ACR-AAPM TECHNICAL STANDARD FOR THE PERFORMANCE OF HIGH-DOSE-RATE BRACHYTHERAPY PHYSICS

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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.

1 lowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (lowa 2013) lowa 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 technical standard was revised collaboratively by individuals with recognized expertise in medical physics, representing the American College of Radiology (ACR), and the American Association of Physicists in Medicine (AAPM).

High Dose Rate (HDR) brachytherapy is a method of delivering therapeutic radiation in which a sealed radioactive source is used to deliver radiation by interstitial, intracavitary, intraluminal, or surface application. The extremely high source strength (or activity) of the HDR source, typically iridium-192 in the range of 16,400 U to 61,500U (4 to 15 curies) or cobalt-60 in the range of 22,800 U to 27,900 U (1.8 to 2.2 curies), permits delivery of the prescribed dose in minutes. This procedure is usually performed on an outpatient basis.

Because the practice of HDR brachytherapy physics occurs under a variety of settings, the judgment of a Qualified Medical Physicist, in conjunction with a radiation oncologist, should be used to apply these standards to individual practices. In addition, radiation safety requirements must comply with appropriate federal and state regulations.

Although a number of reference documents are recommended for suggested reading, 4 documents represent the basis on which much of this technical standard is based: AAPM Code of Practice for Brachytherapy Physics [1], the AAPM Task Group Report on High-Dose-Rate Brachytherapy Treatment Delivery [2], the AAPM Report on Comprehensive Quality Assurance in Radiation Oncology [3], and the AAPM Medical Physics Practice Guideline 13.a [4].

II. QUALITY MANAGEMENT

Quality Management (QM) is, "an overall management system that includes establishing quality policies and quality objectives, and processes to achieve quality objectives through quality planning, quality assurance (QA), quality control (QC), and quality improvement." [5]

II. QUALITY MANAGEMENT

A. Quality Management Team

The QM team defines the individuals who are responsible for, and involved with, the technical aspects of the clinical use of HDR brachytherapy. In general, the supervising physician is responsible for the overall quality and safety of the HDR program. The supervising physician should be an authorized user (AU) as defined by local regulations governing the use of radioactive materials in human subjects. The Qualified Medical Physicist has responsibility and oversight for equipment testing protocols, methods, and criteria for action. As such, the QM team should be led or overseen by the supervising physician with support from the Qualified Medical Physicist. The QM team may also include, if appropriate, at least one technologist who routinely operates the HDR unit. Although different types of physicians (eg radiologists, anesthesiologists, and/or surgeons) may be involved in HDR brachytherapy procedures, the participation of all physicians on a QM team is likely unnecessary.

The QM team should be in communication at regular intervals, (eg, quarterly, semiannually, or annually) to review issues, discuss upcoming activities, and perform general review of past QA and control results. In addition, such correspondence provides an opportunity to discuss any necessary updates to the QM components discussed later in this section.

The QM team should be the group responsible for providing the greatest input on purchasing decisions for new or replacement equipment and the associated accessory hardware and software. A consistent QM approach to hardware and software simplifies the requirements associated with the ongoing QA and control measures.

Members

The Qualified Medical Physicist should work closely with the radiation oncologist and other members of the brachytherapy team to build consensus and document the clinical workflow and resources for specific anatomical sites and treatment modality combinations.

Any new HDR treatment delivery methodology should be discussed with the AU and Qualified Medical Physicist before patient treatment. The AU and Qualified Medical Physicist should agree on the new process, including use of imaging modalities, patient transport procedures, validation and QA steps, etc. Basic standards of practice and prudent courses of action should be determined ahead of time. Any modifications to an existing process (such as using an existing applicator in a different way or site) should be evaluated by the treatment team ahead of time.

The introduction of a new applicator in a clinic should be a team effort because elements of the treatment and patient care specific for that applicator are the responsibility of the entire team. This includes but is not limited to, physician, physicist, dosimetrist, therapist, nurse, surgeon, radiation safety officer, sterilization staff, etc. The team needs to discuss timing, communication, and workflow for applicator implantation, simulation, and treatment in a patient-centric manner. The Qualified Medical Physicist should inform the team about the particular features, constraints, and requirements regarding the applicator and its intended clinical use. This information is often included in the Instructions For Use documentation provided by the manufacturer.

