The Status of Guidance for Safety, Quality Management and Practice for High Dose-Rate Brachytherapy

Bruce R. Thomadsen (Chair)
Departments of Medical Physics and Human Oncology
University of Wisconsin
Madison, Wisconsin

Beth A. Erickson
Department of Radiation Oncology
Medical College of Wisconsin
Milwaukee, Wisconsin

Patricia J. Eifel
Department of Radiation Oncology
M.D. Anderson Cancer Center
Houston, Texas

I-Chow (Joe) Hsu
Department of Radiation Oncology
University of California San Francisco
Helen Diller Family Comprehensive Cancer Center
San Francisco, California

Rakesh R. Patel
Western Radiation Oncology
Mountain View, California

Daniel G. Petereit
Department of Radiation Oncology
John T. Vucurevich Cancer Care Institute
Rapid City Regional Hospital
Rapid City, South Dakota

Benedick A. Fraass
Department of Radiation Oncology
Cedars-Sinai Medical Center
Los Angeles, California

Mark J. Rivard
Department of Radiation Oncology
Tufts University School of Medicine
Boston, Massachusetts
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I. Introduction
The white paper was commissioned by the Board of the American Society for Radiation Oncology (ASTRO) to evaluate the status of safety and practice guidance for high dose-rate brachytherapy. Unlike many of the other treatment modalities considered in this series of white papers on safety guidance, high dose-rate (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 very large and take too long to produce to provide an timely assessment of the need to supplement or compliment the existant documents. The review below 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 two ways: by failures of the persons or equipment involved to perform as intended, and by inappropriate clinical intentions or procedures. Given the maturity of the HDR technology at this point, this 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 0.024%, or 8 events per 33,000 treatments per year, corresponding to five sigma performance.¹ The events have not been due to lack of guidance but either failures to follow the guidance 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 planning²; preventing such errors from becoming events requires adaptation of quality assurance specifically for an individual facility. Recomendations for that will be coming with the publication of the report of Task Group 100 of the AAPM.³

This whitepaper 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 report does not make any new guidance recommendations; it does suggest topics for which new guidelines are needed, and such recommendations will be noted as coming from the panel of authors.

II. General Guidance Documents
Safety and quality in HDR brachytherapy depend on some fairly obvious 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 very complete manner in a series of reports by the AAPM and other organizations.
II A. AAPM Guidance Documents

The following AAPM reports describe important aspects of brachytherapy and HDR safety procedures that this panel recommends be followed in any HDR practice. While Report 41 is an early review of HDR brachytherapy, much of its contents remains valid. In the list below, only Report 46 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 treatment planning system (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: Remote Afterloading Technology

Report 41 was published in 1993 and outlined the first operational standards for remote afterloaders, focusing on HDR Ir 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 quality assurance 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: Comprehensive QA for Radiation Oncology

Report 46 is the 1994 Task Group 40 report that included recommended quality assurance tests for both external beam radiotherapy and brachytherapy. General principles applicable to both fields are development of a quality management program 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 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 external beam radiotherapy, 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 National Institute for Standards and Technology (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
the European Society of Therapeutic Radiology and Oncology (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. (2008) 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 treatment planning systems (TPS) 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 $^{192}$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 external
beam radiotherapy.

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.

**AAPM Report 59: Code of Practice for Brachytherapy Physics**

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 $^{192}$Ir 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: High Dose-Rate Brachytherapy Treatment Delivery**

The AAPM Report 61 is the 1998 Task Group 59 report specific to HDR brachytherapy.
Many operational and safety issues were examined, along with special attention to
treatment delivery errors, their causes, and safety practices to instill towards 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 one 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 post-treatment 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, a joint AAPM-ESTRO report specific to high-energy photon-emitting sources such as HDR $^{192}$Ir and $^{60}$Co is in press. 

