ACR–ABS–ARS PRACTICE PARAMETER FOR TRANSPERINEAL PERMANENT BRACHYTHERAPY OF PROSTATE CANCER

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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), and the American Brachytherapy Society (ABS), and the American Radium Society (ARS).

Radical prostatectomy, external-beam radiotherapy, and prostate brachytherapy all represent well-established options for the treatment of prostate cancer [1-4]. Active surveillance can and should be considered in appropriately selected patients with low-risk disease [5].

Patients with clinically localized prostate cancer can be treated with radical prostatectomy, external-beam radiotherapy, or prostate brachytherapy. It is required that the patient understands the risks and benefits of each option to make an informed decision. It is recommended that patients with localized prostate cancer consult with both a radiation oncologist and urologist to achieve this aim.

A literature search was performed and reviewed to identify published articles regarding practice parameters and technical standards in brachytherapy of prostate cancer. Review of the recent scientific literature regarding permanent transperineal prostate seed implantation reveals significant variation in patient selection, brachytherapy techniques, and medical physics and dosimetric conventions. Despite this range of different procedural practices, interstitial low-dose-rate (LDR) brachytherapy has consistently been shown to be an effective component in the treatment of all prostate cancer risk strata either as monotherapy or as part of a multimodality regimen [3, 6-10].

II. QUALIFICATIONS AND RESPONSILITIES OF PERSONNEL

A. Radiation Oncologist

1. Certification in radiology by the American Board of Radiology (ABR) to a physician who focuses their professional practice to radiation oncology, or certification in Radiation Oncology or Therapeutic Radiology by the ABR, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada (RCPSC), or the Collège des Médecins du Québec may be considered proof of adequate qualification.
   or
2. Satisfactory completion of a residency program in radiation oncology approved by the Accreditation Council for Graduate Medical Education (ACGME), (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA).

3. The radiation oncologist should have formal training in prostate brachytherapy. If this training was not obtained during an ACGME-approved residency or fellowship program, the radiation oncologist should comply with the following requirements:
   a. Appropriate training from an experienced brachytherapist in transrectal ultrasound (TRUS), computed tomography (CT), or magnetic resonance imaging (MRI)-guided prostate brachytherapy.
   b. Additional training through participation in hands-on workshops or under the supervision of a qualified proctoring physician. The proctoring physician should be an experienced prostate brachytherapist with the proficiency to perform the mechanics of the implant procedure and critically assess the dosimetric quality of the implant. The radiation oncologist should have delineated hospital privileges for performing this procedure. These workshops must provide the radiation oncologist with personal supervised experience with seed placement and implant evaluation.

B. Qualified Medical Physicist

For the qualifications of the Qualified Medical Physicist, see the ACR–AAPM Technical Standard for the Performance of High-Dose-Rate Brachytherapy Physics or the ACR–AAPM Technical Standard for the Performance of Low-Dose-Rate Brachytherapy Physics [11, 12].

C. Radiation Therapist

The radiation therapist must fulfill state licensing requirements and be certified in radiation therapy by the American Registry of Radiologic Technologists (ARRT).

D. Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended.

E. Patient Support Staff

Individuals involved in the nursing care of patients should have education or experience in the care of patients who are receiving radiation therapy.

III. PATIENT SELECTION CRITERIA

Candidates for treatment with prostate seed implant alone, as monotherapy, include those for whom there is a significant likelihood that their prostate cancer could be encompassed by the dose distribution from permanent prostate seed implant alone. Patients with a significant risk of disease outside of the implant volume may benefit from the addition of external-beam irradiation and/or androgen deprivation therapy. Specific treatment schemas are evolving, as there are conflicting data regarding the efficacy of combined therapies relative to monotherapy. Consequently, it is suggested that each facility establish and follow its own practice parameters. Ongoing clinical trials will help to better define indications.