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B. Resources

Personnel Requirements

Active brachytherapy programs require physics and support personnel beyond that required for external beam therapy due to the uniqueness and relative complexity of each case. As a special procedure, HDR brachytherapy requires a significant time commitment by the Qualified Medical Physicist to develop and maintain high standards for quality procedures, as well as providing documentation to comply with regulatory agencies. Consequently, these commitments should be included when budgeting personnel requirements.

Required Equipment

Each facility must have access to instrumentation to independently verify the source strength provided by the manufacturer. This must be done with a well ionization chamber and electrometer or other suitable instrument(s) with a calibration performed by an accredited dosimetry calibration laboratory (ADCL) traceable to the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The chamber and electrometer calibration must be performed every 2 years and after any servicing that may affect the systems' calibration [6, 7]. The facility must also have appropriate equipment to verify source position and timer accuracy.

Calibrated survey instruments that are appropriate in energy response and range for the sources used must be available for use at all times [6, 7]. A backup survey meter with valid calibration should be readily available in case the primary instrument fails or has been sent out for calibration. Appropriate local shielding, storage facilities, and transportation containers must be available. Storage containers for emergency use (eg, lead pig) and an emergency kit, including long-handle forceps and applicator specific emergency devices, must be available inside the treatment suite. Further, the treatment room must be equipped with appropriate audio and visual equipment to ensure constant communication and monitoring of patients during treatment delivery.

When applicable, a computerized treatment planning system (TPS) that uses 3-D image data sets (CT, ultrasound, MRI, etc), for delineation of anatomy, applicator reconstruction, and the creation, optimization and evaluation of 3-D dose distributions must be available.

For sealed sources that will be used clinically for a period exceeding 6 months, the facility must have instrumentation to perform leak tests or arrange to have this service provided at intervals not to exceed 6 months.

II. QUALITY MANAGEMENT

C. Service Records

Equipment and relevant software calibrations should be performed as defined by the equipment manufacturer. Some manufacturers require calibrations to be performed by technologists or other clinical personnel, while other manufacturers describe calibrations as part of routine or corrective service. Similarly, some technical

configurations may be required to be done by service engineers, especially at installation, while other configurations may be appropriately adjusted by technologists or medical physicists. For all equipment and relevant software, regular preventive maintenance and corrective service should be performed, documented, and records retained by a service engineer, following the maintenance schedule recommended by the manufacturer. Copies of all service records, including corrective actions, must be shared with, and retained by, the clinic providing patient care. The quality management team should, at minimum, have access to review these records, and if sensible in the context of facility culture and operational practices, it may be best for the quality management team to keep and manage these records.

II. QUALITY MANAGEMENT

D. Records of Devices and Tools

QM of HDR brachytherapy requires accurate and complete installation records of the equipment. At a minimum, the QM team should establish an asset management methodology to track location, manufacturer, model, date of manufacture, sterilization cycles, and unique identifiers of all devices in their purview. The asset management system should serve as either the repository for, or link to, the permanent storage for quality performance records and reports.

In addition to the HDR system itself, the QM team should maintain accurate records of the tools used to perform QC tests. These records should include tool description of type, manufacturer, model, date of manufacture, and unique identifier. The calibration, calibration schedule, and/or intercomparison history and schedule of the applicable tools should be kept with these records to ensure regulatory and policy compliance.

The QM team should include a review of the asset management system as part of its regular meetings. Individual members of the team should be assigned specific data points of interest to oversee. The more detailed and automated the asset management system, the easier the delineation of the data for the QM team members.

Proper maintenance, calibration, QC, and update of all HDR equipment must be performed by a Qualified Medical Physicist or under the supervision of a Qualified Medical Physicist and must meet all applicable federal, state, and local regulations. All users must receive proper and documented training including annual HDR safety training.

II. QUALITY MANAGEMENT

E. Important Policies (as applicable)

Effective QM requires a comprehensive set of policies and guidelines to address all aspects of equipment performance. This subsection lists those aspects of the HDR brachytherapy program that should be included in such documentation.

1. Specifications for calibrations and QC results:

The QM team shall determine the appropriate calibration conditions and expected values and ranges for the QC tests described in section IV. The QC targets should be based on clinical use, regulatory requirements, and scientific guidelines. The QC tests should follow expert consensus standards when available. Manufacturer recommendations are also acceptable.

