Intraoperative radiation therapy using mobile electron linear accelerators: Report of AAPM Radiation Therapy Committee Task Group No. 72

A. Sam Beddar[a)]
Department of Radiation Physics, Division of Radiation Oncology, Unit 94, The University of Texas M.D. Anderson Cancer Center, Houston, Texas 77030

Peter J. Biggs
Department of Radiation Oncology, Massachusetts General Hospital, Boston, Massachusetts 02114

Sha Chang
Department of Radiation Oncology, University of North Carolina School of Medicine, Chapel Hill, North Carolina 27599

Gary A. Ezzell
Department of Radiation Oncology, Mayo Clinic Scottsdale, Scottsdale, Arizona 85259

Bruce A. Faddegon
Department of Radiation Oncology, University of California San Francisco, San Francisco, California 94143

Frank W. Hensley
Department of Radiation Oncology, University of Heidelberg, 69120 Heidelberg, Germany

Michael D. Mills
Department of Radiation Oncology, James Graham Brown Cancer Center, Louisville, Kentucky 40202

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Intraoperative radiation therapy (IORT) has been customarily performed either in a shielded operating suite located in the operating room (OR) or in a shielded treatment room located within the Department of Radiation Oncology. In both cases, this cancer treatment modality uses stationary linear accelerators. With the development of new technology, mobile linear accelerators have recently become available for IORT. Mobility offers flexibility in treatment location and is leading to a renewed interest in IORT. These mobile accelerator units, which can be transported any day of use to almost any location within a hospital setting, are assembled in a nondedicated environment and used to deliver IORT. Numerous aspects of the design of these new units differ from that of conventional linear accelerators. The scope of this Task Group (TG-72) will focus on items that particularly apply to mobile IORT electron systems. More specifically, the charges to this Task Group are to (i) identify the key differences between stationary and mobile electron linear accelerators used for IORT, (ii) describe and recommend the implementation of an IORT program within the OR environment, (iii) present and discuss radiation protection issues and consequences of working within a nondedicated radiotherapy environment, (iv) describe and recommend the acceptance and machine commissioning of items that are specific to mobile electron linear accelerators, and (v) design and recommend an efficient quality assurance program for mobile systems. [DOI: 10.1118/1.2194447]

TABLE OF CONTENTS

I. INTRODUCTION

Intraoperative radiation therapy (IORT) has had a long history in cancer management. The earliest concept of IORT as a cancer treatment modality was introduced in 1909, when Carl Beck attempted to treat patients with gastric and colon cancer.[1] Beck irradiated seven patients with inoperable gastric cancer and one patient with colon cancer by pulling the tumor into the abdominal wound and irradiating it. The treatments were unsuccessful due to low beam energies, low dose rates, and limited radiotherapy equipment, thus hindering these early efforts. It was not until 1984 in Japan,[2] that IORT treatment techniques using megavoltage radiation produced by a linear accelerator (linac) became successful. Therefore, modern IORT practice dates from the work of Abe *et al.*[3] and Abe and Takahashi[4] in Japan published in the early 1970s and 1980s. The practice of IORT was started in the United States in the late 1970s by Goldson at Howard University,[5] Gunderson *et al.* at Massachusetts General Hospital,[6] and Tepper and Sindelar[7] and Fraas *et al.*[8] at the National Cancer Institute.

Initially, IORT flourished in both the academic and community hospital setting. In 1992, Coia and Hanks.[9] reported on a pattern-of-care study that indicated that of 1293 radiation oncology facilities in the United States, 108 reported doing IORT, and 29 of those had two or more residents. With approximately 90 residency training programs in existence at that time, that means that roughly one third were performing IORT. Fewer than 30 centers are now performing IORT. The reasons for this decline in interest are twofold. First, establishing the usefulness of IORT as adjunct therapy has been difficult. Single-institution experiences have suggested the usefulness of IORT for primary T4 and recurrent rectal cancer,[10–13] retroperitoneal sarcoma,[14,15] pancreatic cancer,[16–18] and selected recurrent gynecologic[19–21] and genitourinary malignancies.[22–25] Because of the difficulty in accruing large numbers of patients for these disease sites, it is unlikely that phase III studies evaluating the utility of IORT as a definitive therapeutic modality could be performed unless this were done on an international basis. The exception could be in the area of breast cancer, where significant numbers of patients have already been treated in Europe. Second, the majority of centers use their conventional linacs to perform IORT. In this case, the anesthetized patient must be moved to a sanitized treatment room, accompanied by operating room (OR) personnel. This is technically difficult and relatively inefficient, with the linac often unavailable for conventional treatment for a considerable time for room preparation and waiting for the patient. The uphill battle faced by proponents of IORT is the high cost of a dedicated facility in the OR. A dedicated linac in an OR is no longer a cost-effective option for any hospital when the costs of the machine and radiation shielding are included.

The entry into the field of IORT of mobile linacs that can be used in existing ORs with reduced shielding requirements makes the cost and logistics of setting up an IORT program much easier and therefore provides a stimulus to the field. Two manufacturers of mobile linacs are Intraop Medical Incorporated of Santa Clara, California, which manufactures the Mobetron, and Hitesys of Aprilia, Italy, which manufactures the Novac7. Currently, 26 mobile units are installed in the United States and Europe.[26] Thus, there has been a resurgence of interest in IORT in recent years.

By now, many of the new mobile units have been in operation for several years and we have gained important experience in mobile IORT technology. Although there are many similarities between IORT treatments via stationary units and mobile units, several important considerations are unique to mobile units. This installed base of mobile linacs and the degree of clinical activity that is currently being carried out motivates a review of all the physics procedures associated with operating these units in a clinical setting.

The purpose of this Task Group (TG-72) is to provide sufficient information for a physicist to contribute to the physical aspects of the planning process, such as room selection, estimation of required radiation shielding, and adequate selection of treatment equipment for the prospective IORT program, and to perform the required acceptance tests and commissioning to bring one of these units into clinical operation. There are significant differences between the two mobile systems in their mechanical design, acceleration methodology, dosimetry, and docking. Both the Mobetron and Novac7 are approved by the U.S. Food and Drug Administration (FDA), although there are no Novac7 units currently operating in the United States. This report complements the work of previous Task Groups on IORT[27] and electron-beam dosimetry[28,29] Due to space considerations, we have abbreviated certain sections of the published version of this report. The full unabridged version, with detailed illustrations, is available electronically.[30]

This Task Group has been careful to follow current (AAPM) practice in the use of prescriptive injunctions such as "*must*," "*shall*," and "*should*." Imperatives such as "must" or "shall" apply to matters of compliance with law or regulation. "Recommendations" are applied to procedures that the Task Group deems important to follow, although a physicist may always choose alternatives after careful consideration. "Should" is used to identify suggested procedures to address significant QA issues for which a variety of approaches are reasonable.

