A Review of Safety, Quality Management, and Practice Guidelines for High-Dose-Rate Brachytherapy

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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 reviews current 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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1. Introduction

This white paper was commissioned by the Board of Directors of the American Society for Radiation Oncology (ASTRO) to evaluate the status of safety and practice guidance for high-dose-rate (HDR) brachytherapy. The final document was approved by the Board on September 21, 2013, and has been 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 many of the other treatment modalities considered in this series of white papers on safety guidance, HDR remote-afterloading brachytherapy is a relatively mature technology dating back at least to the 1960s. Several organizations have developed practice guidance documents during this time. The charge was not to duplicate the efforts of previous documents or to consolidate those efforts into a single document; such a document would become too large and take too long to produce to provide a timely assessment of the need to supplement or complement the existing professional society documents. This review considers the guidance documents that exist at this time and whether they adequately address the safety needs of the current state of practice, given the 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/or by inappropriate clinical intentions or procedures. Given the maturity of HDR brachytherapy technology at this point, this white paper considers, from a safety point of view, the adequacy of general physics and quality assurance (QA) guidance as well as the clinical guidance documents that are 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 approximately 0.02%, or 8 events per 33,000 treatments per year, corresponding to 5-sigma performance nationally. The events have not been due to lack of guidance documents from professional societies but from either failures to follow the guidance-document recommendations that had been incorporated into departmental policy or human failures in the performance of tasks. There are recommendations for verification of information used in treatment planning; preventing such errors from becoming events requires QA adaptation specifically for an individual facility. Recommendations for that will be coming with the publication of the Task Group (TG)-100 report of the AAPM.

This white paper recommends that 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.

2. 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 have been addressed in a fairly comprehensive manner in a series of reports by the AAPM and other organizations. A listing of the documents and brief descriptions of what they cover can be found in the appendix.

2.1 HDR brachytherapy procedures

The order of procedural steps in brachytherapy cases exhibits a greater variety than typically found in external beam radiation therapy (EBRT). For example, the conventional tandem and ovoid application for cervical cancer places the applicator and then performs localization and dosimetry while a gynecological template implant may make localization images first, followed by dosimetry and insertion. This variation makes it challenging to map a general brachytherapy treatment process flow chart (see the 2 different example process maps in Figure 1). However, most brachytherapy procedures include the majority of the steps listed in Table 1, though the order of these steps is often specific to a particular application technique. Each different HDR brachytherapy process should include consideration of the 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.

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

HDR brachytherapy is a multidisciplinary treatment modality requiring coordination of several clinicians having a common goal to accurately and safely treat 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 members extend beyond the radiation oncology department and include surgical specialists, such as surgeons with expertise specific to the disease in which brachytherapy is intended. Though other hospital staff
such as nurses, anesthesiologists, and physician assistants, often provide important patient-care functions for HDR brachytherapy patients, the qualifications and roles of those team members directly involved with the radiation therapy decisions are outlined below. These qualifications and roles are based on the Safety is No Accident document and the AAPM TG-59 report (specific to HDR brachytherapy) where appropriate.

Qualifications

Radiation Oncologist

Certification in Radiation Oncology by the American Board of Radiology (ABR) or with some equivalent certification is required. Additional qualifications beyond initial certification are required by the ABR and available at: www.theabr.org. The physician must be licensed by the US Nuclear Regulatory Commission or an Agreement State to use the HDR brachytherapy unit for patient care. Additional training specific to the disease site(s) to be treated with HDR brachytherapy is required. If the radiation oncologist’s formal training did not cover a specific disease site, time should be spent visiting facilities with ongoing programs for receiving peer-to-peer training, such as required by the US Nuclear Regulatory Commission for new types of treatments regulated under title 10 of the Code of Fed-
Table 1. Common procedural steps for safe use of HDR brachytherapy

<table>
<thead>
<tr>
<th>Procedural step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placement of applicator or catheters</td>
<td>Surgery to place catheters or applicator(s) as needed, with particular attention to surgical safety, quality of applicator or catheter geometry with respect to the target, stability of the placement (over the time required for all treatments)</td>
</tr>
<tr>
<td>Localization</td>
<td>Definition of the patient anatomy and applicator or catheter geometry using CT, MR, ultrasound or radiographic imaging, or visualization</td>
</tr>
<tr>
<td>Treatment planning</td>
<td>Definition of target and critical normal tissue volumes by contouring on CT or other cross-sectional imaging; identification of the location of the catheters or applicator(s) in the patient, either planning the location(s), or defining the position(s); selection of source and trajectory constraints</td>
</tr>
<tr>
<td>Optimization</td>
<td>Determination of the optimal distribution of HDR source locations and dwell times to deliver the desired dose distribution</td>
</tr>
<tr>
<td>Plan evaluation</td>
<td>Review of the anatomy, applicator or catheter geometry, source constraints, and dose distributions to the target and normal tissues</td>
</tr>
<tr>
<td>Plan verification and QA</td>
<td>Final checks of all the planning information, including the doses to be delivered to the target and normal tissues</td>
</tr>
<tr>
<td>Physician prescription</td>
<td>Final prescription and directive for the application of the brachytherapy, to be finalized before any treatment occurs</td>
</tr>
<tr>
<td>Preparation for treatment</td>
<td>Transferring the treatment plan information to the HDR treatment unit system with associated QA checks; nursing preparations for patient and treatment</td>
</tr>
<tr>
<td>Pretreatment treatment-unit QA</td>
<td>Checks of HDR treatment unit, transfer tubes, and all other aspects of QA required before treatment</td>
</tr>
<tr>
<td>Catheter or applicator localization check</td>
<td>Verification of the location of the catheters or applicator(s) to be used for treatment to assure correct placement of HDR sources during treatment</td>
</tr>
<tr>
<td>Treatment</td>
<td>Delivery of the planned treatment, monitoring the progress of the source throughout</td>
</tr>
<tr>
<td>Verification</td>
<td>Posttreatment verification of complete source retraction; verification that the dwell times delivered matched those planned</td>
</tr>
<tr>
<td>Documentation</td>
<td>Verifying all appropriate documentation for the treatment</td>
</tr>
</tbody>
</table>

Abbreviations: CT, computed tomography; MR, magnetic resonance; HDR, high-dose-rate; QA, quality assurance.
eral Regulations Part 35.1000 (cf. USNRC 2012). This writing panel recommends direct observation of at least 5 patient treatments specific to each disease site prior to independently performing any HDR brachytherapy procedures. Ongoing self-audit and external audit of the clinical practice is recommended, as is vendor-provided training specific to brachytherapy applicators new to the radiation oncologist.

**Medical Physicist**
Certification in Therapeutic Medical Physics by the ABR, American Board of Medical Physics (ABMP) certification in Radiation Oncology Physics, certification in Radiation Oncology Physics by the Canadian College of Physicists in Medicine, or equivalent certification for the designation of Qualified Medical Physicist is required. Additional qualifications beyond initial certification are required by the ABR and available at: www.theabr.org. As with the radiation oncologist, if the medical physicist’s formal training did not include HDR brachytherapy, this panel recommends additional training, either formal training or visiting facilities with ongoing programs to receive peer-to-peer training (cf. USNRC 2012). This writing panel recommends direct observation of at least 5 patient treatments specific to each disease site prior to independently performing any HDR brachytherapy procedures. Ongoing self-audit and external audit of the clinical practice is recommended, as is vendor-provided training specific to brachytherapy applicators new to the medical physicist.

