Brachytherapy (BT) treatments using temporary application of high-energy (HE) high-dose rate (HDR) or pulsed-dose rate (PDR) sources with mean photon energies > 50 keV [1] are widely applied. The vast majority of radiotherapy departments in Europe providing BT employs HE sources, and approximately 1,200 afterloaders are currently operational across the continent. This technique is successfully applied to diverse pathologies, the most important being cervix [2,3], prostate [4], breast [5,6], and skin [7]. The most commonly used HE source is HDR Ir-192, with PDR Ir-192 used in a minority of centers. In the last years, a considerable number of HDR Co-60 sources have been put to clinical use due to the practical and economic advantages brought by its longer half-life relative to Ir-192.

Source strength calibration is undoubtedly the pillar of accurate BT delivery and global uniformity of practice. Pertinent recommendations have been recently provided by GEC-ESTRO ACROP for low energy (LE) sources (average photon energy < 50 keV) [8]. Corresponding international societal recommendations pertinent to HE HDR-PDR sources date back more than two decades [9–11] and some ambiguities as well as room for improvement in terms of European harmonization were identified.

In BT, a specific value of absorbed dose to water in absolute units of Gy is obtained through the coupling of source strength and absorbed dose rate to water per unit source strength calculated following the TG-43 formalism [12,13] by the American Association of Physicists in Medicine (AAPM). Determination of absorbed dose in absolute units using model-based dose calculation is similarly coupled to source strength [14]. The reference quantity for BT source strength is either reference air-kerma rate (RAKR) with units μGy h⁻¹ at 1 meter as is widely used in Europe, or air-kerma strength S₀ with units μGy h⁻¹ m⁻¹ (frequently designated as 1 U = 1 μGy h⁻¹ m⁻¹) as is used in North America. Note that these quantities are numerically identical as RAKR is defined at 1.00 m. [15,16]. As recommended in the ESTRO Booklet #8 [9], IAEA-TECDOC-1274 [10], and the AAPM TG-56 Report [11] every institution practicing BT must have a system for measuring source strength.
strength with calibration traceability for all source models used in its practice.

The Work Package (WP-21) was initiated within the Brachytherapy Physics Quality Assurance System (BRAPHYS) GEC-ESTRO working group with a focus on HE (HDR-PDR) source calibration. In particular, the charge of WP-21 was to provide guidance to hospital physicists using HE BT sources (Ir-192 HDR and PDR, and HDR Co-60) on:

1. practical considerations of HE source strength measurement by users, including traceability,
2. addressing the ambiguity in the definition of responsibility for source leakage testing prior to clinical use between manufacturer and user,
3. the level of agreement between the source strength measured by the user and that reported in the source certificate provided by the vendor, and
4. procedures required when potential discrepancies exceed an action limit.

The specifics of experimental source strength determination are covered in IAEA guidelines [10] whose update is underway [17]. Thus, the aim of this WP-21 is to offer recommendations to assist medical physicists in the clinic with all other practical aspects, as well as portray the current situation in Europe in terms of sources and calibration laboratories.

The recommendations herein reflect the guidance to the ESTRO BT users and describe the procedures in a clinic or hospital to ensure the correct calibration of HE sources. The responsibility to evaluate the calibration remains with the hospital physicist. Notwithstanding the importance of gradual convergence to internationally harmonized procedures, the end-user must also consider national regulations and recommendations.

The authors want to emphasize that certain materials and commercial products are identified in this report to facilitate discussion and methodology description. Such identification does not imply recommendation nor endorsement by ESTRO or the authors, nor does it imply that the materials or products identified are necessarily the best available for these purposes.

HE sources and afterloaders

HE HDR and PDR BT sources fulfilling Registry Policy are listed on the Brachytherapy Source Registry of the Joint AAPM/IROC Houston Quality Assurance (QA) Center website [18] and the GEC-ESTRO BRAPHYS website [19]. Geometry and dimensions of the source models and consensus dosimetry data can be found in the High Energy Brachytherapy Dosimetry (HEBD) Report [20] except for the microSelectron-PDR v2 (the microSelectron PDR-v2 source has the same geometry as the microSelectron HDR-v2, and differs only in its source strength, suitable for PDR treatments) and the Flexisource Co-60 [21]. An updated list can be obtained in the BRAPHYS website [19] and in the Joint AAPM/IROC Registry [18], Table 1 reflects the sources used routinely in clinical practice. The main characteristics of the afterloaders commercially available and in clinical practice in Europe are summarized in Table 2.

Current societal recommendations

Source calibration is a fundamental issue in BT QA. Several professional societies have issued recommendations that describe generally accepted procedures for BT source calibration. The following short overview is by no means exhaustive and aims at summarizing the current situation based on accessible international and national recommendations available in English. BT physicists should always adhere to the national regulations in their country.

The AAPM TG-40 Report from 1994 recommended source calibration with units of $S_K$ [22]. Furthermore, traceability of source calibration is explained in detail, distinguishing between direct traceability (a source is calibrated either at the U.S. National Institute of Standards and Technology, NIST, or an American Association of Physicists in Medicine - Accredited Dosimetry Calibration Laboratory, AAPM-ADCL), secondary traceability (a source is calibrated in comparison with a source of the same design and comparable strength that was calibrated with direct traceability), and remote traceability (an institution relies on calibration from the manufacturer/supplier), and recommends direct or secondary traceability. The TG-40 Report recommended confirming the source geometry as well as checking for non-uniform physical distribution of the radionuclide, but this is a difficult task and it is hard to quantitatively validate the expected geometry and uniformity.

