

Special Article

# A review of safety, quality management, and practice guidelines for high-dose-rate brachytherapy: Executive summary

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**Abstract** This white paper was commissioned by the American Society for Radiation Oncology (ASTRO) Board of Directors to evaluate the status of safety and practice guidance for high-dose-rate (HDR) brachytherapy. Given the maturity of HDR brachytherapy technology, this white paper considers, from a safety point of view, the adequacy of general physics and quality assurance guidance, as well as clinical guidance documents available for the most common treatment sites. The rate of medical events in HDR brachytherapy procedures in the United States in 2009 and 2010 was 0.02%, corresponding to 5-sigma performance. The events were not due to lack of guidance documents but failures to follow those recommendations or human failures in the performance of tasks. The white paper summarized by this Executive Summary reviews current

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guidance documents and offers recommendations regarding their application to delivery of HDR brachytherapy. It also suggests topics where additional research and guidance is needed.  
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## Introduction

This report was initiated to evaluate the status of safety and practice guidance for high-dose-rate (HDR) brachytherapy. It is the fifth and final installment of a white paper series addressing patient safety commissioned by the American Society for Radiation Oncology (ASTRO) Board of Directors as part of ASTRO's Target Safely Campaign.<sup>1-4</sup> The full-length document (available as online only supplementary material at [www.practicalradonc.org](http://www.practicalradonc.org)) was approved by the Board of Directors on September 21, 2013, and is endorsed by the American Brachytherapy Society (ABS), American Association of Physicists in Medicine (AAPM), American Association of Medical Dosimetrists, and American Society of Radiologic Technologists. The document has also been reviewed and accepted by the American College of Radiology (ACR)'s Commission on Radiation Oncology.

Unlike other treatment modalities considered in this white paper series, HDR remote-afterloading brachytherapy is a mature technology dating back at least to the 1960s.<sup>5</sup> Several organizations have developed practice guidance documents during this time. The charge was not to duplicate previous documents or consolidate those efforts into a single document. Rather, this review considers existing guidance documents and whether they adequately address the safety needs of the current state of practice, given evolving knowledge of the conditions for which the modality applies and the developments in technology. Patients can be harmed in at least 2 ways: by failures of the persons or equipment involved to perform as intended and by inappropriate clinical intentions or procedures. Given the maturity of HDR brachytherapy technology, this white paper considers, from a safety point of view, the adequacy of general physics and quality assurance (QA) guidance, as well as clinical guidance documents available for the most common treatment sites.

The rate of medical events in HDR brachytherapy procedures in the US in 2009 and 2010 was approximately 0.02%, or 8 events per 33,000 treatments per year, corresponding to 5-sigma performance nationally.<sup>6</sup> The events have not been due to lack of guidance documents, but either failures to follow the guidance-document recommendations or human failures in the performance of tasks. There are recommendations for verification of information used in treatment planning but preventing such errors from becoming events requires QA adaptation specifically for an individual facility.<sup>7</sup> Recommendations for that will be coming with the publication of the Task Group (TG)-100 report of the AAPM (unpublished data, Huq MS, Fraass BA,

Dunscombe PB, et al. Application of risk analysis methods to radiation therapy quality management.)

This white paper recommends practitioners become familiar with and follow existing guidance as appropriate. Deviation from consensus recommendations should be supported by clinical studies or pursued in the setting of a clinical trial approved by an institutional review board. This white paper does not make any new guidance recommendations; it suggests topics for which new guidelines are needed, and such recommendations are noted as coming from the writing panel.

## General safety and quality guidance

Safety and quality in HDR brachytherapy depend greatly on some aspects of the process, such as the activities of the medical physicists and the coordination of the brachytherapy team. Practices to maintain safety and quality in brachytherapy are addressed fairly comprehensively in a series of reports by AAPM and other organizations. A listing of the documents and brief descriptions are in the Supplemental Material Appendix found at [www.practicalradonc.org](http://www.practicalradonc.org).