2. Specifications for configuration/setup:

The QM team should establish the appropriate hardware and software configurations for the HDR afterloader and TPSs. Creating standard configurations simplifies oversight and may aid in maintaining the desired consistency across devices when clinics have more than one system. Manufacturer recommendations may be helpful in this regard.

3. Summary of QA and QC frequencies:

The QM team shall create documentation specifying the required frequency for the QA and control activities outlined in this document. The documentation should also include the frequencies for calibration or cross-comparison of tools used to perform QC tests. Manufacturer recommendations may also be acceptable.

4. Review of applicable regulatory and accreditation requirements:

A site's documentation for the QM for HDR systems should include a comprehensive summary of all applicable regulatory and accreditation rules. Many sites are subject to numerous agencies whose rules for which requirements may vary. Applicable rules should serve as the basis for both the tests and their frequencies. When establishing the QM program, these rules and this technical standard should serve as a guide for the QM team. In the case in which there are no applicable rules, the tests and frequencies provided herein may serve as this basis.

5. Requirements for postservice:

Along with documented frequencies for the ongoing QA and QC activities, the QM team should specify the requirements for testing when repairs are performed, components replaced, or the equipment is otherwise modified. Documentation should exist to outline the qualifications of personnel performing repairs or modifications. In addition, the necessary level of Qualified Medical Physicist oversight for work or repairs performed on the system should be outlined. This technical standard suggests relying on the input from the Qualified Medical Physicist for final determination of what is required for a given event. However, identifying a list of common occurrences can aid in expediting and standardizing this response.

6. Personnel roles:

The QM team should clearly define each member's role in ongoing QA and QC. In addition, the team should define personnel who may not be on the QM team but are involved with the operation or maintenance of the HDR brachytherapy system. A policy or guideline that specifies the expectations and formal training for personnel working with the equipment should be established. The facility should have a documented competency plan that details required training for personnel participating in the HDR program.

7. User/operator responsibilities:

The QM team should create a policy or guideline that provides specific expectations and formal training for operators and users of the HDR brachytherapy system. These expectations should summarize each user's responsibility for ensuring the system(s) continue to operate safely and at the required performance level. This policy or guideline may include items such as the responsibility for reporting hardware, software, or facility issues, expectations for performing ongoing QC activities, etc. The facility should also have a documented plan that outlines user/operator responsibilities during HDR emergencies.

8. Reporting criteria for quality evaluation activities:

The documented policies and guidelines should include a component for the reporting of QA and QC activities. This includes the time frames for when activities must be completed and documented. For example, source exchange activities are expected to be completed and reported before the unit is returned to clinical use. The specifics for each activity may be guided by the regulatory and accrediting agencies overseeing the site, and documentation of these expectations provides support to the QM team when performing audits of a site's radiation safety and/or quality program.

In general, the Qualified Medical Physicist must provide a written report of the findings of acceptance testing and performance evaluation to the professional(s) in charge of obtaining or providing necessary service to the equipment and, if appropriate, to the responsible physician(s). Written reports must be provided in a timely manner consistent with the importance of any adverse findings.

If appropriate, the Qualified Medical Physicist should notify the facility to initiate the required service. The facility must complete corrective actions in a timely manner consistent with the importance of any adverse findings. The facility should retain service reports from competent service personnel as verification that the issue(s) were appropriately resolved. The reports may be reviewed by a Qualified Medical Physicist to confirm that the equipment is performing in a safe and acceptable fashion after the required service is performed or as required by federal, state, or local regulations.

F. Reporting structure for issues

Effective QM requires a robust communication framework for the members of the QM team and other partners of the healthcare infrastructure. Physician end users and members of the clinical team should have a clear understanding of how to report quality- and safety-related issues to the QM team for support. As part of the documentation responsibilities for users and other clinical personnel, the reporting tools should be clearly defined. The QM team should use their regularly scheduled meetings to review trends in user issues to verify there are no systematic issues with the HDR brachytherapy program.