**Medical Dosimetrist**
Certification as a Qualified Medical Dosimetrist by the Medical Dosimetrist Certification Board (MDCB, www.mdcb.org) does not solely imply the dosimetrist is qualified to perform treatment planning and assist with HDR brachytherapy procedures. A qualified dosimetrist will have at least 2 years of training in HDR brachytherapy treatment planning for the specific disease site. This writing panel recommends direct observation of at least 5 patient treatments specific to each disease site prior to independently performing any HDR brachytherapy treatment planning. Vendor-provided training specific to brachytherapy applicators new to the medical dosimetrist is required.

**Radiation Therapist**
While some Agreement States may require operators of HDR brachytherapy units to be licensed radiation therapists, certification by the American Registry of Radiologic Technologists (AART, www.aart.org) as a Registered Technologist in Radiation Therapy, RT(T), does not solely imply the radiation therapist is qualified to perform HDR brachytherapy treatments. Similarly, the radiation oncologist may designate any qualified individual such as a radiation therapist, dosimetrist, medical physicist, or nurse to deliver the treatment. Vendor-provided training (or the equivalent in-house training if available) specific to the HDR brachytherapy unit and brachytherapy applicators is required. This panel recommends direct observation of at least 5 patient treatments specific to each disease site prior to independently delivering HDR brachytherapy treatments.

**Surgeon**
Certification is required by the American College of Surgeons (www.facs.org), or other surgical board approved by the American Board of Medical Specialties. Surgeons often specialize with a postresidency fellowship in a specific disease sites or in the field of surgical oncology. Additional training specific to the disease site(s) to be implanted for HDR brachytherapy is required. If the surgeon’s formal training did not cover HDR brachytherapy with a specific clinical applicator or surgical technique, time should be spent visiting facilities with ongoing programs for receiving peer-to-peer training. Direct observation is required of at least 5 patient treatments specific to each disease site prior to independently performing surgery for HDR brachytherapy procedures. This training is supplemented by vendor-provided training specific to brachytherapy applicators new to the surgeon. In collaboration with the radiation oncologist, ongoing self-audit and external audit of the clinical practice is recommended by this panel.

**Roles**

**Radiation Oncologist**
The radiation oncologist is the primary person responsible for the overall care given to the patient receiving HDR brachytherapy. Table 2.1 of the *Safety is No Accident* document indicates radiation oncologist involvement, and often leadership, in all the aspects of radiation therapy. This involvement is similar, yet more important, for HDR brachytherapy, which is generally a more resource-intensive radiation therapy modality than EBRT. The radiation oncologist is responsible for the quality of the brachytherapy implant. He or she must consult with the surgeon in advance to set a program for performing high-quality implants in general, and specific to the particular patient needs for any given implant. Patient follow-up is also conducted in concert with the surgeon.

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The radiation oncologist is responsible for image acquisition, the prescription, contour delineation, and treatment planning to balance target dose deposition while sparing critical structures through setting normal tissue dose constraints. Since HDR brachytherapy generally has fewer treatment fractions than EBRT, knowledge of edema and issues temporally influencing the implant quality must be considered.

Oversight of HDR brachytherapy treatment delivery is also required. From a regulatory perspective, the NRC has mandated (Information Notice 2012-08) that the radiation oncologist (authorized user) and authorized medical dosimetrist must be physically present throughout each HDR brachytherapy treatment, and be within the range of normal, unamplified human voice.

**Medical Physicist**

The medical physicist is the technical expert responsible for knowing the proper functionality of the HDR brachytherapy unit and related systems, such as those for patient imaging and treatment planning. He or she is responsible for acceptance testing, the HDR brachytherapy unit and treatment planning system (TPS) commissioning, and the development and implementation of the departmental quality management program (QMP). This includes periodic assessment of the HDR brachytherapy unit and TPS according to recommendations summarized in the Appendix.

On treatment days, the medical physicist verifies the intended accuracy of patient setup at the HDR brachytherapy unit and patient– applicator alignment with imaging or mechanical measurements, ensures agreement between the prescription and the treatment plan, and strives for its delivery while minimizing the likelihood of errors. Like the radiation oncologist, as mandated by regulatory guidance, the medical physicist is required to be present physically throughout each HDR brachytherapy treatment.

Further, the medical physicist is jointly responsible with the radiation oncologist to address the needed regulatory aspects for compliance, and for notifications of changes or if patients are not treated as intended. Extensive effort is needed by the medical physicist outside of direct patient interactions to ensure that clinical procedures are fluid and performed in an accurate and timely manner with confidence by all HDR brachytherapy team members.

**Medical Dosimetrist**

The primary role of the medical dosimetrist in HDR brachytherapy is treatment planning. He or she can work independently of the medical physicist, yet in concert to develop the treatment plan and prepare detailed written procedures that specify personnel workflow and which TPS options are to be used. The medical dosimetrist will work closely with the radiation oncologist to develop a treatment plan according to the treatment planning objectives to balance target dose deposition while sparing critical structures through setting normal tissue dose constraints. Once approved by the radiation oncologist, the medical dosimetrist will transfer the treatment plan data to the HDR brachytherapy unit, electronic medical record (EMR), and/or patient chart. Sometimes, the medical dosimetrist will be responsible for other tasks in HDR brachytherapy, such as radiation surveys and confirming applicator connections to the HDR brachytherapy unit.

**Radiation Therapist**

The radiation therapist is responsible for assisting the radiation oncologist with patient immobilization and imaging, and supporting the medical physicist or medical dosimetrist in data acquisition for treatment planning. For busy clinics, a dedicated radiation therapist will be trained as a brachytherapy technologist to specialize in this modality. Preceding patient treatment, the radiation therapist will perform daily QA for the HDR brachytherapy unit in accordance with the QMP developed by the medical physicist.

The operator of the HDR brachytherapy unit must perform the following tasks: deliver the treatment plan as generated by the medical physicist or medical dosimetrist, perform a timeout preceding treatment delivery, provide documentation throughout the treatment delivery process, accurately deliver the treatment after pretreatment review, and assist the radiation oncologist with patient discharge or in-patient transfer to a hospital ward. With the nationwide increase of enhanced security measures, the radiation therapist is primarily responsible for securing the HDR brachytherapy unit and providing quick entry to the treatment vault at the end of treatment or in an emergency, should the unit fail to retract the source into the parked position.

**Surgeon**

The principal role of the surgeon is to debulk the tumor when feasible, in pursuit of pathology-confirmed negative margins, and to implant the brachytherapy applicator or device. Advance coordination with the radiation oncologist is essential on the appropriate implantation technique. He or she will sometimes provide assistance with applicator removal.

In general, these roles are not disease-site specific except maybe for the surgeon.