In 1997, the AAPM TG-56 Report recommended to specify source strength by the quantity $S_K$ via a measurement traceable to NIST and that a qualified medical physicist must calibrate the sources before their clinical use [11]. The calibration value determined by the physicist should be used for treatment planning and dose prescription. This approach was supported in a later AAPM report by Butler et al. [23] for low energy BT sources. In addition, the TG-56 Report recommends that when a source package is opened, it must be determined that there is no contamination due to damage during shipping and the documentation is in agreement with the order. The AAPM finds it unnecessary to perform wipe testing of the source capsule, and dose rate measurements are conducted for the package.

The IAEA TECDOC 1274 published in 2002 describes HDR BT source calibration using a well-type ionization chamber (WIC) and emphasized the need for chamber calibration for all qualities for which it is used [10].

The 2004 ESTRO Booklet No. 8 [9] generally adopted the recommendations issued in the TG-56 Report. Wipe testing procedures are described in detail and it is emphasized that the radioactivity level for measuring contamination is low and a good counting geometry and measuring time is needed to obtain an appropriate signal. As direct wipe testing of the source is usually not possible, wipe tests are applied to applicators, transfer tubes, and check cable (if possible) to demonstrate they are free of radioactive contamination. Maximum levels of dose rate surrounding the remote afterloading unit are established in national and international regulations. These measurements are performed during source exchange.

Guidance published in 2007 [1] by AAPM and ESTRO for its members recommended that all source strength determinations done by manufacturers/suppliers of HE BT sources should be performed with equipment traceable to appropriate primary standards. They further recommended that the suppliers should send sources or their reference calibration instrument to a standard dosimetry laboratory at least every year to maintain constancy. Although this recommendation was based on procedures originally established for low energy sources [24], the AAPM confirmed that manufacturers/suppliers are expected to comply with these requirements for HE sources also, albeit with a reduced frequency of two years for Ir-192 and Co-60 sources recommended in more recent recommendations in the HEBD Report [20]. Hence, periodic comparison of the manufacturer’s in-house calibration against a reference standard is obligatory in the U.S. in partial fulfillment of AAPM dosimetric prerequisites and inclusion of HE BT source in the Brachytherapy Source Registry [18].

A comparison of different international dosimetry protocols was published by Zakaria et al. in 2010 [25]. Using measurements
with WICs, free-in-air, and in solid phantoms, they found that source-strength variations were larger for Co-60 sources (2.5 %) relative to Ir-192 (1.2 %). Smaller variations were observed when using only WICs for both radionuclides.

In 2018, reports of the Netherlands Commission on Radiation Dosimetry (NCS) and Canadian Organization of Medical Physicists (COMP) also described calibrations using WICs for HDR-PDR sources [26, 27].

The 2020 DIN Report 6803-2 [28] recommended using a WIC or equivalent measurement method for HE photon BT source calibrations. The calibration must be traceable to a primary standard (e.g., PTB, NPL, or NIST). BT source RAKR values are reported by the manufacturer/supplier and must be verified by the hospital physicist prior to first patient treatment. In another German guidance document, a 1999 DGMP report recommended a PMMA phantom housing a thimble ionization chamber, but allowed a WIC for HE photon BT source calibration [29].

Traceable calibration of equipment to determine BT source strength is, like other quantities in radiotherapy, maintained through a series of unbroken steps, starting from a primary realisation of the quantity at an approved metrology institute (National Metrology Institute, NMI) and disseminated from primary to secondary standards laboratories and to the end user. For interested readers, overviews of primary standards and dosimetry protocols for BT have been published [30, 31]. Traceability to common standards forms the basis of global uniformity of clinical practice, facilitating communication and treatment outcome comparisons within the radiotherapy community, thus being an essential aspect of quality and safety of HDR-PDR BT.

Traceability of a quantity at the end-user (hospital) level is achieved through calibration of equipment against a primary or lower level (secondary) standard which is traceable to the primary. WICs are the recommended instruments to determine BT HDR-PDR source strength at hospitals because of their robustness, stability, and simplicity. For low energy BT seeds, calibrated seeds can be shipped from a calibration laboratory to the end user for the calibration of a WIC. For HDR-PDR sources, however, the dose rate is much higher, and this procedure is usually not feasible. In this case, traceability is achieved by sending the WIC to a primary/secondary laboratory to obtain a calibration coefficient for the WIC.

WICs for use by hospital physicists should be air-filled and vented so that air temperature, pressure and relative humidity inside the chamber are in equilibrium with those outside. Due to the comparatively large air volume of WICs, it takes time for the chamber air to reach equilibrium with the surrounding air (see Figure 3.5, in [9]). A WIC should hence be placed in the

Well chamber calibration traceability and quality assurance

From the point of view of the end user (medical physicist), dose-to-water in a water medium is the desired quantity of interest. As described in the introduction, determination of absorbed dose to water in BT is achieved through the coupling of the source strength in terms of RAKR or $S_N$ with treatment planning system dosimetry calculations. Air kerma (rate) formed the basis of the BT dosimetry chain during the last decades [29].

Traceability of a quantity at the end-user (hospital) level is achieved through calibration of equipment against a primary or lower level (secondary) standard which is traceable to the primary. WICs are the recommended instruments to determine BT HDR-PDR source strength at hospitals because of their robustness, stability, and simplicity. For low energy BT seeds, calibrated seeds can be shipped from a calibration laboratory to the end user for the calibration of a WIC. For HDR-PDR sources, however, the dose rate is much higher, and this procedure is usually not feasible. In this case, traceability is achieved by sending the WIC to a primary/secondary laboratory to obtain a calibration coefficient for the WIC.