A number of different risk stratification systems exist. The majority of these systems divide patients with prostate cancer into low-risk, intermediate-risk, and high-risk groups according to pretreatment prostate-specific antigen (PSA) level, Gleason score, and clinical stage [13, 14]. The volume of cancer on the prostate biopsy specimen also has been shown to affect biochemical outcome and may prove to be useful in further subdividing the established risk categories [15, 16]. The National Comprehensive Cancer Network risk criteria are the most commonly cited and represent the standard for most modern clinical trials [17]. Given the heterogeneity that exists within each of the risk groups, some risk classification systems are now substratifying the classic risk groups to very low, low, favorable intermediate, unfavorable intermediate, high, and very high risk. Monotherapy is sufficient treatment for patients with low-risk prostate cancer. The suitability of LDR brachytherapy as monotherapy for patients with both favorable and unfavorable intermediate-risk prostate cancer has been established by the level 1 data in *RTOG* 02-32. [18-24]. Focal (partial gland) brachytherapy is also being evaluated in the low- and favorable intermediate–risk prostate cancer population but at the present time is considered experimental and should only be performed in the setting of a clinical trial [21]. It should be noted that focal ablative techniques (cryoablation, high intensity focused ultrasound, transurethral ultrasound ablation of the prostate, irreversible electroporation, photodynamic therapy, and laser ablation) are increasingly used by urologists and interventional radiologists for a range of prostate cancer indications; by the same token, focal brachytherapy techniques would not ultimately be eligible for the same indications. At the present time, most high-risk brachytherapy protocols include supplemental external beam with or without androgen suppression [18, 25]. Retrospective studies have reported favorable outcomes comparing brachytherapy with radical prostatectomy and external-beam radiation therapy alone in the high-risk population [6, 7, 9, 10, 26]. Randomized controlled data demonstrate superior biochemical control when dose escalation is achieved with brachytherapy boost compared with external-beam therapy alone [2], although the addition of a brachytherapy boost is associated with a higher incidence of acute and late genitourinary toxicity [27].

External-beam treatment volume and the role of androgen suppression are areas of controversy. Extrapolation from external-beam radiation therapy data suggests that there may be a potential role for androgen suppression in patients with factors that place them at high risk of metastasis but two separate studies found no need for androgen suppression or external-beam radiation [28-30]. The role and duration of androgen suppression therapy in intermediate-risk and high-risk patients treated with brachytherapy have not been established [31].

When supplemental external-beam radiation therapy is used, the optimal treatment volume has not been

established. Some investigators advocate the treatment of a whole-pelvic field in higher-risk patients. Other investigators believe an involved field around the prostate and immediately adjacent structures is appropriate [32-34].

Androgen suppression should not be routinely given for low-risk patients. It can be given to certain low and intermediate risk patients with large glands for volume reduction in those using a technique that requires prostate cytoreduction [35].

The following are potential exclusion criteria for permanent seed brachytherapy:

1. Life expectancy of less than 10 years in the setting of low-risk prostate cancer
2. Unacceptable operative risk

Poor anatomy which, in the opinion of the radiation oncologist, could lead to a suboptimal implant (eg, large or poorly healed transurethral resection of the prostate defect, large median lobe, large gland size, pubic arch interference, or inability to achieve the dorsal lithotomy position

1. Significant obstructive uropathy, although based on PROST-QA no other option offers such patient better quality of life [36]
2. Lymph node involvement
3. Distant Metastases

Modern prostate brachytherapy series demonstrate excellent biochemical and functional outcomes in patients younger than 50 years [37-39]. Young age should not be considered a contraindication to prostate brachytherapy; potentially, these younger patients may have decreased secondary cancer risk due to lower overall radiation burden than those treated with external beam approaches [40, 41].

There are limited contemporary studies reporting outcomes in patients with lymph node involvement treated with prostate brachytherapy as a component of their treatment [42-44]. The recent STAMPEDE H trial supports the use of two fractionation regimens of external radiation to the prostate in patients with low volume metastatic disease but does not address the role of dose intensification with brachytherapy [45]. Thus, brachytherapy is not favored as an appropriate option in such patients until more data are forthcoming, or it is further investigated with the scope of a clinical trial. Additionally, brachytherapy can potentially be used to treat the prostate and the rest of the oligometastatic burden be treated with external beam and systemic therapy.

IV. SPECIFICATIONS OF THE PROCEDURE

A. Written Directive

The terms "written directive," "planning directive," and "prescription" are often used interchangeably. To avoid confusion in this document, "written directive" will be used to indicate the statement of intent required by the Code of Federal Regulations. This is distinct from dosimetric goals, which are used to evaluate the quality of the implant in terms of achieved dose distribution. The word "prescription" is not used.

1. Before the start of implantation: State the treatment site, treatment intent (curative/palliative), radionuclide, and total source strength. To allow for sources planted outside the gland but placed intentionally to contribute to the dose make the treatment site "prostate and periprostatic tissues."
2. After the implantation but before the patient leaves the posttreatment recovery area: State treatment site, the number of sources implanted, the total source strength implanted, and the date.