III. QUALITY ASSURANCE

Quality Assurance is "a component of QM focused on providing confidence that quality requirements will be fulfilled; it includes all activities (planned, systematic, and practice-based activities) that demonstrate the level of quality achieved by the output of a process." [5]

QA refers to administrative policies, QC measures, and consideration of quality improvement objectives that ensure consistent and safe fulfillment of the treatment prescription. The Qualified Medical Physicist is responsible for a QA program that maintains the records regarding appropriate description, calibration, and the current source strength to assure accurate delivery of the prescribed dose to the specified volume [8]. The complexity of brachytherapy procedures necessitates that comprehensive QA include treatment-related devices (eg, planning and imaging systems, applicators, radioactive source, and delivery system) and the clinical process [9].

A. Periodic Review of Settings/Protocols/Clinical Outputs

The Qualified Medical Physicist should review the routine QC results at least annually and report any findings or recommendations to the QM team.

QA for brachytherapy sources includes maintaining an ongoing review for adherence to regulatory and licensing requirements. Accordingly, the Qualified Medical Physicist must develop, implement, supervise, and review the policies and procedures for use of the HDR source(s) and maintain proper written documentation [2]. When these activities relate to radiation safety, they should be performed in compliance with the guidelines established by the institutional radiation safety program.

B. Calibration of Measurement Devices/Tools

Measurement devices should be regularly calibrated or cross-referenced with calibrated devices to ensure the quality of their readings. The Qualified Medical Physicist should adhere to professional practice standards and must meet applicable regulatory requirements.

The constancy of the ionization chamber and electrometer used for calibrating the HDR source(s) should be checked on receipt, after repair, and before each use. The ionization chamber and electrometer must be calibrated at least every 2 years at an ADCL facility or by a calibration laboratory accredited by the AAPM. The sensitivity, linearity, and reproducibility of the instrument must be documented at least annually [10, 11]. Survey instruments must be calibrated at least annually.

C. Periodic Verification of 3rd Party Software

The Qualified Medical Physicist should develop a QA program to review the continued performance and functionality of all software used in the HDR brachytherapy program. This includes in-house developed software such as nomograms and third-party systems for independent dose calculation or fusion/contouring.

Although facilities of all sizes can benefit from an independent peer review process, HDR brachytherapy programs operating with a single Qualified Medical Physicist should institute a documented peer-review mechanism for reviewing the brachytherapy physics program. The review should preferably be performed by a Qualified Medical Physicist that is independent of the HDR program. The review should be performed every 3 years [12, 13].

IV. QUALITY CONTROL

Quality Control is "a component of QM focused on the fulfillment of quality requirements; it includes activities that impose specific quality on a process; and entails the evaluation of actual operating performance characteristics of a device or system, comparing it to desired goals, and acting on the difference; QC works on the input to a process to ensure that important elements or parameters specific to the process are correct." [5]

Equipment performance must be evaluated on installation and monitored at least annually by a Qualified Medical Physicist to ensure proper functioning within the defined performance standards. Additional or more frequent performance monitoring may be necessary in certain situations (eg, after major equipment maintenance or upgrades). Although it is not possible to consider all variations of equipment performance to be monitored, adherence to this technical standard will help to ensure the quality of equipment performance in clinical procedures. Key points to consider are performance characteristics to be monitored, estimated patient radiation dose, qualifications of personnel, and follow-up procedures.

A documented QC program with procedure manuals, records, and intervention results in either soft or hard copy should be maintained [14]. The Qualified Medical Physicist should review these records at least annually.

The QC activities described in this section are broadly separated into 3 categories: acceptance testing and/or commissioning, annual equipment performance evaluation, and continuous QC.

IV. QUALITY CONTROL

A. Acceptance Testing

A Qualified Medical Physicist must conduct initial HDR equipment performance evaluation on installation of the equipment and after major upgrades. This evaluation should be more comprehensive than periodic evaluation and should be completed and documented before clinical use.

Before the initial equipment performance evaluation, electrical safety and informatics connectivity (eg, DICOM transfer) must be verified by appropriate personnel.

Acceptance testing and/or commissioning must include tests performed during the annual performance evaluation and, additionally, should include the following items:

1. TPS

Computerized planning systems must undergo rigorous acceptance tests and commissioning to ensure that the dose-calculation algorithm properly converts the source calibration and conversion factors into the appropriate absorbed dose distribution including dose-volume statistics, if available, and that hardware and software were installed properly $[\underline{6}, \underline{10}, \underline{15}, \underline{16}]$.