WICs for use by hospital physicists should be air-filled and vented so that air temperature, pressure and relative humidity inside the chamber are in equilibrium with those outside. Due to the comparatively large air volume of WICs, it takes time for the chamber air to reach equilibrium with the surrounding air (see Figure 3.5, in [9]). A WIC should hence be placed in the

Well chamber calibration traceability and quality assurance

From the point of view of the end user (medical physicist), dose-to-water in a water medium is the desired quantity of interest. As described in the introduction, determination of absorbed dose to water in BT is achieved through the coupling of the source

Table 1
HDR and PDR brachytherapy sources used in clinical practice. Values of consensus dose rate constant, $c_{\text{con}},$ from [18] and [20].

<table>
<thead>
<tr>
<th>Type</th>
<th>Radionuclide</th>
<th>Source model</th>
<th>Manufacturer</th>
<th>Core</th>
<th>Encapsulation</th>
<th>$c_{\text{con}}$ (cGy/h U⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDR</td>
<td>Ir-192</td>
<td>microSelectron-PDR v2</td>
<td>Elekta</td>
<td>3.5</td>
<td>0.60</td>
<td>0.100</td>
</tr>
<tr>
<td>HDR</td>
<td>Ir-192</td>
<td>GammaMed HDR Plus</td>
<td>Varian</td>
<td>5.0</td>
<td>0.60</td>
<td>0.100</td>
</tr>
<tr>
<td>HDR</td>
<td>Ir-192</td>
<td>microSelectron-HDR v2</td>
<td>Elekta</td>
<td>3.5</td>
<td>0.60</td>
<td>0.100</td>
</tr>
<tr>
<td>HDR</td>
<td>Ir-192</td>
<td>GammaMed HDR v2</td>
<td>Varian</td>
<td>5.0</td>
<td>0.34</td>
<td>0.125</td>
</tr>
<tr>
<td>HDR</td>
<td>Ir-192</td>
<td>Flexisource Ir-192</td>
<td>Elekta</td>
<td>3.5</td>
<td>0.70</td>
<td>0.100</td>
</tr>
<tr>
<td>HDR</td>
<td>Ir-192</td>
<td>Ir.2.A85-2</td>
<td>Bebig Medical</td>
<td>3.5</td>
<td>0.60</td>
<td>0.100</td>
</tr>
<tr>
<td>HDR</td>
<td>Co-60</td>
<td>Flexisource Co-60</td>
<td>Elekta</td>
<td>3.5</td>
<td>0.50</td>
<td>0.150</td>
</tr>
<tr>
<td>HDR</td>
<td>Co-60</td>
<td>Co0.A86</td>
<td>Bebig Medical</td>
<td>3.5</td>
<td>0.50</td>
<td>0.150</td>
</tr>
</tbody>
</table>

Table 2
HDR and PDR brachytherapy afterloaders used in clinical practice.

<table>
<thead>
<tr>
<th>Afterloader, Manufacturer</th>
<th>Source models</th>
<th>Treatment channels</th>
<th>Dwell positions: step size (mm)</th>
<th>Maximum contained activity (GBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexitron, Elekta</td>
<td>Flexisource Ir-192</td>
<td>10, 20, or 40</td>
<td>400: 1</td>
<td>444 for Ir-192</td>
</tr>
<tr>
<td>microSelectron, Elekta</td>
<td>microSelectron HDR-v2</td>
<td>6, 18, or 30</td>
<td>48: 2.5, 5, or 10</td>
<td>81 for Co-60</td>
</tr>
<tr>
<td>BRAVOS, Varian</td>
<td>GammaMed HDR Plus</td>
<td>30</td>
<td>100: 1-99</td>
<td>518 for Ir-192</td>
</tr>
<tr>
<td>VariSource IX, Varian</td>
<td>GammaMed HDR Plus</td>
<td>20</td>
<td>60: 2-99</td>
<td>407 for Ir-192</td>
</tr>
<tr>
<td>GammaMedplus IX, Varian</td>
<td>GammaMed HDR Plus</td>
<td>24</td>
<td>60: 1-10</td>
<td>555 for Ir-192</td>
</tr>
<tr>
<td>SagNiNova, Bebig Medical</td>
<td>Ir.2.A85-2</td>
<td>25</td>
<td>100: 1</td>
<td>481 for Ir-192</td>
</tr>
<tr>
<td></td>
<td>Co0.A86</td>
<td></td>
<td></td>
<td>91 for Co-60</td>
</tr>
</tbody>
</table>
room where measurements are to be performed hours in advance and further, the thermometer to determine air temperature is best placed inside the chamber well. In particular, gas-filled and pressurized WICs should not be used to avoid potential stability problems due to slow leakage of the gas [10]. In addition to a WIC, an electrometer suitable for the range of current/integrated charge to be measured is needed. The electrometer should either be co-calibrated with the WIC (calibration valid for the WIC plus electrometer combination) or separately against a standard for current/charge. A calibrated thermometer and pressure gauge are also required. In addition, a hygrometer should be used to verify that the WIC is used in conditions at which humidity effects can be neglected (range of relative air humidity should be 20 % to 80 %). While $A_{\text{ion}}$ (charge collection efficiency correction at the time of measurement) is used for external radiotherapy measurements and substantially differs from unity for high-energy electron beams, the value is near unity for HDR Ir-192 and Co-60 sources and may be neglected (along with $P_{\text{ion}}$) given the magnitude of other uncertainties.

A WIC calibration is performed under well-defined conditions. The resulting calibration coefficient is strictly valid under these conditions. The calibration certificate must hence provide detailed information so that these conditions can be reproduced by the end-user. If the calibration is for the WIC alone or in combination with an electrometer (WIC + EM) (if so the manufacturer, model and serial number of the EM needs to be specified too).