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. The staffing recommendations in Safety is No Accident are recommended here for HDR brachytherapy. 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, respectively, are required. Thus, for a busy clinic having 1 HDR brachytherapy unit treating 50 HDR brachytherapy 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, respectively. Safety is No Accident did not address in detail the staffing needs for other nonphysician personnel, such as radiation therapists. For the same example, one-half FTE for a dedicated brachytherapy technologist would be appropriate. These estimates should be adjusted slightly upwards if the practice treats a preponderance of patients having 10 treatment fractions, such as for HDR accelerated partial breast irradiation (APBI) or slightly downwards if 3-fraction vaginal cylinder treatments are most common. Hospital administration should follow these staffing recommendations and also provide appropriate additional resources as identified by the HDR brachytherapy team to ensure success of the practice.

2.3 HDR brachytherapy source radionuclides

In the US, there currently is 1 radionuclide (192Ir) used for HDR brachytherapy. In the past few years, HDR brachytherapy using 60Co has become available outside the US with a remote afterloader that can use more than 1 source, such as 2 60Co sources, 2 192Ir sources, or both radionuclides in the same unit. This approach could diminish treatment times and provide better plan customization than use of a single HDR 192Ir brachytherapy source, but offers the 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 recent interest in other radionuclides such as 169Yb, 170Tm, and 170Co. 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 192Ir brachytherapy source designs, and dose sensitivity to design tolerances. These issues need to be resolved. While currently available HDR 192Ir brachytherapy sources all have similar dosimetric properties, remarkably different source or capsule designs or use of other radionuclides will require careful attention of the practitioner to properly integrate new sources into their clinical practice.

2.4 Reported medical events involving HDR brachytherapy

While there have been medical events with HDR brachytherapy, in general it has been a safe treatment modality, with a failure rate of approximately 0.01%-0.02% per procedure.5 The events that have happened provide guidance as to hazards to avoid. 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.2,9

Many of the reported events could occur with any type of HDR brachytherapy treatment. These include:

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 sorted by treatment type include:

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. Gynecological 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 of the events resulted from the person(s) 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 the task execution. These events highlight the importance of peer review and planning the quality management for HDR brachytherapy as discussed in TG-59 report and indi-
Safety and practice guidance for HDR brachytherapy

1. The loss of film and the movement to electronic imaging of HDR brachytherapy technology in the future: numerous anticipated challenges to maintaining safe use clinically. This constantly changing landscape leads to routinely being developed, tested, and implemented with new equipment, new procedures, and new uses for HDR brachytherapy in the future, leading to an increased number of possible processes, types of equipment, and clinical uses. Since each type of equipment, applicator, and clinical use often requires specific procedures to be used to ensure safe application of the technology, one of the increasingly difficult challenges is how to assure that all the variations are used with appropriate process control and quality management. From the simple problem of having more than 1 length of transfer tube to the use of different processes for different clinical procedures (though using the same afterloading device), managing the safe application across all the variations possible is becoming more challenging. New tools to help physicists and physicians manage this complicated landscape will be helpful.

2. The recent replacement of paper charts with EMRs has made it more difficult to draw pictures, which is important as such pictures are a particularly helpful way of describing implants and their relationship to the patient’s anatomy and disease. Though all EMRs allow the acquisition or scanning of drawn pictures, the entire process is different, and the ability to file, document, and review such images at the appropriate times during the clinical process may lead to problems if not used correctly.

3. In many centers, the traditional radiation therapy simulator has been replaced by a computed tomography (CT)-simulator, forcing significant changes in how the HDR brachytherapy procedures are performed. It is not clear that use of 3-dimensional (3D) imaging is better than fluoroscopy for any brachytherapy procedure, however, the dramatic changes associated with the change from fluoroscopy to CT are causing a time of adjustment that will come sooner than many practitioners will like. New procedures and methods are required, and physicians and staff have to learn new techniques. As always, this kind of change can lead to mistakes due to inadequate training, QA, or inappropriate procedures. Retaining fluoroscopy only for occasional HDR brachytherapy procedures could increase risk through loss of the familiarity with the imaging modality. Though the NRC database has not documented events related to this issue so far, this is an important area for continued vigilance.

4. The proliferation of devices, applicators, radionuclides used for various procedures, clinical techniques, and indications for brachytherapy treatment lead to an increased number of possible processes, types of equipment, and clinical uses. Since each type of equipment, applicator, and clinical use often requires specific procedures to be used to ensure safe application of the technology, one of the increasingly difficult challenges is how to assure that all the variations are used with appropriate process control and quality management. From the simple problem of having more than 1 length of transfer tube to the use of different processes for different clinical procedures (though using the same afterloading device), managing the safe application across all the variations possible is becoming more challenging. New tools to help physicists and physicians manage this complicated landscape will be helpful.

2.5 Quality management and checklists for HDR brachytherapy

The documents discussed in the appendix provide guidance for establishing a QMP for HDR brachytherapy. As noted above, the order of procedures for various types of brachytherapy cases vary with the particular application, as do the types of failure modes. Because of these differences, no one set of quality management procedures can apply to all cases, and trying to force a generalized program onto all cases creates a hazardous environment. The TG-59 report presents principles upon which to base an HDR brachytherapy QMP. The tools and process for crafting an effective QMP are discussed in the TG-100 report.

Checklists and forms can be useful tools in maintaining quality and prevention of errors. 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 the various stages of the 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 their societal website as models that facilities can use to craft their own forms.

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

The field of HDR brachytherapy is constantly changing, with new equipment, new procedures, and new uses routinely being developed, tested, and implemented clinically. This constantly changing landscape leads to numerous anticipated challenges to maintaining safe use of HDR brachytherapy technology in the future:

1. The loss of film and the movement to electronic images has great advantages, but it also brings challenges. It is often harder to read or manage the electronic images, and it is usually harder to draw on the e-image so others can review the new information. Though most users have already made the transition to using electronic images in some fashion, it is likely that the standard processes used have not been adapted appropriately in all clinics to make the process easy, efficient, and safe. The use, handling, availability, and documentation of images used within the brachytherapy process can be improved in many systems.

2. The proliferation of devices, applicators, radionuclides used for various procedures, clinical techniques, and indications for brachytherapy treatment lead to an increased number of possible processes, types of equipment, and clinical uses. Since each type of equipment, applicator, and clinical use often requires specific procedures to be used to ensure safe application of the technology, one of the increasingly difficult challenges is how to assure that all the variations are used with appropriate process control and quality management. From the simple problem of having more than 1 length of transfer tube to the use of different processes for different clinical procedures (though using the same afterloading device), managing the safe application across all the variations possible is becoming more challenging. New tools to help physicists and physicians manage this complicated landscape will be helpful.
5. The general complexity of medical care, and the continual increase in scheduling complexity for physicians, physicists, and others is a growing problem for safe HDR brachytherapy delivery; it can disrupt the crucial teamwork that is needed for safe placement of catheters, safe creation of HDR brachytherapy plans, and their delivery to the patient. We must constantly work to make possible the teamwork and crosschecking that is a crucial component of safe HDR brachytherapy treatments, even as the overall complexity of our medical system increases.