The handling of image data and their use in dose calculations must also be verified for accuracy in comparison (when appropriate) to well-established methods of dose calculation. Model-based dose algorithms and the use of media heterogeneity corrections have increased the complexity of the dose calculations that may be employed in brachytherapy [16-18]. Heterogeneity corrections have only recently been made available to the brachytherapy community. The AAPM Task Group 186 Report [16] has raised the major issues in dose calculations that are not addressed by current, water-based calculation guidance documents (the Task Group 43 Report and its updates and supplements). The Qualified Medical Physicist

should consult the model-based dose calculation algorithms report 372 [19] for guidance on commissioning and implementing model-based dose calculation algorithms in brachytherapy with the goal of improving dose calculation accuracy. These new approaches need to be implemented with great care, and all users must receive proper training.

2. Brachytherapy Applicators

The Qualified Medical Physicist must ensure that proper acceptance testing and commissioning as well as a documented QA program is in place for each system before its clinical use [20-22].

The AU and the Qualified Medical Physicist need proficiency in applicator functionality and its use in all clinical scenarios, including emergency situations. Applicators should be imaged in a phantom or water bath using the intended imaging modality before use in a patient. A phantom-based end-to-end dry run test using the applicator, transfer tubes, and active HDR source should also be considered. Although it is typical for a vendor representative to be present for the first use of a new applicator in the clinic, this should not be a replacement for all required tests and preparations before clinical use.

In some cases, the Qualified Medical Physicist may not have access to the applicator before implantation (eg, sterile disposable applicators). In this case, one should use a checklist that includes visual and haptic checks of applicator integrity, correct device size/model and auxiliary components, package integrity, lot number, and expiration date. If possible, one should assemble and check the functionality of the applicator on a sterilized field before its insertion. For all applicators, the Qualified Medical Physicist should be aware of the manufacturer specified lifetime as required by state (or USNuclear Regulatory Commission) regulations.

3. Treatment-delivery unit

Computer-controlled HDR brachytherapy is performed with a high degree of precision and accuracy. The Qualified Medical Physicist must ensure proper acceptance testing and commissioning of the treatment delivery unit including, but is not limited to, source position accuracy, timer linearity and accuracy, and functional interlocks. The qualified medical physicist should establish a QC program to ensure that the intended accuracy and precision are met and maintained.

4. HDR Source

Because the radiation characteristics of the encapsulated source depend on its physical and chemical form, as well as the source encapsulation and the distribution of the radioactivity within the source, the Qualified Medical Physicist must take these factors into account to properly determine the radiation distribution around the source.

HDR brachytherapy source strength must be measured with direct or secondary traceability to national standards. The 1995 AAPM Task Group 43 Report [15], the updated version published in 2004 [10], and its supplements, Supplement 2 from 2017 [23], together with the International Atomic Energy Agency Technical Report 492 [24] and the AAPM Task Group 138 Report [25], should be consulted for calibration protocols of specific HDR source(s) employed for the brachytherapy procedures.

All HDR source(s) must be calibrated at the institution before their first clinical use. The source strength measurement report should include the source type, serial number of the source, source strength from the manufacturer, the date calibration measurements were performed, the equipment used in the calibration, the dosimetry protocol used to determine the source strength, the discrepancy between the measured source strength and the manufacturer's value, and the name of the Qualified Medical Physicist responsible for the calibration. The appropriate source strength must be entered into the treatment console, TPS, and all related software such as for independent dose calculations. An additional qualified individual should perform an independent verification of the implementation of this source strength value.

IV. QUALITY CONTROL

B. Equipment Performance Evaluation

A continuous QC program must be implemented for all HDR brachytherapy systems.

The Qualified Medical Physicist should determine the test frequency and tolerances (in conjunction with manufacturer specifications).

IV. QUALITY CONTROL

C. Continuous Quality Control

At a minimum, the following items should be included in the QC program:

1. TPS

A written treatment-planning system QC program must be implemented to ensure the accuracy of dose-calculation algorithms and source data files including after software and/or hardware changes, [26]. An inservice program should be given for new users and, when appropriate, provided to all users following software releases.