- Information on polarization voltage to be used and its sign (both in WIC and WIC + EM case).
- The calibration coefficient, its units, and uncertainty including coverage factor.
- The type of source(s) and model(s) for which the calibration coefficient is valid.
- Information on the reference conditions of air temperature and pressure under which the calibration coefficient is valid (note that the reference temperature is 20 °C in Europe while it is 22 °C in North America). Information on the range of relative humidity for which it is valid.
- Information on traceability i.e., to which primary standard and, if relevant, information on the secondary standard (WIC model, serial number, year of calibration).
- Information on the source insert used and the height within the WIC at which it places the source. The height within the WIC for HDR sources is typically the point of maximum response of the WIC (also named the “sweet spot”). The point of maximum response is established by stepping the source along the insert and should be checked with each new source.
- Information about the BT source used in the calibration (manufacturer, model, source strength at time of calibration).

The constancy of the WIC-based system for measurement at the hospital level must be guaranteed through an adequate redundancy program. Redundancy allows the institution to verify that the dosimetry system has not changed over time. The TG-40 Report clearly defined the redundancy system as a collection of instruments, radiation sources, and detectors whose radiologic characteristics are predictable with a high degree of reproducibility [22]. These sources and detectors are inter-compared periodically to verify their constancy.

Besides a WIC with a traceable calibration, potential additional components of the redundancy program could be:

(I) A second WIC. This could be alternatively combined with the first one when it is sent to the laboratory for calibration.
(II) A reference long half-life check source (e.g., Cs-137, Am-241, or Sr-90).
(III) A phantom (solid, Krieger phantom or jig) where the source and Farmer chamber have fixed positions [28].
(IV) A linac beam irradiation of the WIC in a well-defined geometric setup [9,33]. However, the associated uncertainty can be too large.
(V) The decayed clinical source prior to exchange. This could be measured and the RAKR is compared (with decay correction) to the value originally measured upon source delivery to the clinic.

To ensure redundancy for HE HDR/PDR source calibration, at least two-components are recommended. Ideally, the preferred solution would be a second WIC (I), which guarantees availability against shipments because of repairs or calibrations.

For Ir-192, an efficient and practical solution to guarantee the long-term stability of the equipment is item V: assaying the source to be replaced and comparing its RAKR with the initial value. This solution has the advantage that measurements are performed on the same source at two different times. In the hospital of a WP-21 member, this has been performed during the last 15 years, reporting differences lower than ±0.5 %. In the case of Co-60, with typical replacement time of years, this evaluation can be adapted on a yearly basis.

According to the TG-40 Report, all components of the redundant system should be inter-compared at least annually. This suggestion is also adopted here. It is recommended that results be documented for all possibilities of chosen components. Response constancy for the components comprising the redundant system should be ideally within 0.5 % and must always be within 1.0 % for HDR-PDR BT sources.

WICs are relatively large ionization chambers generally considered as robust instruments, and data on their long-term stability have been reported [34]. All societal recommendations and national regulations (e.g. Refs. [8,9,11,28,35–37]) indicate it is prudent to establish a 2-year periodicity of WIC recalibration at a calibration laboratory. This calibration laboratory should be an NMI (primary or secondary), an accredited laboratory or a laboratory with a demonstrated high-quality program in transferring traceability. Recalibration must be performed immediately in case of doubtful performance or after repair. Constancy of the equipment should be tested regularly according to the established redundancy program.

In a national regulation [28], it is stated that a detector has to be calibrated every-two years, but the maximum interval between calibrations is extended to 5 years if WIC response constancy is secured by a radioactive check source or a calibrated source. WP-21 considers that, in view of the high stability shown by WICs, the calibration periodicity may be reasonably extended to 5 years as long as adequate constancy control measures within the framework of a strict redundancy program are maintained. This recommendation should not supersede applicable national regulations.

A final note is in order in view of the difference in the half-life of Ir-192 and Co-60 HE sources. An Ir-192 source is typically replaced every 2–4 months and source strength measurement should be performed by the hospital physicist at least at the time of its installation as well as at the time of source exchange as part of a convenient redundancy program. A Co-60 source can be replaced after several years and this WP recommends that its strength should be measured at the time of its installation and at least annually after that to support constancy control.
Labsitories able to provide traceable calibrations to users

Table 3 provides a list of European metrology laboratories with Ir-192 and Co-60 calibration capacities. The list incorporates information on whether the laboratory is a primary standard dosimetry laboratory (PSDL) or a secondary standard dosimetry laboratory (SSDL), web links for contact information, and information on the calibration uncertainty. Note that the PSDLs are intended to provide calibration service to SSDLs and often have a reduced capacity to offer calibration services to end-users. PTW in Germany is not an NMI, however PTW is an SSDL with a high-quality program in transferring traceability, demonstrated, e.g., by their membership in the IAEA network of SSDLs. For some of the laboratories, but not all, the information in Table 3 is included in the Key Comparison Data Base (KCDB), available through BIPM [38].

The PTB in Germany is the only metrology laboratory to provide calibration of equipment to determine the RAKR of HDR Co-60 sources. PTB, as a PSDL, has announced their limited capacity to calibrate equipment for end-users. In an effort to facilitate increased access to traceable Co-60 RAKR determinations, a chamber specific radiation quality correction factor, kQ, was derived based on experimentally verified Monte Carlo calculations [39].

Using the chamber model-specific kQ factor, a Co-60 N_{RAKR} calibration coefficient can be obtained from a calibration coefficient for Ir-192, albeit with a higher uncertainty. Despite the uncertainty increment, WP-21 recommends accepting this procedure as an interim solution, in anticipation of hopefully future increase in availability chain of calibration laboratories offering the direct Co-60 calibration to all end users.

It is important to repeat that a calibration coefficient, N_{RAKR}, is strictly valid only under the conditions specified in the calibration certificate (see previous dicussions and [9,10]).