6. 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 that account for patient anatomy. New procedures for commissioning and new algorithm QA, plus new patient-specific planning checks will be required, as the dose calculation results will be more individualized, and more difficult to check with standardized procedures. Extreme care must be taken during the transition period from dosimetry that did not account for density-heterogeneity corrections to these more sophisticated dose-calculation algorithms, particularly near interfaces and regions of low (eg, air, lung) and high (eg, markers, implants) densities.

7. Current imaging options include, but are not limited to magnetic resonance (MR), CT, cone beam CT, megavoltage and kilovoltage portal imaging, fluoroscopy, portable x-rays, and ultrasound. New methods and imaging that can improve the daily verification of localization and dose delivery will likely be added into the treatment process. This will require additional resources to develop the use of the systems, to define the tolerances required, and to incorporate these new techniques into the routine treatment delivery process.

8. Treatment planning for HDR brachytherapy is expected to change dramatically, and will include the following:
   a. increasing use of diagnostic and functional imaging for target (volume) definition and definition of normal tissues to be avoided;
   b. increased integration or interdigitation of brachytherapy treatments with EBRT (or other ablative) treatments, requiring improved understanding of radiobiological differences between the modalities, and the generation of bio-effect relationships so the various therapies can be integrated knowledgeably;
   c. more adaptive brachytherapy, where the extent of treatment and/or total dose will be modified based on normal tissue or tumor response data from imaging or other physiological 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 of these new features require new training, development of protocols for safe use, and routine and patient-specific QA procedures so that plans developed with these new features are used safely.

9. Image guidance during the surgical implantation of catheters and other applicators is expected to increase dramatically. Many of the tools associated with image guided therapy (including devices like the da Vinci surgical robot), imaging-based surgery using real-time MR, and other types of image guidance are making their way into the OR. Each of these devices or techniques may help surgeons more successfully or precisely position catheters or other applicators for HDR brachytherapy treatment. As this technology becomes more routine, planning for HDR brachytherapy and the transmission of the details of the plan to the surgeon in the OR are expected to change dramatically, influencing the scope, precision, complexity and aggressiveness with which HDR brachytherapy treatments can be conceived and performed. Clearly the changes in precision, complexity, and operational aspects of these new techniques will lead to significant changes in safety procedures and QA needs.

10. A number of researchers are working on robotic devices specifically designed for robot-assisted or robot-performed needle placement for HDR brachytherapy procedures. Eventually these kinds of devices will replace some or all of the manual surgical techniques usually used today. Use of these devices will require greater attention to patient safety, as well as all the usual computer-controlled treatment issues that are currently being wrestled with in EBRT.

11. Potential growth in intraoperative techniques brings the need for more attention to contamination and sterilization risks and increased time constraints, and need for real-time image guided treatment planning.

12. The field faces increased concerns over control and security of brachytherapy sources during procedures, nonprocedure clinical hours and nonclinical hours. These issues will also impact additional staffing, storage, and security requirements.

Given the large number of changes to be expected in coming years within this field, it is clear that safety and quality will require that we continually monitor the
technology and techniques being developed for clinical use, and that safety and QA requirements and techniques be continually updated to appropriately address the constantly changing technology.

3. Clinical Applications

Consideration of safety in HDR brachytherapy immediately leads to consideration of the clinical application of the technology. The ACR periodically issues practice guidance documents for HDR brachytherapy.\textsuperscript{12} Topics addressed in ACR guidance include clinical evaluation, establishing treatment goals, informed consent, applicator insertion, image acquisition, treatment planning and delivery, and follow-up. Under the “Process of Brachytherapy Applicator Insertion” section, the document notes, “Each type of brachytherapy procedure has its own set of unique characteristics. The brachytherapy team should operate according to an established system of procedural steps that have been developed by the radiation oncologist and brachytherapy team members.” Thus, much of the process must be customized for a given practice.

Where applicable, the ACR document defers to other ACR guidance documents, such as the guidance for documentation. For “Qualification for Personnel,” board certification is required for the radiation oncologist and the medical physicist with the therapist staff requiring registration. “Patient Selection” covers a large number of sites, each with a 1-paragraph summary. Most of the recommendations come from investigative articles rather than from a professional society report. The ACR guidance describes the general aspects of an HDR brachytherapy QMP that should be followed. Other parts of the document are discussed under the appropriate headings below. In addition to the qualification of board certification, this panel recommends specific training in each particular procedure to be performed. The training can be from a combination of schools and individual tutorial, but should have a practical, “hands on” portion.

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

- cervix\textsuperscript{13, 14}
- vaginal cuff\textsuperscript{15}
- prostate\textsuperscript{16}
- sarcoma\textsuperscript{17}
- penis (with GEC-ESTRO)\textsuperscript{18}
- accelerated partial breast irradiation\textsuperscript{19}

Guidance documents for clinical brachytherapy are in preparation by the ABS for the following disease sites: skin, CNS, GI, lung/endobronchial, and esophagus.

In the following 7 subsections, the most prevalent clinical applications are considered. In each case, the focus is on what guidance exists from professional organizations to assist practitioners when performing HDR brachytherapy in these particular cases. The list does not attempt to be comprehensive; it would require a textbook to do so. Rather, the sections address those treatment modalities that lend themselves to consensus guidance and either have had guidance documents written or, in the opinion of the panel, should have guidance generated or updated. A notable omission is brachytherapy for head-and-neck cancer. While proven effective, head-and-neck brachytherapy is not practiced widely in the United States (although more than 200 articles have been published on the topic in the last decade). Moreover, it is an eclectic group of diseases, where moving a centimeter dictates a different protocol, making an overall guidance document difficult to assemble.

3.1 Brachytherapy for cancer of the cervix

Brachytherapy is integral in the curative management of cervical cancer and has been used for decades. A recent set of guidelines for brachytherapy for cervical cancer has been published by the ABS, replacing the previous guidelines from 2000.\textsuperscript{13, 14, 20} The ACR has also developed a set of criteria to judge the appropriateness of treatment.\textsuperscript{21, 22} This application of brachytherapy has changed substantially over the last 10 years. Relevant changes include the use of chemotherapy, recognition of the importance of treatment duration, and image guidance. At the same time, the number of cases in the US has continued to decrease, although the disease remains one of the leading causes for women’s death in the developing countries.\textsuperscript{23, 24}

Early-stage cervical cancer can be successfully treated by either primary surgery (radical hysterectomy) or radiation therapy with cure rates above 80% for stage IB-1 disease. Locally advanced-stage cervical cancers (IB-2 and above) should be treated with concurrent chemoradiation therapy, as phase 3 studies have demonstrated an approximate 10% absolute improvement in survival with the addition of chemotherapy, and surgically treated patients will invariably require postoperative radiation with higher late-toxicity rates. The most commonly used cisplatin dose is 40 mg/m\textsuperscript{2} weekly for 5 cycles during EBRT. Cure rates for locally advanced disease, stages IIB and IIIB, are as high as 70% and 50%, respectively.\textsuperscript{25-27} The new guidelines provide recommendations for doses when combining chemotherapy and brachytherapy.