IV. SPECIFICATIONS OF THE PROCEDURE

B. Implant Treatment Planning

Dosimetric planning should be performed in all patients before or during seed implantation. TRUS, CT scanning, or MRI should be used to aid in the treatment planning process [46-53].

IV. SPECIFICATIONS OF THE PROCEDURE

C. Intraoperative Procedure

A transperineal approach under TRUS guidance is recommended for seed implantation. Ideally, the full definition of the prostate in both longitudinal and transverse planes should be available. Typically, a probe with a frequency range between 5.0 and 12.0 MHz is used for the TRUS. It is recommended to use a high-resolution biplanar ultrasound probe with axial and sagittal capability and dedicated prostate brachytherapy software, which displays perineal template and coordinates. For planning purposes, the prostate target (clinical target volume) should be defined, as well as organs at risk (OARs) such as the bladder, rectum, and urethra. Other structures such as the bladder neck and the urogenital diaphragm have also been identified as potential OARs. [54, 55] Definition of the urethral structure may be assisted by placement of a catheter or by injection of aerated gel into the urethra. [56, 57]

There are several acceptable methods for seed insertion. These include, but are not limited to, the following:

1. Using a preloaded needle technique
    a. The preloaded technique is performed based on a preplan and can be used in conjunction with intraoperative planning.
    b. Needles can be placed one at a time, all at once, by row, or based on peripheral and central locations.
    c. Seeds can be "stranded," "linked," or "loose" within each needle [58].
2. Using a free-seed technique
    a. A seed loading device (eg a Mick® applicator) or similar device is used to implant the seeds into the prostate.
    b. Free-seed loading can be based on a preplan or an intraoperative plan.
    c. Needles can be placed one at a time, all at once, by row, or based on peripheral and central locations.

    Additionally, hybrid implantation techniques that use a mix of preloaded needles and free seed placement have been used.

There are some studies showing that injection of an absorbable hydrogel spacer can be used to reduce rectal dose in patients undergoing LDR brachytherapy [59]. The hydrogel can be placed in the space between the posterior prostate and anterior rectum under ultrasound guidance. The timing of hydrogel placement is left at the discretion of the brachytherapist and can depend on a number of factors including the method of dosimetric planning, and whether the implant is done in conjunction with supplemental external beam radiation therapy. Further studies are needed to determine whether hydrogel placement reduces rectal toxicity in the setting of permanent prostate brachytherapy.

For dose calculations, the AAPM Task Group No. 43 Report (TG-43) [60-62]and its successors should be adopted. The precise radiation dose necessary for eradicating prostate cancer by brachytherapy is not absolutely defined. Based on available data, the following recommendations are made for dose prescriptions: for patients with low-risk or favorable disease treated by monotherapy, the prescription dose ranges from 110 to125 Gy for palladium-103 and 140 to 160 Gy for iodine-125 [63-65]. In recent years, there has been experience with cesium-131, and if that isotope is used, reference to current literature is advised. The currently recommended dose is 115 Gy if cesium-131 is used as monotherapy. Doses of approximately 85 Gy are being investigated when combined with external-beam radiation therapy [66]. With external beam plus brachytherapy the recommended external-beam dose to the prostate and periprostatic area is in the range of 20 to 50.4 Gy [19]. Implant technique has been shown to vary substantially among different institutions in terms of seed strength, dose homogeneity, and extracapsular seed placement/margins [67]. With this being the case, dosimetric parameters such as D90 (the minimum dose received by 90% of the target volume) and V100 (the percentage of the target volume receiving 100% of the prescription dose) should be reported in conjunction with prescribed dose to provide a meaningful assessment of implant quality.

Whole-pelvic irradiation may be used in those cases at high risk for pelvic node metastases. The palladium-103 prescription boost dose is in the range of 80 to 110 Gy, and for iodine-125 the prescription boost dose is 100 to 110 Gy [32, 38, 48, 49, 68]. When brachytherapy is used in conjunction with external-beam radiation, it is recommended that the treating clinician consider the biologically effective dose (BED) that results from the combination of these two modalities. Several formulas have been proposed to account for the different dose-fractionation schemas that exist for the external-beam component of treatment and also the various isotopes that can be used in the brachytherapy implant [65, 69, 70]. Given the known correlation between BED and treatment outcome, every effort should be made to attain a BED threshold that will maximize cure while minimizing treatment-related morbidity.