**AAPM Report 62: Quality Assurance for Clinical Radiotherapy Treatment Planning**

The AAPM Report 62 is the 1998 Task Group 53 report covering both external beam radiotherapy and brachytherapy (LDR and HDR) treatment planning. Specific to HDR brachytherapy, comparisons between treatment planning system (TPS) and reference/benchmark plans should be prepared for single- and multiple-source plans. Additionally, several non-dosimetric tests of brachytherapy TPS were recommended such as display of source physical length and diameter, and of 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.

**AAPM Report 128: Quality Assurance tests for prostate brachytherapy ultrasound systems**

The AAPM Report 128 is the 2008 Task Group 128 report that covers ultrasound (US) 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. 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 US 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.

**II B. Other Guidance Documents**

In addition to the AAPM, other organizations have issued guidance documents on HDR brachytherapy physics that this panel endorses.
American College of Radiology
The ACR has two relevant standards documents that provide a general description of HDR brachytherapy practice and physics. The documents give general guidelines with little substance directly related to safety issues.\textsuperscript{12, 13} This panel recommends following these ACR guidance documents as appropriate.

The European Society of Therapeutic Radiology and Oncology
The ESTRO Booklet 8 from 2004 on \textit{A Practical Guide to Quality Control of Brachytherapy Equipment}\textsuperscript{14} is a full-length book detailing quality procedures for brachytherapy, including HDR brachytherapy. 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 devices, TECDOC – 1257 \textit{Implementation of Microsource High Dose Rate (mHDR) Brachytherapy in Developing Countries},\textsuperscript{15} 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,\textsuperscript{16} that includes recommendations on calibration of HDR $^{192}$Ir sources using in-air measurements or reentrant well ionization chambers with calibrations traceable to a primary or secondary calibration standard. As recommended in this IAEA TECEC, this panel recommends only that clinical medical physicists adopt the second method.

II C. Guidance Document Summary
In summary, given the nearly 50 years of experience with HDR 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),\textsuperscript{17} there were more than 500 HDR accidents (including one 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\%,\textsuperscript{18} as noted above. Even though the treatment modality has become a remarkably safe, this panel recommends that aforementioned safety and quality guidance be followed faithfully.
III. 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. These documents tend to be succinct, mostly presenting aspects of the treatments that a clinic needs to address in their standard procedures, but little detail.\textsuperscript{13} Topics addressed in the 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 technological staff requiring registration. Patient Selection covers a large number of sites, each with a one-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 program 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 American Brachytherapy Society has recently prepared guidance documents for the following disease sites relevant to HDR brachytherapy:

- Cervix\textsuperscript{19, 20}
- Endometrium\textsuperscript{21}
- Prostate\textsuperscript{22}

and a guidance document for breast brachytherapy is in preparation.

In the following five sub-sections, 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.

\textbf{III A. 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 have been published by the American Brachytherapy Society (ABS), replacing the previous guidelines from 2000.\textsuperscript{19, 2023} The ACR has also developed a set of criteria to judge the appropriateness of treatment.\textsuperscript{24, 25} This application of brachytherapy has changed much over the last ten 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 U.S. has continued to decrease, although the disease remains one of the leading causes for women's death in the developing countries.\textsuperscript{26,27}

Early stage cervical cancer can be successfully treated by either primary surgery (radical hysterectomy) or radiotherapy with cure rates above 80% for stage IB-1 disease. Advanced stage cervical cancers (IB-2 and above) should be treated with concurrent chemo-radiotherapy as phase III studies have demonstrated an approximate 10% absolute improvement in survival with the addition of chemotherapy, and surgically treated patients will invariably require post-operative radiation with higher late-toxicity rates. The most commonly used cis-platin 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{28-30} The new guidelines provide recommendations for doses when combining chemotherapy and brachytherapy.