II. IORT USING MOBILE VERSUS STATIONARY LINEAR ACCELERATORS

Stationary and mobile linacs for electron beam IORT have many similarities. Both make use of shallow-penetrating radiation. Applicators are used to confine the beam to the volume of interest within the surgical area. Treatment is performed under sterile conditions with the patient anesthetized. Radiation is delivered in a large single fraction. Multiple fields may be used to treat different areas, treat larger fields, or conform better to the target volume. Beam modifiers include bolus, placed at the end of the applicator or on the patient surface, to increase surface dose (with reduced beam penetration), and absorbers such as lead, for shielding critical

structures or field matching.[31–33] A typical IORT treatment using a mobile unit has been described by Domanovic *et al.*[34] in detail in a case study in which IORT was used on a patient with sigmoid carcinoma.

This report concerns differences in IORT with mobile linacs. Some differences apply to any linac (either mobile or stationary) in a dedicated OR. Mobile units and dedicated stationary units both permit treatment in a sterile OR. Special treatment accessories are required for both units, including a couch (surgical bed) to facilitate patient setup. A primary concern is radiation protection during treatment and daily QA. Mobile IORT units are designed primarily for use in an unshielded OR; therefore, exposure limits typically restrict their use to the treatment of a small number of patients per week plus the required daily QA and warmup. To prevent excess exposure in adjacent rooms, especially on the floor below, the maximum beam energy is limited to 10–12 MeV, limiting target coverage to a depth of a few centimeters. A beam stopper is incorporated in some designs, which may interfere with patient setup. In addition to an unshielded OR, one must also plan for a facility for dosimetry and maintenance (which can be the storage room) providing sufficient structural shielding for commissioning, extended dosimetry (e.g., annual calibrations or experiments), and maintenance and adjustment contingencies. Some users have reduced this need by performing preadjustment and commissioning at the manufacturers' facilities.

The application-specific design of mobile units can lead to advantages over conventional units adapted to IORT. For example, electron beams could well have flatter beam profiles than conventional linacs, and the range of motion of the treatment head gives more flexibility in setting up the patient. On the other hand, limitations on these units are imposed by practical concerns of storage, transport, treatment setup, and radiation protection.

Details that differ for mobile units in program implementation, including selection of the rooms required for the different procedures (commissioning, treatment, and storage), are dealt with in Sec. III. Radiation protection issues, arising from the higher leakage and scatter in an unshielded OR, are presented in Sec. IV. Differences in commissioning, including output calibration, are discussed in Sec. V.

III. IMPLEMENTATION OF AN IORT PROGRAM WITHIN AN OPERATING ROOM ENVIRONMENT

A successful IORT program within an OR environment requires careful planning, involving coordination of tasks with timely and efficient communication among several departments. These departments generally include operative services (usually referred to as the OR), radiation oncology, surgery, anesthesiology, and engineering. Depending on the institution, the engineering support personnel may be part of the radiation oncology department. The IORT team and the role of each member of this team have been clearly defined by Task Group 48 (Ref. 27) and therefore will not be dealt with in this report. Other support personnel,[27] such as housekeeping, security staff, transport personnel, and elevator operators, will not be needed because the unit will be in the OR where all IORT treatments will be delivered. Each department will have a significant role in the implementation of such a multidisciplinary program. Consequently, a team approach should be embraced from the beginning.

Implementation of an IORT program using a mobile unit[35] in the OR includes staff preparation, documentation of specialized procedures, and selection of the OR(s) and surgical bed(s).

The following steps will facilitate smooth and efficient implementation of a mobile IORT program:

(1) Interdepartmental meetings early in the planning phase, involving all relevant departments.
(2) A site visit to an institution performing IORT using a mobile system.
(3) A written proposal for program implementation, tailored to the institution.
(4) Development of written procedures.
(5) Selection of the OR(s), storage room and dosimetry facility.
(6) Selection of the surgical bed(s).
(7) Education of staff involved in the IORT procedure and OR staff peripheral to the program.
(8) Scheduled training in the OR.
(9) One or more "dry runs" before the first IORT procedure.

At the beginning of such a program, we believe it is important to have all members of the IORT team involved in all of the initial procedures so they can go through the learning process rapidly, implement the improved methods efficiently, and reach optimum performance of IORT. The training of the rest of the OR staff should follow once the initial IORT team reaches an acceptable level of confidence. A complete discussion of these points is provided in the full electronic report.[30]

IV. RADIATION PROTECTION

Mobile electron linacs are meant to be placed in existing OR suites that have been constructed with no special shielding requirements. These systems are designed with the concept of being utilized to deliver radiation in nonshielded OR rooms and are provided with a beam stopper.[30] The beam stopper for certain mobile IORT units is designed to track the movement of the gantry in all directions so that it will always intercept the primary beam, whereas other beam stoppers must be manually positioned. Radiation leakage results mostly from photon leakage, scatter, and x-ray contamination from the electron beams. The electron scatter produced in the OR has a limited range, and most conventional walls are sufficient to stop the electron scatter produced in the OR.[36] Therefore, radiation safety assessments for these mobile systems consist of performing radiation surveys around the ORs that are intended to be used for IORT and limiting the number of IORT cases that can be performed in any given OR so that the maximum exposure limits are not exceeded.

A. Regulatory considerations

Limits for radiation exposure of personnel are usually regulated by national or state government agencies. In the United States, the National Council on Radiation Protection and Measurements.[37] and the federal government promulgate standards.[38,39] In addition, standards may vary between countries or states and may change with time. This Task Group (TG-72) believes the following to be absolute requirements:

(1) The most current exposure levels applicable to the geographic location (country or state) of the mobile accelerator installation *shall* be adopted.
(2) The site plan *must* be approved by the appropriate regulatory agency before delivery of the unit takes place.
(3) A radiation survey *must* be performed for every OR where the unit will be used and for any other room where the unit could be used (e.g., the dosimetry room).
(4) The survey *must* be performed for the highest electron energy, the largest applicator, and for every anticipated and possible clinical configuration of the unit.
(5) Electrical requirements *should* be evaluated for the ORs selected for IORT, the storage area, and any other room where the unit could be used.
(6) Floor load capacities *should* be evaluated for the rooms selected for IORT, the storage area, any other room where the unit could be used, and all possible transportation routes that could be used.
(7) Exposures accrued by personnel *must* be evaluated according to a radiation safety Quality Management Program.