## HDR brachytherapy procedures

The order of procedural steps in brachytherapy exhibits greater variety than typically found in external beam radiation therapy (EBRT). This variation makes it challenging to map a general brachytherapy treatment process flow chart. However, most brachytherapy procedures include most of the same steps (listed in Table 1 in Supplemental Materials; found at [www.practicalradonc.org](http://www.practicalradonc.org)), though the order of steps is often specific to a particular application technique. Each different HDR brachytherapy process should include consideration of failures that could occur between or during each procedural step and must include quality management procedures to protect against failures. The AAPM TG-59 report discusses this in detail.<sup>7</sup>

## The HDR brachytherapy team: Qualifications, roles, and evolution

HDR brachytherapy is a multidisciplinary treatment modality requiring coordination of several clinicians having as a common goal accurately and safely treating the patient. While the roles and responsibilities of radiation oncology personnel are outlined in the 2012 ASTRO

report *Safety is No Accident* (section 2.1), the HDR brachytherapy team extends beyond the radiation oncology department and includes surgical specialists.<sup>8</sup>

### Qualifications

For specific qualifications and roles, please see the Supplemental Materials (supplemental material can be found at [www.practicalradonc.org](http://www.practicalradonc.org)).

Adequate staffing is needed for the HDR brachytherapy team to perform their roles safely; reduced staffing correlates with increases in medical errors and professional burnout. Specifically, for medical physicists and medical dosimetrists, each licensed unit will require 0.4 and 0.03 full-time equivalent (FTE) staff, respectively. Additionally, 0.008 and 0.003 FTE staff per patient are required. Thus, for a busy clinic having 1 HDR brachytherapy unit treating 50 patients per year, 0.8 and 0.18 FTE medical physicist and medical dosimetrist are required, respectively. Given additional ongoing training and educational commitments, these values should be rounded up to one and one-quarter FTE.<sup>8</sup>

### HDR brachytherapy source radionuclides

In the US, there currently is 1 radionuclide (<sup>192</sup>Ir [iridium]) used for HDR brachytherapy. Recently, HDR brachytherapy using <sup>60</sup>Co [cobalt] became available outside the US with a remote afterloader that can use multiple sources, such as 2 <sup>60</sup>Co sources, 2 <sup>192</sup>Ir sources, or both radionuclides in the same unit. This approach could diminish treatment times and provide better plan customization than a single <sup>192</sup>Ir source, but offers potential for a new safety risk where the sources are inadvertently switched. This issue is not covered in the AAPM TG-59 report.

There has been interest in other radionuclides such as <sup>169</sup>Yb [ytterbium], <sup>170</sup>Tm [thulium], and <sup>57</sup>Co. Potential advantages include longer half-lives and lower photon energy. However, there are concerns for high-energy yet low-intensity photons that reduce would-be shielding advantages, specific activity suitable for capsule sizes similar to current HDR <sup>192</sup>Ir brachytherapy source designs, and dose sensitivity to design tolerances. These issues need to be worked out.

### Reported medical events involving HDR brachytherapy

While there have been medical events with HDR brachytherapy, it has generally been a safe treatment modality. The following discussion reviews errors that led to medical events recorded in the US Nuclear Regulatory Commission's database for the 2010 and 2011 fiscal years.<sup>6</sup>

1. Sources entered into the computer database in the wrong units at the time of assay

2. Wrong step size entered either during treatment planning or treatment-unit programming
3. Wrong dose entered during treatment planning
4. Wrong isodose value selected for dose prescription
5. Wrong length or default length incorrectly used
6. Applicator length measured incorrectly
7. Different transfer tubes used during treatment than assumed during treatment planning
8. Wrong magnification used during treatment planning or other general treatment planning errors
9. Source retracting failures
10. Applicator failure through poor construction, poor maintenance, or misuse

Some failure modes are particular to a given therapeutic application. Examples of these, by treatment type, include the following:

1. Breast brachytherapy
  - a. While already listed above, length failures, either by erroneous measurement or entry [most common failure mode]
  - b. Intracavitary balloons leaking or popping
  - c. Intracavitary applicator rotating from the intended orientation
2. Gynecologic brachytherapy
  - a. Incorrect length for 1 or more parts of the applicator
  - b. Wrong dose specification location; for example, on a cylinder surface or at 0.5 cm away
  - c. Wrong dose or dose combination with EBRT
  - d. Applicator slippage between treatment planning and treatment delivery
3. Intraluminal brachytherapy
  - a. Incorrectly defining starting location for the source
  - b. Catheter shifting from its intended position
4. Prostate brachytherapy
  - a. Needles shifting from their intended position
  - b. Inappropriate optimization

A few events resulted from the person or persons involved in the treatment not understanding the hazards of the procedure or the correct steps. Almost always, though, the individual(s) had been trained and knew what they were supposed to do, but failed in task execution. These events highlight the importance of peer review and planning quality management for HDR brachytherapy.