Several studies have reported lower control of pelvic disease and survival rates when the overall radiation treatment duration is prolonged. Prolongation of the overall treatment time results in an increased failure rate of up to 0.6% per day in stage IB-IIA and 0.86% per day in stage IIB disease.\textsuperscript{28} Overall treatment time should be less than 8 weeks, and any planned interruptions or delays should be avoided. Fractionated HDR brachy-
therapy can be interdigitated with the EBRT. In addition, 2 HDR fractions per week can be safely given once whole-pelvic radiation therapy is complete. Beginning treatment too early for patients with large, bulky tumors and specifying the dose to point A may underdose the tumor volume and lead to poor local control.

Guidance documents also provide information to be included in a prescription, and include the time-dose pattern (total dose and dosing schedule), the dose per fraction given to point A, the technique to be used, and limiting criteria for the maximal doses or dose-rates to be given to the anterior rectal mucosa, bladder, and sigmoid. The radiation oncologist should work in close consultation with the medical physicist to obtain an acceptable treatment plan during image acquisition. After 45 Gy to the whole pelvis, the following fractionation schedules have been reported with control rates comparable to low-dose-rate (LDR) brachytherapy: 5-5.5 Gy × 5, 7 Gy × 4, and 8 Gy × 3. These schedules all approximate an LDR radiobiologically-equivalent dose of 75-85 Gy to point A.

Although prescribing adequate radiation doses and chemotherapy are important to enhance cure rates, technical expertise in placing the tandem and appropriate use of packing are equally important. The ABS guidance notes that the use of intraoperative abdominal ultrasound can be useful to guide and confirm tandem placement. Regardless of the treatment protocol, caution must be taken to avoid uterine perforation with the tandem during insertion. Ultrasound guidance during insertion can help prevent the occurrence of a perforation. CT or MR images made for dose calculation should be reviewed carefully to pre-empt treatment with an undetected perforation.

As reported by the Quality Research in Radiation Oncology (QRRO) group, there is an increased likelihood that a radiation treatment meets established quality standards at academic institutions and at facilities that see more than 500 new patients per year.

One of the most dramatic changes occurred in image guidance and the recommendations of Groupe Européen de Curieothérapie-European Society for Radiotherapy and Oncology (GEC-ESTRO) for target delineation through magnetic resonance imaging. The GEC-ESTRO approach calls for sculpting the dose distribution to the delineated target and prescribing the dose with respect to the target coverage, similar to the approach used in EBRT, rather than using the conventional point A. Implementation of this approach is evolving in the US.

### 3.2 Brachytherapy for cancer of the endometrium

Guidance documents for HDR brachytherapy treatment of cancer of the endometrium posthysterectomy come from the ABS, formerly in a 2000 document, with an update in 2012. The practice has changed in some respects since the 2000 document, with a greater emphasis on the use of vaginal brachytherapy rather than EBRT for select patients with surgically staged disease. A common theme in all of these documents is the importance of verifying the applicator diameter prior to insertion and the importance of confirming applicator placement prior to treatment. For applicators with fixed geometries and dwell positions, the need for individualized treatment planning for each insertion has not been emphasized as it has been for cervix brachytherapy, but a plan should be generated for the first fraction at a minimum. Standard plans are quite acceptable in such approaches. A large number of dose and fractionation schedules have been used successfully, and practitioners should be familiar with those regimens in the guidance documents and the discussions about them before establishing a treatment program. A clear understanding of the fraction size, total dose, and where the dose is specified, as well as an effective process for communication with the HDR brachytherapy team, is integral to safe treatment delivery. A system of checks and independent second checks must also be in place.

Brachytherapy is also applied to the intact endometrium in inoperable cases. Such cases are few compared with posthysterectomy treatments. The existing guidance document is a section of the ABS report from 2000. There are numerous approaches to this treatment, with some summaries of treatment experiences in the literature since the 2000 paper. Given the variety of approaches, it is not clear that a consensus guidance document is appropriate at this time.

### 3.3 Brachytherapy for cancer of the prostate

Brenner and Hall’s seminal paper in 1999 on the radiobiology of prostate cancer first suggested that the $\alpha/\beta$ ratio for the prostate was lower than previously believed. This initiated a paradigm shift in fractionation for prostate cancer and also affected clinical trial design for both EBRT and brachytherapy. Important clinical trials are just beginning to be reported and other ongoing trials will likely have significant impact on future clinical practices.

Early studies utilized HDR prostate brachytherapy in conjunction with conventionally fractionated EBRT to take advantage of brachytherapy’s dosimetry. The clinical advantage of dose escalation using HDR brachytherapy as a boost, combined with EBRT, was demonstrated by 1 retrospective and 2 randomized studies that suggested an HDR brachytherapy boost, compared to EBRT alone, led to improved efficacy as well as less toxicity. The results of these trials strongly suggest there is good rationale for using HDR brachytherapy boost for dose escalation in prostate cancer.

To further exploit prostate cancer’s low $\alpha/\beta$ ratio using hypofractionation, several studies have demon-
Further exploration of fraction reduction may be worthwhile as it would: (1) improve treatment accuracy, (2) decrease patient hospital stay, and (3) improve resource utilization. The feasibility of single fraction HDR brachytherapy boost and HDR monotherapy have been recently published.

Another important emerging application for HDR prostate brachytherapy is for salvage treatment of previously irradiated patients. Local failure after EBRT represents a significant therapeutic challenge in urology. As a result of the flexibility and accuracy of HDR brachytherapy, pilot studies have demonstrated the feasibility of re-irradiating patients with success. These re-irradiations must be done with excellent treatment planning techniques and expertise to avoid the potential risk of late toxicities. Furthermore, long-term results and larger studies are needed to confirm these promising early results.

The first, and only, prospective multi-institutional prostate HDR brachytherapy trial was completed by the Radiation Therapy Oncology Group (RTOG). This trial showed HDR prostate brachytherapy boost (9.5 Gy × 2) is safe and feasible. The protocol also developed a quality assurance mechanism for future HDR brachytherapy research. The completion of this study helped develop the basic guidelines for patient selection, transrectal ultrasound (TRUS)-guided implant technique, CT-based treatment planning, and dosimetry specification parameters for HDR prostate brachytherapy. The ABS recently published a guidance document for HDR prostate brachytherapy that focuses on patient selection and application of the technique.

There have been numerous technical studies performed in HDR prostate brachytherapy. One of the well-known challenges is catheter migration between fractions, which can degrade the dose distribution. Various institutions have developed their own solutions to address this issue. Since there are a variety of different methods to implant and secure catheters, the solution to the problem needs to be adaptable to individual practice and patient anatomy. This panel recommends the clinical guidance of this ABS report be followed for HDR prostate brachytherapy as appropriate.

### 3.4 Brachytherapy for partial breast cancer

APBI is an umbrella term describing a radiation technique in which only the tylectomy cavity and a rim of adjacent breast tissue are treated. Since only a portion of the breast is irradiated, larger fraction sizes are prescribed, most often administered twice daily with an overall treatment duration of 4-5 days rather than 6-7 weeks, thus accelerating the treatment. Other treatment regimens have been used and may be used in the future. Although brachytherapy can be utilized as boost therapy after EBRT, it is now more commonly used as monotherapy following breast-conserving surgery.