B. Radiation site plan

1. Treatment operating rooms

The manufacturer will ordinarily provide a three-dimensional radiation leakage and scatter exposure profile for the IORT unit. If the unit is capable of a range of motions, several profiles will be required to complete the site plan properly. The anticipated workload of each mode and energy will figure into the site plan. This workload, calculated for ORs, should include the MUs for machine warm-up and daily QA but should not include the workload for commissioning and annual QA measurements (see the following section). Mills *et al.*[40] calculated typical workload limits for existing ORs using the Mobetron system and found that it is possible to treat up to four patients per week in an existing, unshielded OR. Therefore, it may be necessary to consider more than one OR for IORT treatments if a higher patient load is anticipated.

2. Commissioning and annual quality assurance location

The shielding of a mobile accelerator is designed for infrequent use for IORT, not for continuous use in an unshielded room.[40] Therefore, it is strongly recommended that a dedicated vault or location for commissioning and annual quality assurance activities be chosen. A separate site plan must be developed for the location chosen for commissioning and annual QA. Even an efficient commissioning will require several hundred thousand MUs.[40] An annual calibration will typically require less than 100 000 MUs. If occupied areas surround the intended location, the user needs to identify the type of occupied areas, the occupancy factor, the use factor, and the maximum exposure level allowed in each of the areas by state regulations. If the vendor provides the leakage data, the maximum workload during working hours can be estimated accordingly. If the maximum workload poses a problem in the acceptance testing and commissioning schedule, one solution is to conduct the procedures outside working hours and establish temporary controls on the surrounding areas. The actual exposure should be measured as soon as the mobile unit is able to generate a beam. The measured exposure values should be used for final workload limit calculations. The workload limit is determined by the maximum allowable weekly or hourly exposure, whichever is higher, in the adjoining area that receives the highest exposure. It is very important to get radiation safety personnel involved in the process early. If the location chosen is not sufficiently shielded and posted to be a controlled area, then steps including temporary barriers and signs, are needed to make it a controlled area during the time of these measurements.

C. Radiation survey

According to current regulatory limits in most states in the United States, the allowable exposure level for uncontrolled areas is 1 mSv per year. This corresponds to a limit of approximately 0.02 mSv per week. In addition, in a noncontrolled area, no more than 0.02 mSv is allowed during any one hour. The regulatory limits allow controlled areas an exposure of 50 mSv per year. This corresponds to a limit of approximately 1 mSv per week. Controlled areas *must* be labeled appropriately, and access by members of the public *must* be restricted. The occupancy factor is 1 for controlled areas in this environment. A radiation survey of the exposure level at various locations outside the OR for the IORT unit *must* be performed in every OR in which the unit will be used. Regulatory agencies require these surveys for any external beam radiotherapy unit. The survey *must* be performed for representative and anticipated worst-case situations of possible clinical configurations of the unit. The measured exposures are used to calculate the final operational limitations of the unit. A final operational plan must take into consideration the MUs generated during patient treatment, warm-up, output, energy check, and adjustment contingencies. Considering an OR with no added shielding, it is common for only a very limited number of patients to be accommodated per week without exceeding regulatory limitations.

D. Exposure rate measurements

Daves and Mills[36] performed a detailed analysis of the shielding assessment on a Mobetron unit. Their method should, in principle, be applicable to the Novac7. Their investigation provided a resource to assess shielding and pa-

tient load restrictions for any facility performing IORT with units similar to the Mobetron. Their exposure rate measurements data indicated that the Mobetron may be operated in an area with no shielding under a nominal patient load expectation. Assuming standard building materials, their results demonstrated that a workload of three to four patients per week in a given OR, including warmup, could be easily accommodated. Such workloads should be assessed for any facility used and will be specific only to that facility. If mobile IORT units are to be used without workload limitations, then they should only be used in shielded ORs.

V. ACCEPTANCE TESTING AND COMMISSIONING

This section provides guidance and practical recommendations on the acceptance testing and commissioning of mobile electron therapy units used for IORT. Published literature relevant to IORT with electron beams includes the Task Group 25[29] and Task Group 39[41] reports on clinical electron beam dosimetry, the TG-48 report[27] on IORT using stationary linacs, Task Group 39 protocol[41] and the Task Group 51 protocol[28] for clinical reference dosimetry of high-energy electron beams. However, several important considerations in IORT accelerator acceptance testing and commissioning procedures are unique to mobile accelerator units. For instance, the lengthy testing procedures that are normally carried out in the dedicated and shielded treatment room vaults for stationary accelerators generally cannot be performed in the heavily scheduled ORs designated for IORT. The radiation exposure rates from these procedures to areas adjacent to the unshielded ORs would most likely exceed the acceptable exposure limits established for stationary accelerators. It is best that these acceptance testing and commissioning procedures be carried out in an existing vault where available.

A. Acceptance testing measurements

A mobile IORT unit must pass acceptance testing according to the manufacturer's specifications. The acceptance testing procedure for a mobile IORT unit includes the following:

(1) Radiation survey.
(2) Interlocks and safety features testing.
(3) Mechanical testing.
(4) Beam characteristics tuning.
(5) Docking system test.
(6) Options and accessories evaluation.