More recently, it has become evident that the use of a radiation source model by the calibration laboratory and another by the end-user contribute to a small but systematic error. A formalism including a source model geometry factor, to account for differences in Ir-192 source model between calibration laboratory and end user, is provided in the British “IPEM code of practise for determination of the reference air kerma rate for HDR 192Ir brachytherapy sources based on the NPL air kerma standard” [40]. Shipley et al., used experimentally verified MC simulations to provide a set of such source model correction factors for HDR Ir-192 sources and the Standard Imaging HDR 1000+ [41]. Until the application of such source model correction factors is appropriately established, WP-21 recommends the direct use of the calibration coefficient as given on the calibration certificate, except in the case that one of the laboratories, based on the existing MC simulations, apply such factor for the end-user and provide appropriate documentation thereof in the calibration certificate.

Impurity and contamination controls

In this Section, two aspects of potential importance regarding the calibration and safety of HE HDR-PDR sources are described. On the one hand, the purity of the radionuclide and, on the other, related to safety, its sealing.

Impurities

Potential radionuclide impurities have a deleterious effect on source calibration accuracy. This is not a concern for HE sources of Co-60 given its decay scheme and the fact that its precursor (Co-59) is monoisotopic [42].

In the case of Ir-192, the level of potential impurities depends on enrichment method / degree and the time period between activation and source delivery to the clinic. The main issue is the presence of Ir-194, an isotope with a half-life of 19.3 h [42]. Since the clinical user is only informed by the source certificate about the time when source strength was measured by the supplier, the time when the material activation took place is unknown and a second measurement after 2 weeks has been recommended by some national guidelines so that consistency with Ir-192 half-life can be used as a proof of radionuclide purity [43].

According to information provided by source suppliers (Michael Andrásy from Bebig, Yury Niatsetski from Elekta, and Sophie Wetherall from Varian, personal communications) all Ir-192 sources are produced by the same manufacturer regardless of the supplier. The material composition of the activity carriers is well defined in mutual agreements and also verified by the supplier. Reactor activation (4 weeks) is followed by a 5-day cooling period before shipment from the reactor to the supplier. The sources are then certified and delivered directly to the customers. Ir-194 activity reduces by a factor of approximately 10^2 every 5 days and source suppliers indicated that the minimum time between source activation and certification is 7–9 days while the typical time between source activation and delivery to the clinic is 7–14 days.

Taking into account the time intervals described above and the typical magnitude of differences observed between source certificate and clinical user experimental determination of HE Ir-192

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Calibration Laboratory</th>
<th>Status</th>
<th>Expanded relative uncertainty (k = 2) in N_{RAKR} [%]</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ir-192</td>
<td>NPL, Great Britain</td>
<td>PSDL,</td>
<td>0.8</td>
<td><a href="https://www.npl.co.uk">https://www.npl.co.uk</a></td>
</tr>
<tr>
<td></td>
<td>PTB, Germany</td>
<td>PSDL,</td>
<td>2.4</td>
<td><a href="https://www.ptb.de">https://www.ptb.de</a></td>
</tr>
<tr>
<td></td>
<td>VSL, Netherlands</td>
<td>PSDL,</td>
<td>1.2</td>
<td><a href="https://www.vsl.nl/">https://www.vsl.nl/</a></td>
</tr>
<tr>
<td></td>
<td>LNE-LNHB, France</td>
<td>PSDL,</td>
<td>1.3</td>
<td><a href="https://www.lne.fr/en">https://www.lne.fr/en</a></td>
</tr>
<tr>
<td></td>
<td>JRCU/GRACCE-IN, Greece</td>
<td>SSDL,</td>
<td>3</td>
<td><a href="https://eae.gr/en/">https://eae.gr/en/</a></td>
</tr>
<tr>
<td></td>
<td>SSM, Sweden</td>
<td>SSDL,</td>
<td>1</td>
<td><a href="https://www.stralsakeretsmyndigheten.se/en/">https://www.stralsakeretsmyndigheten.se/en/</a></td>
</tr>
<tr>
<td></td>
<td>PTW, Germany</td>
<td>SSDL</td>
<td>2.8–3</td>
<td><a href="https://www.ptwdosimetry.com/en">https://www.ptwdosimetry.com/en</a></td>
</tr>
<tr>
<td>Co-60</td>
<td>PTB, Germany</td>
<td>PSDL,</td>
<td>2.2</td>
<td><a href="https://www.ptb.de">https://www.ptb.de</a></td>
</tr>
<tr>
<td></td>
<td>PTW, Germany</td>
<td>SSDL</td>
<td>3.4</td>
<td><a href="https://www.ptwdosimetry.com/en">https://www.ptwdosimetry.com/en</a></td>
</tr>
</tbody>
</table>

| Co-60**     | PTB, Germany          | PSDL,  | 2.2                                               | https://www.ptb.de |
| Co-60***    | PTW, Germany          | SSDL   | 3.4                                               | https://www.ptwdosimetry.com/en |

* Links are to the main web site of the laboratories/institutions. Starting there, a search for calibration service, ionizing radiation, brachytherapy will provide details and contact information.

** Expanded relative uncertainties are given as listed in February 2022 in the BIPM “Key Comparison Data Base” searchable at https://www.bipm.org/kcdb/, except for SSM and PTW for which self-stated uncertainties are provided.

*** Indirect method [39], and overviewed below.
source RAKR [44], WP-21 recommends that radionuclide impurities for Ir-192 BT sources do not require special attention.

Contamination

Contamination is a serious safety concern. As commented before, societal recommendations include the necessity to check possible contaminations.

The source certificate issued by the supplier also includes results of the leakage and contamination tests performed on the source. The typical certificate states that leakage test is passed, and that surface contamination test gives a value < 185 Bq (5 nCi). Some details are typically included, for example, Leakage Test method according to ISO 9978:2020 method Immersion Test (hot liquid) and also the Surface Contamination Test according to the ISO 9978:2020 method Wet Wipe Test [45].