The data supporting APBI has been generated from single-institutional phase 1/2 studies and a recently reported phase 3 study. Local control rates from these studies with 5-10 years of follow-up are greater than 95%, consistent with historical control rates from whole breast irradiation series. In series in which cosmetic results are reported, the rates of good to excellent results range from 75%-100%. The current phase 3 trials of the National Surgical Adjuvant Breast and Bowel Project (NSABP) B39/RTOG 0413 and GEC-ESTRO are comparing conventional whole breast irradiation to APBI utilizing interstitial or intracavitary brachytherapy, or 3D-conformal EBRT.

Appropriate patient selection for APBI is key for successful outcomes and not all candidates for breast preservation are necessarily candidates. Selection criteria have varied in selected series. The randomized RTOG/NSABP study enrolled patients with broader clinical and pathologic selection criteria with the goal of evaluating whether a specific cohort may be at higher risk with APBI. The trial allows age over 18 years, any histology (ductal carcinoma in situ [DCIS], invasive ductal or lobular), tumor size up to 3 cm and up to 3 axillary lymph nodes involved with metastatic disease along with some other pathologic higher-risk features like higher grade, and ER negativity. Additionally, various techniques of APBI have individual technical selection criteria based upon their dose modulation capabilities. The advent of multilumen intracavitary devices combined with 3D treatment planning software has allowed more patients to be treated due to less anatomic restrictions of skin or chest wall spacing and tissue conformance.

While HDR brachytherapy for partial breast irradiation dates to the mid-1990s, most of the publications have been within the last 10 years. Over the last 5 years, the pattern of brachytherapy has changed from predominantly interstitial to intracavitary, and the number of applicators has proliferated. With the change to intracavitary brachytherapy, analysis of the dosimetry has been refined recently, particularly with respect to the effects of inhomogeneities in and around the applicators, and due to the air in the ribs and lungs of the patient and the air outside the patient.

Another major change in this treatment modality has been the advent of electronic intracavitary units. For electronic brachytherapy, ASTRO published a guidance document in 2010. Because this document was published early in the development of this treatment modality, it likely will require revision in the near future. The AAPM has Task Group 182 in the process of generating recommendations for quality management of electronic brachytherapy units and procedures.
ASTRO, ESTRO, and the ACR have published consensus statements regarding proper selection criteria, along with level of supporting evidence. Some documents give a range of doses, the most common through the literature is 34 Gy delivered in 10 fractions over 5 days. The most recent guidance document is that of the ABS. In addition, there is a fairly comprehensive textbook on the topic, however, the book does not represent consensus. Thus, a brachytherapy-specific, technical guidance document is needed for this modality, and the ABS is in the process of generating one.

### 3.5 Intraluminal brachytherapy

HDR brachytherapy has been used for many intraluminal applications, particularly in the bronchus, esophagus, and biliary duct. The goal of most of these treatments is palliation, although some reports address treatments with curative intent.

#### Esophageal cancer

Of these anatomical sites, a consensus guidance document exists only for esophagus, and that, from the ABS, dates from 1997. The guidelines cover brachytherapy both in curative and palliative settings. Since that time, while not a large number of papers have been published on the topic, several have reported on the results of clinical trials or the experience of an investigator. Some of the articles discuss technique advances or the recommendations of the author. One 2002 consensus document discussing HDR brachytherapy in general terms, contains a paragraph on esophageal brachytherapy. The report of a clinical trial (RTOG 9207) comparing EBRT and intraluminal brachytherapy with and without combination chemotherapy, found grade 3 toxicity in almost 60% of the patients, grade 4 toxicity in 24%, and fatalities in 10%. The EBRT used simple ports and no inhomogeneity corrections, and the brachytherapy dose distribution was not optimized. Kumar et al also report on a similar trial using a single chemotherapy agent, observing increases in the chemotherapy arm of ulcers (15% compared to 5%) and strictures (28% vs 13%). While the EBRT portion of the radiation therapy used 3 fields rather than parallel-opposed and corrected for tissue densities, the brachytherapy was still basic. Rosenblatt et al found that adding EBRT to brachytherapy improved overall survival for the first 450 days, but the advantage diminished after that. Trials have shown that stents relieve symptoms immediately and with a duration out to a year, but brachytherapy provides longer lasting relief and better quality of life, even when delivered in a single fraction. However, the combination of stent and brachytherapy causes high rates of complications. Brachytherapy in combination with argon plasma coagulation (APC) is more effective than APC alone and had equivalent results as APC and photodynamic therapy, but with fewer complications and better quality of life. Given the benefits seen in palliation and rendering some tumors operable, and the advances in both EBRT and brachytherapy since the guidance document, the panel recommends that the professional societies generate a guidance document for esophageal brachytherapy.

#### Endobronchial brachytherapy

The ABS published a guidance document for endobronchial brachytherapy in 2001. Since that time, as with the esophageal situation, significant papers have been published, mostly reporting on the experience of the authors. While most have concluded that the treatment modality provided effective treatment, not all have been supportive and some have reported serious toxicities in portions (5%) of the patient population. Most of the papers consider the patient characteristics for which this treatment would prove beneficial and patient factors potentially related to toxicities. Many of the authors recommend further trials. Reveiz et al performed a meta-analysis for treatment effectiveness for non-small cell carcinoma using the Cochrane Central Register of Controlled Trials. They concluded that for palliation, EBRT alone was more effective than endobronchial brachytherapy alone, and were unable to conclude that brachytherapy and EBRT was superior to EBRT alone. Because of the disparate nature of the data, it is not clear how the conclusion would apply to any given treatment regimen. This panel recommends a consensus panel review the existing data and determine whether there is sufficient information to call for a guidance document.

#### Bile duct brachytherapy

In the late 1990s and through the 2000s, several papers showed a survival benefit from the addition of brachytherapy to the treatment of bile duct tumors. While some considered LDR brachytherapy applications, most used HDR brachytherapy. More recent reports have considered combination therapy, including chemotherapy, and still show a distinct advantage to including brachytherapy. Nakamura et al proposed a volume-dose criterion for predicting duodenum toxicity, although most of the papers report little toxicity related to the brachytherapy. Unfortunately, the articles report on many disparate treatment regimens, and several call for a national trial to provide sufficient number of patients to make a definitive determination an appropriate prescribed dose. Given that the reports show a distinct benefit in increasing survival duration, this writing panel recommends that a guidance document on this practice be written and that a clinical trial for biliary duct brachytherapy be considered.

### 3.6 Intraoperative brachytherapy

Intraoperative radiation therapy (IORT) using HDR brachytherapy typically applies radiation therapy to a
tumor bed or the tumor at the time of surgery. However, due to the radiobiological disadvantage of applying a large single dose of radiation, IORT using HDR brachytherapy is generally given as a radiation therapy boost with EBRT to follow. An advantage is the ability to move critical structures away from the target area physically (or through use of internal shielding) to permit delivery of a single fraction of high-dose radiation. However, due to the radiobiological disadvantage of applying a large single dose of radiation, IORT using HDR brachytherapy is generally given as a radiation therapy boost with EBRT to follow. IORT also may be given as monotherapy for early-stage breast cancer. The conventional approach of obtaining 3D imaging of the region to be implanted is generally not possible, and image datasets taken preceding surgery do not match well with the geometry of the patient following surgery. The most common radiation source is $^{192}$Ir, but electronic brachytherapy sources have been used with increasing success to mitigate the need for extensive shielding of the operative environment. Alternatively, a sterile lead-lined box may be assembled for use within the operating room, or the patient can be transported to the radiation oncology department.