The radiation survey at the testing site is conducted as soon as the accelerator is able to produce a stable beam and after a preliminary output calibration. All surrounding areas, including rooms one floor above and below, should be characterized in terms of occupancy factor and radiation control classification (controlled area or uncontrolled area) based on the 10CFR20 report.[38,39] The exposure rates in each of the surrounding areas should be measured under the same irradiation conditions to be used for the acceptance testing procedures, especially with respect to the location of the accelerator in the room. The workload limit for the acceptance and commissioning process can be calculated from the survey result and expressed in terms of MUs per hour. The effect of the workload limit on the anticipated measurements in the testing procedures should be analyzed ahead of time. The total MUs needed for the testing procedures can be estimated based on the type of commissioning dosimetry data to be taken and the measurement devices. For example, one can make the following estimate of the total MUs needed when a water scanner is used for beam profile and percentage depth ionization measurements. Assuming the average scanning speed to be used is 5 mm/sec and the average scan length is 15 cm (the maximum Mobetron applicator size is 10 cm), the beam-on time needed per scan t^{scan} should be less than 100 sec (the actual time to scan 15 cm is 30 sec). If one percentage depth ionization curve and one beam profile will be measured per electron applicator and there are N applicators, the total beam-on time for the ionization curve and profile scanning is $T^{\text{scan}}=2N*t^{\text{scan}}$, which is 1600 sec–less than 30 min. If the accelerator has a nominal MU rate of 1000 MU/min, then 30 min of beam-on time would require 30 000 MU per electron energy. The total beam-on time required for the entire acceptance testing and commissioning process can be estimated in units of T^{scan}. The beam-on time for the above measurements is estimated to be less than ten units of T^{scan}. If the workload limit significantly hinders the commissioning process with the use of a water phantom, one can consider several options to shorten the procedure. These options include: (1) reducing the MU usage when appropriate in the testing procedures by using a low MU rate; (2) replacing the water phantom scans with film; and (3) conducting measurements outside normal working hours.

All interlocks and safety features should be tested following the manufacturer's acceptance testing procedures. One should make sure that these interlocks and safety features, including the emergency off switches, are operational during the normal mode of operation of the unit (e.g., the clinical mode). The mechanical testing includes verifying the full range of gantry motion, including rotational and translational movements. The mechanical movements and controls of mobile IORT units differ significantly in design and function from those of a conventional accelerator. The mechanical movements of the gantry and treatment couch for a conventional accelerator are designed to rotate and translate with respect to a fixed isocenter. In contrast, a mobile accelerator will have no isocenter *per se*, and the geometric accuracy of treatment delivery using a mobile unit will depend solely on the accuracy of the docking. Once the electron applicator is placed inside the patient and aligned to the intended treatment area, the operator should be able to control the gantry movement in all directions available to achieve docking. The proper operation of the beam stopper, if any, should also be verified.

Beam tuning includes adjustments of the beam energy, output rate, and flatness and symmetry of the reference applicator used for output calibration. The manufacturer's installation engineer usually performs the task of beam tuning.

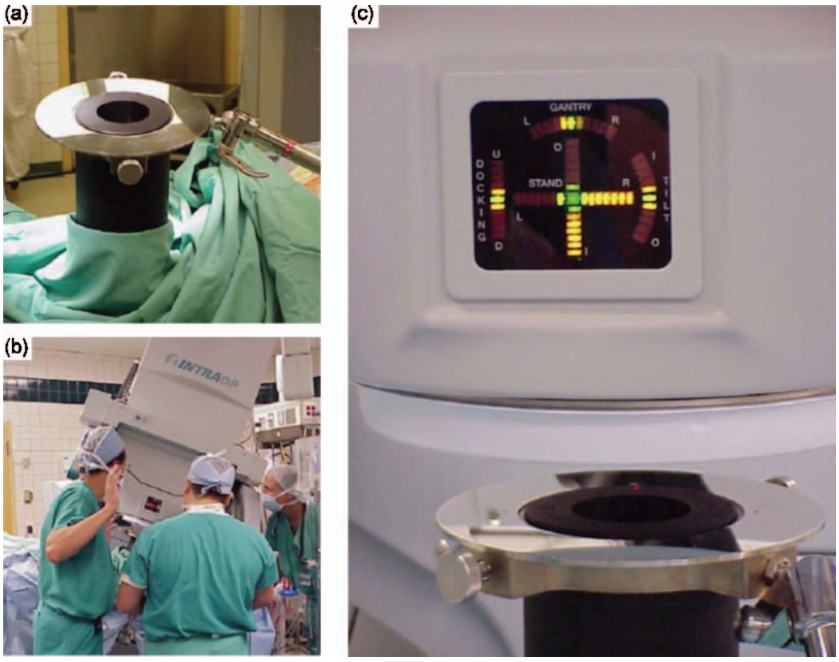

FIG. 1. The soft-docking system used by the Mobetron. (a) The electron applicator, in contact with the tumor bed, is rigidly clamped to the surgical bed using a modified Bookwalter clamp. (b) The gantry being moved for soft docking to the applicator. (c) The LED display and electron applicator. The green light in the center of the display indicates that proper alignment has occurred and the gantry is properly docked. Note the air gap (4 cm ± 1 mm) between the end of the gantry and the top surface of the applicator.

Relative output factors, flatness, and symmetry of all other applicators should be measured afterward by clinical physicists.

Systems with soft docking, such as the Mobetron (Fig. 1), require acceptance testing of the docking system. The soft-docking system, also referred to as air docking,[27,42–45] is more flexible than the hard-docking system of the Novac7 (Fig. 2), in which the coupling of the electron applicator to the accelerator beam collimation system is direct and rigid.[46,47] For the Mobetron unit, the optical docking system consists of a system of laser detecting devices mounted on the accelerator beam collimation system to assist the operator in performing the soft docking of the gantry with the electron applicator. The soft docking is achieved by adjusting the gantry's rotation angle, tilt angle, height, and two translational shifts (longitudinal and lateral) of the gantry in the horizontal plane. The status of each aspect of the alignment is shown on a light-emitting diode (LED) display on the accelerator to guide the operator in the docking process.[48] During irradiation, the docking is interlocked for both alignments of the treatment head with the applicator and for treatment distance. Optical coupling can be very sensitive to the quality of the alignment, whereas the dosimetric quality of the treatment is likely less sensitive. We recommend that the clinical physicist evaluate the change in beam characteristics at clinically realistic conditions when the soft docking is not perfect in the commissioning process, when possible. Note that FDA regulations might prevent the use of a mobile IORT unit without the optical docking interlock. The TG-48 report[27] included a suggestion to make allowances for misalignment in soft docking because precise alignment can be time consuming and difficult to maintain in the presence of applicator motion due to patient breathing. Hogstrom *et al.*[49] recommended that the user perform measurements of beam dosimetry sensitivity versus optical docking accuracy to determine the docking tolerance for clinical use.