From the above list, one of the most common failure types during individual applications is "length" failures, including using the wrong transfer tube, incorrect measurements of transfer tube length, incorrect applicator length measurements, incorrectly defining the starting location, etc. This type of failure should lead vendors and users to specifically develop new or improved equipment and procedures that make length failures less common. More detailed analysis of reported efforts should be performed by professional organizations and researchers

to look for commonalities so mitigation for these common failures can be developed.

### Quality management and checklists for HDR brachytherapy

The documents in the Appendix (Appendix can be found online at [www.practicalradonc.org](http://www.practicalradonc.org)) provide specific guidance for establishing a quality management program for HDR brachytherapy. Checklists and forms can be useful tools in maintaining quality and prevention of errors.<sup>9</sup> A generic checklist for HDR brachytherapy is unlikely to prove useful for a specific procedure. The TG-59 report gives examples of forms for quality control and lists of items to be checked at various stages of treatment that can serve as a model for customization. The ABS is compiling a compendium of checklists for various HDR brachytherapy procedures, and intends to post them on its website as models facilities can use to craft their own forms.

### Anticipated challenges to maintaining quality in HDR brachytherapy in the future

The field of HDR brachytherapy is constantly changing, leading to numerous anticipated challenges.

1. The loss of film and the movement to electronic images has advantages and challenges. The recent replacement of paper charts with electronic medical records has made it more difficult to draw pictures.
2. In many centers, the traditional radiation therapy simulator has been replaced by a computed tomographic (CT) simulator, forcing significant changes in how HDR brachytherapy procedures are performed.
3. The proliferation of devices, applicators, and radionuclides used for brachytherapy treatment lead to an increased number of possible processes, types of equipment, and clinical uses. The general complexity of medical care and continual increase in scheduling complexity for the treatment team is a growing problem for safe HDR brachytherapy delivery, as it can disrupt the crucial teamwork.
4. For many years, nearly all dose calculations for brachytherapy sources, including HDR brachytherapy sources, have been performed using straightforward and simple algorithms. The future, though, will include increased use of model-based algorithms such as Monte Carlo methods. New procedures for commissioning and new algorithm QA, plus new patient-specific planning checks will be required.
5. Current imaging options include magnetic resonance, CT, cone beam CT, megavoltage and kilovoltage portal imaging, fluoroscopy, portable x-rays and ultrasound. New methods and imaging to improve daily verifica-

tion of localization and dose delivery will likely be added, requiring additional resources.

6. Treatment planning for HDR brachytherapy is expected to change dramatically and will include the following:
  - a. Increasing use of diagnostic and functional imaging for definition of target (volume) and normal tissues to be avoided;
  - b. Increased integration or interdigitation of brachytherapy treatments with EBRT (or other ablative) treatments, requiring improved understanding of radiobiologic differences between modalities, and the generation of bio-effect relationships so various therapies can be integrated knowledgeably;
  - c. More adaptive brachytherapy, where the extent of treatment or total dose will be modified based on normal tissue or tumor response data from imaging or other physiologic or functional probes; and
  - d. Increased use of automated optimization that includes new abilities to define dosimetric and bio-effect issues for the optimization cost function.

All these features require new training, development of protocols for safe use, routine- and patient-specific QA procedures.

7. Image guidance during the surgical implantation of catheters and other applicators is expected to increase dramatically.
8. Use of robot-assisted devices will require greater attention to patient safety, as well as all the usual computer-controlled treatment issues currently being wrestled with in EBRT.
9. Potential growth in intraoperative techniques brings the need for more attention to contamination and sterilization risks and increased time constraints.
10. The field faces increased concerns over control and security of brachytherapy sources. These issues will impact additional staffing, storage, and security requirements.

### Clinical applications

Consideration of safety in HDR brachytherapy leads to consideration of the technology's clinical applications. The ACR periodically issues practice guidance documents for HDR brachytherapy.<sup>10</sup> Topics include clinical evaluation, establishing treatment goals, informed consent, applicator insertion, image acquisition, treatment planning and delivery, and follow-up.

The ABS recently prepared guidance documents for the following diseases, sites, or techniques relevant to HDR brachytherapy:

- cervix<sup>11,12</sup>
- vaginal cuff<sup>13</sup>

- prostate<sup>14</sup>
- sarcoma<sup>15</sup>
- penis (with GEC-ESTRO [Groupe Européen de Curiethérapie-European Society for Radiotherapy and Oncology])<sup>16</sup>
- accelerated partial breast irradiation<sup>17</sup>

Guidance documents for clinical brachytherapy are in preparation by ABS for the skin, central nervous system, gastrointestinal, lung or endobronchial, and esophagus.