IORT safety risks include addressing the rush to plan and deliver the therapeutic dose while the patient is compromised in the surgical suite. IORT applicators are often customized right up to the time of brachytherapy delivery and there is potential for error. Catastrophic events can occur if the proper team, training, and processes are not in place.

### 3.7 Skin brachytherapy

The recent rapid rise in the use of HDR skin brachytherapy in the US is thought to be due to a combination of an increasingly aging population living long enough for the development of skin cancers due to skin damage received decades before, and an increase in HDR brachytherapy units combined with a decrease in superficial treatment machines.

Modern skin brachytherapy can provide quick and simple treatment to small flat lesions or a superior dose distribution across complex superficial targets such as face, scalp, highly curved surfaces, perineum, hands, and feet. The sharp dose gradient can be customized to the shape and depth of skin cancers as well as benign conditions, such as keloid prophylaxis. Treatment series have been reported in squamous cell, basal cell, and merkel cell carcinomas, melanoma, cutaneous lymphoma, extramammary Paget’s disease, and keloids. Definitive and palliative treatments have been described with appropriate dose and fractionation schemes.

Solid applicators can be applied to small circular lesions of defined diameter. It is not possible to image with the applicator in place, so preprocedural imaging should be used to determine the treatment depth. For applicators without shape-defining shielding, standard treatments based on the applicator size and target depth may be used. For more complex lesions, a surface mold may be applied, for example, using wax, Aquaplast® (WFR-Aquaplast and Qfix Systems, Avondale, PA), SuperFlab (Civco, Orange City, IA), or simple polyvinylchloride mesh to hold catheters in place. In such cases, the clinical targets should include the gross lesion as well as a clinical target margin and the clinical target depth, preferably determined using CT or MR imaging (MRI) with the applicator in place. Selective use of hypofractionation can safely be practiced where there is little normal late responding tissue at risk. ABS practice guidelines for skin brachytherapy are in preparation.

### 4. Key Measures to Avoid Catastrophic Failures

The following benchmarks provide facilities with 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 the AAPM Task Group 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 the ABS when available for the treatment site.
5. Treatment plans and programs are checked through independent verification before treatment delivery.
6. Daily QA checks of the HDR brachytherapy system are performed before any treatment.

### 5. Summary

Safety in HDR brachytherapy requires careful and consistent attention to all facets of the brachytherapy process. The technical guidance for these procedures has been well established and documented, and these established technical guidance documents should be followed for all procedures. The AAPM has been vigilant and has continued to develop guidance documents to keep up with advancing technology, and ESTRO has also provided considerable guidance for medical physicists.
Safe application of HDR brachytherapy also depends on appropriate clinical decisions on its use, and useful information is often available from clinical guidance documents prepared by the relevant professional societies. While some of the clinical guidance documents for HDR brachytherapy remain current, professional societies (particularly the ABS) have revised those for several clinical sites (gynecological, prostate, and breast) that had fallen out of date to include details necessary for clinical practitioners and those references are provided in this white paper.

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

1. Practitioners should become familiar with all the guidance documents relevant to any procedure they plan on initiating before beginning the practice.
2. Practitioners should follow the recommendations in relevant guidance documents. 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.
3. Practitioners need to receive training in a new procedure before beginning its practice, and the training should include a practical, “hands-on” component. All team members directly involved with the 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 Task Group 40 (Report 46) and AAPM Task Group 56 (Report 59) should be followed. The brachytherapy recommendations of AAPM Task Group 40 (Report 46) should be followed. The authors would note that once the TG-100 failure mode and effect analysis (FMEA) process is widely adopted in the radiation oncology community, the TG-40 recommendations are likely to be updated.
   b. Recommendations of AAPM Task Group 56 (Report 59), Task Group 59 (Report 61), Task Group 53 (Report 62), and Task Group 128 (Report 128) should be followed. 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 that of the manufacturer’s within 5%.
   c. Source strength should be specified in an NIST-traceable quantity such as air-kerma strength; apparent activity is explicitly discouraged.
   d. Source strength should be specified in an NIST-traceable quantity such as air-kerma strength; apparent activity is explicitly discouraged.
5. Professional societies should accelerate the generation of new or updated guidance documents for those disease sites listed in the introduction of section 3 of this document, and while outside the charge of this panel, assess the need for updated guidance documents for APBI using electronic brachytherapy.
6. Collaborative clinical trial groups should consider a trial designed to establish the preferred technique for biliary brachytherapy.
7. The professional organizations, particularly the AAPM, should make it a priority to establish an event report database to gather and analyze events, and to generate potential guidelines to increase the safety of HDR brachytherapy.

References


7. Appendix: Existing General Safety and Quality Guidance

7.1 AAPM Guidance Documents

The following AAPM reports describe important aspects of brachytherapy and HDR brachytherapy safety procedures that this writing panel recommends for any HDR brachytherapy practice. While Report 41 is an early review of HDR brachytherapy, much of its contents remain valid. In the list below, only the report of TG 40 needs an update; AAPM Task Group 100 is focusing on this topic.

There are several other AAPM task groups underway, specifically covering HDR brachytherapy sources such as dose calculations, quality standards, source calibrations, and evaluation of new TPS dose calculation algorithms. Each of these AAPM reports address safety and should be followed for the safe practice of HDR brachytherapy.

AAPM Report 41: Task Group 41. Remote Afterloading Technology

Report 41 was published in 1993 and outlined the first operational standards for remote afterloaders, focusing on HDR Ir brachytherapy sources yielding dose rates greater than 0.2 Gy/minute. Included are special considerations to address for facility design and acceptance testing procedures upon receipt from the manufacturer. Following remote afterloader acceptance, recommendations are provided for source calibration procedures, with acceptable tolerances, and QA procedures for the efficacious use of HDR remote afterloading systems. This panel recommends following the radiation control practices and emergency response procedures of AAPM Report 41.

AAPM Report 46: Task Group 40. Comprehensive QA for Radiation Oncology

Report 46 is the 1994 Task Group 40 report that included recommended QA tests for both EBRT and brachytherapy. General principles applicable to both fields are development of a QMP and a policies and procedures manual, identification of departmental resources needed for the safe operation of the clinic, and installation of a culture committed to quality through establishment of a QA Committee, regular quality audits, and continuous quality improvements.

Specific to brachytherapy, explicit description of the source physical and chemical forms along with the source encapsulation is required. Because HDR brachytherapy is largely radionuclide based, dose rate distributions depend heavily on the physical distribution of the radionuclide and source uniformity. The inventory for brachytherapy sources is often more variable than for EBRT, with multiple sources appearing visually identical. Identification of sources and quality procedures to accurately identify the source(s) needed for a permanent or temporary implant was recommended. Report 46 built off Report 41, requiring traceability of source calibrations to the NIST or an Accredited Dosimetry Calibration Laboratory (ADCL). Requirements for the instrumentation to measure source strength were specified to use reentrant well-type air ionization chambers with atmospheric communication. A joint report by the AAPM and ESTRO is underway on source calibration practice and recommended tolerances between manufacturer and the clinic. This report will follow the approach given by Butler et al for the AAPM Guidelines for low-energy photon-emitting source calibrations.