In the European Commission Directive laying down basic safety standards for protection against exposure to ionizing radiation [46], specific requirements are established for HDR afterloading sources. Regarding leakage, there are specific requirements for undertaking responsibility “to ensure that suitable test, such as leak test based on international standards, are undertaken regularly in order to check and maintain the integrity of each source”.

Another important document to be considered is the recent ACR-AAPM Technical Standard for HDR brachytherapy [47]. With respect to leakage it is stated that “For sealed sources that will be used clinically for a period exceeding 6 months, the facility must have instrumentation to perform leak tests or arrange to have this service provided at intervals not to exceed 6 months”. This affects Co-60 only because Ir-192 is replaced in a shorter period. In some countries, such as Germany, this test is required every year if not defined otherwise by local authorities, and it is typically performed by an external authorized expert. In other countries such testing is required every-three years (Michael Andrássy, personal communication).

The practical reality in the clinical setting must also be weighed in with societal recommendations and legislative requirements in any effort to establish responsibility and frequency of contamination testing.

In an example of an incident, in 2014 radioactive contamination was detected during a routine source exchange by the service engineer of the afterloader manufacturer [48]. Root cause investigation indicated that the origin of the contamination was Ir-192 dust on the supplied source with dust activity exceeding 185 Bq, albeit marginally. The hospital physicist users were advised by the manufacturer to check their afterloader, applicators, and transfer tubes or any relevant system accessory, for contamination. They were to follow their local procedures and immediately contact the manufacturer in case they found levels of radiation exceeding allowable limits as set by the users local radiation authorities. Following this incident, the afterloader manufacturer established a procedure whereby the engineer who performs the Ir-192 source exchange performs a wipe test on channels once the old source has been removed and before installing the new one. This procedure includes the measurement of the samples but the result is only available to the company and not documented and shared with the hospital physicist.

To further illustrate the diversity of situations, another HDR afterloader manufacturer includes a wipe test performed in the most used channels (1, 2, and 3) in the annual maintenance protocol for HDR Co-60. Samples are analyzed by an authorized laboratory which produces an official certificate that is presented to the hospital physicist. However, the same company follows a different protocol for HDR Ir-192 at the time of source exchange, whereby the engineer performs the wipe test sampling and measurement (Aurora Gutierrez from Bebig, personal communication).

Variations in assuming legal responsibility are dependent on the particular country, company, and even source model. The position of some companies is that the leakage evaluation cannot be delegated to the medical device vendor; the source manufacturer is responsible to assure the quality of his product, i.e., in this respect to perform the leak test before shipment and certify this, but not once the source is installed in the afterloader. This position however disregards the fact that source installation in the afterloader is carried out by a specialist engineer on account of the company.

Given this complex issue, WP-21 does not provide an all-encompassing recommendation beyond the fact that the responsibility for the official performance and documentation of this test must be clearly established at each hospital. The ideal option should be to reach an agreement with the afterloader company to carry out the test during the installation of the source (for Ir-192) or during preventive maintenance (for Co-60). The duly accredited documentation must be presented to the hospital physicist who accepts it in the same way as with acceptance of any radiotherapy equipment. The above solution should be proactively pursued in the stage of tendering or contract signing for procuring an afterloader. This solution would be the most logical one, and the entire BT community (societies, national or international guidelines, source manufacturers and afterloader companies) should work to promote this. If the above solution is not possible, then contamination testing responsibility remains with the hospital physicist, and the organization (hospital) should provide sufficient and appropriate resources to accomplish this task.

Source certificate

Each HE HDR-PDR BT source delivered to the clinic is accompanied by a calibration certificate. Among other information required according to ISO 2919:2012 (manufacturer, source classification, serial number, content activity, details of testing for surface contamination and leakage), this certificate includes a source RAKR value at a specified day/time [49]. Hence, source certificate requires interaction between the source manufacturer (or supplier, if different) with dosimetry laboratories maintaining primary or secondary calibration standards. The intent of this interaction is to reduce uncertainty through ensuring traceability of calibration used for the source RAKR value on the source certificate, constancy of this calibration, and constancy of source geometry and internal design. Fulfillment of these three intents is mandated by Medical Device Regulations (Regulation (EU) 2017/745) for Class IIb devices, and in specific ISO 13485:2016 requirements [50,51]. Detailed guidance on meeting these requirements is commonly provided by societal recommendations, ideally with the collaboration of the manufacturers.

Manufacturer/supplier measurements for source RAKR certification are identical to those performed in the clinic, and thus also subject to the previously discussed recommendations. Regarding calibration traceability and constancy, the situation in Europe at the time of writing based on information kindly shared by source manufacturers/suppliers, is as follows (see Fig. 1). All clinically used Ir-192 sources are manufactured by Curium Pharma (Paris, France). Source RAKR specification is performed using a WIC with a calibration verified, or re-adjusted as necessary, through annual shipment of a source for calibration at the PTB. Since differences in the geometry of available Ir-192 BT sources are subtle, the source model sent to PTB annually is alternated, and the chamber