The most prevalent clinical applications are considered in the Supplemental Materials (supplemental materials can be found at [www.practicalradonc.org](http://www.practicalradonc.org)). In each case, the focus is on existing guidance from professional organizations to assist practitioners when performing HDR brachytherapy. The list does not attempt to be comprehensive. A notable omission is brachytherapy for head-and-neck cancer. While effective, head and neck brachytherapy is not practiced widely in the US and, furthermore, is an eclectic group of diseases where moving a centimeter in the anatomy dictates a different protocol, making an overall guidance document difficult to assemble.

### Key measures to avoid catastrophic failures

The following benchmarks provide measures to evaluate compliance with the recommendations of this report.

1. HDR brachytherapy procedures are supported with the appropriate team as described in the report of AAPM TG-59 and the ACR HDR Brachytherapy Practice Standard.
2. Commissioning of the treatment unit, treatment planning system and each new source is performed by a qualified medical physicist and verified through a QA process.
3. Assay of the HDR brachytherapy unit source is performed using a well-type ionization chamber with a calibration traceable to the National Institute of Standards and Technology (NIST) and this assay is performed or confirmed for each source change. Planning system source strength parameters must be updated with each source change.
4. Treatments are performed according to the guidelines from ABS when available.
5. Treatment plans and programs are checked through independent verification before treatment delivery.
6. Daily QA checks of the HDR brachytherapy system are performed.

### Summary

HDR brachytherapy safety requires careful and consistent attention to all facets of the process. Guidance for

these procedures has been well established and documented, and these established documents should be followed for all procedures.

Safe application of HDR brachytherapy also depends on appropriate clinical decisions, and useful information is often available from clinical guidance documents prepared by relevant professional societies. While some documents remain current, professional societies have revised those for several clinical sites (gynecologic, prostate, and breast), which had fallen out of date, to include details necessary for clinical practitioners.

The recommendations in this white paper for improved safety and quality in HDR brachytherapy are the following:

1. Practitioners should become familiar with all guidance documents relevant to any procedure they plan on initiating before beginning the practice.
2. Practitioners should follow recommendations in relevant guidance documents. Deviations should be supported by clinical studies or pursued in the setting of a clinical trial approved by an institutional review board.
3. Practitioners need training in a new procedure before beginning its practice, and training should include a practical, “hands-on” component. All team members involved with radiation therapy decisions should participate in at least 5 proctored cases before performing similar procedures independently.
4. With respect to safety and physics recommendations:
  - a. The safety and emergency-response recommendations of AAPM TG-40 (Report 46)<sup>18</sup> and AAPM TG-56 (Report 59)<sup>19</sup> should be followed.
  - b. Until publication of the AAPM TG-100 report, the brachytherapy recommendations of AAPM TG-40 (Report 46)<sup>18</sup> should be followed.
  - c. Recommendations of AAPM TG-56 (Report 59),<sup>19</sup> TG-59 (Report 61),<sup>7</sup> TG-53 (Report 62),<sup>20</sup> and TG-128 (Report 128)<sup>21</sup> should be followed.
  - d. Calibration of HDR brachytherapy sources should use well-type ionization chambers calibrated in terms of air-kerma strength at a primary or secondary standards laboratory, and the institution’s calibration should agree with the manufacturer’s within 5%.
  - e. Source strength should be specified in a NIST-traceable quantity such as air-kerma strength; apparent activity is explicitly discouraged.<sup>22,23</sup>
5. Professional societies should accelerate generation of new or updated guidance documents for those disease sites listed in the introduction of [section 3 \(Clinical applications\)](#) and, while outside the charge of this panel, assess the need for updated guidance documents for accelerated partial breast irradiation using electronic brachytherapy.
6. Collaborative clinical trial groups should consider a trial designed to establish the preferred technique for biliary brachytherapy.

- The professional organizations should make it a priority to establish an event report database to gather and analyze events and generate potential guidelines to increase the safety of HDR brachytherapy.

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Adherence to this white paper will not ensure successful treatment. Furthermore, this white paper should not be deemed inclusive of all proper methods of care or exclusive of other methods reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific therapy must be made by the physician and patient in light of all circumstances presented by the individual patient. ASTRO assumes no liability for the information, conclusions, and findings contained in its white papers.

This paper was prepared on the basis of information available at the time the writing group was conducting its research and discussions on this topic. There may be new developments that are not reflected in this paper and that may, over time, be a basis for ASTRO to consider updating the paper.

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