This panel recommends the AAPM quality guidance on brachytherapy applicators, and positioning of the sources and dummy markers within these applicators. A series of tests were given for brachytherapy TPSs and resultant dose calculations. Further, recommended safety practices for patient treatments and documentation completed the necessary standards for general brachytherapy physics quality procedures.

A joint ESTRO-AAPM report on clinical dose calculation uncertainties is in progress, addressing observed uncertainties for HDR Ir brachytherapy of the breast, prostate, and for gynecological applications. Until this report is available, this panel recognizes the accepted level of accuracy for brachytherapy dose delivery indicated in AAPM Report 46 as 15%, considerably larger than the 5% level typically identified for EBRT.

Because of the changes in brachytherapy since Report 46 and the coming report of Task Group 100, some of the recommendations in this report may be superseded, and this report may need to be revised in the near future.


The AAPM Report 59 is the 1997 Task Group 56 report and provided additional quantitative tests and standards beyond AAPM Report 46. The frequency and tolerances of these tests were specified. In general, a source positioning tolerance of ± 2 mm relative to the brachytherapy applicator was recommended, along with a temporal tolerance of ± 2% for dwell times in remote afterloading equipment. The accuracy of computer-generated doses in a homogeneous water medium should be within ± 2% relative to that calculated directly from the supplied input data. In agreement with the AAPM, this panel recommends a maximum tolerance of 5% between manufacturer provided air-kerma strength and that measured in the clinic for individual sources, such as an HDR Ir brachytherapy source. Until the joint AAPM-ESTRO report on calibration guidelines for high-energy
 photon-emitting brachytherapy sources is available, the Code of Practice in AAPM Report 59 should be followed.

### AAPM Report 61: Task Group 59. High Dose-Rate Brachytherapy Treatment Delivery

The AAPM Report 61 is the 1998 Task Group 59 report specific to HDR brachytherapy.\(^3\) Many operational and safety issues were examined, along with special attention to treatment delivery errors, their causes, and safety practices to instill toward minimizing their likelihood. Example forms, procedures, checklists, and documentation practices were given and should be customized for each clinic. Workflow diagrams outline recommended operational activities for clinics having either 1 or more physicists. Key items to review when checking the HDR brachytherapy treatment plan are identified. Additionally, a wealth of information and recommendations are provided for patient preparation, implant placement and treatment, and posttreatment QA. The process of data transfer from the TPS to the treatment control workstation is considered. Finally, practical information is given on emergency procedures, related equipment, and categorization of emergency instances. This panel recommends the guidance of AAPM Report 61 be followed for HDR brachytherapy treatment delivery.

While the AAPM Report 84 on low-energy photon-emitting brachytherapy sources provides recommendations for dose calculations such as 2% agreement between doses calculated by the RTP system and the expected doses,\(^1\) a joint AAPM-ESTRO report specific to high-energy photon-emitting brachytherapy sources such as HDR \(^{192}\)Ir and \(^{60}\)Co is recommended.\(^1\)


The AAPM Report 62 is the 1998 Task Group 53 report covering both EBRT and brachytherapy (LDR and HDR) treatment planning.\(^1\) Specific to HDR brachytherapy, comparisons between TPS and reference/benchmark plans should be prepared for single- and multiple-source plans. Additionally, several nondosimetric tests of brachytherapy TPS were recommended, such as display of source physical length and diameter, source active length and diameter, source positioning, source decay, and other planning tools like optimization, dose–volume histogram generation, and digitally reconstructed radiograph generation. Practical aspects are given on data entry for brachytherapy dosimetry parameter reference datasets. Specific to HDR brachytherapy, there is concern for depiction and documentation of the source trajectory. This panel recommends the guidance of AAPM Report 62 be followed for brachytherapy TPS QA.


The AAPM Report 128 is the 2008 Task Group 128 report that covers ultrasound probe usage for both permanent LDR prostate brachytherapy using low-energy photon-emitting sources as well as temporary HDR prostate brachytherapy using high-energy photon-emitting sources.\(^1\) Specifics are given on optimal probe use through adjusting system settings and controlling probe placement. Dozens of quality control tests are identified, with frequencies and tolerances to permit accurate spatial reconstruction and consistently high-quality images. Methods are provided for integration of the ultrasound probe with the system display, brachytherapy templates, and TPS. Techniques show how to resolve imaging artifacts. Example quality control documents are included in the report. This panel recommends the guidance of AAPM Report 128 be followed for HDR prostate brachytherapy ultrasound QA.

### 7.2 Other Guidance Documents

In addition to the AAPM, other professional societies have issued guidance documents on HDR brachytherapy physics that this panel endorses.

### American College of Radiology

The ACR has 2 relevant standards documents that provide a general description of HDR brachytherapy practice and physics.\(^1\) This panel recommends following these ACR guidance documents as appropriate.

### The European Society of Radiotherapy and Oncology

The ESTRO Booklet 8 from 2004 on A Practical Guide to Quality Control of Brachytherapy Equipment is a full-length book detailing quality procedures for brachytherapy, including HDR brachytherapy.\(^1\) While some of the procedures, such as calibration of a HDR \(^{192}\)Ir brachytherapy source in air, are considered outdated because of the uncertainties involved, most of the material remains current and this panel recommends following these quality procedures for HDR brachytherapy where there is not direct overlap with other AAPM, ACR, or ASTRO guidance.
The International Atomic Energy Agency (IAEA)
Finally, the IAEA has written a technical report on HDR brachytherapy devices, TECDOC – 1257 Implementation of Microsource High Dose Rate (mHDR) Brachytherapy in Developing Countries, but this is simply an overview for hospital administrators in developing countries and does not provide new safety guidance. The IAEA also has a technical report, TECDOC – 1274, on the calibration of brachytherapy sources, that includes recommendations on calibration of HDR $^{192}$Ir sources using in-air measurements or re-entrant well ionization chambers with calibrations traceable to a primary or secondary calibration standard. As recommended in this IAEA TECDOC, this panel recommends only that clinical medical physicists adopt the second method.

7.3 Guidance Document Summary
In summary, given the nearly 50 years of experience with HDR brachytherapy devices and clinical application, it is not surprising that the status of general guidance documents dealing with safety, quality, and physics for HDR brachytherapy is relatively complete and remains current and adequate.

Safe and appropriate use of HDR brachytherapy requires that the users follow these established guidance documents and procedures, and not become complacent in their attention to safety. Lack of attention to these procedures can lead to errors or accidents. As described by the International Commission on Radiation Protection (ICRP), there were more than 500 HDR brachytherapy accidents (including 1 death) reported along the entire chain of procedures from source packing to delivery of dose before 2005 worldwide. Since that time, in the United States the rate has stabilized at less than 10 events per year of all kinds, for an error rate of about 0.024%, as noted above. Even though the treatment modality has become remarkably safe, this panel recommends that aforementioned safety and quality guidance be followed faithfully.