy prescribed to a 2 mm depth. Local recurrence at the ELS-treatment site occurred in 30% of patients, at a median time of 9 months following ELS. Although treatment was well tolerated, the rate of local recurrence is concerning. ELS cannot be considered a standard treatment in this setting.

V. EQUIPMENT SPECIFICATIONS

Currently, there are several FDA approved and commercially available devices that utilize ELS. The accelerating potential of these devices (kV) varies from 50 to 100 kV 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, using electronically-generated radiation. Furthermore, these devices are designed to treat small areas (or volumes) at close distances from focus to the target surface (1 to 15 cm). In general, all the ELS devices contain an X-ray tube. In the event of system failure or malfunction, these devices are designed to terminate the treatment and save the treatment data to the permanent electronic storage. A summary of currently available devices is described by D. J. Eaton [22].

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.

VI. PATIENT AND PERSONNEL SAFETY

Institutions using these ELS devices should have a radiation protection program in place to ensure radiation safety for both patients and staff as detailed in Sections 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) [23].
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) [24].
6. Establishment of safety precautions recommended in guidance document CRCPD SSR (Sec. X.11.i) [24].
7. Establishment of a culture of safety (see the ACR–ASTRO Practice Parameter for Radiation Oncology) [1].
8. ELS safety processes should be part of a Continuing Quality Improvement (CQI) program (see the ACR–ASTRO Practice Parameter for Radiation Oncology) [1].

VII. EDUCATIONAL PROGRAM

Continuing medical education 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 continued medical education 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) [25].

VIII. DOCUMENTATION

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

It is the responsibility of the qualified medical director, as defined in the ACR–ASTRO Practice Parameter for Radiation Oncology [1] 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 [1] 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

This collaborative practice parameter has been commissioned and created by the ACR and ABS societies to bring the best practices of the previous standard of therapeutic radiation to a practice that has emerged both within and outside the traditional radiation oncology treatment locations of the radiation oncology center using ELS devices.

This document defines this form of therapy as ELS, related to traditional radiation oncology metrics of beam energy, source-to-surface distance, and radiation source.

This document reiterates, as with all of radiation therapy, a professional standard of evaluation, treatment goals, a robust informed consent process, a quality treatment planning process, safe and well-documented treatment delivery, appropriate documentation, quality assurance and patient follow-up.

This document reasserts the appropriate qualifications of all personnel involved in ELS treatment planning, delivery and patient care.

This document reviews the current state of the evidence basis of the application of radiation therapy with ELS to skin, breast and various other actual or potential sites.

ELS has emerged as an alternative to linear accelerator and high-dose-rate afterloading brachytherapy-based radiation therapy for simple superficial cutaneous targets and for selected intracavitary targets. Ideally 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 practitioners and locations such as non-radiation oncology providers, it is still most important that all elements of these practice parameters are observed to assure the quality of the 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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Collaborative Committee – members represent their societies in the initial and final revision of this practice parameter

ACR
Laurie E. Gaspar, MD, MBA, FACR, Co-Chair
Alan C. Hartford, MD, PhD , FACR
Joshua H. Petit, MD
William Small, Jr., MD, FACR
Paul E. Wallner, DO, FACR

ABS
Phillip M. Devlin, MD, FACR, FASTRO, FFRRCSI (Hon), Co-Chair
Ivan Buzurovic, PhD
D. Jeffrey Demanes, MD, FACR
Michael E. Kasper, MD
Subir Nag, MD, FACR
Zoubir Ouhib, MS, FACR

Committee on Practice Parameters – Radiation Oncology
(ACR Committee responsible for sponsoring the draft through the process)

Alan C. Hartford, MD, PhD, FACR, Chair
Maxwell R. Amurao, PhD, MBA
Nathan HJ Bittner, MD
Nancy A. Ellerbroek, MD, FACR
Beth A. Erickson, MD, FACR
Roger M. Gilbert, MD, FACR
Geoffrey S. Ibbott, PhD, FACR, FAAPM
Lesley A. Jarvis, MD, PhD
Bill W. Loo, MD, PhD
Jeff M. Michalski, MD, MBA, FACR
Christopher H. Pope, MD
Naomi R. Schechter, MD
Nikhil Thaker, MD
Suzanne L. Wolden, MD
Bassem I. Zaki, MD

Seth A. Rosenthal, MD, FACR, Chair, Commission on Radiation Oncology

Comments Reconciliation Committee

William Small Jr., MD, FACR, Chair
Johnson B. Lightfoote, MD, FACR, Co-Chair
David C. Beyer, MD, FACR
Ajay Bhatnagar, MD
Albert L. Blumberg, MD, FACR
Ivan Buzurovic, PhD
D. Jeffrey Demanes, MD, FACR
Phillip M. Devlin, MD, FACR, FASTRO, FFRRCSI (Hon)
Laurie E. Gaspar, MD, MBA, FACR
Alan C. Hartford, MD, PhD
William T. Herrington, MD, FACR
Michael E. Kasper, MD
Subir Nag, MD, FACR
Zoubir Ouhib, MS

Joshua H. Petit, MD
Seth A. Rosenthal, MD, FACR
Timothy L. Swan, MD, FACR, FSIR
Paul E. Wallner, DO, FACR

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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:

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