2. Treatment Delivery Unit:

- a. Autoradiographs or another suitable method of visual verification of source positioning that is approved by the Qualified Medical Physicist must be performed on the HDR source(s) before the first use of the afterloader each treatment day to verify that the source moves to the intended dwell positions. The desired mechanical accuracy and precision are 1 mm or less [6].
- b. Accuracy and linearity of the source dwell time must also be evaluated with the standard performance metric being a quantitative comparison to the baseline result.

3. Brachytherapy Applicators and Transfer Tubes

The applicators and transfer tubes should be visually inspected before each use and annually through radiographic analysis to verify dimensional stability and freedom from cracks, kinks, or physical defects.

4. HDR Source

The Qualified Medical Physicist must determine that the measured source strength is accurate to within ±5% of that reported by the manufacturer before clinical use [3, 6]. Although 5% is the maximum discrepancy allowed, good practice and proper instrument maintenance typically ensures no more than a 3% discrepancy [2]. Larger discrepancies (>3%) should be investigated by cross calibration with different instruments (electrometer, re-entrant ionization chamber, cables) or contacting the source manufacturer.

V. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

A. Qualified Medical Physicist

Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics, and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine (CCPM), the American Board of Science in Nuclear Medicine

(ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the <u>ACR Practice Parameter for Continuing Medical Education (CME)</u>
[27]

The appropriate subfield of medical physics for this standard is Therapeutic Medical Physics. (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

The Qualified Medical Physicist must meet any qualifications imposed by the state and/or local radiation control agency to practice radiation oncology physics and/or to provide oversight of the physics QM program. Regulatory agencies may define requirements for an Authorized Medical Physicist (AMP) for practice covered in this Technical Standard. It is assumed in this Technical Standard that the Qualified Medical Physicist meets all requirements of an AMP within the relevant jurisdiction(s) of their practice.

Similarly, depending on the bylaws of the relevant hospital/institution, the credentials and delineated privileges for the Qualified Medical Physicist should be confirmed through the medical staff membership process in the appropriate category because practice of clinical brachytherapy physics involves direct contact with patients and access of their hospital records.

The Qualified Medical Physicist is responsible for establishing test protocols, test methods, and acceptability criteria and for maintaining proper, complete, and accurate records required by regulatory agencies and accrediting institutions. This may include documentation of the performance of daily QA, source strength verification, applicator commissioning reports, treatment planning QA, and more. The documents should record the results and frequency of these tests. These records should also be available to individuals performing internal audits (eg, institutional Radiation Safety Committee) or external audits (eg, accrediting bodies such as ACR or APEx, or peer review). As discussed in Section IV.A.2. on Brachytherapy Applicators, the Qualified Medical Physicist should oversee the commissioning and QA of any new devices and evaluate intended imaging modalities with device compatibility.

The Qualified Medical Physicist may be assisted by properly trained individuals in obtaining data in accordance with applicable regulations and relevant guidance (eg, AAPM medical physics practice guideline 7.a [28]). Medical physics students, medical physics residents, and medical physicists-in-training may assist the Qualified Medical Physicist based on their training and at the discretion of the Qualified Medical Physicist. These individuals must be properly trained and approved by the Qualified Medical Physicist such that they have knowledge about the techniques of performing tests, functions and limitations of the equipment and test instruments, reasons for the tests, and the importance of the test results. The assisting individual shall be under the general supervision of the Qualified Medical Physicist. The Qualified Medical Physicist is responsible for all tests and must review, interpret, and approve all data as well as provide a signed report with conclusions and recommendations [27]. For the purposes of this standard, general supervision means all testing procedures are performed under a Qualified Medical Physicist's overall direction and control. The Qualified Medical Physicist's presence is not required during the test procedure but must be available by phone to provide assistance and direction if needed. The training of the personnel who perform the test procedure and the maintenance of the necessary equipment and supplies are the responsibility of the Qualified Medical Physicist.

V. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

B. Physician (if applicable)

For Physician qualifications related to HDR brachytherapy, see the <u>ACR-ABS-ASTRO Practice Parameter for the Performance of Radionuclide-Based High-Dose-Rate Brachytherapy</u> [29].

V. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

C. Medical Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended. The Medical Dosimetrist activities should be performed under the supervision of a Qualified Medical Physicist involved with the HDR procedure.

V. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

D. Radiation Therapist

The radiation therapist must fulfill pertinent state licensing requirements and should have American Registry of Radiologic Technologists certification in radiation therapy.