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1 The definitions of COUNCIL DIRECTIVE 2003/122/EURATOM are adopted whereby any natural or legal person who manufactures a source and supplies or makes available a source is termed ‘manufacturer’ and ‘supplier’ respectively [46]. ‘Vendor’ is commonly used instead of ‘supplier’.
calibration is applied for all source designs except for PDR source designs of considerably smaller active core length for which a source specific calibration is used (see also discussion on source design constancy verification in the following). Information in the KCDB available through BIPM indicates a PTB source calibration uncertainty of 1.8 % (k = 2) [38]. The manufacturer issues sealed source certificates including a RAKR specification with 5 % uncertainty (k = 3). Co-60 sources supplied by Bebig (Co0.A86) and Elekta (GK60M24) are both manufactured at Isotope Technologies (Minsk, Belarus). The Co0.A86 source RAKR calibration is performed by the supplier using a Capintec WIC calibrated at PTB using a calibrated source of the same model. The WIC calibration uncertainty is 2.5 % (k = 2) and calibration constancy is verified annually by the supplier through measurements with a source of the same model calibrated at PTB. The supplier issues sealed source certificates including a RAKR specification with 3.2 % uncertainty (k = 2). The WIC calibration uncertainty is 2.5 % (k = 2) and calibration constancy is verified annually by the supplier through measurements with a source of the same model calibrated at PTB. The supplier issues sealed source certificates including a RAKR specification with 3.2 % uncertainty (k = 2). The sealed source certificate indicates 5 % uncertainty. No further information was made available on the coverage factor associated with this uncertainty, the methods used, the periodicity of chamber calibration, or other means of calibration verification.

Apart from the recommendations set forth before, manufacturers/suppliers are encouraged to also consider the following. It is useful to monitor the mean ratio of clinically measured RAKR to that in the source certificate for the early detection of problems with equipment or routines followed at either site [37,52]. Then source manufacturers/suppliers are encouraged to provide identification of the site where the source was calibrated in the accompanying certificate.

Given their difference in organization size, source manufacturers/suppliers are expected to maintain a more competent redundancy program than clinics. At least three components should be considered since this could identify the discrepant instrument. A redundant system with more than three instrument (WIC) components would also add confidence to the constancy of the traceable calibration since a new calibration before the calibration time interval would only be necessary if the group of reliable instruments becomes smaller than three. Use of such a redundant system employing multiple instruments might permit extending the calibration period to 5 years, provided it is properly set up and detailed in the quality management system of the manufacturer/supplier.

Manufacturers or suppliers providing RAKR values should consider compliance to ISO 17025:2005 [53], even if accreditation of compliance is not sought. This standard is deemed an internationally accepted benchmark for the operation of calibration laboratories of any size, and compliance is highly regarded.

Regarding constancy of source geometry and internal design, WP-21 acknowledges that RAKR is not a source assay quantity sensitive enough to pick up all changes of potential impact to dosimetric accuracy for HE BT sources. Monte Carlo simulations have shown that WIC calibrations differ within 1.8 % for different Ir-192 HDR source designs (within 0.4 % if one source design of different active core length is excluded from the comparison) [41,54] and WIC calibrations have been found to agree within uncertainty for all Ir-192 source model except short active core length PDR sources (Curium, private communication). Manufacturers/suppliers must communicate programmed source design changes to the laboratory used for WIC calibration and regulatory entities and related scientific societies that produced consensus dosimetry datasets for the specific source model. It would also be safe to assume that they have established source production tolerances.

Fig. 1. Situation in Europe regarding calibration traceability and constancy. Information kindly shared by source manufacturers and suppliers.
and means to demonstrate conformity of the final product [51]. Nevertheless, research is welcome on the dosimetric uncertainty introduced by source design tolerances and a practical method to verify source design constancy.

**User vs manufacturer RAKR comparison**

Due in part to the logistics of HDR-PDR BT sources not being easily shippable and in part to the fact that HE sources are less sensitive to source design and manufacturing processes, a system similar to that setup for LDR sources does not exist [8]. It is however well recognized in the TG-56 Report [11] and the ESTRO Booklet #8 [9] that the RAKR certificate issued by the supplier of each HDR source should be verified by a hospital physicist using equipment of traceable calibration. Therefore, all HDR-PDR sources to be used in clinical practice must be measured by the user. The frequency for performing source strength assays is before any clinical use and every 12 months thereafter if clinical use continues, as commented in previous Sections. Note that the recommended source assay frequency is independent of source strength, radionuclide, and of course the source model.

Radionuclide properties are taken from the National Nuclear Data Center of Brookhaven National Laboratory [55]. The AAPM and ESTRO recommended [13] the NNDC website [55] as the reference for BT radionuclide half-life ($T_{1/2}$) values and photon energies/intensities. The current half-life values are 73.83 days and 1925.3 days for Ir-192 and Co-60, respectively. It should be noted that the $T_{1/2}$ Value for Co-60 is sometimes provided in the literature with units of years instead of days. Using the average number of days in a year equal to 365.24, $T_{1/2}$ is equal to 5.27 years then. That value is used in the HEBD Report [20]. When that value in years is converted to days using the same factor, it gives $T_{1/2} = 1924.8$ days due to rounding. The last value may be used in some systems, using conversion from years to days. However, the difference between these two half-life values is not significant.

As recommended in the TG-56 Report [11], BT source strengths used for calculations of patient dosimetry should be based on measurements made by a medical physicist using a WIC having traceability to a primary standard [29].

The typical calibration uncertainty expressed in terms of RAKR for HDR/PDR Ir-192 and HDR Co-60 sources reported on a manufacturer’s calibration certificate is about 3.2% (K = 2). Current recommendations [9,11,22,25] establish that source strength differences between clinical measurement and manufacturer’s certificate should be within 5%. In 2020, the American College of Radiology (ACR) in collaboration with the AAPM updated the “ACR-AAPM Technical standard for the performance of high-dose-rate brachytherapy physics” clarifying that although 5% is the maximum discrepancy allowed, good practice and proper instrument maintenance typically insures a 3% of discrepancy. Differences larger than 3% should be investigated by the medical physicist [40,47].