There are no recommendations regarding the selection of radionuclide. One randomized trial examined differences between the two isotopes (palladium-103 and iodine-125), which noted no significant differences in long-term morbidity or PSA-based cancer control [71]. Experience with cesium-131 is less established compared with the other two isotopes, but 5-year biochemical control rates are favorable, and a recently published phase II study demonstrated similar quality of life outcomes among patients treated with palladium-103, iodine-125, and cesium-131 [72, 73].

IV. SPECIFICATIONS OF THE PROCEDURE

D. Postimplant Procedures

Cystoscopy may be performed after the procedure. Cystoscopy allows for the removal of blood clots and misplaced seeds in the bladder and/or urethra. Patients should be advised that there is a risk of seed migration to the lungs or other organs, particularly if loose seeds are employed. Patients should be instructed to monitor their urine for the first three days following the implant procedure. If a seed is passed, it should be retrieved by the patient using tweezers or a spoon rather than touched with their hands and placed in a provided container and returned to the radiation department for proper storage/disposal. Urinary anesthetics, antispasmodics, analgesics, perineal ice packs, and stool softeners may be added in symptomatic patients. Consideration should be given to the prophylactic use of alpha blockers before and after the procedure [74]. Use of prophylactic corticosteroids may also reduce the risk of acute urinary obstructive symptoms [75].

V. DOCUMENTATION

Reporting and communication should be in accordance with the ACR–ARS Practice Parameter for Communication: Radiation Oncology [76].

VI. POSTIMPLANT DOSIMETRY

Postimplant dosimetry assessment is mandatory for each patient. The intent is not merely documentation of seeds and evaluation for a medical event; CT- and/or MRI-based postimplant dosimetry assessment evaluates the quality of the implant. Postimplant dosimetry expresses the actual dose delivered and identifies variance from the original treatment plan. Because quality is correlated with outcome and morbidity, postimplant dosimetry is an objective tool for self-assessment and improvement. Plain radiographs alone are not adequate for dosimetric analysis. We recommend the use of image-based planning such as CT and/or MRI to be completed within approximately 60 days of the brachytherapy procedure to evaluate the relationship of the seeds and the prostate, bladder, and rectum [77-82].

The optimal timing for obtaining the postimplant CT and/or MRI is not known. Implant dosimetry will vary in a predictable fashion depending on when the imaging evaluation is performed. Imaging obtained within 24 hours of the implant procedure will result in lower calculated doses to the prostate and anterior rectal wall, whereas day 30 imaging will predict higher doses to these respective structures [80, 83-85]. Some studies suggest an interval of 2 to 6 weeks postimplant (AAPM TG-64 and TG-137 Reports) [56, 86]. Others have argued that dosimetric evaluation should be performed within 24 hours of implant because this allows for immediate correction of dose deficiency and allows for implant assessment at the time of maximal prostatic edema [87, 88]. Regardless of convention, it is preferred that the timing of postimplant image acquisition be kept consistent within each practice. The TRUS volume study can be fused with the postimplant CT or MRI for the purposes of postimplant

dosimetry [89].

Significant intraobserver variability in the contouring of prostate volumes and normal structures can be noted on postimplant CT scans, and this should be considered before drawing specific inferences regarding dosimetric parameters [90, 91].

The following parameters should be reported:

1. The prescribed (intended) dose.

2. The D90 (defined as the minimum dose received by 90% of the target volume as delineated on the postimplant CT) and the V100 (defined as the percentage of the target volume delineated on the postimplant CT receiving 100% of the prescribed dose) [57, 92-95]. A D90 of at least 90% of the prescription dose and a V100 that corresponds to at least 90% of the contoured prostate are recommended as the current standard of care, but this should be balanced with respect to the morbidity of the adjacent normal tissue doses [64, 65, 96-100]. Reporting of the V150 and V200 (ie, the percentage of prostate volume receiving 150% and 200% of prescribed dose, respectively) should also be considered [94].

3. Doses to OARs, including rectum and prostatic urethra [101-103]. The dose to the rectum is commonly reported as the RV100 and RV150, the volumes in cubic centimeters of the rectal wall receiving 100% and 150% of the prescribed dose, respectively. A peripheral loading pattern is recommended to avoid extreme central doses to the urethra. The performance of postprocedure urethral dosimetry is favored if imaging and postimplant timing readily permit it. Dose to the penile bulb may be reported, but there are conflicting results regarding the clinical utility of this practice parameter [104, 105].