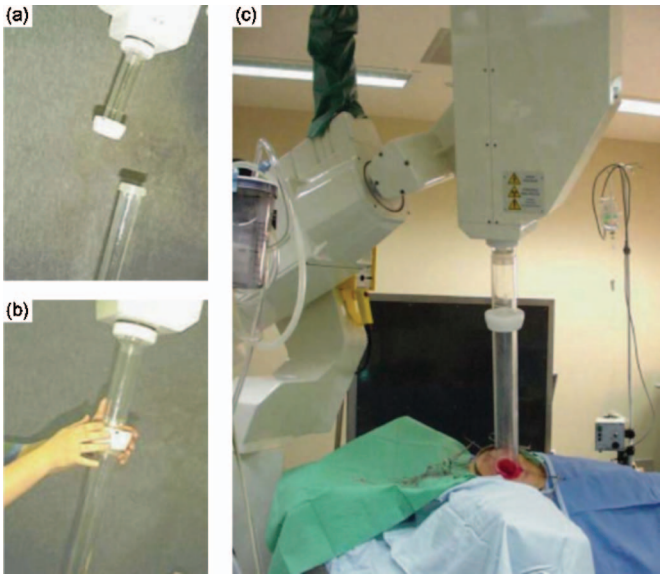

FIG. 2. The hard-docking system used by the Novac7. (a) The accelerator beam collimation system and electron applicator before docking. (b) The hard-docking mechanism. (c) The docked unit, with the electron applicator in contact with the tumor bed.

All accessories supplied with the unit should be individually examined in the acceptance testing process prior to use. The user *should* follow the manufacturer's specifications and tolerance in testing and examining the operation controls, docking system, interlocks, accessories, and any optional devices.

Details of the mobile electron IORT unit acceptance tests are specified in the acceptance test procedure document pro-

TABLE I. Typical procedures required for acceptance testing of a mobile IORT unit.

Procedure	Comment
Radiation survey	Ensure no individual is exposed to radiation levels in violation of regulations, and verify the normal operation of emergency off switches.
Mechanical inspection	Verify the movement range, speed, control, and accuracy of the gantry and beam stopper. Verify the physical sizes of all applicators.
Radiation safety	Verify dose attenuation through the beam stopper.
Beam characteristics	Verify beam energy, surface dose, dose rate, field flatness, symmetry, and x-ray contamination according to specifications. Verify beam energy constancy for all gantry angles.
Dosimetry system	Verify the precision of the backup MU chamber, the linearity and reproducibility of the MU chambers, and the dosimetry interlocks.
Control console	Verify the normal function of each control on the control console.
Docking system	Verify the normal function of the optical docking system.
Options and accessories	Verify normal function.
Safety features	Examine all safety features (emergency off, rad-on light, and audible warning sounds).

vided by the manufacturer. Table I, which lists the items included in the acceptance testing of Mobetron units, is shown as an example.

B. Commissioning and dose measurements

The methodology and equipment that should be used in the acceptance testing and commissioning of electron beams for IORT units *should* follow the general recommendations made in the TG-51 protocol for reference dosimetry on clinical electron beams.[28] This Task Group (TG-72) recommends the use of a water phantom for the beam calibration as described by TG-51. The methods for obtaining relative dosimetry measurements are at the discretion of the responsible clinical physicist, who must make the decision on the basis of multiple considerations, including radiation safety, the clinical accuracy needed for IORT treatment, commissioning time frame, resources available, and the limitations and availability of the measurement devices.

The beam characteristics commonly measured in the commissioning of a mobile IORT unit are listed in Table II.

This Task Group will not make any further recommendations as far as what type or model of ionization chamber or detector should be used for clinical reference dosimetry, because this has been covered elsewhere[27–29,41,50–52] However, several unique aspects in the commissioning of a mobile IORT unit deserve the user's attention. Mobile IORT units have dose rate outputs several times higher than conventional accelerators so that they can deliver large doses (10 to

TABLE II. Typical measurements used in mobile IORT unit commissioning.

Measurements	Comment
Beam profiles (depth dose and cross plane profiles)	Measurements are done for each applicator and beam energy and should extend to regions outside the treatment area.
Leakage profiles	Measurements are done for a limited sample of applicators and beam energies (including the highest beam energy) and should be made lateral to the applicator walls at various depths.
Applicator factors	Applicator factors are relative to a 10-cm circular cone, and the measurements are done at d_{max} for each applicator and beam energy.
Air gap factors	The air gap factor is the ratio of dose with an air gap to the dose without one at d_{max}. Air gap factors are measured at the appropriate depths of d_{max} for each combination of applicator and beam energy.
TG-51 output calibration	Output calibration is done at the TG-51 reference depth d_{ref} using the 10-cm circular applicator. From these measurements the dose/MU at d_{max} is determined.

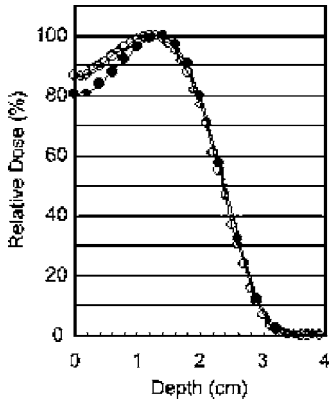

FIG. 3. The central axis percentage depth dose for a 10-cm circular applicator from a stationary linear accelerator (Siemens ME, filled circles) and a mobile linear accelerator (Mobetron, open circles) for a 6-MeV electron beam.

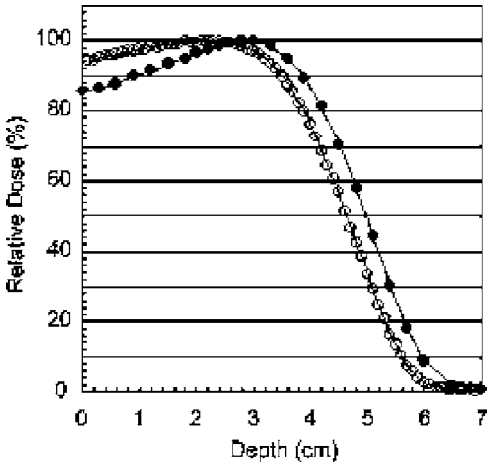

FIG. 4. The central axis percentage depth dose for a 10-cm circular applicator from a stationary linear accelerator (Siemens ME, filled circles) and a mobile linear accelerator (Mobetron, open circles) for a 12-MeV electron beam.