VI. Treatment Considerations

A. Treatment Planning and Imaging

Imaging

Although one can claim that in the modern era some form of imaging (mostly in the United States) is used for guiding the applicator insertion. It is only in the last decade that most HDR brachytherapy procedures have become 3-D image-based, either through single- or multi-imaging modalities. Volumetric imaging is increasingly being used in HDR brachytherapy, through different modalities including CT, MRI, US, and positron emission tomography. The Qualified Medical Physicist must ensure spatial resolution, fidelity, applicator and accessory (eg, dummy markers) compatibility, and appropriate use of each imaging modality used. The AAPM Task Group 303 Report [30] provides guidance on the implementation of MRI in HDR brachytherapy.

In cervical cancer, the Groupe Européen de Curiethérapie (GEC)-European Society for Radiotherapy and Oncology (ESTRO) has published guidelines for image-based HDR of the cervix [2, 31-36], thus creating the basis for the transition from a 2-D, point-based system, to a 3-D, volume-based treatment. Qualified Medical Physicists involved in image-based HDR for the cervix should consult the GEC ESTRO guidelines for a successful implementation of image-guided brachytherapy.

To ensure accurate treatment delivery, particularly when using templated plans or applicator models, confirmation of the applicator size, type and placement is necessary. The Qualified Medical Physicist or appropriately trained medical dosimetrist must be available during image acquisition for HDR brachytherapy planning to ensure that all necessary information is acquired (eg, dummy marker placement/labels). When images are acquired for planning, the use of wire and dummy markers is encouraged, when appropriate, to further ensure the correct delineation of the applicator and dwell positions.

Planning

A correct and accurate specification of the total treatment length (applicator plus transfer tube) is essential for correct treatment delivery. The Qualified Medical Physicist should oversee measurement, confirmation, and recording of this length. Proper applicator reconstruction (including orientation) and identification of the first dwell position are important steps in the planning process. Contours of targets and organs at risk (OARs) as well as dose volume histogram (DVH) parameters for targets (eg, D90, D95, V100, V150, etc) and OARs (eg, D1cm3, D2cm3) should be checked and confirmed with the treating attending physician. Previous external beam and brachytherapy doses to target volumes should also be documented with consideration for radiobiological summation.

At a minimum, treatment planning for all HDR procedures should include the determination of the appropriate dose distribution. A consistent means of specifying and documenting absorbed dose must be in place. Treatment planning documentation should include a description of the technique and applicator, source strength(s), anatomical target description, and dose-to-target volume and/or dose-to-reference point. Isodose distributions in three orthogonal planes containing the points or volume of interest should also be included when possible. Except for simple HDR procedures with well-defined applicator and treatment volume geometries, such as vaginal cylinders, imaged based volumetric computerized treatment-planning algorithms that provide a means to conform the dose distribution to the target and minimize the dose to tissue at risk should be used.

Plan Review

The treatment plan should be independently reviewed by the responsible radiation oncologist and a Qualified

Medical Physicist or an appropriately trained dosimetrist not directly involved with the generation of the treatment plan. The plan review should include, but is not limited to, the following:

- 1. Patient demographic information
- 2. Plan dose/prescription conforms to the written directive
- 3. Applicator type and size, implant geometry and applicator reconstruction (including orientation), channel lengths, first dwell identification, activated dwell positions, and channel mapping
- 4. Radionuclide, source configuration, source strength, implant date, and treatment time
- 5. Volumetric dose coverage of the target and dose constraints of tissue/OARs including a consideration of external beam and previous brachytherapy doses

Independent Dose Calculations

An independent dose calculation method should be used to validate the TPS results. Preferred methods include total dwell time and point-dose verification. This plan-verification step should be performed and reviewed before treatment initiation. Differences in target dose >5% should be investigated and resolved before treatment.

VI. Treatment Considerations

B. Delivery

Corrections for decay of the source strength or activity should be made at intervals consistent with 1% physical decay (daily decay for iridium-192 or monthly decay for cobalt-60). The Qualified Medical Physicist should verify that the -correct source strength, date, and time are displayed at the TCS before treatment initiation [6].

Administration of HDR brachytherapy must be supervised by an AU and an AMP in accordance with state and federal regulations.