Several studies have reported lower pelvic control 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{31} Overall treatment time should be less than 8 weeks, and any planned interruptions or delays should be avoided. Once the tumor has regressed to \textless{} 4 cm, fractionated HDR brachytherapy can be interdigitated with the EBRT. In addition, 2 HDR fractions per week can be safely given once whole pelvic radiotherapy is complete.\textsuperscript{20}

Guidance documents also provide information included on 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 and to the bladder trigone. During the subsequent phases of imaging, treatment planning and treatment delivery the radiation oncologist should work in close consultation with the medical physicist to obtain an acceptable treatment plan.

After 45 Gy to the whole pelvis, the following fractionation schedules have been reported with control rates comparable to LDR brachytherapy: 5 to 5.5 Gy x 5, 7 Gy x 4, and 8 Gy x 3. These schedules all approximate an LDR equivalent dose of 85 Gy to Point A.\textsuperscript{28,32,33}

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 intra-operative abdominal ultrasound can be very useful to guide and confirm tandem placement.\textsuperscript{19}

As reported by the Quality Research in Radiation Oncology (QRRO) group, there is an increased likelihood that radiation treatment met established quality standards at facilities that see more than 500 new patients per year and at academic institutions.\textsuperscript{34,35}

One of the most dramatic changes occurred in image-guidance and the recommendations of GEC-ESTRO for target delineation through magnetic resonance
imaging. The implementation of this technology is evolving in the US is under investigation.

### III B. Brachytherapy for Cancer of the Endometrium

Guidance documents for HDR brachytherapy treatment of the endometrium come from the ABS, formerly in a 2000 document with an update in 2011. The practice has changed in some respects since that time with a greater emphasis on the use of vaginal brachytherapy rather than external beam irradiation for select patients with surgically staged disease. The ACR has also revised their HDR practice standards for endometrial brachytherapy. 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. The need for individualized treatment planning for each insertion has not been emphasized as it has been for cervix brachytherapy, but at a minimum, should be generated for the first fraction. 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 planning physicists is integral to safe treatment delivery. A system of checks and double checks must also be in place.

### III C. Brachytherapy for Cancer of the Prostate

Brenner’s seminal paper in 1999 on the radiobiology of prostate cancer first suggested that the α/β ratio for the prostate was much lower than previously believed. This initiated a paradigm shift in fractionation for prostate cancer and also affected clinical trial design for both external beam radiotherapy and brachytherapy. Important clinical trials are just beginning to be reported and other on-going trials will likely impact significantly future clinical practices.

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

To further exploit prostate cancer’s low alpha-beta ratio using hypofractionation, several studies have demonstrated the feasibility of HDR brachytherapy as monotherapy. The most common hypofractionated HDR monotherapy regimen uses three treatment fractions. Further exploration fraction reduction may be worthwhile as it would: 1) improve treatment accuracy, 2) decrease patient hospital stay, and 3) improve resource utilization. On-going prospective studies use even lower number of fractions for HDR monotherapy. As for HDR boost, one study established that the boost can be given as
a single fraction, in combination with hypofractionated external beam radiotherapy in just three weeks.50

Another important emerging application for HDR prostate brachytherapy is for salvage treatment of previously radiated patients. Local failure after external radiotherapy 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.51, 52 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 RTOG.53 This trial showed HDR prostate brachytherapy is safe and feasible. The protocol also developed a quality-assurance mechanism for future HDR research. The completion of this study helped develop the basic guidelines for 1) patient selection; 2) Trans-rectal ultrasound (TRUS)-guided implant technique; 3) CT-based treatment planning; and 4) dosimetry specification parameters for HDR prostate brachytherapy. The ABS recently published a guidance document for HDR prostate brachytherapy that focus on patient selection and application of the technique.22

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.54-56 Various institutions have developed their own solutions to address this issue.50, 57-60 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.

III D. Brachytherapy for Partial Breast Cancer

Accelerated partial breast irradiation (APBI) is an umbrella term describing a radiation technique in which only the lumpectomy cavity and a rim of adjacent breast tissue are treated. Since only a portion of the breast is irradiated, larger fraction sizes are prescribed, administered twice daily, with an overall treatment duration of 5 days rather than 6 to 7 weeks, thus accelerating the treatment. Although brachytherapy can be utilized as boost therapy after external-beam treatments, it is now more commonly used as monotherapy following breast-conserving surgery.