20 Gy) in a short time (1 to 2 min). The ion recombination correction factor P_{ion} depends on the dose per pulse in accelerator beams and thus will change if either the pulse rate for a fixed dose rate or the dose rate is changed.[28,29,53] At the high dose rates used by mobile IORT units, cylindrical chambers can have large values of P_{ion}. For instance, the value of P_{ion} for a (PTW) cylindrical chamber (Model 30006, inner radius 3.05 mm) exposed to a dose rate of 10 Gy/min is greater than 1.05. However, P_{ion} did not exceed 1.03 for a Markus PTW parallel plate chamber (Model 23343, sensitive volume 0.055 cm^3). This Task Group recommends that chambers with P_{ion} values outside the acceptable range specified by TG-51 *should not* be used for output calibration.

Furthermore, it is essential that the dose per pulse and hence the dose rate be kept fairly stable during data collection, because P_{ion} will no longer be constant and large fluctuations in the dose rate over time will therefore affect ionization measurements. For instance, when measuring applicator output factors, it has been observed that, as the dose rate changed from 10 to 15 Gy/min over the course of one hour, the ion recombination P_{ion} also changed, and thus the output factors appeared to be changing. However, in normal operation where the beam is not used continuously for long time periods, the dose rate of a mobile linac is not expected to vary significantly. For instance, Beddar[54] examined the stability of a Mobetron linac over 20 quality assurance trials and found variation within ±2%. The author also found that hours of inactivity, with the unit powered on (in standby mode) either throughout the day or overnight, led to variations in output of about 1%.

Piermattei *et al.*[55] found that, with high dose values of 30 to 60 mGy per pulse for the Novac7 (compared with 4 to 6 mGy per pulse for the Mobetron), the error in dose resulting from the use of a parallel plate chamber could be as high as 20% due to overestimation of P_{ion}. For different pulse rates, they measured P_{ion} from the ratio of the dose measured by radiochromic film to that measured by the parallel plate chamber uncorrected for ion recombination. Other users of the Novac7,[56] because of this ion recombination issue, have used chemical Fricke dosimeters, provided by the mailed dosimetry service at the Italian Primary Standard Dosimetry Laboratory in Rome, and radiochromic films for dosimetry. Di Martino *et al.*[57] have determined the relationship between P_{ion} and the dose per pulse based on generalized Boag theory. They found good agreement between percent depth dose (PDD) curves evaluated using Gafchromic films and parallel-plate ionization chambers with values of P_{ion} determined for doses of 30 to 130 mGy per pulse. This Task Group recommends determining P_{ion} using the standard two-voltage technique described in TG-51 for doses less than 10 mGy per pulse, and using an alternate method for higher doses per pulse as suggested by the Novac7 users.[55–57]

Another aspect of commissioning a mobile IORT unit is the lack of a gantry isocenter and a surgical bed with precise movement control. Additional time is needed to set up a water phantom. The beam stopper on a mobile IORT unit may also prevent the use of the water phantom support sys-

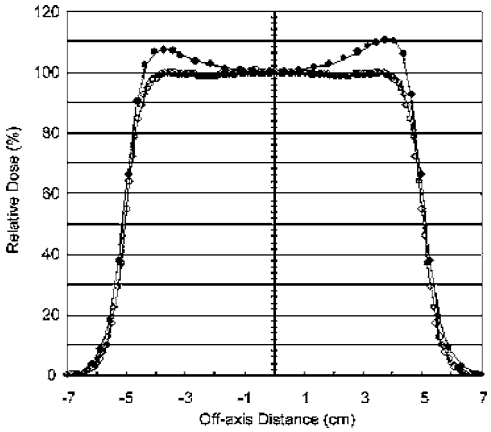

FIG. 5. A beam profile at the depth of d_{max} for a 6-MeV electron beam from a stationary linear accelerator (Siemens ME, filled circles) compared with beam profiles at the depth of d_{max} from a mobile linear accelerator (Mobetron, open circles) for a 10-cm electron applicator.

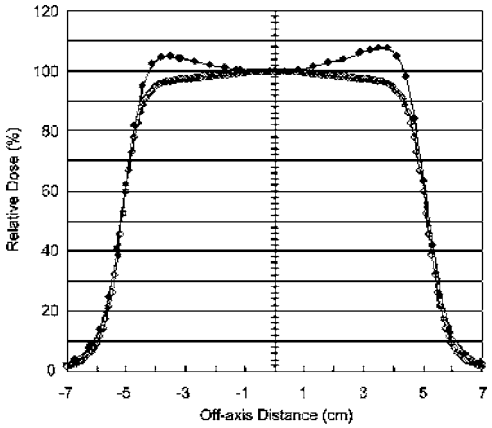

FIG. 6. A beam profile at the depth of d_{max} for a 12-MeV electron beam from a stationary linear accelerator (Siemens ME, filled circles) compared with beam profiles at the depth of d_{max} from a mobile linear accelerator (Mobetron, open circles) for a 10-cm electron applicator.

tem (e.g., table support) that normally comes with most commercial phantom scanners. It may be necessary to build a special low table that straddles the beam stopper.

Figures 3 and 4 show the central axis depth dose curves for 6- and 12-MeV electron beams, respectively, from a stationary linac (Siemens) compared with those from a mobile linac (Mobetron) for a 10-cm electron applicator. All depth dose curves were measured using the method described by the TG-51 protocol[28] The depth dose curves of the mobile unit have a higher surface dose, which can be attributed to a greater proportion of energy-degraded, scattered electrons in the beam. Figures 5 and 6 show beam profiles at the depth d_{max} for 6 and 12 MeV electron beams obtained from a conventional accelerator (Siemens) and a mobile IORT unit (Mobetron). The difference between the flatness and symmetry curves shown in Figs. 5 and 6 can be attributed to differences in the source-to-surface distance variation and the scattering foil design. The mobile units have smaller horns in their beam profiles, a desirable feature for delivery of a uniform dose within an IORT field. Typical isodose distributions for IORT mobile units are shown in Figs. 7 (Mobetron) and 8 (Novac7). Leakage beam profiles that extend beyond the applicator walls are needed to estimate the dose to normal tissue close to the applicator. This was discussed in the TG-48 report,[27] which also included typical scans measured lateral to the applicator walls.

VI. RECOMMENDED QUALITY ASSURANCE

Individual state regulations require certain QA practices for medical linacs; these requirements differ from state to state, and some may not be well suited to these special-purpose devices. The physicist *must* ensure that the use of mobile IORT equipment complies with any relevant regulations and/or apply for exemptions where justified.