The Qualified Medical Physicist must develop a process to ensure that the technical aspects of the HDR treatment are correct for the specific patient before each treatment. When a new plan is not generated for each insertion of multifraction HDR treatments, a process should be established to validate that parameters used for treatment of the first fraction remain valid for the remaining treatment fractions and that the source strength/treatment times have been appropriately adjusted.

The position of intracavitary, intraluminal, interstitial, and surface applications must be verified before treatment. Imaging techniques that monitor the constancy of the HDR applicator/catheters relative to the target tissues and tissues at risk should be considered for documentation in the validation process. Images, when acquired, should be with the patient in the treatment position. The responsible radiation oncologist should be present with the Qualified Medical Physicist or dosimetry personnel during applicator localization. Before treatment initiation, the localization images, when acquired, should be approved by the responsible radiation oncologist.

All multichannel treatments should include a check by a second member of the brachytherapy team to verify that the HDR afterloader channels have been correctly connected to the catheter/applicator. Before each treatment, a dummy wire check should be done to confirm that all catheters/applicators are properly seated and unobstructed.

A calibrated survey meter must be present at the treatment unit and used for all pre- and posttreatment measurements. A pretreatment survey of the patient should be conducted. At the completion of treatment delivery, after the source has been retracted, a posttreatment radiation survey of the patient must be conducted and documented as part of the treatment record under the supervision of the Qualified Medical Physicist. The transfer tube(s) and the HDR unit must also be surveyed to ensure that the source is indeed retracted inside the HDR unit.

All patient specific documentation created or used in patient treatment should be either uploaded to the patient's Electronic Medical Record or otherwise available for audit by regulators and other parties who may need access to the information. Documentation may include:

- 1. An HDR treatment plan which displays pertinent information regarding the case. This may include the source, source strength, a description or visualization of the loading pattern used, dose prescription, activated dwell positions, DVH data, and isodose curves.
- 2. Independent verification of treatment time/dose (secondary dose calculation)
- 3. Survey information (pre- and postpatient treatment)
- 4. Checklist that are used by the treatment team
- 5. Applicator placement verification (eg, imaging)
- 6. Other required documentation such as verification of time outs, AU and AMP present during treatment, confirmation of completion of treatment delivery, etc.

Personnel (AU, AMP, dosimetrist, and/or therapist) present at the HDR console during the treatment of the patient must, at a minimum, be trained in emergency procedures and operation of the afterloader. Although training provided by the manufacturer is preferred, in-house training provided by an individual having received previous manufacturer training is sufficient.

VII. RADIATION SAFETY

Radiation safety practices must be consistent with the institution's radioactive material license, license amendments, and existing regulations [6, 7, 37]. The Qualified Medical Physicist, in conjunction with the radiation safety officer, should be responsible for developing, overseeing, and documenting radiation safety procedures. These include, but are not limited to, written procedures regarding ordering, securing, receiving, returning, and/or disposing of HDR radioactive materials and for performing patient surveys preceding and following source removal. Specifically, the following radiation safety measures should be established and documented[1]:

- a. An inventory control program to locate and identify the HDR source(s) at any time
- b. Procedures for managing the transport of radioactive material. This should include wipe tests of the packaging on receipt and before shipping and surveys of the source container on arrival.
- c. Emergency procedures for retrieving the HDR source(s) from the patient
- d. Checking the functionality of the backup battery of the HDR unit
- e. Procedures for checking the safety interlocks and the audio and visual communications between the patient and operator of the treatment-delivery unit
- f. Procedures for checking the safety interlock of the treatment room door
- g. Participation in training of professional and technical staff regarding HDR at least annually
- h. Presence and proper functioning of the in-room monitor and remote alarm, their backup battery, and the portable survey instrument
- i. Assuring visibility at all times of the remote alarm outside of the treatment room
- j. Assuring the security of the HDR unit
- k. After each source change, the old source must be placed inside the vendor-supplied container, with proper paperwork and shipping label attached, sealed, and locked up securely inside the treatment room or appropriately secure hot lab room. The user should arrange for pickup of the container to return to the vendor as soon as possible and ensure confirmation of the receipt of the source from the manufacturer is received to assure its safe delivery.
- I. Policies for personnel monitoring of radiation exposure

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

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading ACR Position Statement on Quality Control and Improvement, Safety, Infection Control and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-PositionStatements/Quality-Control-and-Improvement).

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

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