The data supporting APBI has been generated from single-institutional phase I/II studies and a recently reported phase III study. Local control rates from these studies with 5 to 10 years of follow-up are greater than 95%, consistent with historical control rates from whole breast irradiation series.61-65 In series in which cosmetic results are reported, the rates of good to excellent results range from 75%-100%.61-65 The current phase III trials of the National Surgical Adjuvant Breast and Bowel Project (NSABP) B39/Radiotherapy Oncology Group (RTOG) 0413 and GEC-ESTRO are comparing conventional whole breast irradiation to APBI utilizing an interstitial, intracavitary or 3D-conformal external beam approach.
Appropriate patient selection for APBI is key for successful outcomes and not all candidates for breast preservation are necessarily candidates.\textsuperscript{66, 67} Selection criteria have varied in selected series. The current randomized RTOG/NSABP study is enrolling 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 (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 PBI have individual technical selection criteria based upon their dose modulation capabilities as well. The advent of multi-lumen 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 ten years. Over the last five 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 outside the patient and ribs and lungs in the patient.\textsuperscript{68-70}

Another major change in this treatment modality has been the advent of electronic intracavitary units.\textsuperscript{70-74} For electronic brachytherapy, ASTRO published a guidance document in 2010.\textsuperscript{75} Because this document was published very early in the development of this treatment modality, it likely will require revision in the near future.

ASTRO, ESTRO and the ACR have published consensus statements regarding proper selection criteria along with level of supporting evidence.\textsuperscript{76-78} Some documents give a range of doses, the most common through the literature is 34 Gy delivered in ten fractions over five days. Although no organization has published official treatment planning guidance documents, the ABS has published two descriptive papers, termed updates, that in part provided guidance.\textsuperscript{79, 80} In addition there is a fairly comprehensive textbook on the topic.\textsuperscript{81} The book does not represent consensus, however. Thus, a brachytherapy-specific, technical guidance document is needed for this modality, and the ABS is in the process of generating one.

\textbf{III E. 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.

\textbf{Esophageal cancer}

Of these anatomical sites, a consensus guidance document exists only for esophagus, and that, from the ABS, dates from 1997.\textsuperscript{82} 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.\textsuperscript{83-101} Some of the articles discuss technique advances or the recommendations of the author.\textsuperscript{69, 102-106} One 2002 consensus
document discussing in general terms HDR brachytherapy, contains a paragraph on
esophageal brachytherapy. In summary, given the age of the ABS guidance
document and the work published since, a new set of guidelines is warrented
particularly dealing with CT and MR guidance and patient selection.

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 some 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. 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

Very little has been published on intraluminal HDR brachytherapy in the bile duct over
the last 10 years, particularly in the last 5 years (for example, see references 123-136).
Given that the reports show a distinct benefit in increasing survival duration, this panel
recommends that a guidance document on this practice be written.

IV. 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 and prostate) that
had fallen out of date to include details necessary for clinical practitioners, and those
references are provided in this document.

The recommendations in the white paper for improved safety and quality in high dose-
rate 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, “hand-on” component.

4. With respect to safety and physics recommendations:
   a. The safety and emergency-response recommendations of AAPM Report 46 should be followed.
   b. Until publication of the report of AAPM TG 100, the brachytherapy recommendations of AAPM report 46 should be followed.
   c. Recommendations of AAPM Reports 59, 61, 62 and 128 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%.

5. Professional Societies should generate new or updated guidance documents for endoesophageal and biliary brachytherapy, and assess the need for an updated guidance documents for endobronchial brachytherapy and APBI using electronic brachytherapy.

6. The ABS should expedite the completion of its guidance document on APBI brachytherapy.

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