A. Previous quality assurance recommendations for medical linear accelerators

Any discussion of QA for mobile linacs used for IORT must acknowledge the recommendations published in the Task Group 40 report.[58] regarding QA for medical linacs in general. In addition, the TG-48 report[27] discussed specific QA issues for linacs used for IORT. Table III summarizes the pertinent recommendations of these previous, complementary reports regarding dosimetric and mechanical QA.

B. Quality assurance for mobile electron accelerators

When adapting these recommendations to mobile accelerators, the clinical physicist needs to deal with some conflicting considerations. These units are partially disassembled and transported each day of use. They forgo adjustable collimator jaws and eliminate bending magnets to reduce weight and radiation leakage. These design elements simplify the system, but they make the electron beam energy more dependent on variations in rf power generation and coupling to the accelerator. Therefore, on one hand, there are reasons to perform more frequent beam measurements than with conventional installations. On the other hand, the equipment is used in ORs with little or no added shielding, so radiation safety considerations argue for limiting the beam time for QA as much as possible. These competing concerns can be partially resolved by developing an efficient QA process, but they do present an ongoing challenge.

Output and energy can be checked efficiently with the use of a dedicated solid phantom in which a dosimeter can be

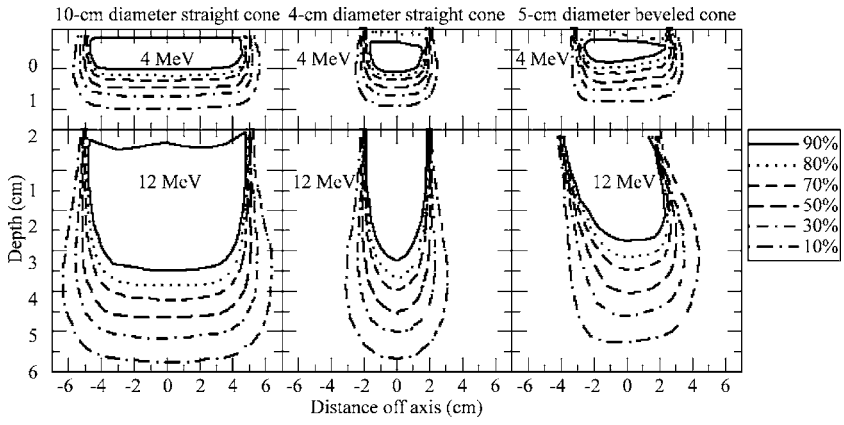

FIG. 7. Typical isodose distributions measured from the Mobetron for the 4- and 12-MeV beams using the largest applicator (10-cm diameter), a smaller applicator (4-cm diameter), and an applicator with a 30-deg bevel (5-cm diameter).

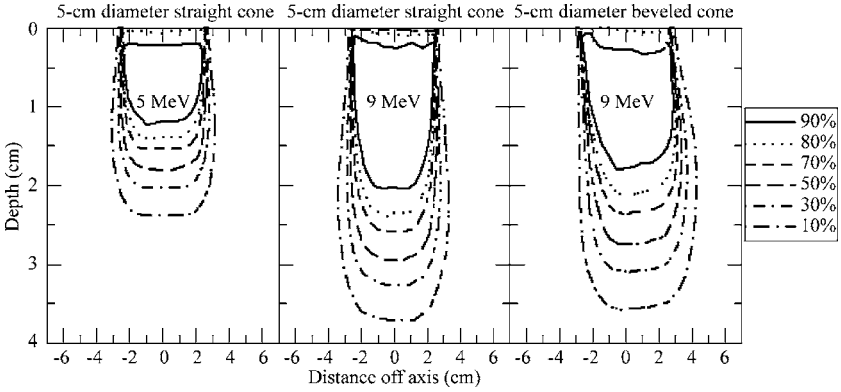

FIG. 8. Typical isodose distributions from the Novac7 for 5- and 9-MeV beams using an electron applicator with a straight cone of 5 cm diameter and for the 9-MeV beam using a 22.5-deg beveled applicator with a 5-cm diameter.

placed at two depths: near the depth of dose maximum and at a point on the depth dose curve in the 50–80% range. The output constancy is taken from the measurement near d_{max} and the energy constancy from the ratio of the two readings. This Task Group *recommends* that for mobile accelerators, the electron output constancy be checked each day of use. The electron energy check *should* also be checked daily. If it proves to be sufficiently consistent, then the physicist may judge it reasonable to reduce the frequency to monthly after properly documenting the energy consistency.

When judging how many MUs to apply to these measurements, the physicist needs to ensure that the beam runs long enough to enable all interlocks. (Some machines disable some dosimetry interlocks during an initial period.)

For a machine having four energies, a typical protocol is to warm up the machine and dosimeter with about 400 MU and then check the output and the electron energy for each energy with single 200-MU readings. The total number of MUs used for daily QA may exceed the number of MUs used for treatment. Given that the machine is prepared for use more often than it is actually used, more beam time (and ambient radiation) may be allocated to QA than to treatment. Hence, there is good reason to carefully assess which readings and how many MUs per reading are necessary for QA. Use of a dual channel dosimeter to simultaneously acquire readings at two depths would be advantageous.

Both the accelerator characteristics and the docking mechanism affect the flatness and symmetry of the treatment fields. This is especially true for machines using soft-docking mechanisms. This Task Group recommends that field flatness *should* be checked monthly, in accordance with TG-40. The docking apparatus *should* be checked for basic integrity each day of use, in accordance with TG-48. This Task Group (TG-72) further recommends that the alignment of soft-docking systems *should* be checked at least monthly. For systems that use special attachments for routine QA, this Task Group recommends that, at least annually, the flatness and symmetry of the beams *should* be checked in the soft-docked configuration used clinically.

For mobile systems, the practical question of when to set up the machine and do the QA checks takes on added significance. As with any multidisciplinary, single-dose procedure, the tolerance for machine downtime is very low, but the need to move and set up the machine adds complexity and the possibility of malfunctions. Consequently, there can be value to setting up and testing the basic operation of the machine on the day before its intended use. Recommended dosimetric QA can follow on the day of treatment, preferably early enough to permit some troubleshooting if needed. This is a labor-intensive process that can be simplified if experience with the machine demonstrates its reliability.

As for any radiation treatment equipment, annual QA checks *should* repeat critical elements of the initial acceptance testing and commissioning. The task is likely to be complicated by workload limitations, however, unless the unit can be moved into a shielded environment. For example,

TABLE III. Summary of the quality assurance recommendations for electron accelerators made by previous task groups.