In comparison to the assay tolerances for LE BT sources [8], HE source assays require tighter tolerances due to their lower calibration uncertainties [29]. The ratio \(\frac{RAKR_{hosp}}{RAKR_{vendor}} - 1\) of five different clinics using six different HDR Ir-192 source models ranged from 0.8% to 2.4% [56]; however, a factor of two better agreement was observed for the same HDR Ir-192 sources at other clinics [57,58]. A survey was performed by WP-21 to assess the current level of agreement between RAKR$_{hosp}$ values in Europe at the time of writing these recommendations, as reported on certificates issued by source manufacturers/suppliers [44]. The survey included 18 clinical centers from 8 European countries, including BRAPHYS and GEC-ESTRO committee members, where HDR and PDR BT is routinely used. This allowed adequate statistics and provided basic sample stratification to avoid potential bias due to the use of a particular methodology, clinical practice, or national regulations. Data on HDR Ir-192, PDR Ir-192, and HDR Co-60 sources were reported, together with information about the clinical practice followed for each set of measurements. In the case of Ir-192, RAKR$_{hosp}$ values differing more than 3% from RAKR$_{vendor}$ account for less than 1% of the data sample. For Co-60, all measured values fell within a 3% interval.

Therefore, an action level criterion of 3.0% is recommended for HE source assays in comparison to RAKR$_{vendor}$. If \(\left|\frac{RAKR_{hosp}}{RAKR_{vendor}} - 1\right| > 3.0\%\), the physicist should discuss with the manufacturer/supplier to resolve the discrepancy, and not use the source for patient treatment until the discrepancy is solved.

When comparing RAKR values obtained by the physicist with that in the manufacturer/supplier certificate, it is convenient to collect the history of the differences to observe the trends in the ratio between hospital and vendor values in detail [37,57]. This will help in communicating with the manufacturer in the event of possible discrepancies that exceed the recommended 3.0% tolerance.

**Recommendations**

In this report, the strength of the recommendation is classified by adopting the terminology typically used in societal guidelines:

- MUST or MUST NOT: used to indicate that adherence to the recommendation is considered necessary to conform to this practice guideline
- SHOULD OR SHOULD NOT: used to indicate a prudent practice for which exceptions may occasionally be made in appropriate circumstances

With the main aim being a high quality and safe HDR-PDR implant and taking into account the clinical practice scenario, WP-21 establishes the following recommendations:

1. It is the responsibility of the hospital medical physicist to assay BT sources. Administrators must facilitate the required resources. The assay must be performed before clinical use.
2. The recommended equipment toward such assay is a WIC with a source-holder insert, an electrometer, a barometer, and a thermometer. All devices must be calibrated at least every 2 years. Due to the stability shown by the well chambers, it is reasonable to extend the calibration periodicity to 5 years as long as adequate stability control conditions and a very strict redundancy program is maintained. This recommendation cannot supersede applicable national regulations on this matter.
3. A convenient redundancy program must be available. Recommended equipment is another WIC in analogy with the common practice in linac-based external-beam radiotherapy dosimetry. Response constancy for the components comprising the redundant system should ideally be within 0.5% and must always be within 1.0%. All components should be intercompared at least annually.
4. An Ir-192 source is typically replaced every 3–4 months and RAKR measurement must be performed by the hospital physicist at least at the time of its installation. It should also be done at the time of source exchange as part of the redundancy program. In the case of Co-60, the RAKR must be measured at the installation and at least annually; this will support constancy control.
5. The source model used by the calibration laboratories can be different from the hospital source in which the calibrated WIC will be used. Until an appropriate application of these
model correction factors is established, direct use of the calibration coefficient provided by the laboratory is recommended, except in the case that the calibration laboratory applies this model correction based on MC simulations or measured data. The method must be well documented in the source certificate.

6. With respect to the use of $k_{Q}$ in Co-60 despite the increased uncertainty, it is recommended to accept this procedure as an interim solution in anticipation of a future increase in calibration laboratories offering direct Co-60 calibration to clinical users.

7. Given potential variations and the complex context of contamination testing, WP-21 does not provide an all-encompassing recommendation beyond the fact that the responsibility for the official performance and documentation of this test must be clearly established at each hospital. A convenient option should be to reach an agreement with the afterloader company to carry out the test during installation of the source (for Ir-192) or during preventive maintenance (for Co-60). Documentation must be presented to the hospital physicist who accepts it in the same way as with acceptance of any radiotherapy equipment. The above solution should be proactively pursued in the stage of tendering or contract signing for procuring an afterloader. This solution would be the most logical one, and the entire BT community (societies, national or international guidelines, source manufacturers and afterloader companies) should work to promote this. If the above solution is not possible, then it remains the responsibility of the hospital physicist, who must have sufficient resources to accomplish this task.

8. A tolerance criterion of 3.0 % is recommended for HE BT source assays in comparison to $RAKR_{vendor}$. If $\left| \frac{RAKR_{manu}}{RAKR_{vendor}} - 1 \right|$ exceeds 3 %, then the physicist should discuss it with the manufacturer/supplier to resolve the discrepancy. Source $RAKR$ used for calculations of patient dosimetry should be based on measurements made by the physicist.

9. As adherence to ISO2919:2012, the manufacturer/supplier calibration certificate must include $RAKR_{manu}$, the associated uncertainty and coverage factor of this value, the date and time associated with the $RAKR_{manu}$ value, standardized date and time format (e.g., [59]), and information about traceability to an $RAKR$ standard. If due to regulations or administrative purposes the activity of the ordered lot (apparent and/or contained) is included on the manufacturer/supplier calibration certificate, the assumed conversion factor(s) regarding $RAKR$ must be explicitly stated.

10. An efficient and vendor-independent solution to monitor and assure HDR-PDR source design constancy should be developed and promoted. Manufacturers are responsible for keeping the consistency of the radiation source design and reporting any changes. Manufacturers/suppliers must communicate programmed source design changes to the laboratory used for WIC calibration and regulatory entities and related scientific societies that produced consensus dosimetry datasets for the specific source model.

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