VII. RADIATION SAFETY AND PHYSICS QUALITY CONTROL

A. TRUS Imaging System

The report of the AAPM Ultrasound Task Group 128 [106] for acceptance testing and quality assurance and the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [107] provide guidance for ultrasound imaging units. Physicists and physicians should pay attention to spatial resolution, grayscale contrast, geometric accuracy, and distance measurement. The correspondence between the electronic grid pattern on the ultrasound image and the template grid pattern should be verified before the procedure as part of the ultrasound quality assurance.

B. Computerized Planning System

The computerized planning system should be commissioned by the Qualified Medical Physicist before clinical use. The AAPM TG-40 Report [108] should be followed. In addition, dose-rate calculations from planning systems should be compared with the AAPM TG-43 Report [62, 109]. The Qualified Medical Physicist and/or radiation oncologist should also be familiar with the AAPM TG-64 Report [86].

C. Brachytherapy Source Calibrations

The recommendations set forth by the AAPM TG-40 [108], TG-56 [110], and TG-64 [86] reports and the recommendations of AAPM Low Energy Brachytherapy Source Calibration Working Group [111] should be followed for calibrating brachytherapy sources.

D. Implantation Procedure

The radiation oncologist will verify the position of the prostate gland relative to the template coordinates. The total number of seeds implanted should be verified at the end of the implant procedure. At the completion of the implant, a radiation survey of the patient and the room should be conducted with an appropriately calibrated survey instrument. Patient survey measurements should be performed at the

surface of the patient and at 1m distant from the patient. The room survey should include the vicinity of the implanted area, the floor, the waste fluids/materials, linens, and all applicators. Before the release of the patient, the Qualified Medical Physicist, or an appropriately trained member of the physics staff, and/or the radiation oncologist or radiation safety staff should review the postimplantation survey results to confirm that all pertinent federal and state regulations regarding the release of patients with radioactive sources have been followed. The brachytherapy team must follow the new 10 CFR Part 35 applicable to the permanent implant brachytherapy.

E. Postimplant 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. This is the responsibility of the licensee. The radiation oncologist or their designee (radiation safety officer or medical physicist) should provide the verbal and written radiation safety instructions after implant. This description must be in compliance with state and federal regulations.

VIII. FOLLOW-UP

Follow-up of definitively treated cancer patients is part of radiation oncology practice, as noted in the ACR–ARS Practice Parameter for Radiation Oncology [112]. Postoperative follow-up should consist of sufficient visits within the first 3 months to ensure patient safety and comfort and to minimize acute complications associated with the radiation therapy procedure. The frequency and sequence of subsequent visits may vary among the radiation oncologist, urologist, and other physicians involved in the care of the patient. The radiation oncologist should make an effort to obtain long-term follow-up on patient status.

The best definition of biochemical PSA failure has yet to be determined for brachytherapy patients [113]. The current American Society for Radiation Oncology Phoenix PSA failure definition is most commonly used [114]. PSA failure can also be defined according to an absolute threshold (ie, PSA exceeding a certain level), but when using such a definition, adequate time should be allowed for the PSA to reach its nadir. In a large multi-institutional study, patients who reached a PSA = 0.2 ng/mL by 4 years after permanent LDR prostate implant were found to have a freedom from recurrence rate of 98.7% at 10 years. One benefit to a threshold definition of biochemical failure is that it better facilitates comparison of treatment outcome with prostatectomy [115]. Consideration should be given to the PSA bounce or spike phenomenon in cases of spurious PSA elevation following implantation [116-118]. Although most spikes occur at 18 to 30 months, they can occur much later. Other clinical laboratory and radiologic studies may be performed when clinically indicated. If there is concern regarding recurrence, other treatment options can be considered. Prostate-specific membrane antigen PET scans are likely to change not only the eligibility of patients for brachytherapy but also alter our understanding of efficacy. The ACR is working on a guidance document to elaborate this emerging aspect of prostate cancer care.

IX. SUMMARY

Transperineal prostate brachytherapy is an effective modality for treating prostate cancer. Its safe and effective execution is a complex process that requires coordination between the radiation oncologist and other health professionals. Appropriate patient selection criteria and quality assurance procedures are important for a successful program.

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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.

Development Chronology for this Practice Parameter

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