Parameter	TG-40	TG-48
Output constancy	3% tolerance for daily QA. 2% tolerance for monthly and annual calibrations.	Follow TG-40.
Depth dose	Range of energy ratios corresponding to 2-mm shift in depth dose for monthly and annual calibrations.	Same as TG-40 for annual calibrations. Follow standard departmental procedures for monthly calibrations.
Flatness and symmetry	3% tolerance for monthly checks. 2% tolerance for annual calibrations.	Same as TG-40 for annual calibrations. Follow standard departmental procedures for monthly calibrations.
Applicator output factors	2% tolerance, checks performed annually.	Same as TG-40.[a]
Output versus gantry angle	2% tolerance, checks performed annually.	None.
Monitor chamber linearity	1% tolerance, checks performed annually.	None.
Docking mechanism	Not applicable.	To be checked each day of use.

[a]TG-48 specifically recommended checking all applicators and energies with a tolerance of 2–3 % for a few years and then sampling (Ref. 27) after that if results warrant.

TABLE IV. Summary of the quality assurance recommendations for mobile electron accelerators used for IORT.

Parameter	Tolerance	Action level
Day of use		
Output constancy	3%	Recommended
Energy constancy	Range of energy ratios corresponding to 2-mm shift in depth dose	Recommended
Door interlocks	Functional	Recommended
Mechanical motions	Functional	Recommended
Docking system	Functional	Recommended
Monthly		
Output constancy	2%	Recommended
Energy constancy	Range of energy ratios corresponding to 2-mm shift in depth dose	Recommended
Flatness and symmetry constancy	3%	Recommended
Docking system	Functional	Recommended
Emergency off	Functional	Recommended
Annually		
Output calibration for reference conditions	2%	Required
Percent depth dose for standard applicator	2 mm in depth over the range of clinical interest	Required
Percent depth dose for selected applicators	2 mm in depth over the range of clinical interest	Recommended
Flatness and symmetry for standard applicator	2%	Required
Flatness and symmetry for selected applicators	3%	Recommended
Applicator output factors	2–3 %	Recommended
Monitor chamber linearity	1%	Recommended
Output, PDD, and profile constancy over the range of machine orientations	As above	Recommended
Inspection of all devices normally kept sterile	Functional	Recommended

it may be necessary to use film instead of a scanning water phantom. If the initial commissioning and subsequent annual QA tests are to be done in different environments with different dosimeters, then appropriate baseline measurements should be done during the commissioning.

Table IV summarizes the QA recommendations for mobile electron accelerators used for IORT. The term "constancy" refers to agreement with original commissioning data.

In addition to these elements of dosimetric and mechanical machine QA, there are aspects of procedural QA that should be considered. In the OR environment, the attending radiation oncologist will usually be scrubbed and may verbally indicate the key elements of the prescription (applicator, energy, dose, etc.) to the person who will perform the MU calculation and program the machine. There are two likely sources of error in such a scenario. One is that the treatment planner may misunderstand the physician's verbal instructions. Another is that the planner may make a mistake in the calculation or in programming the treatment console. The team tasked with clinically implementing IORT will need to recognize this potential for error and design procedures accordingly. For example, the planner can use both manual and computerized calculation methods, thus double checking the mechanics of the calculation. In addition, the calculation can be written out in such a way that the physician can check that the prescription has been properly understood. Finally, a second person, such as the physician or another physicist, can check that the energy and MUs have been properly programmed. Having more than one person check the critical elements in a single-shot procedure is crucial.

The Radiation Therapy Oncology Group continues to sponsor the Radiological Physics Center (RPC) QA program for interinstitutional clinical trials. TG-48 recommended in its report[27] that the RPC TLD service be used as part of an outside, independent check on an institution's dosimetry. This Task Group (TG-72) reemphasizes that recommendation and strongly recommends institutions using mobile accelerators to use the services of RPC, before the initiation of treatments if possible.

As part of a comprehensive QA program, the annual review should include an assessment of clinical procedures and radiation safety procedures, maintenance history, and spare parts inventory.

VII. CLINICAL ASPECTS OF IORT TREATMENT DELIVERY: DOSE SPECIFICATION

Traditionally, IORT procedures performed under the Radiation Therapy Oncology Group protocol have specified that the 90% isodose line covers the target volume, whereas

the International Commission on Radiation Units (ICRU) and Measurements Report 35 (Ref. 59) recommends that the dose be prescribed at d_{max}. Therefore, TG-48 recommended that both the 90% dose and the maximum dose should be reported. Since the publication of the TG-48 report, neither the ICRU nor any other institution has achieved a formal agreement on dose specification for IORT. However most IORT groups follow the convention of prescribing to the 90% isodose level to ensure coverage of the target by the 90% isodose line. This Task Group recommends that the dose be prescribed at the 90% isodose level and then the dose be reported at both the 90% level and d_{max}.

VIII. RECOMMENDATIONS FOR FUTURE CONSIDERATIONS

Many aspects of IORT are still in an investigative and less standardized state than external beam radiation therapy. Therefore, in existing IORT programs, several centers have developed specialized applicators,[4,8,42,45,47,60,61] alignment aids,[62] and other technical equipment to adapt to institutional methods or requirements, such as patient case selection and surgical techniques. For instance, the treatment of extended tumor sites (e.g., sarcomas located on extremities) may require the development of applicators and techniques for field abutment.[8] Other design features of mobile IORT machines may limit the development of some specialized equipment. Adaptations of site-developed equipment, and possibly advice by the manufacturer, may be necessary to allow for the use of the soft-docking aids provided with the linacs.

The management of cancer using IORT is limited to the delivery of one single dose during surgery, which is an occasional modality that can hardly be postponed or repeated. Therefore, machine interlocks, which exclude patient treatment, should be restricted to those that are necessary to warrant patient safety and to avoid machine damage. Interlocks of lower priority (e.g., those that are triggered by slight applicator misalignments or machine instability) should be well documented and their effect on the dose distribution well quantified so that, if necessary, an override can be considered at the time of treatment. Apart from few early phantom measurements on beam inclination and gaps,[33,42,49] the effects of beam misalignment, gaps, bolus, changes of penumbra, and tissue inhomogeneities in realistic patient geometries are not well investigated. Further research is needed in these areas, and further development is necessary in the treatment planning of IORT for realistic patient geometries.

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[a]Electronic address: abeddar@mdanderson.org

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